Long Medical Laboratory, CR No. 334 (1994)

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Long Medical Laboratory,	DATE: September 23, 1994
Petitioner,	
- v. -	Docket No. C-94-294
	Decision No. CR334
Health Care Financing Administration.	

DECISION

This case arises under the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a (referred to in this Decision as "CLIA" or "the Act") and implementing regulations in 42 C.F.R. Part 493. By letter (notice) dated June 3, 1993 1/, the Health Care Financing Administration (HCFA) notified Petitioner that it had determined to revoke Petitioner's CLIA certificate and that it was cancelling Petitioner's approval to receive Medicare reimbursement for its services. Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. 2/ On May 25, 1994, I held a hearing in Ocala, Florida. Subsequently, the parties submitted briefs. 3/

I. Issues, findings, and conclusions

The June 3, 1993 and June 28, 1993 letters from HCFA to Petitioner assert more than one basis for the imposition of sanctions. However, HCFA is now relying on a single contention as justification for revoking Petitioner's CLIA certificate and cancelling its approval to receive reimbursement from Medicare. This contention is that Petitioner intentionally submitted proficiency testing samples to a reference laboratory, in violation of 42 U.S.C. 263a(i)(4) and 42 C.F.R. 493.1840(b). Based on this contention, there are two issues in this case. These are:

1. Whether Petitioner intentionally submitted proficiency testing samples to a reference laboratory in violation of applicable law and regulations; and

2. Whether such action by Petitioner justifies revocation of Petitioner's CLIA certificate and cancellation of its approval to receive reimbursement from Medicare.

I conclude that Petitioner intentionally submitted proficiency

testing samples to a reference laboratory in violation of applicable law and regulations. I conclude further that HCFA's determination to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare reimbursement for its services is mandated under CLIA and applicable regulations. I premise these ultimate conclusions on the following findings of fact and conclusions of law. After each finding or conclusion I set forth the pages in this Decision in which I discuss the applicable law and evidence which supports it.

1. It is a violation of CLIA and applicable regulations for a laboratory intentionally to submit a proficiency testing specimen to a reference laboratory. Pages 3 - 6.

2. Under CLIA and applicable regulations, a laboratory intentionally submits a proficiency testing specimen to a reference laboratory when it does so deliberately, and not inadvertently. Pages 5 - 6.

3. HCFA is required to revoke a laboratory's CLIA certificate and cancel its approval to receive Medicare reimbursement for its services where it is established that the laboratory intentionally referred a proficiency testing specimen to a reference laboratory. Pages 3 - 6.

4. If a laboratory has intentionally referred a proficiency testing sample to another laboratory, that laboratory's motive for referring the sample is irrelevant as a defense against HCFA's revocation of its CLIA certificate or its approval to receive Medicare reimbursement. Pages 5 - 6.

5. Petitioner referred proficiency testing specimens to a reference laboratory. Pages 6 - 9.

6. Petitioner's referral of proficiency testing specimens to a reference laboratory was intentional and not inadvertent. Pages 6 - 9.

7. HCFA was required to revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare reimbursement. Pages 3 - 13.

II. Governing law

A. CLIA

Congress enacted CLIA in order to assure that clinical laboratories perform medical tests accurately. CLIA was intended by Congress to establish a single set of standards to govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. See H.R. Rep. No. 899, 100th Cong., 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N. 3828. 4/

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. The

Act 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). The Act 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).

It is apparent, both from the Act itself and its legislative history, that Congress considers proficiency testing conducted pursuant to standards developed by the Secretary to be an important factor in assuring that clinical laboratories conduct tests accurately and reliably. The Act directs the Secretary to develop standards for proficiency testing. 42 U.S.C. 263a(f)(3). The House of Representatives committee report (cited above) which supported the Act provides that:

> To maintain its certification under the bill, a laboratory would have to participate successfully in a proficiency testing program that met standards established by the Secretary. The Committee believes that proficiency testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes.

1988 U.S.C.C.A.N. 3849 (emphasis added).

Implicit in CLIA is Congress' finding that, in order to be meaningful, a laboratory must perform proficiency tests at its own premises. The Act mandates revocation of a CLIA certificate for improper referral of proficiency testing samples by a laboratory. It states that:

> Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year . . . .

42 U.S.C. 263a(i)(4).

B. Regulations

Regulations governing performance of proficiency tests by clinical laboratories are contained in 42 C.F.R. 493.801. A clinical laboratory must enroll in an approved proficiency testing program. 42 C.F.R. 493.801. The laboratory must notify the Department of Health and Human Services of each program or programs in which it chooses to participate to meet proficiency testing standards. 42 C.F.R. 493.801(a)(1). It is obligated to examine or test each proficiency testing sample that it receives in the same manner as it tests patient specimens. 42 C.F.R. 493.801(b). The laboratory must not send proficiency testing samples to another laboratory for any analysis which the laboratory is certified to perform itself. 42 C.F.R. 493.801(b)(4). The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all

proficiency testing samples. 42 C.F.R. 493.801(b)(5).

Regulations which implement CLIA parallel the Act's requirement that the Secretary revoke a laboratory's CLIA certificate where that laboratory improperly refers a proficiency testing sample to a reference laboratory. 42 C.F.R. 493.1840(b). The regulations provide also that, in the case where HCFA revokes a laboratory's CLIA certificate, HCFA will cancel that laboratory's approval to receive Medicare reimbursement for its services. 42 C.F.R. 493.1842(a).

C. The meaning of the word "intentionally"

The mandatory revocation provision of both the Act and the regulations applies to a laboratory which "intentionally" refers proficiency testing samples to another laboratory for analysis. This term is not defined. However, it is apparent, from both the language of CLIA and the regulations, that it was intended that this term be given its common and ordinary meaning. "Intention" is defined to mean a determination to act in a certain way. Webster's New Collegiate Dictionary, 1975 ed., at 601. "Intentional" or "intentionally" means to act by intention or design. Id. Thus, when one acts "intentionally," he or she acts deliberately.

A laboratory contravenes the prohibition against referrals of proficiency tests by deliberately referring proficiency testing samples to another laboratory. Inadvertent referrals of such samples do not contravene the prohibition. The necessary elements of a violation consist of: (1) a referral by a laboratory to another laboratory of a proficiency testing sample, and (2) knowledge by the referring laboratory that the sample it is referring is a proficiency testing sample. If it is established that a laboratory has deliberately referred a proficiency testing sample to another laboratory, then that laboratory's motive for referring the sample is irrelevant. The Act and regulations do not distinguish between deliberate referrals that are motivated by good intentions and those which are motivated by some other purpose.

III. Relevant facts

This is my analysis of the evidence which led me to make the findings above. In subpart A, I analyze the evidence concerning Petitioner and its activities. These facts are, essentially, background facts, and they are not in dispute. In subpart B, I analyze the evidence concerning HCFA's allegation that Petitioner referred proficiency testing samples to another laboratory. In subpart C, I analyze the evidence about Petitioner's intent. In subpart D, I discuss Petitioner's arguments concerning its motive for referring tests.

A. Petitioner

Petitioner is a clinical laboratory in Ocala, Florida. Petitioner began operating in 1968. Tr. at 102. 5/ It is owned jointly by Edwin Albert Long and his wife, Mary F. Long. Id.; P. Ex. 2 at 2. Mr. Long and his wife perform all of the clinical testing done by Petitioner. Tr. at 103. Clinical tests performed by Petitioner

include tests in the areas of bacteriology, parasitology, general immunology, routine chemistry, urinalysis, endocrinology, and hematology. HCFA Ex. 1 at 3; Tr. at 103 - 104.

B. Petitioner's submission of proficiency testing samples to a reference laboratory

The preponderance of the evidence in this case establishes that, beginning in March 1992, and for at least one year thereafter, Petitioner routinely referred proficiency test samples to a reference laboratory for testing. Petitioner admits referring proficiency test samples to a reference laboratory. That admission is substantiated by exhibits in evidence. Tr. at 57, 181; HCFA Ex. 3, 5, 6, 10 - 14, 16.

In March 1993, Petitioner was surveyed by representatives of the Florida Agency for Health Care Administration. Tr. at 30, 37. This is the State agency in the State of Florida which performs inspections for HCFA pursuant to CLIA. Tr. at 30. Among other things, the inspectors examined the way in which Petitioner was performing proficiency testing. Tr. at 37.

In connection with the survey, the inspectors obtained documents from Petitioner and from a laboratory to which Petitioner had referred specimens for tests. The inspectors obtained documents also from the American Association of Bioanalysts (AAB), the organization which ships specimens to clinical laboratories for proficiency tests and which compiles records as to the proficiency test performance of laboratories.

The inspectors discussed with Mr. Long allegations that Petitioner had referred proficiency test samples to a reference laboratory. Mr. Long admitted to the inspectors that Petitioner had done so, using fictitious patient names to conceal from the reference laboratory the fact that the referred specimens were constituted from proficiency test samples. Tr. at 57. Mr. Long made the same admission during his testimony at the hearing in this case. Tr. at 181. Petitioner denies that it reported to AAB the results of the tests it obtained from the reference laboratory as being the results it obtained on proficiency tests. For reasons which I explain in subpart C, I find this denial to be not credible.

The documents which the inspectors obtained from AAB include copies of reports of proficiency tests submitted by Petitioner and attested to by Albert Long, for four groups of tests in 1992, and one group of tests in 1993. HCFA Ex. 10 - 14; Tr. at 49 - 52. The documents which the inspectors obtained from a reference laboratory document bacteriology tests which were requested from that laboratory by Petitioner between March 1992 and March 1993, and which were performed for Petitioner by the reference laboratory. HCFA Ex. 16; Tr. at 52.

Comparison of these documents establishes a pattern of referrals of tests by Petitioner to the reference laboratory, which produced results similar to those which Petitioner reported subsequently as the results of its proficiency tests. HCFA Ex. 3; Tr. at 54 - 61. For example, on November 18, 1992, Mr. Long attested to AAB that

results of proficiency tests performed by Petitioner established the presence of the following organisms: E. Cloacae (test #1), B-Strep (A) (test #2), and E. Coli (test #5). HCFA Ex. 3 at 2. On November 16, 1992, the reference laboratory had reported to Petitioner identical results for tests that had been referred to it by Petitioner. Id.

The inference which I draw from these similarities is that Petitioner referred proficiency tests to another laboratory and then reported the results of these tests to AAB as the results of its own tests. That inference is supported strongly by additional evidence obtained by the inspectors in connection with the March 1993 survey.

Documents which the inspectors obtained from the reference laboratory prove that Petitioner labeled with fictitious patient names the specimens which it referred to the reference laboratory. HCFA Ex. 16. That, coupled with Mr. Long's admission that he labeled the samples with fictitious patient names, suggests that Petitioner sought to conceal from the reference laboratory the fact that these samples were, in actuality, proficiency test samples that AAB sent to Petitioner.

Petitioner's inability to document the proficiency tests which it allegedly performed between March 1992 and March 1993 provides additional support for my conclusion that Petitioner referred these tests to another laboratory. The only documentation of proficiency tests which Petitioner was able to produce to the inspectors who visited Petitioner in March 1993 consisted of documents pertaining to proficiency tests which Petitioner alleged to have performed in that month. HCFA Ex. 6; Tr. at 39 - 40. This inability to produce documentation of proficiency tests performed prior to March 1993, stands in contrast to the fact that Petitioner produced detailed documentation of actual patient tests which it had performed at its facility during the March 1992 through March 1993 period. HCFA Ex. 5; Tr. at 39.

Furthermore, the documents which Petitioner produced pertaining to the proficiency tests which it allegedly performed in March 1993 are scanty and incomplete. HCFA Ex. 6. This stands in contrast with the more detailed documents which Petitioner provided to inspectors relating to tests of patients' specimens which had been performed on its premises. HCFA Ex. 5. The inference which I draw from comparing documentation of in-house patient tests with alleged documentation of proficiency tests is that the alleged documentation of proficiency tests does not, in fact, document tests that were actually performed by Petitioner.

C. Petitioner's intent

As I find in subpart II C of this decision, a laboratory refers proficiency tests "intentionally" if it does so deliberately, and not inadvertently. The uncontroverted evidence in this case is that Petitioner referred proficiency test samples to another laboratory intentionally. Petitioner has admitted doing so. Tr. at 57, 181. The exhibits confirm a pattern of deliberate referrals of proficiency tests. There is nothing in the record of this case

to suggest that the referrals were inadvertent.

D. Petitioner's asserted motive for referring proficiency tests

As I discuss at subpart II C of this decision, a party's motive for referring proficiency tests is irrelevant under CLIA and implementing regulations, so Long as it is shown that the party referred the tests intentionally. A party cannot defend its deliberate referral of a proficiency test by attempting to show that it referred the test for honorable reasons.

Petitioner alleges that it referred proficiency tests to another laboratory in order to check on the quality of that laboratory's services. Petitioner alleges also that it did not report to AAB as its own proficiency test results the results of proficiency tests that it received from the reference laboratory. These allegations do not controvert my finding that Petitioner referred these tests intentionally. Indeed, Petitioner's defenses are an admission of its intent. Therefore, I would find that Petitioner referred proficiency tests intentionally even if I accepted as true Petitioner's asserted motive for referring these tests, or its allegation that it did not report to AAB the results it received from the reference laboratory. However, I find not credible either Petitioner's explanation for its referrals of proficiency tests or its allegation that it did not report to AAB as its own test results the results it received from the reference laboratory.

I am not persuaded by Petitioner's assertion that it was referring proficiency tests in order to check on the quality of services provided by the reference laboratory. There was no need for Petitioner to refer tests in order to determine whether the reference laboratory was proficient in its testing. Had Petitioner been interested in checking the quality of tests performed by the laboratory to which it referred specimens, it merely had to request that the laboratory's proficiency test results be provided to it. Both CLIA and the regulations require the Secretary to make all proficiency test results available to the public. 42 U.S.C. 263a(f)(3)(F); 42 C.F.R. 493.801(a)(4)(ii). 6/

Petitioner alleges that it did not report to AAB as its own test results the results of the proficiency tests it referred to another laboratory. This assertion is not credible. In order to accept this assertion, I would have to find that Petitioner performed its own proficiency tests on portions of the samples it received from AAB, and that, simultaneously, it referred portions of these same samples to another laboratory. There is simply no credible evidence in the record which might support such findings. As I find above, Petitioner has not provided credible proof that it actually performed these proficiency tests. It produced only documentation relating to tests it allegedly performed in March 1993. HCFA Ex. 6. The records which allegedly document these tests are scanty and incomplete.

Furthermore, Petitioner's allegation that it was performing its own proficiency tests is belied by evidence showing that Petitioner reported to AAB as its own proficiency test results the test

results it received from the reference laboratory. The evidence establishes that, for each of the proficiency tests which Petitioner referred to another laboratory, the results of those tests were sent to Petitioner shortly before it reported test results to AAB. HCFA Ex. 3. This pattern, coupled with the absence of documentation showing that Petitioner performed the proficiency tests, suggests strongly that Petitioner relied on the reference laboratory's reports as a basis for its reports to AAB.

Petitioner avers also that it reported to AAB only proficiency tests in areas in which it conducted testing. It asserts that it would report to AAB that it referred tests in those areas where it did not perform testing at its premises. That assertion may literally be true. But it begs the question of whether Petitioner used the reports it received from the reference laboratory as the basis for the proficiency test results it did furnish to AAB.

The credible evidence of record shows that, from early 1992 through March 1993, Petitioner was referring all of its proficiency tests to a reference laboratory. HCFA Ex. 16. I infer from the record of this case that Petitioner would review the results of the proficiency tests it received from the reference laboratory. It would report as its own test results those tests which involved areas of testing that Petitioner performed on its own premises. It would tell AAB that it referred those tests which did not involve areas of testing that it performed on its premises. See HCFA Ex. 3. Nevertheless, it relied on the reference laboratory to the extent that it reported at least some of that laboratory's test results as its own test results.

IV. Petitioner's additional affirmative defenses

Petitioner asserts that HCFA failed to provide it with notice of CLIA requirements. It contends that, as a consequence, it is being held accountable unfairly to standards of which it had no knowledge. I am not satisfied that Petitioner proved that it was unaware of HCFA standards relating to proficiency testing. Mr. Long admitted that he knew that a "cardinal principal" of proficiency testing is that a laboratory not report as its own results test reports that it obtains from another source. Tr. at 177.

However, it is not necessary for me to find either that Petitioner knew or did not know about CLIA standards in order for me to decide this case. Petitioner had a duty to familiarize itself with applicable standards before applying to be certified pursuant to those standards. Inasmuch as it was Petitioner's duty to be aware of the standards, HCFA cannot be held responsible, either for Petitioner's failure to be aware of the standards, or for HCFA's asserted failure to provide Petitioner with a copy of the standards.

The application for certification under CLIA which Petitioner submitted over Mr. Long's signature provides that:

> The applicant hereby agrees that such laboratory identified herein will be operated in accordance with applicable standards

found necessary by the Secretary of Health and Human Services to carry out the purposes of . . . [CLIA].

HCFA Ex. 1 at 4. Petitioner could not have agreed to operate in accord with applicable standards under CLIA without agreeing also to do whatever was reasonably necessary to familiarize itself with the standards. Thus, in applying for CLIA certification, Petitioner assumed the duties of learning applicable standards and obeying them.

Petitioner argues also that, inasmuch as it is licensed by the State of Florida, it should enjoy "automatic certification" under CLIA. This is, in effect, an argument that CLIA requirements are subordinate to State licensing laws. I disagree with this contention. It is plain from the language of CLIA and its legislative history that Congress intended CLIA to supersede State licensing laws, to the extent that any conflict might exist between CLIA and State laws. Furthermore, there is no evidence that a conflict exists in this case between Florida licensing laws and CLIA. Petitioner has not shown, for example, that Florida law would permit it to refer proficiency tests to a reference laboratory.

Much of Petitioner's arguments are devoted to what it contends constitutes unreasonable interference by HCFA in the operations of independent clinical laboratories. In effect, Petitioner asserts that these laboratories operated successfully for many years pursuant to State licensing requirements. Therefore, according to Petitioner, federal interference in the operations of such laboratories is unreasonable.

This argument ignores a fundamental premise of CLIA, which is that State regulation of clinical laboratories was not functioning effectively to assure that these laboratories produced accurate test results. CLIA was enacted by Congress to provide some national, uniform standards for the operation of clinical laboratories.

This concludes my analysis of the law and evidence in this case.

Steven T. Kessel
Administrative Law Judge

1. Following Petitioner's receipt of HCFA's June 3, 1993 notice, Petitioner submitted material to HCFA in an attempt to correct the deficiencies cited in the notice. By letter of June 28, 1993, HCFA notified Petitioner that its submission of June 10, 1993 did not provide a sufficient basis to rescind HCFA's cancellation of its approval to receive Medicare reimbursement for its services. HCFA stated, however, that it would treat Petitioner's June 10, 1993 submission as a request for a hearing and would delay the revocation of Petitioner's CLIA certificate pending a hearing before an administrative law judge.

2. Although Petitioner was timely in filing its hearing request with HCFA, the request and HCFA's notice were not received by the Civil Remedies Division of the Departmental Appeals Board until February 1994. The case was docketed immediately upon receipt of these documents.

3. Following this hearing, Petitioner offered two additional exhibits. These exhibits were attached by Petitioner to memoranda which he submitted on June 27, 1994 and July 15, 1994. I have marked the attachment to Petitioner's June 27, 1994 submission as P. Ex. 20. I have marked the attachment to Petitioner's July 15, 1994 submission as P. Ex. 21. I am not admitting these exhibits into evidence. They were presented untimely by Petitioner and Petitioner has offered no legitimate reason for their untimely presentation.

4. The Act defines a clinical laboratory to be a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

42 U.S.C. 263a(a).

5. Inexplicably, the transcript refers at page 102 to "Judge Leahy" as presiding over the hearing. Administrative Law Judge Mimi Hwang Leahy of the Board did not participate in the hearing and has had no responsibility for hearing and deciding this case.

6. A better explanation for Petitioner's referral of proficiency tests is that it lacked confidence in its own performance of these tests. Petitioner received a score of 37.5 from AAB for proficiency tests which it reported to AAB in the third quarter of 1991. HCFA Ex. 8; Tr. at 44 - 49. At that time, the minimum passing score for proficiency testing results was 70. Tr. at 48.

Central Valley Medical Laboratory, **CR** No. **335** (1994)

$05:Civil Money Penalty

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Central Valley Medical Laboratory,	)	DATE: September 28, 1994
Petitioner,	)	
- v. -	)	Docket No. C-94-062
	)	Decision No. CR335
Health Care Financing Administration.	)	

DECISION

This case is governed by the Clinical Laboratory Improvement Amendments of 1988 (referred to throughout this decision as "CLIA" or "the Act"), 42 U.S.C. 263a, and implementing regulations at 42 C.F.R. Part 493. On November 15, 1993, the Health Care Financing Administration (HCFA) notified Central Valley Medical Laboratory (CVML or Petitioner) that HCFA had determined to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare payments for its services. HCFA advised Petitioner that it had based its determination on Petitioner's refusal to comply with a directed plan of correction which HCFA had imposed previously, resulting in immediate jeopardy to individuals served by Petitioner. HCFA stated that its determination was justified also by a pattern of failures by Petitioner to comply with the requirements of regulations published pursuant to CLIA.

By letter dated January 13, 1994, Petitioner requested a hearing. I held a hearing in San Francisco, California, on May 10 and 11, 1994. Subsequently, the parties submitted briefs. 1/

I have considered the relevant evidence, the applicable law, and the parties' arguments. I conclude that HCFA's determination in this case is supported by the preponderance of the evidence and the law, and I sustain it.

I. Issues and Conclusions

There are two broad issues in this case which I have resolved in favor of HCFA. In resolving these issues, I make specific conclusions of fact and law. These conclusions are set forth

below, beneath the relevant issues. In setting forth these conclusions, I cite to relevant portions of the decision, at which I discuss my conclusions in detail.

A. Was HCFA authorized to revoke Petitioner's CLIA certificate and to cancel Petitioner's approval to receive Medicare reimbursement for its services based on a pattern of noncompliance by Petitioner with conditions for certification under CLIA? With respect to this issue, I conclude that:

1. Petitioner consistently has failed to comply with conditions for certification under CLIA. Pages 10 - 14.

2. Petitioner's failure to comply with conditions for certification under CLIA is due to the failure of its owner and operator to exercise effective supervision of Petitioner's operations, to institute meaningful quality controls, and to correct deficiencies that were identified in Petitioner's operations. Pages 10 - 14.

3. The condition level deficiencies in Petitioner's operations comprise a pattern of deficiencies in management and in quality control. Pages 15 - 18.

4. The pattern of failure by Petitioner to comply with conditions for certification under CLIA demonstrates that Petitioner is incapable of providing services to its clients which are consistent with the requirements of CLIA and with implementing regulations. Pages 15 - 18.

5. Petitioner's pattern of failure to comply with conditions for certification under CLIA caused immediate jeopardy to individuals whose tests were performed by Petitioner. Pages 15 - 18.

6. HCFA was authorized by Petitioner's pattern of failure to comply with conditions for certification under CLIA to revoke Petitioner's CLIA certificate and to cancel Petitioner's approval to receive reimbursement from Medicare for its services. Page 21.

B. Was HCFA authorized to revoke Petitioner's CLIA certificate and cancel Petitioner's approval to receive Medicare reimbursement for its services, based on Petitioner's failure to comply with a directed plan of correction? With respect to this issue, I conclude that:

7. Petitioner was required by a directed plan of correction imposed by HCFA to supply HCFA with a list of physicians and clients who had requested that Petitioner perform cytology tests. Page 15.

8. Petitioner did not comply with the directed plan of correction. Pages 18 - 20.

9. Petitioner's failure to comply with the directed plan of correction was due to the failure of its owner and operator to

supply HCFA with the list of physicians and clients required by the plan of correction. Pages 18 - 20.

10. Petitioner's failure to comply with the directed plan of correction resulted in immediate jeopardy to patients whose tests had been performed by Petitioner. Pages 18 - 20.

11. HCFA was authorized by Petitioner's failure to comply with the directed plan of correction to revoke Petitioner's CLIA certificate and to cancel Petitioner's authority to receive reimbursement from Medicare for its services. Page 21.

II. Governing law

A. CLIA

Congress enacted CLIA in order to assure that clinical laboratories perform medical tests accurately. CLIA was intended by Congress to establish a single set of standards which govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. H.R. Rep. No. 899, 100th Cong., 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3829 - 3836 (House Report).

The Act defines a clinical laboratory to be:

> a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

42 U.S.C. 263a(a).

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. The Act 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). The Act 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)(1).

The Act directs the Secretary to establish standards for cytology testing by clinical laboratories. 42 U.S.C. 263a(f)(4). 2/ The specific requirements for cytology testing reflect Congress' concern about the potential adverse consequences to patients of PAP smear readings based on improperly prepared slides, or of PAP smears being read by inadequately trained or overworked laboratory employees. House Report at 3852.

Under CLIA, the Secretary may impose sanctions against clinical laboratories which have been certified, but which no Longer meet the requirements for certification. These may consist of intermediate sanctions, including any of the following, either individually or in combination: directed plans of correction, civil money penalties, or payment of costs for outside monitoring of laboratories. 42 U.S.C. 263a(h).

The Act provides for revocation of a CLIA certificate under specified circumstances. These include, among other things, failure by a laboratory's owner or operator to comply with statutory requirements for certification or with standards issued by the Secretary, failure by the owner or operator to respond to reasonable requests by the Secretary for materials or information, or failure by the owner or operator to abide by an intermediate sanction issued by the Secretary. 42 U.S.C. 263a(i)(1)(C), (D), (G).

Although not explicitly stated in the Act, it is apparent that Congress intended that the Secretary employ intermediate sanctions as a remedy to bring noncompliant clinical laboratories into compliance with CLIA certification standards. The more serious sanction of revocation is intended to be applied in cases where laboratories are incapable of complying with standards, where they refuse to comply, or where they fail to cooperate with reasonable requests by the Secretary which are intended to monitor their compliance with CLIA or to protect individuals, including Medicare beneficiaries, from the possible adverse consequences of noncompliance.

B. Regulations

Regulations issued by the Secretary pursuant to CLIA establish standards for certification of clinical laboratories in addition to those contained in the Act. The regulations establish a framework for inspection of clinical laboratories and for certification of laboratories. They provide for the imposition of sanctions in the event that laboratories fail to comply with applicable standards.

The regulations define a CLIA certificate to be a certificate which is issued to a clinical laboratory by HCFA (the agency which has been delegated authority by the Secretary to administer CLIA) after an inspection that finds the laboratory to be in compliance with all condition level requirements. 42 C.F.R. 493.2. 3/ The regulations define condition level requirements to mean those requirements for certification under CLIA established in subparts G through Q of 42 C.F.R. Part 493. Id.

The regulations provide for an enforcement process to assure that clinical laboratories comply with the requirements of CLIA and applicable regulations. Enforcement is intended to protect individuals served by laboratories against substandard testing, to safeguard the public against health and safety hazards which might result from noncompliance, and to motivate laboratories to comply with CLIA requirements. 42 C.F.R. 493.1804(a)(1) - (3).

The regulations give HCFA two types of administrative remedies which it may employ in appropriate cases. These are alternative sanctions and principal sanctions. The alternative sanctions which HCFA may apply in the appropriate case correlate with the intermediate sanctions described in CLIA. They consist, individually or in combination, of directed plans of correction, onsite monitoring, and civil money penalties. 42 C.F.R. 493.1806(c)(1) - (3); see 42 U.S.C 263a(h). The regulations provide also that, for laboratories that participate in Medicare, alternative sanctions may include suspension of payments for Medicare services. 42 C.F.R. 493.1807(b).

The elements of the alternative sanctions which HCFA may impose are explained by the regulations. 42 C.F.R. 493.1832 - .1836. Directed plans of correction are described in 42 C.F.R. 493.1832. As one element of a plan of correction, HCFA may direct a laboratory to submit, within 10 calendar days of notice to the laboratory of the plan, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other time frame specified by HCFA. 42 C.F.R. 493.1832(b)(2)(i).

Principal sanctions consist of remedies which HCFA may impose for any of the reasons set forth in section 263a(i)(1) of the Act. 42 C.F.R. 493.1840(a). For example, HCFA may impose principal sanctions where a laboratory has not complied with applicable standards, where its owner, operator, or employees have not complied with reasonable requests by HCFA for information or materials, or where the laboratory has not complied with an alternative sanction. 42 C.F.R. 493.1840(a)(3), (4), (7); see 42 U.S.C. 263a(i)(1)(C), (D), (G). Principal sanctions may include revocation of a laboratory's CLIA certificate and cancellation of its approval to receive Medicare payments for its services. 42 C.F.R. 493.1806, .1807, .1840(a), .1842.

The regulations permit HCFA to revoke a laboratory's certificate where the laboratory continues to pose immediate jeopardy to individuals. 42 C.F.R 493.1812(b). The regulations provide that HCFA will always cancel a laboratory's approval to receive Medicare reimbursement where HCFA revokes that laboratory's CLIA certificate. 42 C.F.R. 493.1842(a)(1). They provide also that HCFA may cancel a laboratory's authority to receive reimbursement from Medicare for its services where the laboratory fails to comply with condition level requirements or correct deficiencies within the time specified by HCFA. 42 C.F.R. 493.1842(a)(2).

The regulations implement Congress' intent that alternative sanctions be used as a mechanism to remedy deficiencies, but also to encourage laboratories to comply with CLIA. They implement Congress' intent further by reserving principal sanctions for those circumstances where laboratories have demonstrated that they are either incapable of complying with CLIA or where they have failed to comply with alternative sanctions which HCFA has imposed previously. The factors which HCFA considers in determining to impose a particular sanction are specified by 42 C.F.R. 493.1804(d). Paraphrased here, they include:

(1) whether deficiencies identified by HCFA pose immediate jeopardy to individuals whose tests the laboratory performs; 4/

(2) the nature, incidence, severity, and duration of the deficiencies or noncompliance identified by HCFA;

(3) whether the same condition level deficiencies have been identified repeatedly;

(4) the accuracy and extent of laboratory records relevant to noncompliance by a laboratory and their availability to HCFA or to individuals or entities who operate on HCFA's behalf;

(5) the relationship of deficiencies to each other;

(6) the overall compliance history of a laboratory;

(7) the outcome that HCFA intends to achieve through application of a sanction;

(8) whether the laboratory has improved its operations after being given a reasonable opportunity to correct deficiencies; and

(9) any recommendation by a State agency operating on HCFA's behalf as to which sanction would be appropriate.

III. Relevant facts

Subpart A of this section provides background about Petitioner and its ownership and operation. None of these facts is disputed by the parties. Subpart B of this section concerns surveys of Petitioner which were conducted by the State survey agency on behalf of HCFA, the findings of these surveys, and the alternative sanctions which HCFA imposed on Petitioner in order to remedy deficiencies which the surveys uncovered. 5/ Petitioner disputes at least some of the findings of deficiencies which I discuss in subpart B. However, for reasons which I shall explain in subpart B, these findings are administratively final and cannot now be disputed.

As I discuss in more detail below, there are only four questions of fact which are within my authority to decide. The first question is whether condition level deficiencies found by State agency surveyors constitute a pattern of deficiencies in the management of Petitioner's operations, as opposed to separate, unrelated incidents. The second question, assuming such a pattern exists, is whether this pattern proves that Petitioner is incapable of providing laboratory services in compliance with CLIA or poses immediate jeopardy to individuals who rely on Petitioner to perform clinical tests, including PAP smears. I discuss my findings concerning these two questions in subpart C of this section.

The third question is whether Petitioner's director and owner failed to comply with a directed plan of correction. The fourth question is whether failure to comply with a directed plan of correction posed immediate jeopardy to individuals whose tests had

been performed by Petitioner. I discuss my findings concerning the third and fourth questions in subpart D of this section.

A. Petitioner

Petitioner is a clinical laboratory in Modesto, California. Petitioner has operated under various names and with different combinations of owners since 1981. Tr. 5/11 at 197 - 99. 6/ It has operated under its current name since 1991. Tr. 5/11 at 197. Mahindokht Raiszadeh, M.D., has directed Petitioner since its inception. Tr. 5/11 at 199. Dr. Raiszadeh has been the sole owner of Petitioner since August 1992. Id. Dr. Raiszadeh is a physician who is licensed to practice medicine in the States of Arizona and California. Tr. 5/11 at 195. She specializes in the fields of clinical and anatomical pathology, and has been board certified in these fields since 1975. Tr. 5/11 at 196.

Petitioner's services have included tests in the areas of chemistry, hematology, serology, cytology, pathology, histopathology, and bacteriology. Tr. 5/10 at 38 - 39, Tr. 5/11 at 199. The services provided by Petitioner have been provided either directly by Dr. Raiszadeh or by employees working under her supervision. Tr. 5/11 at 199 - 203. Dr. Raiszadeh has been responsible for establishing Petitioner's operating procedures and for monitoring the quality of its services. Id.

B. Condition level deficiencies in Petitioner's operations and HCFA's efforts to remedy those deficiencies with alternative sanctions

Petitioner was surveyed by the State survey agency on behalf of HCFA on five separate occasions beginning in December 1992. These surveys produced findings of numerous and repeated condition level deficiencies in Petitioner's operations. HCFA attempted to remedy these deficiencies by imposing alternative sanctions, including a directed plan of correction.

The intent of the regulations governing appeals of HCFA's initial determinations is that such determinations become final where a party fails to appeal, fails to appeal timely, or abandons an appeal. The regulations provide that hearings in cases involving initial determinations made under CLIA are conducted pursuant to the regulations contained in 42 C.F.R. Part 498. 42 C.F.R. 493.1844(a)(2). A laboratory that is dissatisfied with an initial determination by HCFA under CLIA may request a hearing before an administrative law judge to contest that determination. The Part 498 regulations provide that a party must request a hearing within 60 days of its receipt of a notice of an initial determination. 42 C.F.R. 498.40(a)(2).

The various alternative sanctions imposed by HCFA, including the directed plan of correction, were initial determinations which Petitioner had the right to contest in administrative hearings. However, Petitioner either did not request hearings concerning the determinations to impose these sanctions, or, in the case of one of the determinations, withdrew the hearing request that it had filed. 7/ HCFA's initial determinations to impose alternative sanctions

against Petitioner thus became the Secretary's final determinations, as did the State agency findings of condition level deficiencies on which HCFA based these initial determinations.

Petitioner seeks now to contest at least some of HCFA's initial determinations that condition level deficiencies existed. Petitioner's posthearing brief. I conclude that Petitioner's objections to the findings are either untimely or were made by it previously in connection with a hearing request which Petitioner withdrew. Therefore, I accept the findings of condition level deficiencies made by the State agency in its five surveys of Petitioner. I conclude also that Petitioner no Longer has the opportunity to dispute the authority of HCFA to impose alternative sanctions against it based on the findings of these surveys.

The first of the five surveys was conducted on December 9, 1992. The surveyors found seven condition level deficiencies. HCFA Ex. 1. A condition level deficiency was found in quality control in the performance of moderate and high complexity tests. HCFA Ex. 1 at 11 - 12; 42 C.F.R. 493.1223. Condition level deficiencies were found in the areas of bacteriology and hematology testing. HCFA Ex. 1 at 12 - 15; 42 C.F.R. 493.1227, 493.1253. Condition level deficiencies were found in the performance of the laboratory director of a laboratory performing both moderate and high complexity testing. HCFA Ex. 1 at 16, 26; 42 C.F.R. 493.1403, 493.1441. A condition level deficiency was found in the performance of the general supervisor of a laboratory performing high complexity testing. HCFA Ex. 1 at 31; 42 C.F.R. 493.1459. Finally, a condition level deficiency was found in quality assurance in the performance of moderate and high complexity tests. HCFA Ex. 1 at 35 - 36; 42 C.F.R. 493.1701.

The surveyors concluded that Petitioner was not following manufacturers' instructions in the performance of tests, was not documenting quality control checks, or, in some cases, was not performing such checks. HCFA Ex. 1 at 8, 13. The surveyors found that Dr. Raiszadeh was permitting unlicensed and unsupervised personnel to make quality control decisions routinely. Id. at 17. The surveyors found also that Dr. Raiszadeh was failing to carry out her overall duties to supervise and exercise oversight over Petitioner's activities. Id. at 31.

HCFA provided Petitioner the opportunity to submit a plan of correction to remedy the deficiencies found in this survey. HCFA Ex. 2, 3. Petitioner did not respond. HCFA gave Petitioner a second opportunity. HCFA Ex. 4. This time, Petitioner responded; however, HCFA determined the response to be inadequate and incomplete. HCFA Ex. 5.

The State agency resurveyed Petitioner on February 17, 1993. On this occasion, the surveyors found nine condition level deficiencies in Petitioner's operation. HCFA Ex. 6. Essentially, the surveyors' findings were the same as those in the first survey. Id.; Tr. 5/10 at 78. However, at this second survey, the surveyors examined more closely the chemistry testing being performed by Petitioner. The surveyors found additional deficiencies in this area, associated essentially with their findings that Petitioner's

employees were making numerous unauthorized adjustments to laboratory equipment which was being used to perform chemical analysis. HCFA Ex 6 at 18; Tr. 5/10 at 79 - 80.

On March 2, 1993, the State agency advised Petitioner that it was recommending that HCFA impose principal sanctions against it, consisting of suspension of Petitioner's CLIA certificate and suspension of Petitioner's receipt of Medicare and Medicaid reimbursement. HCFA Ex. 8. On March 3, 1993, HCFA advised Petitioner that it had determined to suspend its CLIA certificate and to suspend Medicare and Medicaid reimbursement to Petitioner. HCFA Ex. 9.

The State survey agency conducted a third survey of Petitioner on March 18, 1993. Based on this survey, the surveyors concluded that two condition level deficiencies persisted. HCFA Ex. 10. These deficiencies were in the areas of quality assurance and in the performance of the duties of laboratory director for a laboratory performing moderate complexity testing. Id. at 23 - 24, 31 - 32; 42 C.F.R. 493.1403, 493.1701. Several of the deficiencies which the surveyors found at this survey had been found to exist in previous surveys. For example, the surveyors found that Petitioner's employees continued to make unauthorized adjustments to laboratory equipment used to perform chemical analysis. HCFA Ex. 10 at 20.

On the basis of this survey and the two previous surveys, HCFA imposed alternative sanctions against Petitioner. HCFA Ex. 13. These sanctions, which were communicated to Petitioner in a notice dated March 30, 1993, supersede the principal sanctions which HCFA advised Petitioner it was imposing in its March 3, 1993 notice to Petitioner. Id.; see HCFA Ex. 9. The alternative sanctions consisted of onsite monitoring of Petitioner and suspension of Medicare payments to Petitioner. Petitioner requested a hearing, but then withdrew the request. Supra n.6.

The State survey agency surveyed Petitioner for a fourth time on April 29, 1993. The survey was conducted as part of the onsite monitoring alternative sanction which HCFA had imposed against Petitioner. The surveyors found three condition level deficiencies. HCFA Ex. 38. Once again, the surveyors documented problems in operating the equipment used to conduct chemistry tests. Id. at 10 - 11, 18. They again found that Dr. Raiszadeh, acting in her supervisory capacity, had failed to assure that Petitioner met the quality of service requirements of CLIA regulations. Id. at 23 - 28. They found a continuing failure by Petitioner to maintain a quality assurance plan and a continuing deficiency in assuring that accurate laboratory testing services were being provided. Id. at 31 - 36.

On June 9, 1993, HCFA advised Petitioner that, based on the findings of the April 29, 1993 survey, the alternative sanctions previously imposed by HCFA would remain in effect. HCFA Ex. 39 at 1 - 2. HCFA further advised Petitioner that it had determined to impose an additional alternative sanction consisting of a directed plan of correction. Id. at 2. Petitioner was advised of its right to request a hearing regarding this determination. Id. However,

Petitioner did not request a hearing.

Petitioner sent its own proposed plan of correction to HCFA on June 4, 1994. However, after reviewing Petitioner's proposal, HCFA determined that it was inadequate. HCFA provided Petitioner with an explanation for its determination on July 15, 1993. HCFA Ex. 40. In response, Petitioner supplied additional information and explanation to HCFA. HCFA reviewed the additional material, and on August 23, 1993, advised Petitioner that it failed to resolve HCFA's concerns about ongoing deficiencies in Petitioner's operations. HCFA Ex. 41. HCFA advised Petitioner that the previously determined alternative sanctions would remain in effect. Id.

The State agency conducted a fifth survey of Petitioner from August 23 - 26, 1993. This survey was triggered by Petitioner informing HCFA that it had decided to discontinue testing in several specialties and subspecialties, but that it intended to continue to conduct tests in the areas of cytology and histology. Tr. 5/11 at 47 - 48. The State agency concluded that, given Petitioner's history of deficiencies, it could not be entrusted to perform testing in these areas without an additional survey being conducted. Id.

The August 1993 survey focused on Petitioner's conduct of cytology tests. HCFA Ex. 42. The surveyors concluded that Petitioner manifested four condition level deficiencies. Id. One of these specifically related to the manner in which Petitioner performed cytology tests. Id. at 9 - 16; 42 C.F.R. 493.1257. The others consisted of repeat findings of deficiencies in the performance of duties by the laboratory director, the technical supervisor, and in quality assurance. HCFA Ex. 42 at 16 - 28; 42 C.F.R. 493.1441, .1447, .1701.

The surveyors concluded that the cytology testing performed by Petitioner manifested serious deficiencies, which resulted in a failure by Petitioner to assure accurate and reliable testing. HCFA Ex. 42 at 10. The surveyors reviewed 421 PAP smear slides and found them to be unreadable due to inadequate preparation or poor staining. Id. at 11. They found that Petitioner had nevertheless issued patient test reports for all 421 of these PAP smears. Id.

The surveyors found additional deficiencies involving the manner in which Petitioner performed cytology tests. They found that Petitioner had not maintained accurate records of the number of PAP smear slides that were being read during a 24-hour period. HCFA Ex. 42 at 10. They found that Petitioner was not comparing malignant and premalignant gynecology reports with previous test results. Id. They found several cases in which Petitioner had rendered negative reports on PAP smear slides which demonstrated apparent abnormalities. Id. at 23 - 24.

On September 15, 1993, HCFA informed Petitioner that, based on the results of the August survey, it had determined to impose additional sanctions. HCFA Ex. 45 at 1 - 2. HCFA advised Petitioner that it was proposing to revoke Petitioner's certificate in cytology because there existed immediate jeopardy to patients

being served by Petitioner. Id. HCFA advised Petitioner that, pending revocation, additional sanctions would apply. These additional sanctions included limitation of Petitioner's CLIA certificate in cytology and limitation of Medicare and Medicaid payments in cytology. Id. Petitioner was advised that, effective September 29, 1993, it could conduct no additional tests in cytology. Id. HCFA told Petitioner that these sanctions would not be rescinded unless HCFA could verify that the deficiencies had been corrected.

On September 20, 1993, Petitioner replied by advising HCFA that, effective September 27, 1993, it would discontinue testing in cytology. HCFA replied to Petitioner by letter dated October 1, 1993. HCFA Ex. 46. HCFA advised Petitioner that it was imposing alternative sanctions consisting of limitation of Petitioner's certificate in cytology and suspension of Petitioner's Medicare and Medicaid payments in cytology. HCFA advised Petitioner further that it was imposing a directed plan of correction. Id. at 2. Petitioner was directed to:

> submit to the State Survey Agency within 10 calendar days, a list of the names and addresses of the physicians, and other clients who have used the laboratory's services in Cytology during the period January 20, 1993 to the present.

Id. HCFA advised Petitioner that it was entitled to request a hearing regarding this determination. Id. Petitioner did not request a hearing.

C. Petitioner's pattern of condition level deficiencies and the potential for harm resulting from those deficiencies

It is evident from the foregoing that, despite repeated surveys by HCFA and the imposition of alternative sanctions aimed at remediation, Petitioner has persisted in manifesting condition level deficiencies in its operations. There is a definite pattern to these deficiencies, and I conclude from this pattern that Petitioner either is incapable of, or unwilling to, correct them. I conclude, furthermore, that the nature of these deficiencies is such as to pose a risk of serious harm to individuals whose tests were performed by Petitioner. This constitutes immediate jeopardy within the meaning of relevant regulations. 42 C.F.R. 493.2.

A central finding in each of the survey reports is the failure of Dr. Raiszadeh, acting as Petitioner's director, to assert meaningful control over the quality of the tests which Petitioner performed. These tests included bacteriology tests, chemistry tests, and preparation of slides of PAP smears, as well as the reading of those slides. Numerous errors were identified in the performance of these tests. They included failure to perform the tests in accordance with the directions issued by the suppliers of testing materials and the manufacturers of equipment utilized by Petitioner. They included failure to produce slides of PAP smears which were readable.

Another central finding in each of the survey reports is the failure of Dr. Raiszadeh, in her capacity of director and

supervisor, to establish procedures which addressed the performance deficiencies identified by the surveyors or to supervise employees effectively. Thus, the surveyors repeatedly identified the same errors in the management of equipment to perform chemistry tests. The surveyors also repeatedly identified failures by Petitioner to document its procedures adequately and to establish meaningful quality control protocols.

The deficiencies in operations identified by the State agency surveyors must be attributed largely to Dr. Raiszadeh's failure to supervise adequately Petitioner's operations or to implement meaningful quality control. It is apparent also that Dr. Raiszadeh did not institute meaningful changes in Petitioner's operations despite repeated surveys and findings of deficiencies, coupled with the imposition of alternative sanctions by HCFA.

These repeated deficiencies establish a pattern of deficiencies, both in the performance of tests by Petitioner and in the management of Petitioner's operations. This pattern of deficiencies placed individuals whose tests were performed by Petitioner at a risk of serious harm and, thus, in immediate jeopardy. The deficiencies identified by the surveyors relate directly to the quality and reliability of tests performed by Petitioner. For example, the surveyors found that Petitioner's staff repeatedly was making unauthorized adjustments to chemistry testing equipment, thereby jeopardizing the accuracy of the tests. These tests had been referred to Petitioner by physicians in order to assist them in diagnosing their patients' medical conditions. Both the referring physicians and their patients were at the mercy of Petitioner's testing procedures. Petitioner's quality deficiencies called into question the accuracy of the test results which it reported to physicians, and the diagnoses that these physicians may have made based on those reported test results.

I conclude, furthermore, that Petitioner's failure to prepare properly PAP smear slides in 421 cases, coupled with its sending of reports based on those slides, is not only a part of this pattern, but in and of itself demonstrates deficiencies which pose a serious risk of harm and immediate jeopardy to patients. These slides were prepared from tests which were made to detect the possible presence of malignancies. Physicians relied on Petitioner's interpretation of the tests to decide whether additional procedures were necessary. Tr. 5/10 at 250 - 51.

Petitioner asserts that the deficiencies identified by the surveyors do not establish a pattern of deficiencies in Petitioner's operations. Petitioner's posthearing brief at 4. Petitioner argues that it may be inferred that these deficiencies showed no jeopardy to patient care because HCFA allegedly "removed" its suspension of Petitioner's CLIA certificate on March 30, 1993.

The record does not support this assertion. The notice which HCFA sent to Petitioner on March 30, 1993 does not reflect a determination by HCFA that the deficiencies identified to Petitioner posed no jeopardy to patient care. To the contrary, that notice states:

Failure to meet these . . . [CLIA] requirements and standards therein seriously limits the facility's capacity to furnish an adequate level of quality of care or services.

HCFA Ex. 13 at 1. HCFA's determination to impose alternative sanctions in lieu of principal sanctions may indicate that, as of March 30, 1993, HCFA had not given up hope that Petitioner might cure its deficiencies. However, it does not by any stretch suggest that HCFA had concluded that the existing deficiencies were less than serious, or that they did not threaten patients with serious harm. Furthermore, my conclusion that the pattern of deficiencies at Petitioner poses immediate jeopardy to individuals is based on the entire record of the inspections of Petitioner, and not on the record as it stood on March 30, 1993.

Petitioner argues also that the survey which was performed on April 29, 1993 showed that the deficiencies identified by the surveyors did not pose immediate jeopardy to patients. Petitioner's posthearing brief at 4; see HCFA Ex. 38. I do not agree with Petitioner's characterization of the results of this survey. As I find above, the surveyors who conducted the April 29, 1993 survey identified three condition level deficiencies. HCFA Ex. 38. Although the surveyors did not state explicitly that these deficiencies constituted immediate jeopardy, it is apparent from the deficiencies that they addressed the central issue of the reliability and quality of Petitioner's services. Moreover, my conclusion that Petitioner's deficiencies pose immediate jeopardy to individuals is based on the cumulative record of deficiencies and not solely on the April 29, 1993 survey.

Finally, Petitioner asserts that the reports of surveys contain inaccuracies and unjustified conclusions. As I find above, Petitioner had the opportunity to challenge the findings of these surveys and HCFA's determinations which were based on these surveys, and either failed to avail itself of the opportunity or withdrew its hearing request. It would not be appropriate now for me to permit Petitioner to bootstrap into this case arguments that it had the opportunity to make previously, but which it did not make.

I conclude from the pattern of deficiencies manifested by Petitioner that it is incapable of complying with the requirements of CLIA. The record of this case establishes repeated identification of serious deficiencies by State agency surveyors. These deficiencies, as I have found, did not vary substantially from survey to survey. They were so serious as to call into question the capacity of Petitioner to conduct tests that were reliable and accurate. HCFA attempted repeatedly to encourage Petitioner to ameliorate these deficiencies, to no avail.

D. Petitioner's failure to comply with the directed plan of correction and the potential for harm arising from Petitioner's failure to comply

On October 1, 1993, HCFA imposed a directed plan of correction on Petitioner which required Petitioner, within 10 days, to supply HCFA with a list of the names and addresses of physicians and other

clients who had requested that Petitioner perform cytology services after January 20, 1993. HCFA Ex. 46 at 2. HCFA contends that Petitioner refused to comply with this directive. Petitioner denies that it refused to comply. Petitioner's posthearing brief at 5 - 6.

Dr. Raiszadeh and Petitioner failed to comply with the directed plan of correction. I conclude that this failure placed in immediate jeopardy those individuals whose PAP smears had been processed and interpreted by Petitioner.

HCFA premised the plan of correction on its conclusion that, in 421 instances, although Petitioner prepared PAP smear slides which could not be read meaningfully, Petitioner had, nonetheless, sent reports to physicians in those cases. HCFA concluded that it was urgent that these physicians be notified so that they could make informed judgments as to whether their patients could be retested for the presence of abnormalities or malignancies. As one of the surveyors testified, based on her findings:

> [T]hese 421 patients think that they have a negative PAP smear when, in essence, they may not because you can't tell what was on these slides.

Tr. 5/10 at 250.

The directed plan of correction was unequivocal. Petitioner could have complied simply by furnishing HCFA with the names and addresses of physicians and other clients who requested that Petitioner perform tests beginning on January 20, 1993.

However, notwithstanding Petitioner's assertions to the contrary, the record demonstrates that Dr. Raiszadeh and Petitioner did not comply with the plan. In the weeks subsequent to the imposition of the plan, there were several conversations between a HCFA representative and Dr. Raiszadeh about the plan. In those conversations, Dr. Raiszadeh made it plain that she would not comply with the plan. On October 15, 1993, in a telephone conversation, Dr. Raiszadeh advised the HCFA representative that Petitioner was ceasing its operations and that, therefore, it did not need to provide HCFA with a client list. Tr. 5/11 at 100 - 01. In a followup conversation on October 18, 1993, Dr. Raiszadeh stated that she had decided to notify clients herself and would not be providing HCFA with a client list. Id. at 101.

Petitioner did not send a list of physicians and clients to HCFA in compliance with the directed plan of correction. On November 20, 1993, nearly two months after HCFA had imposed the plan, Petitioner sent HCFA a letter which listed the names of five physicians. CVML Ex. 20. That letter did not purport to contain a complete list of the names of the physicians or clients who had referred samples to Petitioner, it did not provide any information which would enable HCFA to ascertain whether these physicians had referred samples to Petitioner after January 20, 1993, and it did not provide HCFA with the addresses of the physicians who were listed. Id.

Petitioner sent letters also to various physicians informing them

that their patients had abnormal cytology tests. CVML Ex. 15, 17. These letters do not comply with the directed plan of correction. First, they do not purport to constitute complete notification of physicians or clients who patronized Petitioner after January 20, 1993. More important, the directed plan of correction did not offer Petitioner the option of notifying physicians and clients in lieu of providing HCFA with a list of those individuals. One obvious purpose of the plan was to give HCFA the opportunity to provide these individuals with notification in order to assure that they were properly notified of Petitioner's deficiencies. Implicitly, HCFA had determined that Petitioner could not be trusted with that responsibility.

On November 30, 1993, HCFA told Dr. Raiszadeh that her submission of November 19, 1993 did not constitute compliance with the directed plan of correction. HCFA Ex. 49; see CVML Ex. 20. It provided Dr. Raiszadeh and Petitioner with an additional opportunity to comply with the plan. HCFA Ex. 49. HCFA received no response.

As I find above, Petitioner's failure to produce readable PAP smears in 421 cases, coupled with its preparation and transmission of reports to physicians in those cases, placed the individuals whose PAP smears were involved in immediate jeopardy. These individuals were placed in additional jeopardy by the failure of Dr. Raiszadeh and Petitioner to comply with the directed plan of correction. It was urgent that HCFA be able to notify the physicians whose patients' PAP smears were involved that the results might be inaccurate. Potentially, any of these individuals could have had a malignancy which had not been detected. The failure of Dr. Raiszadeh and Petitioner to respond to the directed plan of correction by providing HCFA with the list of physicians and clients mandated by the plan resulted in a delay in notification of the physicians.

HCFA was able eventually to construct a list of physicians who had referred PAP smears to Petitioner. HCFA sent a letter of notification to these physicians in December 1993. HCFA Ex. 50. This was more than two months after HCFA had imposed the directed plan of correction and after fruitless efforts to obtain a list of referring physicians and clients from Dr. Raiszadeh and Petitioner.

IV. HCFA's authority to impose principal sanctions

Petitioner engaged in a pattern of deficiencies which posed immediate jeopardy to individuals and which established Petitioner to be incapable of meeting the requirements of CLIA. Petitioner failed to comply with a directed plan of correction, placing individuals in immediate jeopardy. I conclude that HCFA was justified in imposing the principal sanctions which it imposed in this case either by Petitioner's pattern of deficiencies or by its failure to comply with the directed plan of correction.

To briefly restate my analysis of the basis for the imposition of principal sanctions, such sanctions may be imposed under CLIA and relevant regulations where a laboratory fails to comply with CLIA requirements, where it fails to comply with an alternative

sanction, or where it fails to respond to HCFA's reasonable requests for information. 42 U.S.C. 263a(i)(1); 42 C.F.R. 493.1840(a). 8/

The relevant law and the evidence in this case give HCFA ample grounds to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare reimbursement for its services. It is evident that alternative sanctions have failed to induce Petitioner to comply with CLIA. Petitioner consistently has failed to comply with CLIA certification requirements and in doing so has posed immediate jeopardy to individuals. Petitioner has failed to comply with an alternative sanction, the directed plan of correction. This failure also has placed individuals in immediate jeopardy. These failures are the direct consequence of the failures of Petitioner's owner and director, Dr. Raiszadeh, to comply with the requirements of CLIA or with the alternative sanctions which HCFA imposed against Petitioner.

This concludes my analysis of the law and evidence in this case.

_____
Steven T. Kessel
Administrative Law Judge

1. With its posthearing brief, Petitioner submitted a letter requesting that I admit in evidence four additional exhibits. One of the exhibits, CVML Exhibit (Ex.) 29, had been offered and rejected at the hearing. Also, I am rejecting the other exhibits, CVML Ex. 4, 6, and 11. Although these three had been listed as proposed exhibits, they were not offered at the hearing. See Transcript, May 11, 1994, at 235 - 38. Their presentation after the hearing is untimely and Petitioner has offered no legitimate reason for their untimely presentation.

2. The Secretary is directed to establish cytology testing standards that include standards governing: (i) the maximum number of cytology slides that may be screened by an individual in a 24-hour period; (ii) record-keeping of cytology tests; (iii) rescreening of cytological preparations; (iv) periodic confirmation and evaluation of the proficiency of individuals who perform cytology tests; (v) procedures for detecting inadequately prepared slides and for assuring that no diagnoses are made based on inadequately prepared slides; (vi) requirements that all cytology tests be performed on the premises of a laboratory that is certified to perform such tests; (vii) requirements for retention of cytology slides by clinical laboratories; and (viii) standards requiring periodic inspection of laboratories performing cytology tests. 42 U.S.C. 263a(f)(4)(B).

3. The regulations specify also that a CLIA certificate may consist of a certificate which has been issued where a laboratory has been found to be out of compliance with one or more condition level requirements, and where alternative sanctions have been

imposed by HCFA. 42 C.F.R. 493.2. Alternative sanctions are defined to be synonymous with intermediate sanctions as specified by the Act. Id.

4. The term "immediate jeopardy" is defined at 42 C.F.R. 493.2 to mean:

> a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

5. Surveys of Petitioner were conducted on HCFA's behalf by the Office of Laboratory Field Services of the California Department of Health Services. This agency is the State agency which HCFA has authorized to conduct surveys for it of clinical laboratories in California.

6. The transcript for May 10, 1994 contains pages numbered 1 - 322. The transcript for May 11, 1994 contains pages numbered 1 - 238. I cite to the May 10 transcript as "Tr. 5/10 at (page)." I cite to the May 11 transcript as "Tr. 5/11 at (page)."

7. On March 30, 1993, HCFA advised Petitioner that it was imposing alternative sanctions, based on findings of condition level deficiencies at a survey conducted on March 18, 1993. See HCFA Ex. 10. Petitioner requested an administrative hearing regarding this determination. I scheduled a hearing in the case. On September 24, 1993, Petitioner notified me that it was withdrawing its request for a hearing. On October 6, 1993, I dismissed Petitioner's hearing request.

8. Both the Act and regulations provide that principal sanctions should be imposed based on a failure by a laboratory's owner or operator to comply with CLIA requirements or to fulfill obligations established by the Act and regulations. That test is met here. Dr. Raiszadeh is the owner and operator of Petitioner. There is no question in this case that actions of Petitioner or failures of Petitioner to act were the consequence of decisions made by Dr. Raiszadeh.

Center Clinical Laboratory, CR No. 358 (1995)

$05:Civil Money Penalty

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Center Clinical Laboratory,	DATE: February 15, 1995
Petitioner,	
- v. -	Docket No. C-93-096
	Decision No. CR358
Health Care Financing Administration.	

DECISION

This action was brought by Center Clinical Laboratory (Petitioner) to contest the findings made and actions taken by the Health Care Financing Administration (HCFA) to enforce the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

The administrative actions at issue ensued from a survey conducted by HCFA's agent under CLIA, the New Jersey Department of Health (State agency), during February and March of 1993. HCFA Exhibits (Ex.) 1, 1a, 1b, 127, 128. HCFA agreed with the State agency that Petitioner failed to meet various conditions of coverage necessary for CLIA certification. HCFA Ex. 127. Between May 27 and June 1, 1993, HCFA imposed various sanctions on what HCFA called a "fast-track" pursuant to its determination that Petitioner posed "immediate jeopardy" to patient health and safety. 1/ HCFA Posthearing Brief (Br.) at 8. After deciding to suspend Petitioner's CLIA certificate while imposing an "alternative sanction" 2/ and directing Petitioner to submit its list of clients for notice of the sanctions, HCFA then revoked Petitioner's CLIA certificate either on June 1 or June 25 of 1993. 3/ HCFA Br. at 2; HCFA Ex. 127, 128. Petitioner timely filed a request for hearing.

During a prehearing conference with the parties, I established one of the issues in this case as "[w]hether the sanctions imposed by HCFA against the laboratory are sanctions authorized by the Act." Order and Notice of Hearing dated October 20, 1993. With respect to the burden of proof in this case, I stated that HCFA "shall have the burden of coming forward with evidence that the sanctions it imposed are authorized." Id. Neither party objected. During hearing, 4/ HCFA specifically noted the foregoing issue in questioning a HCFA official. E.g., Tr. 24.

For the reasons that follow, I have decided in favor of Petitioner on the issue of whether the sanctions HCFA imposed were authorized by law. I have not decided the other issues raised by the parties, i.e., whether deficiencies existed as alleged by HCFA and whether such deficiencies warrant sanctions for reasons I discuss below, which include Petitioner's closure since May of 1993. The authority issue is dispositive for deciding which party is entitled to the relief sought. My finding that HCFA imposed sanctions that were unauthorized entitles Petitioner to the relief it seeks: restoration of its CLIA certificate. See Petitioner's Posthearing Brief (P. Br.) at 19.

ISSUES AND CONCLUSIONS

All issues resolved in this decision relate to HCFA's authority to impose the following sanctions against Petitioner under the facts of this case:

A. suspending Petitioner's CLIA certificate effective June 1, 1993 (HCFA Ex. 127);

B. imposing the "alternative sanction" of directing Petitioner to provide an "acceptable plan of correction .... prior to June 1st," or have its CLIA certificate revoked (HCFA Ex. 127);

C. requiring Petitioner to submit a list of its clients within 10 days of May 27, 1993, to enable HCFA to send out notices of the sanctions imposed against Petitioner (HCFA Ex. 127);

D. "suspending [Petitioner's] approval to receive Medicare payment for services ....." effective June 1, 1993 (HCFA Ex. 127);

E. revoking Petitioner's CLIA certificate effective either on June 1 or June 25, 1993 (HCFA Br. at 1; HCFA Ex. 128);

F. continuing in effect the "suspension" of Petitioner's approval to receive Medicare payment for services (HCFA Ex. 128).

With respect to HCFA's authority to impose the foregoing sanctions in this case, I have concluded that:

1. HCFA's decision of May 27, 1993 to suspend Petitioner's CLIA certificate effective June 1, 1993, was premature and not in accordance with HCFA's obligations under 42 C.F.R. 493.1812.

2. HCFA's decision to impose an alternative sanction of directing Petitioner to submit an "acceptable plan of correction . . . prior to June 1st" was improper, and the "alternative sanction" imposed by HCFA was not authorized under the regulations.

3. HCFA's "suspending [Petitioner's] approval to receive Medicare payment for services ...." was an invalidly imposed principal sanction, and HCFA has not imposed a directed portion of a plan of correction within the meaning of the regulations.

4. HCFA's actions of June 1, 1993, purporting to revoke Petitioner's CLIA certificate and cancel Petitioner's approval to receive Medicare payment also exceeded its authority under the regulations.

5. HCFA's actions and omissions in this case do not represent harmless error.

6. It is not necessary or feasible for me to decide at this time whether Petitioner had condition level deficiencies in February through March of 1993.

ANALYSIS OF LAW AND FACTS

I. HCFA's actions on May 27, 1993 exceeded those authorized by the Secretary's regulations.

I will begin my analysis of HCFA's authority to impose the particular sanctions at issue by focusing on the following portions of HCFA's letter dated May 27, 1993:

> You are out of compliance with these conditions as evidenced by the State survey February 18 - March 10, 1993, and subsequent State analysis of your records. The State has recommended to our office that these deficiencies, which result from the pervasive occurrence of management sanctioned fictitious patient test results and fabricated control data, has created a situation of immediate jeopardy to patient health and safety.
>
> Accordingly, we have determined that it is necessary to apply the principal sanction of suspension of your CLIA registration certificate effective June 1, 1993. In addition, we are also suspending your laboratory's approval to receive Medicare payment for services concurrently with the CLIA suspension. You should . . . provide a list of the names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory during the past year, within ten days of this notice.
>
> You should be aware that 42 C.F.R. 493.1832 provides that your clients should be notified of this action. In addition, as an alternative sanction under this regulation, you are directed to provide an acceptable plan of correction to the cited deficiencies prior to June 1st. Should you fail to provide an acceptable plan of correction your CLIA certification will be finally revoked. [A]ny implementation will be subject to State onsite monitoring.

HCFA Ex. 127.

HCFA's letter purports to notify Petitioner that HCFA has determined that Petitioner's deficiencies pose immediate jeopardy to patients. As a result of this determination, HCFA states that it is imposing four sanctions: (1) suspending Petitioner's CLIA certificate; (2) suspending Petitioner's approval to receive

Medicare payments; (3) directing Petitioner to provide a list of its clients within ten days; and (4) directing Petitioner to provide an acceptable plan of correction prior to June 1st. For the reasons discussed below, I conclude that each of these sanctions, at least as applied by HCFA in this case, was unauthorized. As a preliminary matter, I will explain the rights and obligations that the regulations impose on HCFA when it makes a determination of immediate jeopardy.

A. The regulations specify the remedies HCFA may impose on laboratories it determines pose immediate jeopardy.

I do not have jurisdiction to review the merits of HCFA's determination that a laboratory's deficiencies pose immediate jeopardy. 42 C.F.R. 493.1844(c)(6). However, I have the authority to review HCFA's imposition of sanctions after it determines immediate jeopardy. See 42 C.F.R. 493.1844(b)(1), (3).

Subpart R of 42 C.F.R. Part 493 sets forth the policies and procedures that HCFA is to follow to enforce the requirements applicable to laboratories under CLIA and under section 1846 of the Act. 42 C.F.R. 493.1800(b)(1). The Secretary has explained by regulation that the enforcement mechanisms set forth in subpart R are intended to protect those served by laboratories, to safeguard the general public against health and safety hazards, as well as "[t]o motivate laboratories to comply with CLIA requirements ...." 42 C.F.R. 493.1804(a). Therefore, I will analyze the regulatory requirements and HCFA's actions in light of the remedial purpose of protecting public health and safety.

As HCFA was aware, the provisions of 42 C.F.R. 493.1812 are applicable to cases where HCFA determines that a laboratory's condition level deficiencies pose immediate jeopardy. See, e.g., HCFA Ex. 128; HCFA Br. at 2. This regulation provides HCFA with two principal avenues by which to take action against a laboratory whose condition level deficiencies pose immediate jeopardy: one in an administrative forum and the other in federal court. 42 C.F.R. 493.1812, 1844.

When HCFA chooses the administrative forum to protect the public's health and safety, HCFA assumes the following rights and obligations, pursuant to its immediate jeopardy determination:

(a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.

(b) If the findings of a revisit survey indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

42 C.F.R. 493.1812(a), (b). As defined by the Secretary's regulation and noted in HCFA's May 27, 1993 letter, the suspension

or limitation of a CLIA certificate constitutes a "principal sanction." 42 C.F.R. 493.1806(b). 5/

In addition, HCFA may bring suit in federal court to enjoin or restrain the continuation of activities which, in HCFA's view, pose substantial hazards to the public health. 42 C.F.R. 493.1806(d), .1812(c). 6/

In this case, HCFA did not bring any action in federal court against Petitioner, its managers, or its employees after finding immediate jeopardy. Therefore, based on HCFA's contention that it proceeded under 42 C.F.R. 493.1812, I have compared HCFA's administrative actions to those required by subparts (a) and (b) of the regulation.

The plain language of subsections (a) and (b) of 42 C.F.R. 493.1812 establishes a sequence of steps which HCFA must pursue in the administrative enforcement process. Specifically, the regulation requires HCFA to give a laboratory reasonable assistance and an opportunity to eliminate the problems which led to HCFA's finding of immediate jeopardy before HCFA formulates a decision on whether to suspend the laboratory's CLIA certificate. This sequence of steps advances the Secretary's interest in public health and safety. HCFA may not immediately suspend a CLIA certificate upon finding immediate jeopardy. If the immediate jeopardy is sufficiently significant to warrant discontinuing the laboratory's activities forthwith, the proper course for HCFA to take is to file suit and seek an injunction or restraining order in court. 42 C.F.R. 493.1812(c).

Even after HCFA has taken the requisite steps that would permit it to suspend the laboratory's CLIA certificate, this principal sanction may be put into effect "no earlier than 5 days after the date of notice of suspension or limitation." 42 C.F.R. 493.1812(b). However, there is no prohibition against putting these sanctions into effect after a Longer period.

B. HCFA's decision of May 27, 1993 to suspend Petitioner's CLIA certificate effective June 1, 1993 was premature and not in accord with HCFA's obligations.

1. HCFA provided Petitioner with no meaningful opportunity to remedy the immediate jeopardy alleged by HCFA.

In this case, I find as a threshold matter that HCFA lacked the authority to suspend Petitioner's CLIA certificate on May 27, 1993. I have noted that one of the purposes of the regulations is to motivate laboratories to comply with CLIA requirements, so that the public may receive safe and reliable laboratory services. However, Petitioner's suspension, as implemented by HCFA, failed to serve this remedial purpose. This is so because HCFA failed to give Petitioner any meaningful opportunity to remove the alleged jeopardy.

When HCFA determines that a laboratory's deficiencies pose immediate jeopardy, HCFA may not suspend the laboratory's CLIA

license until after HCFA has required the laboratory to take immediate action to remove the jeopardy and then found, pursuant to a revisit survey, that the laboratory has not eliminated the jeopardy. 42 C.F.R. 493.1812(a), (b). I do not read HCFA's letter dated May 27, 1993 as meeting HCFA's obligation to direct Petitioner to take those specific actions that would immediately remove the jeopardy. 42 C.F.R. 493.1812(a). HCFA's letter proceeded from summarizing the State agency's recommended findings of immediate jeopardy to HCFA's announcing: "Accordingly, we have determined that it is necessary to apply the principal sanction of suspension . . . ." HCFA Ex. 127. 7/ HCFA's letter then informed Petitioner that suspension had been imposed and would take effect on June 1, 1993. HCFA Ex. 127. The contents of the letter are insufficient to meet the remedial purposes of 42 C.F.R. 493.1812.

HCFA has introduced an undated letter from the State agency to Petitioner, which may or may not have been sent in May of 1993. HCFA Ex. 1b; see Tr. 18. HCFA has not argued that this letter satisfies the requirements of 42 C.F.R. 493.1812(a). However, had such an argument been made, I would reject it.

This undated letter indicates that a "Statement of Deficiencies (HCFA 2567)" (HCFA Ex. 1 at 1 - 6) prepared by the State agency surveyors also was sent to Petitioner as an enclosure and that the State had made a determination of imminent jeopardy due to fictitious, unsubstantiated, or unreliable patient test results. HCFA Ex. 1b. However, even assuming that the undated letter was sent prior to May 27, 1993 and that HCFA's agent may require Petitioner to take those immediate actions necessary for the removal of imminent jeopardy, 8/ the State agency's letter did not tell Petitioner the actions that must be taken by Petitioner to remove the jeopardy. The undated letter merely told Petitioner that, if Petitioner disputed the correctness of the cited deficiencies, Petitioner could forward a "credible allegation of compliance" to HCFA. HCFA Ex. 1b.

The information sent by the State agency and HCFA to Petitioner concerning the immediate jeopardy determination does not obviate the need for HCFA to require Petitioner to remove the jeopardy alleged by HCFA. See 42 C.F.R. 493.1812(a). HCFA sent Petitioner its letter dated May 27, 1993, and the State agency indicated that it was sending Petitioner the "Statement of Deficiencies (HCFA 2567)" and the "Survey Report" under separate covers. 9/ However, the information contained in both the "Survey Report" and "Statement of Deficiencies" is at variance with the conclusions summarized by HCFA in its May 27, 1993 explaining its finding of immediate jeopardy.

The findings of the February/March 1993 survey are contained in the "Statement of Deficiencies (HCFA 2567)" and "Survey Report" forwarded to Petitioner by the State agency. In these documents, the State agency noted its conclusion that fictitious urine microscopic results were being reported routinely. HCFA Ex. 1 at 3, 7. However, with respect to whether such activities were known to Petitioner's management, the State surveyors had stated merely: "the director must either have been aware of how those results were

obtained . . . or he must have been unaware of how the laboratory was being operated." HCFA Ex. 1 at 3 (emphasis added). With respect to the alleged fabrication of control data, the State agency's survey report informed HCFA: "[E]ither the laboratory's recorded control results were not genuine analytical values or, if they were real values, then the test system was consistently out-of-control." HCFA Ex. 1 at 26 (emphasis added). In its undated letter to Petitioner concerning its recommendations to HCFA, the State agency did not allege any "management sanctioned" improprieties; nor did the State agency allege any fabricated control data as a basis for its immediate jeopardy determination. HCFA Ex. 1b.

In the State's May 25, 1993 letter to notify Petitioner of the State's findings and the imposition of sanctions under State law, the State asserted management involvement in "deceptive practices." HCFA Ex. 114. 10/ The letter summarized the State of New Jersey's dealings with Petitioner. HCFA Ex. 114. The State noted that the alteration of control data had been observed during the surveys of 1990 and 1991, and that the State had assessed civil monetary penalties against Petitioner for these infractions in 1991. HCFA Ex. 114.

However, HCFA stated to Petitioner in its May 27, 1993 letter that it (HCFA) was using evidence from "the State survey February 18 - March 10, 1993," and that:

> The State has recommended to our office that these deficiencies, which result from the pervasive occurrence of management sanctioned fictitious patient test results and fabricated control data, has created a situation of immediate jeopardy . . . . Accordingly, . . . it is necessary to apply the principal sanction of suspension . . . .

HCFA Ex. 127. HCFA did not purport to have used the results of any earlier survey conducted by the State or for HCFA. Nor did HCFA purport to have taken into consideration the State's prior imposition of sanctions under State law during 1991.

Without doubt, HCFA may draw its own conclusions or adopt opinions that the State agency made known to HCFA but did not share with Petitioner. See HCFA Ex. 1a at 2. 11/ However, the information made available to Petitioner on or about May 27, 1993 does not adequately inform Petitioner of the remedial actions that must be taken by Petitioner to remove the jeopardy perceived by HCFA. I trace the cause of HCFA's conduct in this action to the State agency's recommendation that "HCFA take appropriate action to remove that jeopardy," (HCFA Ex. 1a at 2)(emphasis added), by immediately precluding Petitioner's operation and by revoking Petitioner's CLIA certificate (HCFA Ex. 1b). HCFA appears to have accepted and followed the literal terms of those recommendations. Such recommendations were inconsistent with the requirements of the Secretary's regulations, which obligate HCFA to give Petitioner appropriate notice of the necessary remedial actions and entitle Petitioner to a reasonable opportunity to remove the jeopardy before HCFA proceeds to close down Petitioner's operation as a means for removing the jeopardy. See, e.g., 42 C.F.R.

493.1804(a)(3), 1812(a).

I am aware that the State agency believed Petitioner's managers were flouting federal law, as well as the laws of at least two States. For example, the State agency told HCFA in its transmittal report that Petitioner's managers had "irrevocably betrayed the public trust and
. . . demonstrated that they are contemptuous of all laboratory laws and regulations," and "much of [Petitioner's] testing was performed in violation of New York State's laboratory laws." HCFA Ex. 1a at 2. Without doubt, the State agency was entitled to convey those opinions to HCFA in May of 1993, and HCFA could reasonably choose to believe the opinions of its agent when, as HCFA acknowledged at hearing, HCFA had had no direct dealings with Petitioner. E.g., Tr. 34 - 35, 38 - 39. 12/ However, given the surveyors' comments in the "Survey Report" and "Statement of Deficiencies" that were transmitted to both HCFA and Petitioner (e.g., Tr. 14, 17 - 18, 32, 38 - 39), HCFA should have been aware of the possibility that Petitioner's management may not have known how the deficiencies found in 1993 had occurred or their full extent. Therefore, Petitioner's management may have needed HCFA's assistance to eliminate quickly any resultant jeopardy perceived by HCFA. If HCFA had followed the requirements of 42 C.F.R. 493.1812 on May

27, 1993, its actions would have accommodated those possibilities and fulfilled the remedial purposes of the law.

I have considered the possibility of construing HCFA's imposition of an "alternative sanction" as HCFA's requirement that Petitioner take very immediate actions ("prior to June 1st") to remove the jeopardy. However, the nature of the "alternative sanction" in this case (i.e., for Petitioner to submit a plan of correction acceptable to HCFA) is so vague and subjective that it defeats the mandate of the regulation that HCFA require immediate action by Petitioner to remove the jeopardy. In addition to having placed Petitioner under an unreasonably short timetable (as discussed below), HCFA's letter did not specify those elements that must be contained in a plan that HCFA would find acceptable. HCFA Ex. 127. As also discussed below, the meaning HCFA has since given to its requirement for an "acceptable plan" is not persuasive, not consistent with other facts in this case, and could not have been anticipated by Petitioner.

In addition, even reading HCFA's May 27, 1993 letter as requiring immediate action by Petitioner to remove imminent jeopardy, the letter goes on to announce HCFA's decision, as of that date, to suspend Petitioner's CLIA certificate effective June 1, 1993, an action which was improper under the regulations. See, e.g., Tr. 39. Contrary to the requirements of 42 C.F.R. 493.1812, HCFA made its decision to suspend the CLIA certificate before the expiration of the "alternative sanction" and without having made provisions for conducting any revisit survey that may have been warranted, if HCFA had given Petitioner a reasonable opportunity to remedy the alleged jeopardy. 13/

The unique facts in this case especially necessitated HCFA's

issuing clear directives to Petitioner on how HCFA expected Petitioner to eliminate the jeopardy that allegedly existed at or about the time of its May 27, 1993 sanction notice. In addition to those discrepancies already discussed above, I note also that the State of New Jersey had imposed various State sanctions against Petitioner pursuant to State law on May 25, 1993. The State summarily suspended Petitioner's license to operate as of May 25, 1993, it ordered Petitioner to cease and desist from all laboratory operations "effective immediately," and it assessed a fine of $100,000 against Petitioner. HCFA Ex. 114. There is no evidence that Petitioner had a license from another state. Petitioner has been closed since the end of May 1993. E.g., Tr. 935.

The regulations do not permit me to review the merits of HCFA's May 27, 1993 determination of immediate jeopardy. 42 C.F.R. 493.1844(c)(6). However, the actions taken by the State of New Jersey on May 25, 1993, together with Petitioner's closure a few days thereafter, are intervening events that should have changed the conditions that had previously constituted immediate jeopardy. For example, the effect of the State's cease and desist order or Petitioner's closure should have eliminated the occurrence of those fabricated test results which, prior to May 25, 1993, had allegedly posed immediate jeopardy.

If HCFA concluded otherwise, I cannot disturb that conclusion. However, it behooves HCFA to explain the nature of the immediate jeopardy it perceived after the State of New Jersey had suspended Petitioner's license and placed it under a cease and desist order, and Petitioner had closed its operations. It behooves HCFA also to explain by what means it expected Petitioner to eliminate any immediate jeopardy perceived by HCFA when Petitioner was unable to operate as a laboratory in New Jersey, was not operating as a laboratory in New Jersey, and did not appear to have a license to operate as a laboratory elsewhere. Since the regulation contemplates the possibility of a revisit survey for HCFA to verify the elimination of the jeopardy (assuming that HCFA had truly discerned some immediate jeopardy that remained to be eliminated after May 25, 1993 and gave Petitioner the opportunity to remedy it), HCFA also should have explained how it could have resurveyed a laboratory to ascertain compliance when that laboratory could not operate and had closed. See 42 C.F.R. 493.1812(b). No such explanation was made in HCFA's notice letters to Petitioner or in the proceedings before me. Under the Secretary's regulations, a determination of immediate jeopardy does not serve as an excuse for revoking a laboratory's CLIA certificate, as indicated by HCFA's actions in this case.

2. HCFA failed to adhere to the time requirements specified in the Secretary's regulation, and Petitioner's history does not excuse HCFA's omissions.

HCFA has failed also to comply with the regulatory requirement that HCFA "suspends ... the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension . . . ." 42 C.F.R. 493.1812(b) (emphasis added). The regulation does not state that HCFA may place the sanction into effect on the fifth day after the date of notice. I read the words as meaning that the

sanction may go into effect only when five full days have elapsed after the date of notice. Here, there are only four full days between the date of HCFA's notice letter (May 27, 1993) and the effective date of suspension (June 1, 1993).

HCFA argues that the five day limitation of 42 C.F.R. 493.1810(c)(2)(i) authorized HCFA to take swift action. HCFA Br. at 43. However, I note that 42 C.F.R. 493.1810 is titled "[i]mposition and lifting of alternative sanctions." This regulation does not pertain to the imposition of principal sanctions such as the suspension of Petitioner's CLIA certificate. The swiftness of HCFA's actions cannot be contrary to the Secretary's regulation that is applicable to the course of action HCFA has chosen (e.g., imposing the principal administrative sanction of suspension, as opposed to seeking a temporary restraining order in court).

HCFA contends that Petitioner had "a history back in 1990 and 1991 of deficiencies" relating to fictitious reporting of data. Tr. 8. According to HCFA, Petitioner had several years of notice and warnings to stop reporting fictitious test results and fabricating control data. HCFA Br. at 49. HCFA claims also to have given Petitioner "three opportunities" (i.e., three surveys) before HCFA decided that Petitioner was no Longer trustworthy. Tr. 8. However, I find that Petitioner's history does not justify HCFA's imposing sanctions prematurely.

The regulation HCFA applied against Petitioner was 42 C.F.R. 493.1812 (e.g., HCFA Br. at 2), which did not take effect until February 28, 1992. 57 Fed. Reg. 7237 (1992). Even if the regulation could be applied retrospectively to sanction Petitioner for the results of the 1990 and 1991 surveys, the evidence does not establish that any notice of immediate jeopardy was issued to Petitioner pursuant to the 1990 or 1991 surveys. Nor does the evidence establish that HCFA had required the laboratory to take immediate action to remove any immediate jeopardy that may have resulted from the 1990 or 1991 deficiencies. 14/

In addition, HCFA's letter dated May 27, 1993 referred only to the February/March 1993 survey and the conclusions based on that survey. HCFA Ex. 127. HCFA did not claim to have reviewed any Statement of Deficiencies or Survey Report for the 1990 or 1991 surveys when it decided to impose sanctions on May 27, 1993. HCFA's official testified that, in order to make the decisions reflected in its letter of May 27, 1993, HCFA had reviewed four documents it received from the State agency: the transmittal form and attachment (HCFA Ex. 1a), the Statement of Deficiencies (HCFA Ex. 1 at 1 to 6), the surveyors' narrative report (HCFA Ex. 1 at 7 to 34), and an undated letter advising Petitioner of the State agency's recommendations to HCFA (HCFA Ex. 1b). Tr. 14 - 18. HCFA did not conduct an independent survey of Petitioner at any time, but a professional component of HCFA did evaluate the contents of the above-mentioned four documents. Tr. 34 - 35, 38 - 39.

Therefore, even though the survey conducted in 1993 was the third survey of Petitioner and might even be termed a "resurvey" due to requirements of the CLIA laws and the State agency's allocation of

its resources, 15/ the 1993 survey was not done in the context of 42 C.F.R. 493.1812(b). In May of 1993, HCFA was not attempting to sanction Petitioner for the outcome of the 1990 and 1991 surveys. The Petitioner's history does not make valid HCFA's decision to summarily suspend Petitioner's CLIA certificate on May 27, 1993. For this reason, and for the reasons discussed above, HCFA's imposition of the principal sanction of suspension of Petitioner's CLIA certificate was unauthorized and premature.

C. HCFA's decision to impose the alternative sanction of directing Petitioner to submit an "acceptable plan of correction . . . prior to June 1st" was improper, and the "alternative sanction" imposed by HCFA was unauthorized.

1. HCFA lacked authority to impose any alternative sanction in the manner it did on May 27, 1993.

An alternative sanction may be imposed in lieu of, or in addition to, a principal sanction. 42 C.F.R. 493.1806(c). In this case, HCFA imposed what it styled an "alternative sanction" in addition to those principal sanctions it imposed. HCFA Ex. 127. 16/

However, just as HCFA's imposition of the principal sanction of suspension was unauthorized, HCFA's attempt to impose alternative sanctions was similarly flawed. Even though HCFA may use an alternative sanction to bring about compliance in the case of immediate jeopardy, HCFA may not impose any alternative sanction immediately upon finding imminent jeopardy. See 42 C.F.R. 493.1810, 1812. Before deciding to impose any alternative sanction, HCFA has an obligation to notify the laboratory of HCFA's proposal to impose it, permit the laboratory an opportunity to respond, and acknowledge the receipt of any response provided by the laboratory. 42 C.F.R. 493.1810(a) - (c); see also, 42 C.F.R. 493.1832(b)(1)(i).

As applicable to this case, 42 C.F.R. 493.1810 ([i]mposition and lifting of alternative sanctions) required HCFA to issue two distinct types of notices to Petitioner. Subsection (a) required HCFA to issue a "notice of noncompliance and of proposed [alternative] sanction"; subsection (c) required HCFA to issue a "notice of imposition of [alternative] sanction." 17/ There are non-duplicative requirements specified in each of these subsections for the timing and contents of these two different types of notices; both must be sent out even if immediate jeopardy is involved.

To the extent that the notice requirements for imposing an alternative sanction may seem cumbersome in the context of an immediate jeopardy situation, I note that HCFA is not required to impose an alternative sanction to redress immediate jeopardy. 42 C.F.R. 493.1812. HCFA must require the laboratory to take immediate action to remove the jeopardy; however, HCFA may impose an alternative sanction to help bring the laboratory into compliance. 42 C.F.R. 493.1812(a). Therefore, if HCFA wishes to use an alternative sanction in an immediate jeopardy case, it also must adhere to the process and purposes specified in the

regulations applicable to alternative sanctions.

In a notice of noncompliance and of proposed alternative sanction, HCFA or its agent must state the rationale for the proposed alternative sanction and inform the laboratory that it has at least 10 days to respond to the notice. 42 C.F.R. 493.1810(a), (b). Even when HCFA finds immediate jeopardy and wishes to impose an alternative sanction, there exists no regulatory authority for HCFA to dispense with notifying a laboratory of HCFA's finding of noncompliance and of the proposed sanction, as such notice is required by 42 C.F.R. 493.1810(a). Nor is there any regulation authorizing HCFA to shorten or eliminate this minimum 10-day notice and response period for any reason when HCFA sends out its notice of noncompliance and of proposed sanction.

Assuming that HCFA has complied with the regulatory requirements for issuing a notice of noncompliance and of proposed alternative sanction, HCFA (not its agent) may then send out a notice of imposition of alternative sanction, which must contain, inter alia, written acknowledgement of any evidence or information the laboratory may have sent, aLong with the authority and rationale for the imposed sanction. 42 C.F.R. 493.1810(c). It is the notice of the imposition of an alternative sanction (not the notice of noncompliance and of proposed alternative sanction) that HCFA must provide "at least 5 days before the effective date of the sanction" if HCFA finds immediate jeopardy. 42 C.F.R. 493.1810(c)(2)(i). In the absence of immediate jeopardy, HCFA would be obligated to provide its notice of imposition of sanction at least 15 days before the effective date of the alternative sanction. 42 C.F.R. 493.1810(c)(2)(ii).

In this case, HCFA failed to send out a notice of noncompliance and of proposed alternative sanction. HCFA also did not provide Petitioner with a minimum of 10 days to respond to such a notice. Instead, HCFA notified Petitioner of the noncompliance in the same May 27, 1993 letter that imposed an "alternative sanction." Even in imposing an "alternative sanction" in its May 27, 1993 letter, HCFA failed to give Petitioner notice "at least 5 days before the effective date of sanction," June 1, 1993. 42 C.F.R. 493.1810(c)(2)(i) (emphasis added); HCFA Ex. 127. The words used in the regulation cannot be read as authorizing HCFA to impose an "alternative sanction" that takes effect on the day of the notice letter and lasts less than five days thereafter. HCFA Ex. 127 (see reference to "prior to June 1st").

Also, the State agency's undated letter to Petitioner does not satisfy the notice requirements of 42 C.F.R. 493.1810. See HCFA Ex. 1b. First, HCFA's agent may give notice of the noncompliance and any alternative sanction it proposes against a laboratory; but HCFA itself must give written notice of HCFA's decision to impose an alternative sanction. 42 C.F.R. 493.1810(a), (c). Therefore, the State's undated letter cannot be construed as a written notice of HCFA's decision to impose the "alternative sanction" at issue.

Next, with respect to the issue of whether the State's undated letter may constitute a valid notice of noncompliance and of

proposed alternative sanction, there are several problems which preclude the letter from meeting the requirements of 42 C.F.R. 493.1810(a). As already noted, notice of noncompliance and of proposed alternative sanction must precede the notice of imposition of alternative sanction. There is no proof in this case that the undated letter was sent out or received in advance of HCFA's May 27, 1993 decision to impose an alternative sanction that same day. See, e.g., Tr. 18.

Also, the State's undated letter does not inform Petitioner that the State agency, as HCFA's agent, is proposing to impose any alternative sanctions against Petitioner. Instead, the undated letter summarily asserts that the State agency has recommended that HCFA take "[i]mmediate action to preclude continued operation of the laboratory" and revoke Petitioner's CLIA certificate. HCFA Ex. 1b. Neither revocation nor the preclusion of continued operation is an alternative sanction, and neither is a sanction that can help bring Petitioner into compliance with the CLIA requirements. See 42 C.F.R. 493.1806(c), 1807(b), and 1812(a). The undated letter also contains no projected effective date or duration of any proposed sanction, as required by 42 C.F.R. 493.1810(a)(4). The undated letter from the State to Petitioner was not a notice of noncompliance and of proposed alternative sanction within the meaning of 42 C.F.R. 493.1810(a).

This undated letter does not notify Petitioner that Petitioner has a minimum of 10 days to respond under 42 C.F.R. 493.1810(a)(6). More importantly, even if the undated letter had been sent to Petitioner at the earliest possible date and contained something that could be considered a proposal to impose an alternative sanction, this undated letter would not have provided Petitioner with the required 10 days to respond. Because the State agency did not send its survey findings and recommendations to HCFA prior to May 21, 1993 (HCFA Ex. 1a; Tr. 14, 18), the State's undated letter to Petitioner referencing those findings and recommendations to HCFA also could not have been sent before May 21, 1993. By May 27, 1993, HCFA had already made its decision to impose the "alternative sanction." HCFA Ex. 127. Therefore, even if the facts were construed in the best light possible for HCFA, Petitioner was still deprived of the 10 days to respond to any finding of noncompliance or proposed alternative sanction that may have been contained in the State's undated letter. 42 C.F.R. 493.1810(a)(6), (b).

For all of the foregoing reasons, I conclude that on May 27, 1993, HCFA was without authority to put into effect what it styled an "alternative sanction."

2. The time limit imposed by HCFA in its "alternative sanction" was not intended to help bring Petitioner into compliance.

Deferring my discussion of the legitimacy of HCFA's "alternative sanction" in this case, I will discuss at this juncture the function served by HCFA's requiring Petitioner to submit an "acceptable plan of correction" prior to June 1, 1993.

The regulations permit HCFA to impose an alternative sanction "to

help bring the laboratory into compliance." 42 C.F.R. 493.1812(a). An alternative sanction continues until the earlier of either the laboratory's correcting all condition level deficiencies, or the effective date of HCFA's suspension, limitation, or revocation of the laboratory's CLIA certificate. 42 C.F.R. 493.1810(d). The duration of an alternative sanction is subject to adjustment by HCFA, because it is dependent on the effective date of any suspension or other principal sanction HCFA imposes.

The chronology of events in this case does not permit the inference that HCFA was using its "alternative sanction" to achieve the goal specified by 42 C.F.R. 493.1812(a). I note by way of example that the "alternative sanction" imposed by HCFA on May 27, 1993 referenced a deadline of "prior to June 1st" while the suspension HCFA had already decided to impose was scheduled to take effect immediately after the deadline, on June 1st. In addition to the previously discussed problems with the State's undated letter and enclosure to Petitioner, there was also no evidence showing how or when the letter dated May 27, 1993 from HCFA's regional office in New York City was delivered to Petitioner's address in New Jersey, or whether it was delivered in sufficient time for Petitioner to have provided HCFA with anything prior to June 1, 1993. This is especially problematic when three of the four days permitted by the terms of HCFA's letter had been taken up by an intervening Saturday (May 29), Sunday (May 30), and legal holiday (Memorial Day, May 31). See HCFA Br. at 46.

Even if HCFA's May 27, 1993 letter had been hand-delivered to Petitioner's address on the same day, the "alternative sanction" imposed by HCFA was only in effect for less than five days. See 42 C.F.R. 493.1810(d)(2). By providing Petitioner with less than five days to receive and act on HCFA's requirements under the "alternative sanction," HCFA was not using the "alternative sanction" to help Petitioner achieve compliance as required by 42 C.F.R. 493.1812(a). The totality of facts discussed herein leaves little doubt that HCFA knew Petitioner would have no realistic chance to provide HCFA with an "acceptable plan of correction" prior to June 1, 1993. HCFA was using the "alternative sanction" to "preclude [Petitioner's] continued operation," as recommended by the State. HCFA Ex. 1b.

I find disingenuous HCFA's arguments that "[t]he enforcement regulations allow five days to correct immediate jeopardy situations without regard to holidays or weekends," (HCFA Br. at 46), and "[t]he regulations prescribe that, when immediate jeopardy exists, HCFA may require the laboratory to take immediate action to remove the jeopardy within five days from HCFA's notice." HCFA Br. at 43 (emphasis original). First, HCFA's letter did not even provide Petitioner with the five days HCFA now asserts the regulations prescribe. (May 27 to "prior to June 1" does not equal five days.) Also, it makes no sense for HCFA to think that Petitioner could have remedied any immediate jeopardy during those days when HCFA's notice letter was in transit and before Petitioner learned of HCFA's determinations or requirements. The State agency surveyors did not conduct what is commonly called an "exit conference" with Petitioner at the close of the February/March,

1993 survey; nor had they otherwise informally explained their conclusions to Petitioner. HCFA Br. at 48. 18/ In addition, no regulation specifies that immediate jeopardy must be eliminated by a laboratory within five days of the day a notice letter is dated. Nor do the regulations specify any deadline that must be imposed by HCFA when it requires immediate remedial action.

The regulation identified by HCFA to justify its actions requires a minimum of five full days between the date of the notice of imposed sanction and the effective date of the sanction. See HCFA Br. at 43 (citing 42 C.F.R. 493.1810(c)(2)). This regulation does not authorize HCFA to require the submission of an "acceptable plan" in less than five days in this case. None of the Secretary's regulations means that, whenever HCFA sends out a notice identifying the sanctions that HCFA has decided to impose due to its determination of immediate jeopardy, HCFA then acquires the authority to set a deadline of less than five days for a laboratory to remove the immediate jeopardy. HCFA has the authority to set a deadline for a laboratory to eliminate immediate jeopardy and to bring itself into compliance. E.g., 42 C.F.R. 493.1812(a). However, the deadline set by HCFA must be consistent with the remedial purposes of the law and appropriate to the circumstances of each case.

I have already noted that, on May 25, 1993, the State of New Jersey had summarily suspended Petitioner's license and ordered Petitioner to cease and desist from all laboratory operations immediately, and Petitioner closed at the end of May 1993. HCFA has not identified any federal interest that was being served or protected by HCFA's imposing the "alternative sanction" at issue on May 27, 1993 and setting a deadline of "prior to June 1," after the State had already imposed its own sanctions against Petitioner. Therefore, even though HCFA has the discretion to set deadlines to bring about compliance and eliminate immediate jeopardy, HCFA has failed to exercise its discretion properly in this case.

3. HCFA has not provided a satisfactory explanation of what plan, if submitted prior to June 1, 1993, would have constituted an "acceptable plan of correction."

HCFA's May 27, 1993 letter stated that, under the "alternative sanction" imposed by HCFA, Petitioner should submit an "acceptable plan of correction" prior to June 1st for the State's review, and any implementation of that plan would be subject to onsite monitoring by the State agency. HCFA Ex. 127. Given the State of New Jersey's summary suspension of Petitioner's license on May 25, 1993 and Petitioner's obligation to comply immediately with the State's cease and desist order of the same date (HCFA Ex. 114), I am unable to imagine the nature of any plan of correction that Petitioner could have formulated and implemented, with onsite monitoring by the State agency, on or after May 27, 1993. HCFA has never satisfactorily defined an "acceptable plan of correction," as that term was used in its May 27, 1993 letter.

The regulations do not use the term "acceptable plan of correction" in the context of actions required when condition level deficiencies exist at a laboratory, as HCFA alleged was the case

here. Instead, according to the Secretary's regulation:

> If a laboratory has deficiencies, that are not at the condition level, the following rules apply:
>
> (a) Initial action. The laboratory must submit a plan of correction that is acceptable to HCFA in content and time frames.

42 C.F.R. 493.1816 (emphasis added). Thus, HCFA's reference to an "acceptable plan of correction" in its May 27, 1993 letter is at least inconsistent with its assertions that Petitioner's deficiencies were at the condition level and caused immediate jeopardy.

HCFA attempted to establish at hearing that an "acceptable plan of correction" is the equivalent of, or must include, "a credible allegation of compliance." HCFA's May 27, 1993 letter stated that Petitioner should submit an "acceptable plan of correction" for review by the State. HCFA Ex. 127. However, the official testifying for HCFA at hearing, Dudley Lamming, stated that "acceptable" meant acceptable to Annemarie Schmidt, his supervisor at HCFA and the person who signed the notice letters on HCFA's behalf. Tr. 39 - 40. Even though Mr. Lamming did not claim to have made any of the decisions at issue on HCFA's behalf (See Tr. 39 - 40), I must consider his explanations of what might have been construed as an "acceptable plan" by HCFA because HCFA did not call Ms. Schmidt to testify.

Mr. Lamming merged the concept of "a credible allegation of compliance" with the "acceptable plan of correction" required by HCFA's May 27, 1993 letter. He said, for example, that HCFA gave Petitioner time to "come in with a credible plan of compliance" (Tr. 39) and that Petitioner's alternative to a hearing was to provide HCFA with "an acceptable credible allegation of compliance" (Tr. 44). A "credible allegation of compliance," as explained by Mr. Lamming and as defined by regulation, must be made by a representative of a laboratory that has a history of maintaining a commitment to compliance and of taking corrective action when required. Tr. 19; 42 C.F.R. 493.2. Also, according to Mr. Lamming, none of Petitioner's responses were credible and acceptable to HCFA because none contained any admission of the deficiencies found by HCFA. See Tr. 22 - 23, 32, 46 - 47. He especially noted that even Petitioner's last letter to HCFA's Regional Office (i.e., Petitioner's request for hearing dated June 15, 1993) could not be considered an acceptable or credible plan of correction because it lacked an admission of the deficiencies. 19/ Tr. 22 - 23, 47.

HCFA's efforts to equate "acceptable plan of correction" with an admission of deficiencies and a "credible allegation of compliance" further underscore that HCFA knew or should have known that it was imposing conditions with which Petitioner could not meaningfully comply. First of all, Petitioner had received instructions from the State agency which conflicted with HCFA's position that a credible allegation of compliance must contain an admission of the alleged deficiencies. The State agency's undated letter to

Petitioner indicates that "a credible allegation of compliance" should be used to challenge the alleged deficiencies:

> If you believe that the cited deficiencies are not substantially correct, it is your responsibility to contact the federal regional office (RO) with a credible allegation of compliance. The RO will advise you of the sanctions to be imposed and/or the enforcement actions to be taken. At that time you will also be notified of your appeal rights.

HCFA Ex. 1b (emphasis added).

Moreover, the State agency believed that Petitioner had a poor and deteriorated compliance record, and Mr. Lamming stated the same conclusions in his testimony for HCFA. E.g., Tr. 23, 47; HCFA Ex. 110 and 114. If an "acceptable plan of correction" were "a credible allegation of compliance" or must contain "a credible allegation of compliance," then the opinions of HCFA and the State agency that Petitioner's compliance record was poor and deteriorated would have automatically precluded their accepting any plan submitted by Petitioner between May 27 and 31, 1993. See 42 C.F.R. 493.2. In addition, the regulations provide that "a credible allegation of compliance" must be "realistic in terms of its being possible to accomplish the required corrective action between the date of the exit conference and the date of the allegation." 42 C.F.R. 493.2. As noted above, there was no exit interview conducted after the February/ March 1993 survey, and at all times since May 25, 1993, Petitioner has been unable to operate due to the sanctions imposed under New Jersey law. Under the facts of this case, no plan formulated by Petitioner after receipt of HCFA's May 27, 1993 letter could have satisfied the "realistic" and "possible" elements of a "credible allegation of compliance." There was no legitimate reason for HCFA to require Petitioner to submit a plan of correction that HCFA would have to reject if HCFA were incorporating the requirements of "a credible allegation of compliance," as it alleged.

Even more importantly, under the regulations, a "credible allegation of compliance" serves to lift an alternative sanction already imposed. 42 C.F.R. 493.1810(e)(2). Thus, by definition, a "credible allegation of compliance" or its equivalent cannot itself be an "alternative sanction." Therefore, I reject HCFA's ex post facto definition of its "alternative sanction" for this reason as well.

I also find unpersuasive HCFA's use of Petitioner's hearing request as evidence that Petitioner has remained unwilling to provide an "acceptable plan of correction." Petitioner filed the hearing request after the expiration of HCFA's unreasonably short deadline for submitting a plan of correction and after all sanctions had been imposed by HCFA. HCFA's own letters instructed Petitioner that its request for hearing should specify challenges to HCFA's findings. See HCFA Ex. 127, 128. Therefore, the absence of any plenary admissions of wrongdoing in Petitioner's July 15, 1993 request for hearing does not indicate that Petitioner was unwilling to prepare a plan acceptable to HCFA, if HCFA had provided reasonable advance notice and clearer directives concerning the

contents of the plan it wanted from Petitioner. In addition, Mr. Lamming was questioned during hearing about Petitioner's more recent offer to do whatever the State agency wanted it to do and to have as many inspections made as the State agency wished; yet, Mr. Lamming's response was that HCFA's knowledge of such offers would not have necessarily made any difference in deciding that Petitioner never submitted an "acceptable" plan. Tr. 31 - 32; see also P. Ex. 24.

D. HCFA has not imposed an "alternative sanction" authorized by law.

Even though HCFA did not admit to having made any errors in this case, I have considered the HCFA may have meant to offer Petitioner the opportunity to submit an "acceptable plan of correction . . . prior to June 1st" as an alternative to a sanction, but it mistyped the foregoing phrase as an "alternative sanction" in its May 27, 1993 letter. However, HCFA cited 42 C.F.R. 493.1832 in the sentence immediately preceding its statement,

In addition, as an alternative sanction under this regulation, you are directed to provide an acceptable plan of correction to the cited deficiencies prior to June 1st.

HCFA Ex. 127. The regulation cited by HCFA in its May 27, 1993 letter deals with imposing a directed plan of correction and a directed portion of a plan of correction, which are alternative sanctions. Because HCFA has indicated its awareness of alternative sanctions in citing 42 C.F.R. 493.1832, I do not find that HCFA had mistyped "an alternative to sanction" as "an alternative sanction." I conclude that HCFA meant to require the submission of an "acceptable plan of correction . . . prior to June 1st" as an "alternative sanction."

Even though I am without power to modify HCFA's choice of alternative sanctions, I have authority to decide whether a sanction imposed by HCFA was in fact an "alternative sanction" that HCFA had the discretion to impose. 42 C.F.R. 493.1844(b)(3), (c)(4). Moreover, as discussed elsewhere in this decision, whether providing an "acceptable plan of correction . . . . prior to June 1st" is an authorized alternative sanction has ramifications for the legitimacy of other sanctions also imposed by HCFA. The facts before me establish that HCFA's "alternative sanction" was not authorized by law.

"Alternative sanction" is synonymous with the term "intermediate sanction" as used in section 1846 of the Social Security Act. 42 C.F.R. 493.2. Section 1864 defines an intermediate sanction as a sanction that does not exceed one year and may be used by the Secretary in lieu of canceling immediately the clinical laboratory's approval to receive Medicare payments. Section 1846(a). The Act directed the Secretary to develop and implement a range of intermediate sanctions. Section 1846(b)(1). Accordingly, the regulations promulgated by the Secretary define "alternative sanctions" to include:

(1) a directed plan of correction as set forth at 42 C.F.R. 493.1832, and

(2) state on-site monitoring as set forth at 42 C.F.R. 493.1863.

42 C.F.R. 493.1806(c). 20/ HCFA's actions in this case do not fall within the definition of either of these alternative sanctions.

Even though HCFA's "alternative sanction" in this case directs Petitioner to take an action within a specific time frame, I conclude that HCFA's requirement is not a directed plan of correction. See 42 C.F.R. 493.1832. To impose a directed plan of correction, HCFA must:

(i) [give] the laboratory prior notice of the sanction and opportunity to respond in accordance with 42 C.F.R. 493.1810;

(ii) [direct] the laboratory to take specific corrective action within specific time frames in order to achieve compliance.

42 C.F.R. 493.1832(b)(1). These requirements were not satisfied by HCFA in this case. HCFA gave no notice of the sanction and no opportunity for Petitioner to respond in accordance with 42 C.F.R. 493.1810. Placing the onus on Petitioner to submit a plan of correction prior to June 1, 1993 that would be acceptable to HCFA does not satisfy the requirement, under 42 C.F.R. 493.1832(b)(1)(ii), that HCFA direct the laboratory to take specific corrective action.

If HCFA had intended to impose a directed plan of correction under 42 C.F.R. 493.1832, HCFA failed also to apply the following relevant provisions of the regulation pertaining to a directed plan of correction:

(c) Duration of directed plan of correction If HCFA imposes a directed plan of correction, and on revisit it is found that the laboratory has not corrected the deficiencies within 12 months from the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval for Medicare payment of its services, and notifies the laboratory of HCFA's intent to suspend, limit, or revoke the laboratory's CLIA certificate.

(2) The directed plan of correction continues in effect until the day suspension, limitation, or revocation of the laboratory's CLIA certificate [becomes effective].

42 C.F.R. 493.1832(c). With respect to the duration or termination of any directed plan of correction, 42 C.F.R. 493.1934(c) is consistent with 42 C.F.R. 493.1812 in also not permitting HCFA to decide on suspending Petitioner's CLIA certificate on the same day that HCFA imposes a directed plan of correction.

HCFA's official, Mr. Lamming, testified that it was unacceptable to require the State agency or HCFA to tell Petitioner what to do as a plan of correction. See Tr. 31 - 32. This testimony reinforces my conclusion that HCFA's "alternative sanction" in this case was not intended to place Petitioner under a directed plan of correction. However, even if such had been HCFA's intent, HCFA's failure to follow the requisite regulatory steps shows that the "alternative sanction" HCFA imposed against Petitioner was unauthorized as a directed plan of correction.

Similarly, HCFA's reference, in its letter of May 27, 1993, to subjecting implementation of any "acceptable plan" to onsite monitoring by the State agency does not satisfy the regulatory definition of the alternative sanction of State onsite monitoring. See HCFA Ex. 127. As an alternative sanction, onsite monitoring must be required by HCFA on an intermittent or continuous basis, and the costs are to be paid by the laboratory, based upon a formula contained in the regulations. 42 C.F.R. 493.1836(a). HCFA's imposition of its "alternative sanction" does not refer to any of the foregoing, even assuming there was some laboratory activity to be monitored in this case after the State of New Jersey suspended Petitioner's license and ordered it to cease all laboratory operations on May 25, 1993. See HCFA Ex. 114.

In addition, if it intended to impose onsite monitoring as an authorized alternative sanction, HCFA was required to notify Petitioner of the proposal to impose the onsite monitoring sanction, permit Petitioner at least 10 days to respond, and then notify Petitioner of the decision to impose this alternative sanction at least five days before the effective date of the sanction where immediate jeopardy is found. 42 C.F.R. 493.1836(b) (incorporating the requirements of 42 C.F.R. 493.1810). HCFA did not follow any of these procedures. Therefore, I conclude that HCFA's reference to the onsite monitoring of an "acceptable plan" also does not constitute an authorized alternative sanction.

E. HCFA's "suspending [Petitioner's] approval to receive Medicare payment for services . . . ." was an invalidly imposed principal sanction, and HCFA has not imposed a directed portion of a plan of correction within the meaning of the regulations.

The contents of HCFA's May 27, 1993 letter raise the question of whether, in directing Petitioner to provide a list of its clients within 10 days, HCFA intended to impose a directed portion of a plan of correction in conjunction with an alternative sanction of suspending all or part of Medicare payments to Petitioner. If HCFA intended to do so, I conclude that any such sanctions were invalidly imposed.

The regulation states that, when HCFA does not impose a directed plan of correction (and no directed plan of correction was imposed here), HCFA must at least impose a directed portion of a plan of correction when it imposes one of the remaining alternative

sanctions of State onsite monitoring, civil monetary penalty, or suspension of Medicare payments. 42 C.F.R. 493.1832(a). When it imposes a directed portion of a plan of correction, HCFA directs a laboratory to do the following:

> to submit to HCFA, the State survey agency, or other HCFA agent, within 10 calendar days after the notice of the alternative sanction, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory . . . within any . . . timeframe specified by HCFA.

42 C.F.R. 493.1832(b)(2)(i). 21/ The purpose for imposing the directed portion of a plan of correction is to enable HCFA to notify the laboratory's clients of the laboratory's noncompliance, together with the nature, effective date, and status of the alternative sanctions imposed against the laboratory. 42 C.F.R. 493.1832(b)(2)(ii).

Since the purpose of the directed portion of a plan of correction is to enable HCFA to give notice of the alternative sanction that was imposed against the laboratory, it would make no sense to construe the directed portion of a plan of correction as an alternative sanction in and of itself. See 42 C.F.R. 493.1832(b)(2). A directed portion of a plan of correction has no purpose or use unless HCFA has imposed one of the three enumerated alternative sanctions. See 42 C.F.R. 493.1832. In addition, the directed portion of a plan of correction is also not within the definition of a principal sanction. See 42 C.F.R. 493.1806(b), .1807(a).

Neither may HCFA impose a directed portion of a plan of correction for a principal sanction. That is, HCFA is not entitled to require the submission of a client list when suspending, limiting, or revoking a CLIA certificate, or, in the case of a laboratory participating in Medicare, canceling the laboratory's approval to receive Medicare payment for services. See 42 C.F.R. 493.1806(b), 1807(a), 1832(b)(3). However, if HCFA is imposing a principal sanction following an alternative sanction, and HCFA has already obtained a list of laboratory clients in conjunction with the use of an alternative sanction described above, then HCFA may use that list to give notice of the imposition of a principal sanction as well. 42 C.F.R. 493.1832(b)(3). 22/

In this case, no alternative sanction of civil monetary penalty has been imposed by HCFA, and I have already found that HCFA has not imposed an alternative sanction of State onsite monitoring. However, HCFA's May 27, 1993 letter mentions three matters in succession:
1) suspending Petitioner's approval to receive Medicare payment for services concurrently with the CLIA suspension; 2) directing Petitioner to provide a list of clients within 10 days of the May 27, 1993 notice letter; and 3) the provision in 42 C.F.R. 493.1832 referencing notice to Petitioner's clients. HCFA Ex. 127. HCFA's reference to these three matters raises the question of whether HCFA was properly imposing a directed portion of a plan of correction in conjunction with having imposed the alternative

sanction of suspending Petitioner's Medicare payments, as authorized by 42 C.F.R. 493.1832(a).

HCFA's May 27, 1993 reference to "suspending" Petitioner's "approval to receive Medicare payment for services concurrently with the CLIA suspension" is ambiguous, because HCFA has mixed words from the regulation describing a principal sanction with those describing an alternative sanction. For example, "suspension" of Medicare payment comes from the provision explaining an alternative sanction; while "approval to receive Medicare payment" and "concurrently with the CLIA suspension" are, respectively, words and concepts taken from the provision explaining a principal sanction. 42 C.F.R. 493.1807(a), 1807(b), 1808(a).

HCFA's subsequent letter, dated June 1, 1993, resolves the ambiguity by representing that HCFA had suspended Petitioner's approval to receive Medicare payment under the authority of 42 C.F.R. 483.1808. HCFA Ex. 128. The regulation cited by HCFA specifies in relevant part that, when HCFA suspends or revokes any CLIA certificate, HCFA concurrently cancels the laboratory's approval to receive Medicare payment for its services. 42 C.F.R. 483.1808(a). Cancellation of Petitioner's approval to receive Medicare payment is a principal sanction. 42 C.F.R. 493.1807(a). HCFA is not authorized to require a client list from Petitioner because HCFA has imposed a principal sanction. 42 C.F.R. 493.1832(b)(3).

Since HCFA has authority to impose a directed portion of a plan of correction only in conjunction with an alternative sanction of civil monetary penalty, State onsite monitoring, or suspension of Medicare payments (42 C.F.R. 493.1832(a)), HCFA's requirement for a client list from Petitioner was not an authorized directed portion of a plan of correction. I therefore conclude that HCFA's requirement that Petitioner provide a client list has no legal force under the facts of this case.

On the remaining question of whether HCFA's cancellation of Petitioner's approval to receive Medicare payment was authorized, I begin by noting that the legitimacy of this principal sanction is dependent upon the validity of HCFA's suspension of Petitioner's CLIA certificate. 42 C.F.R. 493.1808. I have already discussed, in part I.B. of this decision, the reasons why HCFA's suspension of Petitioner's CLIA certificate was improper and invalid. Therefore, HCFA's resultant cancellation of Petitioner's approval to receive Medicare payment concurrent with the suspension of the CLIA certificate is also invalid and not authorized by 42 C.F.R. 493.1808.

II. HCFA's actions of June 1, 1993, purporting to revoke Petitioner's CLIA certificate and cancel Petitioner's approval to receive Medicare payment also exceeded its authority under the regulations.

I will next focus on HCFA's letter dated June 1, 1993, in which it announced the following actions:

As of close of business June 1st, the State agency has advised us that it has not received an acceptable plan of correction from your laboratory. Therefore under the provisions of 42 C.F.R. 493.1812, we are proceeding with the revocation of your CLIA certification. The effective date of the revocation will be June 25, 1993. Medicare payment suspension remains in effect in accordance with the provision of 42 C.F.R. 493.1808.

HCFA Ex. 128. I conclude that HCFA was without authority to revoke Petitioner's CLIA certificate or "suspend" Medicare payments to Petitioner, as it purported to do on June 1.

In its letter, HCFA cited 42 C.F.R. 493.1812 as authority for its decision to revoke Petitioner's CLIA certificate. However, HCFA implemented its revocation decision in a manner not permitted by that regulation. Even assuming that HCFA had imposed a valid alternative sanction in this case pursuant to 42 C.F.R. 493.1812(a), the expiration date of the alternative sanction cannot immediately result in a decision by HCFA to revoke Petitioner's CLIA certificate as indicated in HCFA's June 1, 1993 letter. 23/ The regulation cited by HCFA plainly states that, if the jeopardy still persists after HCFA has satisfied its obligations (i.e., directed immediate action to remove the jeopardy, imposed an alternative sanction to help bring about compliance, conducted a revisit, and found that the jeopardy has not been eliminated), HCFA must first consider suspending or limiting the CLIA certificate before it may "later" revoke the certificate. 42 C.F.R. 493.1812(a), (b). As discussed above, HCFA altered the process and prematurely decided on May 27, 1993 to suspend Petitioner's CLIA certificate effective June 1, 1993. On June 1, 1993, HCFA further abrogated the regulatory process and procedures by using the expiration of its "alternative sanction" as reason for imposing the revocation sanction against Petitioner.

In addition, contrary to regulation, HCFA made the revocation effective prior to an administrative law judge decision in this case. The regulation provides that, if HCFA has not determined immediate jeopardy and the laboratory appeals, no principal sanction (i.e., no suspension, limitation, or revocation of a laboratory's CLIA certificate) may go into effect prior to the administrative law judge's issuance of a hearing decision upholding the suspension or limitation. 42 C.F.R. 493.1840(d), .1844(d)(2). Where HCFA has found immediate jeopardy and the laboratory appeals, only the suspension and limitation of a CLIA certificate may go into effect during the pendency of an appeal. 24/ 42 C.F.R. 493.1844(d)(2)(ii). There exists no exception to the rule that, if a hearing request has been filed, HCFA may not revoke a CLIA certificate until after an administrative law judge upholds the revocation in a decision issued pursuant to hearing. 42 C.F.R. 493.1840(e), .1844(d)(2). 25/ If the continuation of any activity by the laboratory during the administrative appeal process constitutes a significant risk to public health, HCFA may file suit in federal court to restrain or enjoin such activity. 42 C.F.R. 493.1812(c).

In this case, HCFA informed Petitioner, by letter dated June 1,

1993, that revocation of its CLIA certificate would become effective on June 25, 1993. HCFA Ex. 128. 26/ HCFA did not acknowledge any exception to having the revocation go into effect on the date designated by HCFA. See, e.g., Tr. 43 - 44. HCFA continues to argue in these proceedings that the revocation of Petitioner's CLIA certificate was placed on a "fast-track" that involved the use of procedures applicable to immediate jeopardy cases and that the revocation imposed may be stopped only through verification of Petitioner's compliance. E.g., HCFA Br. at 2, 8, 43. In fact, the revocation should not have gone into effect in this case.

For the foregoing reasons, I find that the decision made by HCFA on June 1, 1993 to revoke Petitioner's CLIA certificate was not authorized by 42 C.F.R. 493.1812(b). I further find that HCFA was not authorized to make the revocation of Petitioner's CLIA certificate effective before I have issued my decision on Petitioner's appeal. Because the revocation action was unauthorized, HCFA also was without authority on June 1, 1993 to maintain in effect the prior cancellation of Petitioner's approval to receive Medicare payment. 27/

III. HCFA's actions and omissions in this case were not harmless errors.

I have considered the possibility that HCFA's actions and omissions in this case may have amounted to harmless error. I considered this possibility because HCFA sought to demonstrate through the use of the State agency surveyors' testimony that Petitioner's owner, the owner's father and brother, Petitioner's manager, and Petitioner's director were dishonest people who operated a facility that was Long overdue for a shutdown. I have concluded that HCFA's errors in this case are too numerous, egregious, and prejudicial to be construed as harmless.

As the Secretary's agent under CLIA, HCFA's responsibility is to implement the Secretary's regulations. As earlier discussed, the regulations applicable to this case confer rights on laboratories operating under CLIA, and they limit the discretion HCFA may exercise in situations like this one, where HCFA received very strong urging from the State agency to terminate the operation of a laboratory without further ado. The deadlines and procedures set forth in the Secretary's regulations serve to protect the rights of the public at large as well as those of the laboratories operating under CLIA. The effects of those regulations would be rendered meaningless if HCFA were at liberty to deviate from the timetables and processes specified in those regulations whenever it thought its deviation harmless in the context of bringing about a result allegedly deserved by a laboratory.

There is no presumption in the Secretary's regulations that a laboratory should be shut down if it has condition level deficiencies, is alleged to have a poor compliance history, or poses immediate jeopardy. The Secretary's regulations make very clear that every laboratory, regardless of its offenses under CLIA, must be given an opportunity by HCFA to remedy its own

deficiencies, including those deficiencies which resulted in HCFA's finding of immediate jeopardy. Such an opportunity cannot be provided by HCFA in a context devoid of fairness and reasonableness, as occurred here. For HCFA to close a laboratory, whether through the use of suspension or revocation of the laboratory's CLIA certificate, is to be a remedy of last resort -- not first resort -- under the Secretary's regulations. Yet, every action HCFA took from May 27, 1993 onward was directed at ensuring that Petitioner would close without affording it any meaningful opportunity to remedy the problems and retain its CLIA certificate.

I am not persuaded by HCFA's suggestion that Petitioner would have failed to remedy the jeopardy or failed to come into compliance with CLIA even if HCFA had fulfilled its obligations to Petitioner. The evidence before me indicates, for example, that, if HCFA had imposed a directed plan of correction as provided by the Secretary's regulations and for the purpose of helping to bring Petitioner into compliance, Petitioner's managers would likely have followed it. Moreover, at all times relevant to this case, HCFA had the opportunity to sanction Petitioner at the appropriate time, if circumstances warranted, and with use of the appropriate process.

I noted earlier, as a corollary matter, that the State of New Jersey summarily suspended Petitioner's license on May 25, 1993 and ordered Petitioner to cease and desist from all laboratory operations immediately. Such evidence fails also to indicate a need for HCFA to shortcut the rights and remedies specified by the Secretary's regulations after it asserted the existence of immediate jeopardy on May 27, 1993. In short, there was no legal or logical justification for HCFA to have preempted the timetables or procedures specified by the regulations applicable to this case.

Finally, the instant administrative hearing is at the end stage of the enforcement process, and I am unable to take the procedural steps that HCFA should have taken before the case reached me. The Secretary has vested in HCFA the discretion to initiate enforcement proceedings within the parameters created by her regulations. As discussed earlier, the Secretary's regulations require HCFA to determine, for example, whether deficiencies pose immediate jeopardy, what remedial actions are needed, when the resurvey is to be conducted, which sanctions (if any) should be proposed, and what effect is to be given to any responses Petitioner may provide to the proposed sanctions. E.g., 42 C.F.R. 493.1810, .1812. HCFA is the only entity that has the authority to implement the remedies that were previously available, including directing the State agency to resurvey Petitioner to ascertain the elimination of immediate jeopardy, formulating a directed plan of correction, or requiring continuous or intermittent monitoring of a plan of correction by the State survey agency. E.g., 42 C.F.R. 493.1832, .1836.

For the foregoing reasons, the enforcement process cannot be begun anew by an administrative law judge at the hearing stage of the case. Consistent with my duties as an adjudicator, I have

determined that HCFA acted improperly in its dealings with Petitioner. HCFA's failure to exercise its discretion within the bounds of the regulations at the beginning stage of the enforcement process harmed Petitioner's rights and the rights of the public to proper implementation of the Secretary's regulations.

IV. It is not necessary or feasible for me to decide at this time whether Petitioner had condition level deficiencies in February through March of 1993.

I will not adjudicate the issue of whether HCFA, in analyzing information provided to it by the State agency, correctly found condition level deficiencies based on the survey conducted during February and March of 1993. There is no need to do so given what has taken place since May of 1993. Whether or not condition level deficiencies existed in February and March of 1993, Petitioner has been closed since May of 1993. E.g., Tr. 935. As a practical matter, HCFA's concern for the general public welfare and the existence of jeopardy to patients should have been alleviated by Petitioner's closure.

In addition, Petitioner has consistently indicated its willingness to follow directives issued by HCFA or the State agency to overcome the deficiencies alleged by HCFA. E.g., Tr. 31 - 32; P. Ex. 24. Now that Petitioner has heard several days of testimony explaining the few pages of summaries that were provided to it during the enforcement process, Petitioner should have a better understanding of what HCFA meant and wanted. Petitioner should take them into consideration if it ever operates again under CLIA. As noted above, HCFA has the option of seeking an injunction or restraining order in court if Petitioner's activities ever pose a significant hazard to public health.

In addition, even if I were to adjudicate the issue of whether Petitioner's deficiencies in early 1993 warranted the imposition of sanctions and I found in HCFA's favor, HCFA remains the Secretary's delegate for enforcing compliance through the imposition of sanctions. For the reasons previously discussed, it would be improper for me to step outside my role of a neutral adjudicator to take on the duties of an enforcement official. Therefore, my adjudicating the allegations of deficiencies cannot result in my providing the relief sought by HCFA: revoking Petitioner's CLIA certificate. See HCFA Br. at 53.

If Petitioner resumes operation once again, HCFA or the State agency may survey it to ascertain whether deficiencies exist and what actions are warranted. If HCFA makes determinations adverse to Petitioner at that time, Petitioner then will have the opportunity to come before an administrative law judge to litigate the merits of any alleged deficiencies. HCFA will have the opportunity to prove the continuation of any pattern or practice at that time as well. Until Petitioner resumes operation and HCFA determines Petitioner's resumed operation to be out of compliance with CLIA requirements, my resources and the resources of the parties can be better utilized elsewhere.

CONCLUSION AND ORDER

Because the sanctions imposed by HCFA were not authorized by the regulations, I set them aside and order that Petitioner's CLIA certificate and approval to receive Medicare payment for services be restored to the same status they had prior to May 27, 1993.

If HCFA believes that, despite Petitioner's closure since May of 1993, HCFA needs to make determinations on new issues (such as if or which sanctions should be imposed forthwith in lieu of those I have vacated), HCFA may file a remand motion for my consideration pursuant to 42 C.F.R. 498.56(d).

Mimi Hwang Leahy
Administrative Law Judge

1. "Immediate jeopardy" is defined by 42 C.F.R. 493.2, as follows:

> a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

Condition level deficiency means "noncompliance with one or more condition level requirements." 42 C.F.R. 493.2.

2. As I will explain below, all laboratories are subject to three alternative sanctions authorized by the regulations: 1) a "directed plan of correction;" 2) "state onsite monitoring," or 3) a "civil money penalty." 42 C.F.R. 493.1806(c). Laboratories that participate in Medicare are subject to an additional alternative sanction, suspension of their Medicare payments. 42 C.F.R. 493.1807(b).

3. HCFA states in its posthearing brief that the effective date of the revocation was June 1, 1993. HCFA Br. at 1. HCFA's letter of June 1, 1993 indicated an effective date of June 25, 1993. HCFA Ex. 128.

4. The transcript of hearing (Tr.) incorrectly designates Leslie A. Weyn as an attorney who appeared on behalf of the Department of Health and Human Services. Tr. 2. Ms. Weyn is a staff attorney with the Departmental Appeals Board of HHS. She was present at the hearing as an assistant to me and did not have any representational role in this case.

5. For all laboratories, the revocation of a CLIA certificate is the other principal sanction the Secretary's regulations authorize HCFA to take. 42 C.F.R. 493.1806(b). For laboratories that participate in Medicare, canceling their approval to receive Medicare payment is an additional principal sanction authorized by the Secretary's regulations. 42 C.F.R. 493.1807(a).

6. Criminal sanctions are available as well, whether or not there is immediate jeopardy. An individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined. 42 C.F.R. 493.1800(a)(3)(i), 1806(e).

7. HCFA itself described its May 27, 1993 letter as having "specified the non-compliant regulations and the conclusion that fictitious patient test results and fabricated control data created a situation of immediate jeopardy to the patient health and safety." HCFA Ex. 128.

8. It is HCFA that must require the laboratory to take immediate action to remove the jeopardy and may impose alternative sanctions to help bring about compliance. 42 C.F.R. 493.1812(a). Unlike other parts of the regulations, section 493.1812 does not state that either HCFA or HCFA's agents may take action. Compare 42 C.F.R. 493.1812(a) with 42 C.F.R. 493.1810(a). HCFA's agents are separately defined in the regulations. See 42 C.F.R. 493.2.

9. The State's undated letter does not mention that it was enclosing a copy of the more detailed "Survey Report" also prepared by the State surveyors (HCFA Ex. 1 at 7 to 34). See HCFA Ex. 1b. However, the State sent a copy of the "Survey Report" with another letter to Petitioner dated May 25, 1993. HCFA Ex. 114.

The State's undated letter concerns the State's involvement with HCFA and the CLIA sanctions. The State's May 25, 1993 letter concerns only the State's findings and its imposition of sanctions under State law.

10. In this case, the New Jersey Department of Health had a dual role. It acted as HCFA's agent under CLIA, and it took actions on behalf of the State of New Jersey to enforce and implement State laws. I have been referring to the New Jersey Department of Health as the "State agency" when it acted as HCFA's agent. I refer to it as "the State" or "the State of New Jersey" when I discuss actions it took on behalf of the State government to enforce the State's rights.

11. The evidence does not show that the State agency shared with Petitioner the State agency's transmittal memo to HCFA (HCFA Ex. 1a). Moreover, HCFA's conclusions of May 27, 1993 are also not fully consistent with the transmittal report.

12. At hearing, I had the opportunity to evaluate the demeanor of Petitioner's witnesses and to consider whether there was a basis

for the State agency's opinion of Petitioner's management. I was not persuaded that Petitioner or its managers were contemptuous of laws and regulations, or that they had irrevocably betrayed the public trust. Nor was I persuaded that the New Jersey Department of Health, had the expertise or authority to determine whether Petitioner was performing tests in violation of New York State's laboratory laws. See HCFA Ex. 1a at 2. In fact, there was no evidence that Petitioner was operating in New York or obliged to follow New York's laboratory laws, even assuming that HCFA or the State of New York had authorized the New Jersey Department of Health to evaluate whether New Jersey laboratories are in compliance with New York laws.

13. HCFA contends that it would have conducted a revisit survey immediately if it had received an acceptable plan of correction. HCFA Br. at 45. As discussed below, the evidence does not support the existence of any intent on HCFA's part (as of May 27, 1993, when it issued its sanction notice) to obtain an "acceptable plan" from Petitioner or to conduct a resurvey.

14. On September 24, 1990, the State surveyed Petitioner to ascertain whether State and federal requirements were being met. HCFA Ex. 107. The State notified Petitioner that recurrence of the deficiencies found during the September 1990 survey (i.e., unsubstantiated or altered test results) would lead to adverse State licensure action, the imposition of financial penalties, and a determination that the laboratory was not in compliance with the Condition of Participation for providers of Medicare laboratory services. HCFA Ex. 107.

In January 1991, the State resurveyed Petitioner and concluded that Petitioner was altering control and patient test values. HCFA Ex. 110. Based on this survey, by notice dated February 21, 1991, the State sought to impose only State sanctions against Petitioner. HCFA Ex. 110. At an informal hearing before the State, the State and Petitioner reached an agreement; Petitioner waived its right to a formal hearing and agreed to pay, in installments, the $8,000 penalty assessed under State law. HCFA Ex. 110 - 13. Pursuant to the January 1991 survey, the State did not recommend that HCFA impose sanctions, and HCFA took no action against Petitioner.

HCFA sent no notice to Petitioner referencing the results of these two surveys.

15. According to testimony at the hearing, the CLIA laws require that laboratories be inspected at least once every two years. Tr. 53. Several months prior to February of 1993, HCFA sent out a letter to state agencies asking that priority be given to surveying various types of laboratories, including those that had been found out of compliance with conditions of participation in CLIA. Tr. 14. Gerda Duffy, the surveyor in charge of the team that surveyed Petitioner during February and March of 1993, testified to the shortage of staff (three people in addition to herself) to conduct CLIA inspections of the approximately 100 laboratories in New Jersey. Tr. 49, 53. As a result of the shortage of staff, she and her department use the priority instructions issued by HCFA. Tr. 54 - 55. Ms. Duffy claimed to

have known of Petitioner's compliance history when the New Jersey Department of Health decided to survey Petitioner in the winter of 1993. Tr. 55.

16. I discuss, in subpart D, below, my reasons for having concluded that HCFA did not mean to say an "alternative to a sanction" when it used the term "alternative sanction" in its letter of May 27, 1993.

17. Since the regulation is titled "[i]mposition and lifting of alternative sanction," I construe its subparts as dealing only with alternative sanctions.

18. HCFA argues that the regulations do not require an "exit conference," that the lead surveyor had made herself available to answer questions from Petitioner's Director before the State sent its Statement of Deficiencies to Petitioner, and that Petitioner had received several years of notice and warning (i.e., since the 1990 survey) to stop creating fictitious results and data. HCFA Br. at 48 - 49. HCFA's arguments still raise the question of the reasonableness of HCFA's actions. For example, it does not seem reasonable to set a deadline of less than five days for an "acceptable plan" if HCFA were aware that the State agency had chosen not to conduct an "exit conference" for the 1993 conference and Petitioner's Director had chosen not to discuss the deficiencies prior to Petitioner's receiving written notice of them. Nor does it seem reasonable for HCFA to expect Petitioner to know (for purposes of submitting an "acceptable plan" prior to June 1st) how immediate jeopardy was created in 1993 by the same alleged deficiencies that apparently had not created immediate jeopardy in 1990 or 1991.

19. I conclude that HCFA introduced Mr. Lamming's testimony analyzing Petitioner's subsequently filed request for hearing as a possible "plan of correction" because HCFA is aware of the problems associated with writing Petitioner a letter on May 27, 1993 to require a response "prior to June 1st." Mr. Lamming's testimony concerning the hearing request was elicited by HCFA without even an allegation that the responsible decision-maker, Annemarie Schmidt, had undertaken the analysis described by Mr. Lamming.

20. HCFA's requirement for the submission of an "acceptable plan of correction" prior to June 1, 1993, bears no resemblance to the other alternative sanctions authorized by law (i.e. civil monetary penalties and the suspension of Medicare payments).

21. By definition, a directed portion of a plan of correction involves only the submission and use of a list of the sanctioned laboratory's clients. 42 C.F.R. 493.1832(b)(2). Therefore, the "acceptable plan of correction" required by HCFA cannot be considered a directed portion of a plan of correction.

22. The regulation at 42 C.F.R. 493.1844(g) is in accord. It states in relevant part:

> If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for

its services, HCFA . . . may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures set forth at 493.1832.

23. The regulation at 42 C.F.R. 493.1840(a)(7) authorizes the suspension, limitation, or revocation of a CLIA certification when the laboratory's owner, operator, or employee(s) fails to comply with an alternative sanction imposed under Subpart R. However, HCFA did not claim to have relied on this subsection. In addition, as I have already discussed, what HCFA called an "alternative sanction" is not cognizable under Subpart R. The basic requirements of 42 C.F.R. 493.1812 are not obviated when HCFA ties the failure to comply with an alternative sanction to immediate jeopardy. See 42 C.F.R. 1840(d). In a later portion of this decision, I will discuss also the absence of any regulation permitting HCFA to revoke a CLIA certificate prior to an administrative law judge's decision upholding the revocation.

24. If an administrative law judge's decision upholds a suspension imposed because of immediate jeopardy, that suspension becomes a revocation. 42 C.F.R. 493.1844(d)(4)(ii).

25. The regulation titled "[e]ffective date of adverse action" is also in accord. It states, in relevant part:

> When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of [HCFA's] notice.

42 C.F.R. 493.1844(h)(1)(emphasis added). Any revocation that takes place pursuant to an administrative law judge's decision would satisfy the requirement that the revocation take place at least five days after the day HCFA issued its notice letter.

26. When sending out its sanction notice pursuant to a finding of immediate jeopardy, HCFA may specify an effective date for revoking a laboratory's CLIA certificate that is at least five days after HCFA's notice. 42 C.F.R. 493.1844(h)(1). If HCFA determines that there exists no immediate jeopardy, HCFA may specify in its sanction notice an effective date for the revocation that is at least 15 days after HCFA's notice. 42 C.F.R. 493.1844(h)(2).

Here, HCFA's June 1, 1993 letter indicates that it chose a revocation date of June 25, 1993, which suggests the possibility that HCFA no Longer perceived any immediate jeopardy as of June 1, 1993. See 42 C.F.R. 493.1844(h)(2) and my previous discussions of the sanctions imposed by the State of New Jersey on May 25, 1993. HCFA later stated in its post-hearing brief that it revoked Petitioner's CLIA certificate on June 1, 1993, which is not in compliance with any regulation.

27. HCFA used the term "medicare payment suspension." HCFA Ex. 128. However, because it cited 42 C.F.R. 493.1808 as authority, I find that HCFA was canceling Petitioner's approval to receive Medicare payment concurrent with HCFA's revocation of Petitioner's

CLIA certificate.

Center Clinical Laboratory, DAB No. 1526 (1995)

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: July 31, 1995
Center Clinical Laboratory,	Docket No. C-93-096
	Decision No. 1526
Petitioner,	
- v. -	
Health Care Financing Administration.	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

The Health Care Financing Administration (HCFA) appealed the decision by Administrative Law Judge Mimi Hwang Leahy (ALJ Decision) to set aside sanctions HCFA imposed against the Center Clinical Laboratory (Petitioner) under the **Clinical** Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations. On May 27, 1993, HCFA had determined, based on a survey performed by the New Jersey State Department of Health, that Petitioner did not meet seven CLIA conditions of certification. These deficiencies were determined to create a situation of "immediate jeopardy to patient health and safety." Consequently, HCFA suspended Petitioner's CLIA certificate effective June 1, 1993 and concurrently suspended Petitioner's approval to receive Medicare payment for services. HCFA also directed Petitioner to submit a list of Petitioner's clients within 10 days and an acceptable plan of correction to the cited deficiencies prior to the effective date of the suspension. When HCFA did not receive an acceptable plan of correction by that effective date, it revoked Petitioner's CLIA certificate, stating that the revocation would be effective June 25, 1993.

Petitioner requested a hearing before an ALJ on the sanctions imposed by HCFA. Following Petitioner's hearing, the ALJ set aside HCFA's sanctions and ordered HCFA to restore Petitioner's CLIA certificate and its approval to receive Medicare payments. The ALJ concluded

that HCFA's decision to impose the principal sanction of suspension of Petitioner's CLIA certificate was "premature" and that this sanction and the others imposed by HCFA were unauthorized under the regulations because HCFA had imposed the sanctions in a procedurally deficient manner. Having thus set aside on procedural grounds all of the sanctions imposed by HCFA, the ALJ did not reach the question of whether the seven condition-level deficiencies cited by HCFA actually existed or whether the deficiencies warranted the sanctions HCFA imposed.

In HCFA's appeal to the Board, HCFA asserted that it had complied with all of the procedures prescribed under the CLIA statute and regulations for imposing the sanctions in question. HCFA clarified only that since Petitioner had requested an ALJ hearing following HCFA's decision to revoke Petitioner's CLIA certificate, the revocation necessarily could not become effective until the ALJ had issued a decision upholding the suspension and revocation.

For the reasons discussed below, we reverse the ALJ Decision and remand this case to the ALJ to consider the substantive grounds for these sanctions. We conclude that HCFA complied with all procedural requirements contemplated by the statute and regulations in imposing the sanctions at issue here. The statute and regulations provide wide discretion to HCFA in selecting appropriate sanctions to respond to a laboratory's non-compliance with CLIA requirements. Where the laboratory's deficiencies pose an immediate jeopardy to health or safety, the statute contemplates that HCFA may suspend the CLIA certificate prior to an ALJ hearing, and the regulations expressly authorize HCFA to impose an immediate suspension (with only a five-day delayed effective date). The ALJ erred in her decision by ignoring this express authority under the statute and regulations to impose an immediate suspension and by misinterpreting the effect of procedures in the regulations designed to apply where HCFA has decided to impose an alternative sanction instead of an immediate suspension. These procedures potentially require at least a 10-day period to respond to an initial notice, subsequent notice of imposition of the sanction, a specified period of time for the laboratory to come into compliance, a revisit to determine whether the laboratory did come into compliance and, finally, where the laboratory did not come into compliance, a notice of principal sanction with at least a five-day delayed effective date. These particular procedures are required only in the imposition of an alternative sanction and simply are not required by the regulations for imposing the principal sanction of immediate suspension. We also find clear authority under the regulations for the remaining sanctions HCFA imposed.

Even if we had agreed with the ALJ that HCFA had been procedurally deficient in some way (which we do not), we would not agree that Petitioner had been harmed by the deficiency, since its operations had already been suspended under state law and had remained suspended throughout this appeal. Finally, we question in any event the ALJ's authority to "set aside" the principal sanction of suspension under the very serious circumstances raised here based solely on alleged procedural deficiencies without first determining whether those deficiencies were or could have been cured.

We also agree with the argument raised by HCFA in its appeal brief that the ALJ Decision generally misconstrues HCFA's responsibilities in determining what a laboratory must do in order to comply with CLIA requirements and fails to give full weight to one of the primary concerns addressed by the CLIA legislation, the need for an immediate response to circumstances that place patient safety or health at risk. See HCFA Appeal Brief (Br.) at 10-13.

Our decision is based on the entire record before the ALJ as well as the brief submitted by HCFA in support of its request for Board review. Although Petitioner had the opportunity to respond to HCFA's brief, it declined to do so, relying entirely on the analysis of the issues in the appealed ALJ decision. Neither party requested an opportunity for an oral argument.

Statute and Regulations

The **Clinical** Laboratory Improvement Amendments of 1988 (section 353 of the Public Health Service Act; 42 U.S.C. _ 263a), henceforth referred to as "CLIA," establishes requirements for all laboratories that perform **clinical** diagnostic tests on human specimens and requires a federal certification scheme to be applied to all such laboratories. See _ 493.1800(a)(2) in 42 C.F.R. Part 493, Subpart R. 1/ CLIA certification of a laboratory is dependent upon whether the laboratory meets the conditions of coverage set out at 42 U.S.C. _ 263a(f)(1)(E) and 42 C.F.R. __ 493.1 et seq., in addition to other CLIA requirements. Each "condition," as set forth in the statutes and regulations, represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. Failure by a laboratory to comply with even a single condition represents a serious breakdown in one of the major health care delivery or safety systems of the laboratory, all of which are critical to ensuring the provision of acceptable health care services and essential for purposes of the laboratory's operations.

The CLIA statute and implementing regulations grant the Secretary broad enforcement authority to ensure that

laboratories remain in compliance with CLIA requirements throughout the life of their CLIA certification. This enforcement authority includes the use of principal sanctions affecting the laboratory's ongoing operations (suspension, limitation, or revocation of the CLIA certificate) where the laboratory is out of compliance with one or more conditions of certification. Indeed, the CLIA statute expressly provides that the Secretary may suspend or limit the CLIA certificate prior to a hearing, and provides that opportunity for a hearing in that instance must be provided on an expedited basis. 42 U.S.C. _ 263a(i)(2). The legislative history discusses the purpose for prehearing sanctions as follows:

> The Committee included this prehearing exclusion to allow the Secretary the opportunity to respond promptly to situations in which a laboratory's failure to comply may sacrifice the integrity of test results. Where this occurs or where a laboratory's interference with the Secretary's ability to make a determination about laboratory quality occurs, it is imperative that the Secretary have the authority either to force prompt compliance or to move quickly to protect the public health. The Committee has been informed that, under current law, lengthy court proceedings and appeals may interfere with the Secretary's ability to stop a laboratory from operating irrespective of the seriousness of the violations.
>
> The bill's requirement of a prompt opportunity for a hearing is designed to limit the potential adverse effects on a laboratory of such a pre-hearing determination by the Secretary and to allow a timely airing of the issues.

H.R. Rep. No. 899, 100th Cong., 2nd Sess., at 35 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3856.

The enforcement authority also includes the use of alternative sanctions, which include a directed plan of correction, state on-site monitoring, and civil money penalties. With respect to a directed plan of correction, the legislative history noted that:

> a directed plan of correction would be particularly appropriate where a laboratory is out of compliance . . ., but where imposition of such a sanction in lieu of revocation, suspension or limitation would not place the health of patients in jeopardy.

H.R. Rep. No. 899, 100th Cong., 2nd Sess., at 33 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3854.

The preamble to the final regulations, moreover, states that alternative sanctions "offer laboratories the opportunity to come into compliance within a specified

period of time instead of immediately having their CLIA certificates suspended, limited, or revoked, or their Medicare approval cancelled." 57 Fed. Reg. 7223 (Feb. 28, 1992) (emphasis supplied). The Secretary may also in prescribed circumstances enter into a civil suit to enjoin laboratory activity that constitutes a significant hazard to the public health.

The enforcement scheme in the regulations at 42 C.F.R. Part 493, Subpart R affords HCFA broad discretion in selecting the appropriate sanction to meet particular deficiencies identified in surveys of the operations of the laboratories. Perhaps foremost among the factors HCFA must consider is whether the deficiencies pose an "immediate jeopardy." 2/ When a laboratory's deficiencies have been found to pose an immediate jeopardy, the enforcement scheme contemplates that HCFA will require the laboratory to take immediate action to remove the jeopardy. Section 493.1812. Further, the regulations specifically provide that the determination by HCFA that a laboratory's deficiencies pose an immediate jeopardy is solely within HCFA's discretion and is not subject to further review. Section 493.1844(c)(6).

In order to fulfill its statutory obligation to ensure that **clinical** laboratories remain in compliance with CLIA requirements, HCFA contracts with state health departments to conduct on-site surveys of the laboratories to determine whether federal requirements are met. State surveyors conduct federal surveys of laboratories pursuant to the detailed rules in 42 C.F.R. Part 488 entitled "Survey and Certification Procedures." These regulations recognize that "surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance." 42 C.F.R. _ 488.26(b)(3). HCFA stated in its brief to the Board (p. 4) that:

> [t]he professional judgment of the surveyors is the cornerstone of the survey and certification process. Without reliance on the surveyors' expertise in the area of their specialty, the government's efforts to regulate laboratories . . . would fail.

The preamble to the final regulation describes the respective roles of the state surveyors and HCFA as follows:

> The surveyors whom we employ to inspect laboratories are laboratory professionals. They are trained extensively by both HCFA and their respective States in proper inspection techniques under CLIA. They use their professional judgment and expertise in making recommendations. . . . The surveyors' recommendations are reviewed by the supervisory staff of the State agency or other HCFA agents, and

> are further reviewed by the HCFA Regional Office (RO). The RO makes the final determination of compliance or noncompliance and imposes the sanction(s) that would in the opinion of the RO, most likely precipitate correction.

57 Fed. Reg. 7224 (Feb. 28, 1992).

Background to the Current Appeal

The ALJ did not make specific findings of fact as such. The underlying facts set out below are drawn either from factual findings in the text of the ALJ Decision or from HCFA's statement of facts in its appeal brief. HCFA asserted that the "underlying" facts were not in dispute. Petitioner did not file a response to HCFA's brief and, therefore, did not dispute any of the facts described in HCFA's statement.

Pursuant to an agreement under section 1864 of the Social Security Act between the Secretary and the State of New Jersey (State), the New Jersey Department of Health (DOH) conducted an on-site survey of Petitioner during nine days in February and March of 1993 to determine whether Petitioner was in compliance with CLIA requirements. 3/ HCFA Exhibits 1, 1a, 1b, 127, 128. (HCFA 1, 1a, 1b, 127, 128.) After the survey and a subsequent review of the laboratory's records were completed, DOH determined that Petitioner had engaged in deceptive practices and reported fictitious test results, had used improper test procedures and incorrect normal ranges for diagnostic tests, and had failed to protect specimens. HCFA 114, at 1-2.

This was not the first instance where Petitioner's alleged noncompliance with laboratory regulations raised issues about the reliability of its test results. The State of New Jersey had surveyed Petitioner in September 1990 to ascertain whether State and federal requirements were being met and had found deficiencies involving unsubstantiated or altered test results. The State notified Petitioner that recurrence of the deficiencies would lead to adverse State licensure action, the imposition of financial penalties, and a determination that the laboratory was not in compliance with the Conditions of Participation for providers of Medicare laboratory services. ALJ Decision (Decision) 16, fn. 14; HCFA 107.

Moreover, in January 1991, the State resurveyed Petitioner and concluded that Petitioner was altering control and patient test values. HCFA 110. Based on this survey, the State sought to impose State sanctions against Petitioner. At an informal hearing before the State, the State and Petitioner reached an agreement whereby Petitioner waived its right to a formal hearing

and agreed to pay in installments the $8000 penalty assessed pursuant to State law. HCFA 110-113. Pursuant to the January 1991 survey, the State did not recommend that HCFA impose sanctions, and HCFA took no action against Petitioner. Decision 16, fn. 14.

As a result of the 1993 survey findings and Petitioner's past history of noncompliance, the State, on May 25, 1993, ordered an immediate suspension of Petitioner's license, and entered a cease and desist order covering all of its laboratory operations aLong with a fine of $100,000. HCFA 114 at 1-2. At or about the same time, the State also notified Petitioner that it would recommend to HCFA that the conditions at the laboratory posed an immediate jeopardy to the health and safety of the patients it served, and that HCFA should take immediate action to revoke Petitioner's CLIA certification. A detailed statement of deficiencies and the survey report were enclosed with this correspondence to Petitioner. HCFA 1-b.

Upon receipt of the statement of deficiencies from DOH, HCFA reviewed the matter and determined in a notice dated May 27, 1993, that Petitioner failed to meet seven of the conditions of certification under CLIA. HCFA also concurred that the situation at the laboratory posed an immediate jeopardy. HCFA then advised Petitioner of the CLIA sanctions it was imposing as follows:

> Accordingly, we have determined that it is necessary to apply the principal sanction of suspension of your CLIA registration certificate effective June 1, 1993. In addition, we are also suspending your laboratory's approval to receive Medicare payment for services concurrently with the CLIA suspension. You should . . . provide a list of the names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory during the past year, within ten days of this notice.
>
> You should be aware that 42 CFR 493.1832 provides that your clients should be notified of this action. In addition, as an alternative sanction under this regulation, you are directed to provide an acceptable plan of correction to the cited deficiencies prior to June 1st. Should you fail to provide an acceptable plan of correction your CLIA certification will be finally revoked. Your plan of correction should be submitted to the New Jersey State Health Department for review and any implementation will be subject to State onsite monitoring.

HCFA 127, at 2.

As of the close of business on June 1, 1993, DOH advised

HCFA that it had not received an acceptable plan of correction; instead Petitioner simply denied the existence of the deficiencies. Hearing Transcript (Tr.) 22-24; HCFA 128. HCFA then sent a second letter to Petitioner informing it that:

> under the provisions of 42 CFR 493.1812, we are proceeding with the revocation of your CLIA certification. The effective date of the revocation will be June 25, 1993. Medicare payment suspension remains in effect in accordance with the provisions of 42 CFR 493.1808.

HCFA 128.

Following this and the prior May 27 notice, both of which advised Petitioner of its right to request a hearing before an ALJ, Petitioner requested a hearing. A five-day hearing was held before the ALJ from April 18 through 22, 1994. The ALJ Decision appealed from here was rendered on February 15, 1995.

HCFA argued on appeal that it acted properly in its May 27 and June 1 notices. HCFA's actions included: the principal sanction of suspension of Petitioner's CLIA certificate to be effective June 1st, suspension (or cancellation) of Petitioner's approval to receive Medicare payment for services provided, the direction to provide a list of clients within 10 days and an acceptable plan of correction before June 1st, and the principal sanction of revocation of the CLIA certificate effective June 25th. We discuss below HCFA's authority under the statute and regulations to take each of these actions.

Petitioner did not submit an appellate brief to the Board, relying instead on the ALJ's findings and Decision.

Analysis

1. HCFA acted properly in imposing all of the sanctions in question.

A. Suspension of Petitioner's CLIA certificate with a five-day delayed effective date

The primary error in the ALJ Decision is its failure to recognize HCFA's clear authority to impose an immediate suspension (with only a five-day delayed effective date) where a laboratory's deficiencies pose immediate jeopardy. Specifically, the regulations provide that where a laboratory's deficiencies pose immediate jeopardy, the effective date of a suspension need only be five days after the date of the notice. 42 C.F.R. _ 493.1844(h)(1). We conclude that HCFA's effective date

here reasonably complied with the terms of this regulation. HCFA's notice dated May 27, 1993 suspended Petitioner's CLIA certificate effective June 1, 1993. June 1st was five days after May 27th, and thus HCFA's effective date complies with the regulatory time frame. 4/

There is no evidence in the preamble or the regulation itself, moreover, that a "day" (within the "5 days" specified by the regulation) was to be given anything other than its plain meaning. Thus, we see no reason why weekends or holidays within the five days should be excluded when applying this regulation. These days would potentially be days the laboratory could use to take steps to bring itself into compliance. Moreover, where an immediate jeopardy exists from a laboratory's continued operation with cited deficiencies, we know of no reason why HCFA should view a weekend or a holiday as any less perilous to patient health and safety than a week day.

The only other pertinent procedural requirement specified for a suspension is that HCFA's notice to the laboratory must include the "reasons" for the suspension. 42 C.F.R. _ 493.1844(g). 5/ HCFA here clearly complied with that requirement. It referred to the survey performed by DOH from February 18 to March 10, 1993 and the subsequent State analysis of the laboratory's records. It then identified with regulatory citations all seven of the CLIA conditions of certification that had been found to be out of compliance. Finally, it referred to the recommendation from the State that the deficiencies created a situation of immediate jeopardy to patient health and safety. This is an adequate statement of HCFA's reasons in our view. 6/

Aside from sections 493.1844(g) and (h), several other sections of the regulations emphasize that HCFA has broad discretion in selecting principal sanctions such as an immediate suspension when the laboratory's deficiencies pose immediate jeopardy and when there may be several other serious factors present as well. For example:

o Section 493.1800(a)(2)(iii)(b) refers to the Secretary's broad enforcement authority, including suspension of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate. (Petitioner was found to be out of compliance with seven such requirements.)

o Section 493.1804(b)(2) specifies that HCFA may impose one or more principal sanctions when HCFA or HCFA's agent finds that a laboratory has condition-level deficiencies.

o Section 493.1804(d) provides that HCFA's choice of sanction should be based on consideration of one or more factors that include, but are not limited to, nine listed

factors. Practically every single factor listed in the regulation could be relevant here to substantiate the seriousness of the circumstances raised and, consequently, the severity of sanction that would be appropriate.

o Section 493.1806 confirms that the Secretary may impose any of three principal sanctions including suspension and revocation of the CLIA certificate when a laboratory is out of compliance with one or more CLIA conditions.

o Section 493.1814 confirms that the Secretary may suspend or revoke the CLIA certificate without first imposing an alternative sanction even if the laboratory's condition-level deficiencies do not pose immediate jeopardy.

o Section 493.1812(a) provides that where the laboratory's deficiencies do pose immediate jeopardy, HCFA requires the laboratory to take immediate action to remove the jeopardy.

The preambles to the proposed and final versions of the regulations provide further confirmation that HCFA may impose an immediate suspension (with a five-day delayed effective date) when a laboratory's deficiencies pose an immediate jeopardy. Much of this confirmation was already discussed in the background to our analysis. Perhaps the most explicit evidence, however, is the following statement from the preamble to the final regulation. The preamble states:

> We realize that a laboratory's failure to make corrections very quickly in immediate jeopardy situations will trigger the suspension or limitation of the laboratory's CLIA certificate, thus causing full or partial closure of the facility. However, as noted above, the imposition of these sanctions before a hearing is clearly authorized by section 353(i)(2) of the [Public Health Service] Act. If laboratories are concerned with maintaining access to testing, they should focus all efforts on the expedited correction of their deficiencies, and not on the receipt of an "expedited" hearing, by which we assume the commenters mean a hearing before the adverse action is taken. But conducting hearings within the 5 days before principal sanctions become effective in immediate jeopardy situations would be virtually impossible. When there are life-threatening deficiencies, action must be taken no later than this.

57 Fed. Reg. 7232 (Feb. 28, 1992).

The ALJ Decision nevertheless found that HCFA was procedurally deficient in imposing the suspension here

because it did not also provide certain additional procedural protections ordinarily pertaining to the imposition of alternative sanctions, which are set out in section 493.1812(b), and with greater specificity in sections 493.1810 and 493.1832. Indeed, the ALJ Decision relies on procedures specified in section 493.1812(b) as the primary basis for setting aside HCFA's suspension of Petitioner. ALJ Decision at 6-17. However, this provision of the regulations, which admittedly is not as clear as it might be, simply does not apply to the situation where HCFA decides to impose an immediate suspension. Rather, it was designed to respond to the type of immediate jeopardy situation where HCFA in its discretion does not impose an immediate principal sanction such as suspension but rather an alternative sanction that may or may not ultimately lead to a principal sanction. 7/ This additional flexibility for HCFA was one of the primary changes authorized by CLIA, and the procedures that would apply in that eventuality are outlined in section 493.1812(b), and in other provisions that apply specifically to alternative sanctions such as sections 493.1810 and 493.1832. The latter sections, like section 493.1812(b), contemplate that there will be a "revisit" to the laboratory. Section 493.1812(a), however, clearly does not require HCFA to respond with procedures pertaining to an alternative sanction in every instance of an immediate jeopardy. In requiring a laboratory to take immediate action under section 493.1812(a), HCFA clearly may still impose an immediate principal sanction.

This interpretation is confirmed by section 493.1814 (and by the wide range of other regulatory provisions discussed previously and the preamble quotations) as well as by CLIA and its legislative history. Indeed, section 493.1814 specifically concerns those actions available to HCFA in the less serious situation where a laboratory's deficiencies do not pose an immediate jeopardy, and it explicitly still authorizes HCFA to impose a principal sanction without recourse to a "revisit" or any other ancillary procedure of an intermediate sanction. Section 493.1814(b) also more clearly explains that certain ancillary procedures apply only if HCFA imposes alternative sanctions rather than principal sanctions.

Thus, we conclude that where section 493.1812(a) contemplates that HCFA will require the laboratory to take immediate action to remove the jeopardy, section 493.1812(a) may reasonably be interpreted to be authorizing HCFA to use any of the sanctions available to it, either alone or in conjunction with other sanctions, including principal sanctions, such as immediate suspension or revocation, or one of the alternative sanctions. If HCFA chooses to apply an alternative sanction such as a directed plan of correction rather than a principal one, then it must, however, also follow the procedures that are outlined in section 493.1812(b),

which require suspension when compliance is not achieved by means of the alternative sanction. (Although alternative sanction procedures may subsequently lead to a suspension of the CLIA certificate, HCFA of necessity would not have already decided to impose a suspension at the time it imposes the alternative sanction.)

However, if HCFA in an immediate jeopardy situation chooses in its discretion to impose an immediate principal sanction such as a suspension, it necessarily has to apply only the procedures that the regulations require for that sanction, which would not include, among other things, a "revisit" to the laboratory. We have discussed the applicable requirements from sections 493.1844(g) and (h) at length above. The imposition of a suspension with a five-day delayed effective date requires the laboratory to take immediate action to remove the jeopardy as contemplated by section 493.1812(a). Moreover, as we discuss below, HCFA gave Petitioner guidance on how to remove the jeopardy by directing it to submit an acceptable plan of correction prior to the effective date of the suspension and by giving Petitioner explicit notice concerning the conditions in the regulations that were out of compliance. We discussed previously in footnote 6 other aspects of the notice provided to Petitioner. The circumstances of this case, as alleged by HCFA, would clearly justify, in our view, HCFA's use of an immediate suspension rather than recourse to an alternative sanction. 8/

Finally, even if we were to agree with the ALJ that section 493.1812(b) at least requires a "revisit" to the laboratory even before HCFA can effectuate a principal sanction, we find that a revisit clearly would have been unnecessary under the circumstances here where Petitioner had not even submitted an acceptable plan of correction, much less a credible allegation of compliance, by the close of June 1, 1993. Thus, HCFA would have had no basis to conclude that the laboratory had made sufficient changes in its operations to eliminate the immediate jeopardy, and thus to merit a revisit, before the suspension became effective.

Accordingly, we conclude that the ALJ erred when she concluded that HCFA's suspension of Petitioner was "premature" and unauthorized.

B. Cancellation of approval to receive Medicare payments

We conclude that HCFA's cancellation of Petitioner's approval to receive Medicare payments was also fully authorized under the circumstances here because 42 C.F.R. _ 493.1808(a) provides that whenever HCFA suspends the CLIA certificate, HCFA must concurrently cancel the laboratory's approval to receive Medicare payment for its

services. See also 42 C.F.R. _ 493.622. The ALJ erroneously viewed HCFA's suspension of Medicare payments as invalidly imposed when, in fact, the regulations make clear that an operative CLIA certificate is a condition precedent to the receipt of Medicare reimbursement for services.

C. Plan of correction

In addition to imposing the principal sanctions of suspension of Petitioner's CLIA certificate and cancellation of Medicare payments, HCFA's notice of May 27, 1993 directed Petitioner to send a complete client list within 10 days of the notice (because section 493.1832 "provides that your clients should be notified of this action") and "as an alternative sanction" under section 493.1832, directed Petitioner to provide "an acceptable plan of correction to the cited deficiencies prior to June 1st."

We conclude that HCFA had authority under the CLIA regulations to require both the client list and submission of a plan of correction. Section 493.1844(g)(1) specifically states that where HCFA imposes a suspension, HCFA may give notice to laboratory clients according to procedures set forth in section 493.1832. Section 493.1844(g)(1) therefore merely incorporates by reference the notice procedures that would ordinarily apply for a directed portion of a plan of correction in section 493.1832(b)(2)(i). These procedures require a laboratory to submit a client list to HCFA within a 10-day time frame. Thus, we conclude HCFA's request for a client list here was clearly authorized by section 493.1844(g)(1), which incorporates by reference the notice procedures in section 493.1832.

We also conclude that HCFA could under these same authorities require a laboratory to submit a plan of correction. Section 493.1844(g)(1) expressly authorizes HCFA to rely on procedures for client lists in section 493.1832 and in no way precludes HCFA from directing submission of a plan of correction as well. The ALJ erred in viewing HCFA's May 27 notice as actually imposing an alternative sanction of a directed plan of correction. Under section 493.1832(b)(1)(ii), what HCFA does when imposing a directed plan of correction is to direct a laboratory to "take specific corrective action within specific time frames in order to achieve compliance." Here, HCFA simply required submission of an acceptable plan of correction. When Petitioner failed to submit such a plan, HCFA revoked its CLIA certificate, thus never actually directing Petitioner to take specific corrective action within specific time frames to achieve compliance. Since HCFA never in fact imposed this alternative sanction, the procedures for actually imposing it do not apply.

In any event, HCFA's directive concerning the submission of an acceptable plan of correction served at least two purposes under the regulatory enforcement procedures. It gave Petitioner notice of an action it could take to begin removing the immediate jeopardy as contemplated by section 493.1812(a), and it required Petitioner to initiate what ultimately could have become a directed plan of correction to serve as an alternative sanction to the principal sanction of revocation. We should also note that if HCFA had given Petitioner a Longer amount of time than five days to submit an acceptable plan of correction, the suspension would already have been in effect on the date the plan was submitted. Even if Petitioner could not have complied with the five-day time frame given, it was clearly to its advantage to submit a plan of correction at the earliest possible date thereafter, since the revocation effective date would be delayed until the ALJ decision. Thus, we conclude that HCFA's decision to direct an acceptable plan of correction with a very short time frame was under the circumstances here consistent with HCFA's regulatory authority to impose an immediate principal sanction of suspension under sections 493.1844(g)(1) and (h) and section 493.1812(a), as well as its authority to subsequently revoke the CLIA certificate.

D. Revocation

We conclude that HCFA clearly had the authority to revoke Petitioner's CLIA certificate based on the same grounds as its decision to suspend the certificate and on Petitioner's failure to submit an acceptable plan of correction before the effective date of the suspension. HCFA clarified in its request for review of the ALJ Decision that, in view of Petitioner's request for an ALJ hearing, the revocation would go into effect only should the suspension and revocation be upheld by the ALJ. Section 493.1844(d)(2). The mere specification of a different effective date in the June 1st notice is not inconsistent with the regulation since it was unclear at that time whether Petitioner would appeal.

Thus, we conclude that HCFA has fully complied with all procedural requirements in imposing the sanctions at issue here.

2. Even if the imposition of any of the sanctions had been procedurally defective, the deficiency could not have been harmful to Petitioner under the circumstances here, nor would it have justified setting aside the sanctions in their entirety.

Even if we were to conclude that the imposition of any of the sanctions in question was procedurally defective, we

would still not conclude that the deficiency was harmful to Petitioner under the circumstances here. 9/ The State of New Jersey had already suspended Petitioner's license to operate its laboratory two days prior to HCFA's May 27, 1993 notice and had provided opportunity for a State hearing and a State hearing decision within 48 hours of the laboratory's hearing request. New Jersey's suspension was based on findings of the same State survey that HCFA had relied upon in imposing its sanctions two days later. Although the record demonstrates that the laboratory did timely request an administrative hearing from the State on May 28th (one day after HCFA's notice), the ALJ Decision found that at all times since May 25, 1993, Petitioner has been unable to operate due to the sanctions imposed under New Jersey law. Decision at 26, 14. Under these circumstances, any purported procedural deficiency on HCFA's part, if such in fact existed, could not have had any impact on Petitioner's ongoing operations. New Jersey's actions had preceded HCFA's and caused Petitioner's entire operations to cease. The only way Petitioner could have established that HCFA's procedures were harmful to its continued operation would have been if Petitioner had been able to demonstrate that the State suspension had been subsequently withdrawn at a time when HCFA had improperly imposed or retained its sanctions.

We also question whether the ALJ's remedy of setting aside in their entirety the principal sanctions at issue here was necessarily appropriate even if Petitioner had been able to demonstrate that HCFA's procedures had been deficient, without at least considering whether any deficiency could have been cured by, for example, modification of an effective date. The ALJ Decision cited no authority in the CLIA statute or regulations for setting aside principal sanctions on the procedural grounds (such as deficiencies in notice or effective date) here considered, nor did it identify any case law in support of setting aside sanctions of this type for procedural deficiency or for requiring HCFA to demonstrate that its actions and omissions were harmless.

Aside from the lack of any explicit authority for the ALJ's remedy, we question whether the remedy is consistent with the overall purposes of the CLIA legislation. While the CLIA provisions unquestionably allow laboratories to contest survey findings on the merits in an administrative review process, they are perhaps primarily designed to induce a laboratory to come into compliance with CLIA requirements during the pendency of the review process as a response to the principal or alternative sanctions imposed by HCFA. Where HCFA determines that the laboratory's deficiencies pose an immediate jeopardy (a non-reviewable decision), the regulations contemplate that HCFA will impose sanctions that will bring about an immediate response to

deficiencies posing the jeopardy. If a laboratory has any question concerning the time frame for sanctions designed to induce an immediate response, the reasons for sanctions, or what is expected of it in response to the sanctions, the laboratory is obliged under the regulatory and statutory scheme to contact State officials or appropriate HCFA officials so that it can proceed immediately to correct the deficiencies it concedes may exist.

In a situation where a laboratory has a history of serious non-compliance and as many as seven alleged condition-level deficiencies raising an immediate jeopardy to patient health and safety, that laboratory must be prepared to take very serious and immediate steps to eliminate the jeopardy if it believes that it will not be able to successfully contest the findings of noncompliance. The procedures are simply not designed to encourage laboratories to delay making the necessary changes for several months until the hearing is held or for several additional months until the hearing decision is issued.

Moreover, HCFA cannot ultimately come in and tell a laboratory how it must manage its operations so that it can come into compliance. It is up to the laboratory to determine what steps, no matter how drastic, are needed to rectify the conditions that gave rise to the finding of immediate jeopardy and, where appropriate, to incorporate those steps into an acceptable plan of correction. See 42 C.F.R. __ 488.18(b)(3) and 488.28(a). We detailed in footnote 6 the various forms of notice about potential areas of noncompliance Petitioner received prior to HCFA's May 27th notice. Moreover, in that notice, HCFA identified each CLIA condition that had not been met and included the regulatory citation for each condition. HCFA directed Petitioner to submit an acceptable plan of correction to DOH, indicating that any implementation would be subject to State on-site monitoring. State officials had already imposed their own sanctions prior to HCFA's imposition of sanctions, providing Petitioner with the full survey report and the "Statement of Deficiencies" (HCFA 2567). Thus, Petitioner necessarily should have worked with these officials as well as HCFA officials in developing an acceptable plan of correction so that it could eliminate the jeopardy and come into compliance simultaneously with State and federal laws. In making its findings, HCFA had relied on the judgment of state survey officials, which it clearly had the right to do under the statute and regulations.

Even if Petitioner could not have submitted an acceptable plan of correction within five days as required, it clearly could have done so within a very short time frame thereafter. In authorizing a five-day delayed effective date for a suspension, both the statute and regulations

clearly contemplate that a laboratory in immediate jeopardy circumstances may have to cease operations temporarily before it can make the necessary changes in its operations to be permitted to resume operations.

Moreover, the fact that Petitioner here was required to cease operations by the State before the federal requirements were invoked should not have any bearing on the procedures here set by HCFA. Contrary to what is implied in several instances in the ALJ Decision, a laboratory may still be required to demonstrate its capacity and intent to comply with the CLIA requirements even though it has been forced to cease operations either under state or federal enforcement procedures (or, as in the case here as of June 1, 1993, under both procedures). In any event, the decision as to whether to reinstate a suspended CLIA certificate is not a decision that may be made by the ALJ or by the Board under CLIA enforcement procedures, but by the State survey officials and HCFA Regional Office officials. See section 493.1844(c)(3).

3. The proper appellate remedy is to remand this case to the ALJ for a determination on the merits.

In addition to requesting that the Board reverse the ALJ Decision, HCFA asked the Board to proceed to rule on the merits of the deficiencies cited by HCFA and uphold HCFA's suspension and revocation of Petitioner's CLIA certificate and cancellation of Medicare payments.

The Board, however, when functioning in an appellate role, does not customarily proceed to make factual findings based on the hearing record developed by the ALJ, since the ALJ observed the witnesses during their testimony and the record demonstrates that witness credibility and demeanor were a consideration. We therefore remand this case to the ALJ so that the ALJ can consider the substantive issues raised by Petitioner's hearing request, and in particular, can decide whether there were condition-level deficiencies during the February and March 1993 survey of Petitioner.

We should add, however, that, contrary to statements made in the ALJ Decision at 39-40, there is no reason why a decision on the substantive issues would not be feasible or necessary at this time. The CLIA enforcement scheme contemplates essentially two routes for non-compliant laboratories to take when faced with sanctions from HCFA. They can contest the existence of the deficiencies identified by the state surveyors and relied upon by HCFA for the decision to sanction or they can correct the deficiencies and thereby avoid full implementation of the sanctions being imposed. If, as here, a laboratory ceases operations because of state sanctions imposed between the time it is surveyed and the time HCFA decides to impose CLIA sanctions, that fact may have a bearing on

the laboratory's ability and inclination to correct its deficiencies in order to avoid full implementation of the CLIA sanctions. The closing of the laboratory, however, has no bearing whatsoever on the issue posed to the ALJ here: whether the laboratory had any condition-level deficiencies at the time of the survey. That decision is still quite feasible, and indeed absolutely necessary under the statutory and regulatory scheme. (Furthermore, it has particular relevance to the owners and operators of the laboratory. No person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued. 42 U.S.C. _ 263a(i)(3).)

Finally, we should also note that if the ALJ determines that Petitioner did have any condition-level deficiency as determined by the State surveyors and HCFA, the ALJ does not have to step outside her role as adjudicator to take on the duties of an enforcement official as she suggested she might. Decision at 40. The ALJ merely has to affirm the principal sanctions being imposed by HCFA: suspension, revocation, and cancellation of Medicare payments. The regulations provide, as HCFA here clarified, that HCFA's decision to revoke becomes effective after a hearing decision by the ALJ upholding HCFA's decision is issued. Section 493.1844(d). Moreover, alternative sanctions, such as a directed plan of correction, are no Longer relevant since they are designed to prevent the principal sanctions from going into effect and therefore may themselves continue in effect only until a suspension or revocation becomes effective. Section 493.1810(d)(2).

Conclusion

On the basis of the foregoing analysis, we reverse the ALJ Decision, which set aside, for procedural deficiencies, the sanctions HCFA imposed against Petitioner, and we remand this case to the ALJ for a decision on the substantive merits of the sanctions.

_____
Judith A. Ballard

_____
M. Terry Johnson

_____
Donald F. Garrett
Presiding Board Member

1. All subsequent references to sections of regulations in this decision, unless otherwise noted, will be to sections in 42 C.F.R. Part 493, Subpart R (1993) entitled "Enforcement Procedures." Other aspects of the CLIA requirements are implemented elsewhere in 42 C.F.R. Part 493.

2. "Immediate jeopardy" has been defined in the regulations as:

> a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public.

42 C.F.R. _ 493.2.

In discussing HCFA's range of choice in sanctions, the preamble to the proposed rule states that there are situations which almost always can be classified at face value as being condition-level deficiencies with immediate jeopardy. The example given in the preamble is the situation where laboratory test results are reported for tests that were never performed. This situation

merits being classified as "immediate jeopardy" because:

> in such a fraudulent situation, falsifying test results can yield accuracy on only a random basis. The danger to patients represented by groundless test reports and the corresponding implications for inaccurate diagnosis and the inability to render early and/or correct treatment, could depending on the actual physical state of the patient be life threatening.

56 Fed. Reg. 13,433-13,434 (April 2, 1991).

Moreover, the preamble to the final regulations states the following concerning the sanctions in an immediate jeopardy situation:

> If the deficiencies are determined to pose immediate jeopardy to the health and safety of individuals served by the laboratory . . ., the sanctions imposed will, of necessity, be more severe than those used in situations which are less threatening, and will consist of at least one principal sanction. When there is not immediate jeopardy, alternative sanctions rather than principal sanctions would be imposed first, thus allowing the laboratory a Longer period of time to come into compliance.

57 Fed. Reg. 7224 (Feb. 28, 1992).

3. In this case, DOH had a dual role. It acted as HCFA's agent under CLIA, and it took actions on behalf of the State of New Jersey to enforce and implement State laws.

4. Section 493.1844(h)(1) specifically provides as follows:

> (h) Effective date of adverse action. (1) When the laboratory's deficiencies pose immediate jeopardy, the effective date of the adverse action is at least 5 days after the date of the notice.

HCFA's use of the fifth day after the notice as the effective date here is in our view at least a reasonable interpretation of the language and is consistent with the

plain wording. HCFA's interpretation permits the effective date itself to be five days after the date of the notice as the wording seems to allow. The ALJ nevertheless concluded that the regulation required the effective date to be the day beyond five days after the date of the notice. Even if the ALJ interpretation was also a reasonable interpretation, HCFA's interpretation was entitled to deference, since HCFA is the administering agency for CLIA enforcement and the drafter of the regulation. Furthermore, the ALJ did not cite to any evidence that Petitioner had relied on a different interpretation from HCFA's. In any event, HCFA's interpretation was not so clearly erroneous that it should have been the basis for setting aside the entire suspension. The ALJ should have considered merely modifying the effective date of the suspension by one day.

We should add, however, that the ALJ never addressed the requirements in section 493.1844(h)(1), but rather addressed identical language from section 493.1812(b) that applies only where HCFA has decided to impose an alternative sanction in advance of any principal sanction such as suspension, and where HCFA thereafter decides to suspend the CLIA certificate because the alternative sanction did not cause the laboratory to come into compliance. It is clear from HCFA's notice here, however, that HCFA was not imposing an alternative sanction in advance of a suspension, but was rather imposing an immediate suspension. Thus, the provisions of section 493.1844(h)(1) apply.

5. Section 493.1844(g) provides as follows:

> (g) Notice of adverse action. (1) If HCFA suspends, limits, or revokes a laboratory's CLIA certificate or cancels the approval to receive Medicare payment for its services, HCFA gives notice to the laboratory, and may give notice to physicians, providers, suppliers, and other laboratory clients, according to the procedures et forth at _ 493.1832. . . .
> (2) The notice to the laboratory--
> (i) Sets forth the reasons for the adverse action, the effective date and effect of that action and the appeal rights if any; . . .

6. If Petitioner needed further information concerning the cited deficiencies, the survey findings or the issue of immediate jeopardy, the regulatory enforcement scheme contemplates Petitioner should have contacted the appropriate state survey officials or HCFA

officials immediately. In any event, the record here indicates that, just one day after HCFA's notice, Petitioner was already appealing New Jersey's suspension of Petitioner's state license based on the same state survey results relied upon by HCFA and that Petitioner was fully aware of the nature of the deficiencies at issue in those proceedings. Petitioner Ex. 15. As part of those proceedings, DOH had sent Petitioner, in advance of HCFA's May 27th notice, both the "Statement of Deficiencies" (HCFA 2567) and the "Survey Report." HCFA 1-b; 114. The record also demonstrates that, while the survey was in process, which was several months in advance of sanctions from either HCFA or New Jersey, survey officials discussed apparent serious deficiencies they had identified with Petitioner's management and employees. Tr. 92. Further, the record demonstrates that the lead surveyor telephoned Petitioner's Director before the State sent its notice of deficiencies and advised him that the findings were "very serious" and that "if he wanted to ask any questions, if he had any concerns that he wanted to meet with the [surveyors] or with [the lead surveyor] or wanted any information to ask." Tr. 93-94. Finally, HCFA argued that the types of deficiencies cited, especially with reference to fictitious patient test results and fabricated control data, were repeat deficiencies from prior years. HCFA Post-Hearing Br. 49.

7. The language of section 493.1812(a) and (b) is as follows:

> _ 493.1812 Action when deficiencies pose immediate jeopardy
>
> If a laboratory's deficiencies pose immediate jeopardy, the following rules apply:
>
> (a) HCFA requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance.
> (b) If the findings of a revisit indicate that a laboratory has not eliminated the jeopardy, HCFA suspends or limits the laboratory's CLIA certificate no earlier than 5 days after the date of notice of suspension or limitation. HCFA may later revoke the certificate.

8. Contrary to what the ALJ Decision suggests, moreover, the procedures attendant to an immediate administrative suspension differ substantially from a

civil injunction against the continued operation of the laboratory contemplated by sections 493.1846 and 493.1812(c), and HCFA might still in appropriate instances of a "significant hazard to the public health" decide to bring suit in a U.S. District Court rather than or in addition to using an administrative remedy.

9. Many of the procedural deficiencies the ALJ Decision found had occurred were not even identified by Petitioner in its brief before the ALJ, much less alleged by Petitioner to have caused it harm under the particular circumstances here. See Petitioner's Post Hearing Brief dated October 25, 1994.

Center Clinical Laboratory, CR No. 411 (1996)

$05:Civil Money Penalty

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Center Clinical Laboratory,	DATE: February 15, 1996
Petitioner,	
- v. -	Docket No. C-95-160 Decision No. CR411
Health Care Financing Administration.	

DECISION ON REMAND

Background

The procedural history of this case is contained in my prior decision, CR358 (1995), and in the decision of the appellate panel of the Departmental Appeals Board, DAB 1526 (1995), which reversed my decision and remanded the case to me for further proceedings. In its decision, the appellate panel has set forth the interpretations of the regulations that govern the outcome of this case. The appellate panel concluded that I erred in setting aside the sanctions imposed by the Health Care Financing Administration (HCFA) on procedural grounds. The panel determined instead that HCFA had acted properly in imposing all of the sanctions in question. DAB 1526, at 11 - 20.

In accordance with the appellate panel's directives on remand, I have evaluated the evidence concerning the sole factual issue remaining in this case: whether Petitioner had any condition-level deficiency as determined by the State surveyors and HCFA. As the appellate panel stated in the last paragraph of its decision,

> [I]f the ALJ determines that Petitioner did have any condition-level deficiency as determined by the State surveyors and HCFA,
>
> . . . [t]he ALJ merely has to affirm the principal sanctions being imposed by HCFA: suspension, revocation, and cancellation of Medicare payments. The regulations provide, as HCFA here clarified, that HCFA's decision to revoke [Petitioner's CLIA Certificate] becomes effective after a hearing decision by the ALJ upholding HCFA's decision is issued. [42 C.F.R.] Section 493.1844(d). Moreover, alternative sanctions, such as a directed plan of correction, are no Longer relevant since they are designed

to prevent the principal sanctions from going into effect and therefore may themselves continue in effect only until a suspension or revocation becomes effective. Section 493.1810(d)(2).

DAB 1526, at 24.

The appellate panel has determined that HCFA acted properly in imposing all of the sanctions in issue (id. at 11 - 20), that an affirmation of the principal sanctions imposed by HCFA depends solely on the existence of condition-level deficiencies (id. at 24) and the other sanctions also imposed by HCFA are no Longer relevant (id.). Accordingly, I have reviewed the record as a whole and now make the following findings material to the issues on remand.

Findings of Fact and Conclusions of Law

1. During February and March of 1993, the New Jersey Department of Health, acting as agent for HCFA, surveyed Petitioner under the Clinical Laboratory Improvement Act (CLIA). HCFA Exhibits (Exs.) 1, 1b, 127, 128.

2. Between May 27 and June 1, 1993, HCFA imposed various sanctions under CLIA pursuant to its determination post survey that Petitioner's deficiencies posed "immediate jeopardy" to patient health and safety. HCFA Exs. 127, 128; see 42 C.F.R. 493.2 (definition of "immediate jeopardy").

3. HCFA's determination of "immediate jeopardy" is not reviewable in this forum. 42 C.F.R. 493.1844(c)(6).

4. The principal sanctions HCFA imposed are the suspension and revocation of Petitioner's CLIA certification and the cancellation of Petitioner's approval to receive Medicare payment. HCFA Exs. 127, 128; 42 C.F.R. 493.2, .1806(b), .1807(a).

5. A condition-level deficiency means noncompliance with one or more requirements identified as "conditions" within subparts G through Q of 42 C.F.R. Part 493. 42 C.F.R. 493.2.

6. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart H (re participation in proficiency testing). Pages 4 - 6, herein.

7. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart J (re the management of patient tests). Pages 6 - 10, herein.

8. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart K (re quality control of tests). Pages 11 - 13, herein.

9. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R.

Part 493, Subpart P (re quality assurance). Pages 13 - 14, herein.

10. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart M, insofar as they pertain to the responsibilities of laboratory directors and supervisors. Pages 13 - 14, herein.

11. HCFA properly imposed principal sanctions against Petitioner. Findings 4 - 10; DAB 1526, at 24.

Discussion

By way of overview, I note that all of the condition-level deficiencies alleged and proven by HCFA are inter-related by facts or logic. See Tr. 347 - 48. I find persuasive HCFA's use of Petitioner's records to prove HCFA's contention that Petitioner had incurred condition-level deficiencies as a laboratory performing tests of moderate or high complexity. 1/ Petitioner had made its records available to the surveyors during the February - March 1993 survey, and the records randomly selected for review by the surveyors reflected ongoing chaotic, inconsistent, inadequate, and sometimes aberrant methods for performing proficiency tests and patient tests, identifying patient test specimens and reporting patient test results, and performing required quality control procedures. In the absence of any substantive or credible rebuttal by Petitioner, the nature and extent of such problems establish that Petitioner had violated the conditions for performing proficiency tests (Subpart H), management of patient tests (Subpart J), and quality control (Subpart K).

Since there is no evidence that Petitioner had taken meaningful steps to ascertain and correct the foregoing condition-level deficiencies, it is reasonable to conclude also that Petitioner has failed to meet the condition-level requirements for quality assurance (Subpart P) and for Petitioner's laboratory director and supervisor to perform their duties as specified by the regulations (Subpart M). The quality assurance condition requires the laboratory to ensure the quality of its own work through a continuing self-monitoring process, and the condition pertaining to laboratory directors and supervisors requires that these individuals effectuate their responsibilities so that proficiency testing, patient testing, quality control, and other requisite procedures are implemented in accordance with CLIA requirements. 42 C.F.R. Part 493, Subparts M and P.
Therefore, the evidence supports the conclusion that if Petitioner had complied with the conditions for quality assurance and for its laboratory director and supervisor to perform their responsibilities as required by the regulations, Petitioner should not have incurred condition-level deficiencies for performing proficiency tests, patient test management, or quality control.

I discuss below the condition-level deficiencies proven by HCFA on the basis of evidence which I find to be credible and essentially unrebutted by Petitioner.

A. Petitioner was not in compliance with the condition of participation governing proficiency testing of samples.

Subpart H of the regulations sets forth the condition for the performance of proficiency tests by laboratories performing tests of moderate or high complexity. 42 C.F.R. Part 493, Subpart H. Proficiency testing is a system used to check a laboratory's ability to perform certain patient tests. Tr. 900. Four times each year, a proficiency testing organization approved by HCFA sends out a set of five proficiency testing samples of unknown values to the laboratory for testing by that laboratory. Tr. 900 - 02. The regulations are specific in requiring that the laboratory: 1) test its proficiency samples in the same manner as it tests its patient specimens; 2) test its proficiency samples the same number of times as it routinely tests patient samples; 3) document the handling, preparation, processing, examination, and each step in the testing and reporting of proficiency testing samples; and 4) maintain, for a minimum of two years, the relevant records (including the attestation statement documenting that the proficiency testing samples were tested in the same manner as patient specimens). 42 C.F.R. 493.801(b).

During the February - March 1993 survey, the surveyors analyzed Petitioner's records concerning its performance of proficiency chemistry tests in 1992. See, e.g., HCFA Ex. 1 at 33; HCFA Ex. 97; Tr. 899 - 908. The surveyors concluded that Petitioner was not performing its proficiency tests in the same manner and with the same frequency that it was routinely performing its patient tests. HCFA Ex. 1 at 33. For example, in 25 out of the 27 proficiency chemistry tests reviewed by one surveyor, Petitioner had tested its proficiency chemistry samples more than once, even though the results from these samples were all within the normal range. Tr. 904 - 12. In contrast, Petitioner did not retest any patient specimen that had attained a normal result, and Petitioner did not consistently retest patient specimens that attained abnormal or odd results. Id. In addition, by comparing the contents of the proficiency test reports and the documents Petitioner generated in preparation of those reports, the surveyors found instances where Petitioner reported proficiency test results which, according to Petitioner's work papers, Petitioner had not attained. Tr. 907 - 08.

There is no logical reason for repeatedly testing proficiency samples having normal results, especially when Petitioner appears to know this from its routine practice of not testing patient specimens more than once after attaining a normal result. Tr. 906. Nor can Petitioner's retesting of numerous proficiency samples having normal results be reconciled with its practice of failing to retest patient samples even when those patient samples have very odd or abnormal results. These disparities in methodologies violate Petitioner's obligation to conduct its proficiency tests in the same manner and for the same number of times that it routinely performs patient tests. See 42 C.F.R. 493.801(b) and (b)(2). In addition, the conclusion that Petitioner violated the recordkeeping requirements of 42 C.F.R. 493.801(b)(5) is shown by the absence of correlation between some of the proficiency test results reported by Petitioner and the documents supplied to the

surveyors for review.

Petitioner acknowledges that the regulation governing proficiency testing requires the laboratory to process proficiency test samples in the same manner as it does patient specimens. P. Br. at 14. Nevertheless, Petitioner argues that it was in compliance, even though it did not test patient samples and proficiency testing samples the same number of times. Id. Petitioner argues that its practice does not violate the regulation. Petitioner's argument is plainly wrong, however, as 42 C.F.R. 493.801(b)(2) quite specifically requires that proficiency samples be tested the same number of times as patient specimens.

On the basis of the foregoing evidence and the absence of any credible proof supporting a contrary conclusion, I find that Petitioner violated the condition for performing proficiency tests in the manner required by 42 C.F.R. 493.801.

B. Petitioner was not in compliance with the condition of participation governing patient test management.

Subpart J of the regulations sets forth the condition for patient test management in laboratories performing moderate or high complexity tests. 42 C.F.R. Part 493, Subpart J. To satisfy this condition, the laboratory must employ and maintain a system that provides for, inter alia, the proper identification, preservation, and processing of patient specimens, and the accurate reporting of results. 42 C.F.R. 493.1101. It is incumbent upon the laboratory to ensure the reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. 42 C.F.R. 493.1101, .1107.

The laboratory also must send test reports promptly to the authorized individual who requested the test. 42 C.F.R. 493.1109. This means, for example, that the laboratory should have in place an adequate system for reporting patient test results in a timely, accurate, reliable, and confidential manner. 42 C.F.R. 493.1109(a). The laboratory must make available to the authorized person who requested the test the "reference" or "normal" ranges determined by the laboratory, and the laboratory must develop and follow written procedures for immediately reporting any imminent life-threatening results or "panic values" to the authorized individual who requested the test. 42 C.F.R. 493.1109(d), (f). The laboratory must also retain copies of test records and test reports for specified periods of time after the results are sent promptly to the authorized individual who requested the test. 42 C.F.R. 493.1107, .1109. For example, immunohematology test records and reports must be maintained by the laboratory for at least five years, and pathology test reports must be retained for a minimum of 10 years after the date of reporting. Id.

The evidence in this case establishes that Petitioner did not comply with the condition of participation for patient test management, for three reasons. First, Petitioner's practices did not assure the proper identification of patient specimens. Second, Petitioner failed to maintain the records required by regulation. Third, Petitioner did not insure that test results were promptly

reported to the individual that requested them.

1. Petitioner failed to insure that patient specimens were properly identified.

During their review of Petitioner's records and practices, the surveyors discovered that Petitioner's identification of culture plates was inadequate. A surveyor testified that the markings on the culture plates indicated only the date the culture was made and the last three digits of the patient identification number. Tr. 503, 505 - 07. This identification was inadequate because, as explained at the hearing, the lab must have a record system that permits the tracking of a patient specimen from entry to final report. Tr. 246 - 48. However, the surveyors found it impossible at times to confirm that patient specimens had been identified correctly because neither the patients' names nor their identification numbers had been entered in Petitioner's work records. HCFA Ex. 1 at 14. Instead, Petitioner entered in its records only the last one or two digits of the patients' identification number, which, in its entirety, should consist of nine digits containing also the year, month, day, and sequence in which Petitioner had logged in the physician's request for testing the specimen. Id. Even though Petitioner routinely entered the testing date and date of specimen collection in its work records, such entries were not adequate for accurately identifying patients from Petitioner's work records. Id. Because in several cases specimens were collected or tested on days that differed from those on which the doctors gave their orders or when Petitioner received the specimens, it was not appropriate to construe the two dates appearing in Petitioner's work records as the missing digits from the patient identification numbers. Id.

The surveyors found also that Petitioner accepted some urine specimens in unlabeled containers, which, even if the patient's name had been written on the lid of the container, presented the risk of having the contents of the container associated with the wrong lid and wrong patient name. Tr. 339 - 43, 351 - 52. Petitioner admitted that it does not keep all information on the specimen containers, but it alleges that it maintains all the necessary information on the request forms, which are logged in with the specimen. P. Ex. 15 at 3. However, the request forms and log information reviewed by the surveyors contradict Petitioner's allegations. Petitioner's records reveal that Petitioner: 1) failed to include in its accession number system the dates on which specimens were collected; 2) assigned duplicate numbers to some specimens; 3) failed to assign consecutive numbers to specimens collected from one collection station; 4) omitted the names and addresses of some physicians who requested tests; and 5) failed to indicate which of two collection stations the specimens came from. Tr. 249 - 89.

2. Petitioner failed to keep adequate records of its test results.

In addition to its inadequate identification of patient specimens, Petitioner also was not in substantial compliance with the regulation's recordkeeping requirements under the patient test

management condition. For example, Petitioner's supervisors were unable to produce any work records to support the parasitology results it reported for 1992. Tr. 415 - 17; HCFA Ex. 1 at 12 - 13. The regulations require such records to be kept for a minimum of two years. 42 C.F.R. 493.1107. Moreover, even though Petitioner produced its 1993 work records for parasitology, its recordkeeping systems or techniques were so defective that the surveyor was not able to track various specimens from their accession report to the actual work records. Tr. 415 - 17. Another surveyor described similar unsuccessful attempts to establish a correlation between Petitioner's immunohematology reports and actual work records. Tr. 915 - 17. Petitioner is required to maintain immunohematology records for a minimum of five years. 42 C.F.R. 493.1107, .1109. During the February - March 1993 survey, the surveyor randomly selected for review the records and reports for 10 patients tested during a three-month period during 1992. Tr. 915 - 17. She could not find the actual work records for five of the these 10 patients. Id.

Even though Petitioner later submitted a "quality control book" (P. Ex. 6), purporting to substantiate the performance of the tests for all 10 patients, the surveyor noted several reasons for doubting the truth of the information contained in the book. First, the book was submitted only after Petitioner had received notice of the deficiencies. Tr. 918. Moreover, the tests in issue were done manually and not on machines. Tr. 926. Even if a quality control test should have been run on these types of tests, a laboratory should not do a quality control test on actual patient specimens, because a quality control test involves working with samples of known values, whereas actual patient specimens have unknown values. Tr. 918 - 22, 926, 928. The surveyor noted also that the contents of the "book" later produced by Petitioner is highly suspect in that it coincides in all respects with the information the surveyor examined in the laboratory, except that it also has information pertaining to the other five patients (and only the five other patients) in issue for the same time period. Tr. 918 - 22. The surveyor's observations are well-reasoned and persuasive. By contrast, the testimony introduced by Petitioner in defense of the existence of the "book" and its contents appears contrived and conveniently self-serving. See Tr. 937 - 42; P. Ex. 15 at p. 4.

3. Petitioner failed to report test results in a timely and accurate manner.

I found persuasive also HCFA's conclusion that Petitioner failed to meet the timely test reporting requirements of Subpart J. One surveyor testified from the review of Petitioner's records that some tests were completed within 48 hours, but Petitioner took four days to report those results. Tr. 530 - 35. With respect to the requirement for reporting "panic values" or results having life-threatening implications, HCFA showed that Petitioner's records do not contain notations of what action, if any, was taken on the reporting of "panic values." Tr. 314. Even if Petitioner had written policies in place for providing prompt notice of "panic values" to doctors or other authorized individuals who requested the tests, Petitioner's agents and employees did not appear to follow any consistent procedures when they were obligated to report

life-threatening results. Tr. 311 - 12. The surveyors found also many instances where Petitioner failed to report abnormal or spurious tests and inaccurately reported patient results. Tr. 318 - 39; HCFA Ex. 1 at 32.

Through the testimony of at least one of its witnesses, HCFA acknowledged the various possibilities that may have accounted for the grossly abnormal patient test results reviewed during the survey: a bad test system, bad specimens, or patients who were truly very ill. Tr.
889 - 90, 893. However, as also discussed below, if the abnormal results were due to a bad test system or bad specimens, Petitioner took none of the remedial actions required by the regulations. Similarly, if the abnormal test results accurately reflected the serious illness of patients, Petitioner failed to contact the doctors in the manner required by Subpart J. Tr. 890 - 91. In fact, the records reviewed by the surveyors show that, in several instances, abnormal results appear to have been deliberately deleted from patient reports. Tr. 892 - 95.

HCFA's evidence shows also that Petitioner was reporting incorrect and incomplete normal ranges, in contravention of the regulatory requirement that pertinent "reference" or normal ranges, as determined by the laboratory performing the tests, be made available to those who order or will utilize the tests. 42 C.F.R. 493.1109(d); HCFA Ex. 1 at 20 - 23. At the hearing, one of HCFA's witnesses testified that Petitioner reported incorrect normal ranges for potassium in its chemistry test results. Tr. 876 - 78. Petitioner's failure to report the normal range of tests correctly or completely is seen also in its reporting of only the normal ranges for males in certain tests where the normal ranges are gender-dependent. HCFA Ex. 1 at 22. I agree with HCFA's interpretation that the regulation, in requiring that the pertinent normal or "reference" ranges be made available, means that the correct ones be made available. See 42 C.F.R. 493.1109(d). 2/ Petitioner did not prove its assertions that it reported "accepted medical ranges" and used a "medically accepted formula" in calculating the patient test results. See P. Ex. 15 at 5.

For the foregoing reasons, I conclude that HCFA has proven that Petitioner had condition-level deficiencies in the management of patient tests.

C. Petitioner was out of compliance with the condition of participation governing quality control for labs performing moderate or high complexity tests.

Subpart K of the regulations contains the requirements that must be satisfied by laboratories performing tests of moderate or high complexity in order to meet the condition of quality control. 42 C.F.R. Part 493, Subpart K. Quality control refers to techniques for measuring the accuracy of tests by performing the tests on materials for which the correct values are known. Tr. 353 - 54. Under the regulations, a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient tests and results.

42 C.F.R. 493.1201(b). As especially relevant to this case, the regulation is specific that the laboratory must perform and document its control procedures using at least two levels of control materials each day of testing. 42 C.F.R. 493.1202(c)(4). In addition, the laboratory must take remedial actions when appropriate and document such remedial actions. 42 C.F.R. 493.1219, .1221.

In order to ascertain the validity of Petitioner's quality control data, the surveyors chose to review the control records for Petitioner's platelet testing system, automated complete blood count (CBC) system, and chemistry profiling system. HCFA Ex. 1 at 24. At the very basic level, the surveyors found that many of Petitioner's control results were illegible, and no control results were recorded on some days. Tr. 366 - 68; HCFA Ex. 1 at 24. These facts support the conclusion that Petitioner was not performing the required control tests on each day of testing.

At the hearing, one of HCFA's witnesses detailed the various problems found in the review of Petitioner's control data for platelet testing system. Tr. 362 - 92. She explained the significance of the information contained in control product inserts provided by the manufacturer, which list the true or target values for the control material of a particular batch within a particular lot. Tr. 357 - 58, 368 - 72. Petitioner's control records for platelet testing were aberrant in the following respects: 1) the recurrence of a few specific values; 2) the appearance of the same two Low Level control values in 12 out of 15 instances; 3) the recurrence of consecutive identical sets of Normal Level and High Level control results within a short period of time; and 4) the absence of corresponding changes in the High Level control values reported by Petitioner when the lot number and target levels of the platelet controls changed. HCFA Ex. 1 at 24 - 26; Tr. 372 - 92. Based on these and like problems in Petitioner's control records, I agree with the surveyors' conclusion that Petitioner's quality control system for platelet testing was unsatisfactory. HCFA Ex. 1 at 24 - 26.

The surveyors concluded also that Petitioner's quality control of its CBC test system was unsatisfactory because the accuracy of Petitioner's control data in this area could not be verified, for several reasons. HCFA Ex. 1 at 26. At the hearing, one of the surveyors explained the workings of a Coulter Counter analyzer, which performs the CBC tests for Petitioner and should automatically print out dates and sequence numbers. Tr. 395 - 98. However, the analyzer printouts provided by Petitioner did not have the dates or proper sequence numbers, and Petitioner had discarded the carbon copies of its original analyzer printouts. Tr. 398 - 401; HCFA Ex. 1 at 26. In addition, the information on the originals was very difficult to read. Id. Without sequencing numbers, there was no way for the surveyors to know when the control data were generated: whether they were generated on certain days and used for other days, or generated on each day of patient testing as required by the regulations. Tr. 399 - 400. Even though the surveyor could not be certain whether Petitioner had falsified its CBC control data, she testified that laboratories have been known to generate multiple copies of control results on

a day when their analyzer is operating properly, so that these control results could be used on other days when their equipment is not operating properly or when they do not care to run control tests. Tr. 402 - 04. This testimony underscores the importance of having verifiable control data in order to satisfy the condition for quality control.

In the area of patient chemistry testing, the surveyors discovered that Petitioner was calculating certain results incorrectly, and was not investigating or correcting problems that produced spurious test values. See HCFA Ex. 1 at 20 - 23. Petitioner was using the wrong formula to calculate low density lipoprotein (LDL), which caused the wrong results to be reported. HCFA Ex. 1 at 22 - 23; Tr. 567 - 77. Petitioner could not identify a reference source for the single normal LDL range it was reporting for both sexes. Petitioner claimed to have been relying on the same range reported by the previous laboratory owner for the LDL tests. HCFA Ex. 1 at 22; Tr. 565 - 68.

In addition, the surveyors found frequent instances of biased results in the small sample of Petitioner's records randomly selected for review. HCFA Ex. 1 at 21; Tr. 542 - 62. That is to say, instead of finding patient values equally distributed around the mean of the normal range for a particular test (i.e., 50 percent above and 50 percent below), the surveyors found higher percentages of results at either above the mean to create a positive bias, or at below the mean to create a negative bias. Thus, due to such biases, Petitioner was obtaining an unusually high percentage of abnormal values. HCFA Ex. 1 at 21.

Even though Petitioner's records provided repeated indications of possible malfunctioning of its test systems or equipment (e.g., Tr. 389 - 92, 893), Petitioner undertook no remedial action as required by the regulations. Instead, Petitioner likely deleted information from its test reports by manually overriding certain machine generated data that reflected the existence of its systemic or equipment problems. Tr. 893 - 95.

This and like evidence of record prove that Petitioner failed to satisfy the condition of quality control.

D. Petitioner's deficiencies in proficiency testing, patient test management, and quality control demonstrate that Petitioner failed also to comply with the conditions of participation governing quality assurance and those governing laboratory directors and supervisors.

Subpart P of the regulations contains the requirements for the condition of quality assurance. 42 C.F.R. Part 493, Subpart P. For quality assurance, the laboratory must have ongoing monitoring and evaluation of its test management system and quality control system. 42 C.F.R. 493.1703, .1705. For example, the regulations require that the laboratory assess its quality control system to determine whether its corrective actions have effectively responded to the following: 1) problems identified during the evaluation of calibration and control data for each test method; 2) problems identified during the evaluation of patient test values

for the purpose of verifying the reference range of a test method; and 3) errors detected in reported results. 42 C.F.R. 1705. In addition, the laboratory must document all quality assurance activities and make such records available to the Department of Health and Human Services. 42 C.F.R. 493.1721.

Subpart M of the regulations contains the requirements for laboratory directors and supervisors to perform certain specified responsibilities. In a laboratory performing moderate and highly complex tests, a laboratory director must provide overall management and direction in accordance with the regulations, and his responsibilities include ensuring that proficiency test samples are tested as required under Subpart H, ensuring that quality control and quality assurance programs are established and maintained, and ensuring that all necessary remedial actions are taken and documented. 42 C.F.R. 493.1403, 493.1407, 493.1445. In a laboratory performing highly complex tests, there must be a general supervisor whose responsibilities include being accessible to testing personnel, providing day-to-day supervision of high complexity testing, and ensuring that acceptable levels of analytic performance are maintained. 42 C.F.R. 493.1459, 493.1463. In addition, the general supervisor may be delegated the laboratory director's responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications and ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning. 42 C.F.R. 493.1463(b)(1), (2).

The problems discussed in the earlier sections of this decision and substantiated in the record support the conclusion that Petitioner failed to comply with the conditions for quality assurance and that its laboratory director and general supervisor failed to perform their responsibilities in accordance with the regulations. Because of Petitioner's deficiencies in the areas of proficiency testing, patient test management, and quality control, Petitioner's integrity depended upon its supervisor and director performing their duties properly and undertaking meaningful quality assurance. Only by complying with the regulatory requirements for quality assurance and laboratory directors and supervisors found in Subparts P and M could Petitioner have begun to eliminate on its own the continuing systemic problems found by the surveyors. However, whether it was Petitioner's noncompliance with Subparts P and M that caused the condition-level deficiencies under Subparts H, J, and K, or vice versa, the results were the same: Petitioner did not conduct the required self-evaluation, was not ascertaining its own mistakes and problems, and did not implement any of the necessary remedial actions through its director or supervisor.

For these reasons, I conclude that Petitioner had failed to comply with the conditions at 42 C.F.R. Part 493, Subparts P and M.

Conclusion

For the reasons discussed above, I find that Petitioner was out of compliance with a number of Medicare Conditions of Participation. I conclude, therefore, that HCFA was authorized to impose the

principal sanctions of revocation of Petitioner's CLIA certificate and cancellation of Medicare payments to Petitioner.

_____
Mimi Hwang Leahy
Administrative Law Judge

1. Petitioner has not disputed that the regulations governing laboratories performing moderate or high complexity tests apply to its operations.

2. The reporting of incorrect and incomplete normal ranges shows also that Petitioner violated the conditions of quality control and quality assurance, discussed below.

Blanding Urgent Care Center Laboratory, CR No. 438 (1996)

$05:Civil Money Penalty

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Blanding Urgent Care Center Laboratory,	)	DATE: September 30, 1996
	)	
Petitioner,	)	
	)	
v.	)	Docket No. C-95-171
	)	Decision No. CR438
Health Care Financing Administration.	)	
	)	

DECISION

I conclude that Petitioner, Blanding Urgent Care Center Laboratory, is subject to revocation of its CLIA 1/ certificate for a one-year minimum mandatory period, and to concomitant cancellation of Medicare 2/ payments for laboratory services.

In reaching this conclusion, I determine that the word "intentionally" is defined differently in CLIA for civil violations than for criminal violations.

Procedural Background

Only civil violations are alleged in this case. In a letter to Petitioner dated June 15, 1995, the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services (DHHS), proposed to revoke Petitioner's CLIA certificate for one year, pursuant to 42 C.F.R. 493.1840(b), and stated it would suspend Petitioner's Medicare payments for all tests.

HCFA's letter further informed Petitioner that the proposed revocation was the consequence of Petitioner having intentionally referred certain of its proficiency testing samples, for 2nd quarter 1994 and 1st quarter 1995, to the San Juan Hospital laboratory, rather than conducting the tests at Petitioner. HCFA's letter added that the referral was revealed through a survey conducted by the Utah Department of Health,

Division of Laboratory Services, on May 17, 1995.

In a letter dated August 10, 1995, Petitioner requested a hearing, contending that Petitioner lacked the requisite intent to warrant revocation of its CLIA certificate, with regard to both the 2nd quarter 1994 and 1st quarter 1995 proficiency testing samples. Further, Petitioner contended, with regard to the 1st quarter 1995 proficiency testing samples, it conducted the tests only in its own laboratory and did not send the samples elsewhere.

Subsequently, the parties filed cross motions and briefs. 3/ The facts presented therein are assumed to be true for purposes of this Decision. I find that no facts of decisional significance are in dispute, and consequently there is no need for an in-person hearing.

Based on the evidence in the written record and the law, in light of the parties' written arguments, I affirm HCFA's determination to revoke Petitioner's CLIA certificate for a one-year minimum mandatory period, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

Issue

The issue is whether Petitioner intentionally referred its proficiency testing samples to another laboratory for analysis.

Factual Background

Proficiency testing is designed to determine a laboratory's accuracy in performing testing for its patients. Each laboratory enrolls in a proficiency testing program and is sent specimens [proficiency samples] for testing, approximately three times a year. The specimens are clearly marked as proficiency testing samples, so the technician receiving them knows they are test materials, not patients' specimens. The laboratory that is being tested is required to test the proficiency samples the same way it tests patients' specimens.

On May 15, 1995, the Utah Department of Health, Division of Laboratory Services (State PT agency) 4/, began a survey of Petitioner, a laboratory located in Blanding, Utah. The State PT agency requested Petitioner's proficiency testing records and was informed that those records were not available at that time because they were stored at San Juan Hospital. The technical consultant for Petitioner, Michael LaGiglia,

served also as the technical consultant and general supervisor for the San Juan Hospital laboratory, which is located in Monticello, Utah, approximately 22 miles from Petitioner. Mr. LaGiglia informed the State PT agency that Petitioner's records would be made available on the following day, May 16, 1995. On May 17, 1995, the State PT agency returned to Petitioner and examined the proficiency testing (PT) records. HCFA Ex. 3.

2nd Quarter 1994 Proficiency Testing Samples

Review of Petitioner's 2nd quarter 1994 hematology proficiency testing reports showed that the handwritten results retained by Petitioner did not match the results that had been reported to the PT agency. HCFA Ex. 3. The results reported to the PT agency for Petitioner's 2nd quarter 1994 hematology proficiency testing matched an instrument printout which could not have been created by the type and model of instrument used at Petitioner, but in fact was created on an instrument such as that present and used in the San Juan Hospital laboratory. HCFA Ex. 3.

Mr. LaGiglia tested Petitioner's 2nd quarter 1994 hematology proficiency testing samples both at Petitioner and at the San Juan Hospital laboratory. P. Br. 3 - 4. The retesting of Petitioner's 2nd quarter 1994 hematology proficiency testing samples at the San Juan Hospital laboratory was done as an "internal quality control measure." Mr. LaGiglia was unaware that his retesting of Petitioner's 2nd quarter 1994 hematology proficiency testing samples at the San Juan Hospital laboratory was prohibited by law. P. Br. 4, 14.

The test results on Petitioner's 2nd quarter 1994 hematology proficiency testing samples from both Petitioner and the San Juan Hospital laboratory were recorded at Petitioner. Mr. LaGiglia mistakenly submitted the results from the San Juan Hospital laboratory as Petitioner's test results on the 2nd quarter 1994 hematology proficiency testing samples. P. R. Br. 7.

In explaining Petitioner's 2nd quarter 1994 hematology proficiency testing results to the State PT agency on May 24, 1995, Mr. LaGiglia stated that proficiency testing samples from Petitioner are brought back to San Juan Hospital and run on a test machine that is different from the one present at Petitioner, and the results are compared. According to Mr. LaGiglia, it was the "practice" to compare Petitioner's proficiency testing results with San Juan's proficiency testing results before reporting the results to the PT agency. HCFA Ex. 3.

1st Quarter 1995 Proficiency Testing Samples

Examination of Petitioner's 1st quarter 1995 hematology proficiency testing records by the State PT agency revealed proficiency testing results logged in on a patient log sheet that did not match the results reported to the PT agency. HCFA Ex. 3.

Petitioner and the San Juan Hospital laboratory received separate proficiency testing samples on approximately the same date. The technical consultant analyzed San Juan Hospital laboratory's sample at San Juan Hospital and subsequently analyzed Petitioner's sample at Petitioner. The technical consultant noticed that the white blood cell count results obtained at Petitioner were dissimilar to those obtained at San Juan Hospital. The technical consultant assumed the discrepancy indicated that Petitioner's analyzer needed to be recalibrated. The technical consultant proceeded to recalibrate Petitioner's analyzer and performed the tests again. The result that was obtained after recalibration was closer to that of San Juan Hospital and was reported to the PT agency. HCFA Ex. 2; P. Br. 4, 7; P. R. Br. 5.

Statute and Regulations

CLIA provides both civil sanctions and criminal sanctions:

Civil Sanctions

Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in section (h) 5/ of this section.

42 U.S.C. 263a(i)(4).

The implementing regulations regarding such civil sanctions provide:

The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HCFA of the receipt of those samples.

42 C.F.R. 493.801(b)(4).

Adverse action based on improper referrals in proficiency testing. If HCFA determines

that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis,
HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money
penalty.

42 C.F.R. 493.1840(b).

Criminal Sanctions

Any person who intentionally violates any requirement of this section or any regulation
promulgated thereunder shall be imprisoned for not more than one year or fined under Title 18, or both,
except that if the conviction is for a second or subsequent violation of such a requirement such person shall
be imprisoned for not more than 3 years or fined in accordance with Title 18, or both.

42 U.S.C. 263a(l).

The implementing regulations regarding such criminal violations provide:

Definitions. Intentional violation means knowing and willful noncompliance with any
CLIA condition.
42 C.F.R. 493.2.

Section 353 also [p]rovides for imprisonment or fine for any person convicted of
intentional violation of CLIA requirements.

42 C.F.R. 493.1800(a)(3)(i).

Criminal sanctions. Under section 353(1) of the PHS [Public Health Service] Act, an
individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

42 C.F.R. 493.1806(e).

Findings of Fact and Conclusions of Law

1. Petitioner is a laboratory located in Blanding, Utah that has been certified under CLIA since 1993.

2. CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human
specimens. 42 U.S.C. 263a; 42 C.F.R. 493.1800.

3. Petitioner's technical consultant's reporting, by mistake, to the PT agency the San Juan Hospital
laboratory results as Petitioner's test results, on Petitioner's 2nd quarter 1994 hematology proficiency
testing samples, is irrelevant.

4. Petitioner's technical consultant knew he was retesting Petitioner's 2nd quarter 1994 hematology proficiency testing samples in the San Juan Hospital laboratory. HCFA Ex. 3; P. Br. 4, 14. Thus, Petitioner's technical consultant's action was deliberate, not inadvertent. Decision at 10 - 16.

5. Although Petitioner's technical consultant's retesting, in the San Juan Hospital laboratory, of Petitioner's 2nd quarter 1994 hematology proficiency testing samples, was done as an "internal quality control measure," his motive is irrelevant.

6. It is irrelevant that Petitioner's technical consultant was unaware that his retesting, in the San Juan Hospital laboratory, of Petitioner's 2nd quarter 1994 hematology proficiency testing samples was prohibited by law.

7. Based on the dissimilarity between Petitioner's first white blood cell count results from Petitioner's 1st quarter 1995 hematology proficiency testing samples, and those he had obtained at the San Juan Hospital laboratory, Petitioner's technical consultant recalibrated Petitioner's analyzer and retested Petitioner's proficiency testing samples. HCFA Ex. 2; P. Br. 4, 7; P. R. Br. 5.

8. Petitioner's technical consultant knew he was recalibrating Petitioner's analyzer and retesting Petitioner's 1st quarter 1995 hematology proficiency testing samples, based on the dissimilarity in results between the first white blood cell counts obtained at Petitioner and those he had obtained at the San Juan Hospital laboratory. HCFA Ex. 2; P. Br. 4, 7; P. R. Br. 5. Thus Petitioner's technical consultant's action was deliberate, not inadvertent. Decision at 10 - 16.

9. A laboratory that obtains analysis of its proficiency testing samples from another laboratory violates 42 U.S.C. 263a(i)(4) regardless of whether the laboratory reports to the PT agency its own results or the results obtained from the other laboratory.

10. Information gleaned from proficiency testing samples at the San Juan Hospital caused Petitioner's technical consultant to realize that Petitioner's analyzer needed recalibration. Petitioner then recalibrated the analyzer and retested Petitioner's proficiency testing samples after the recalibration. P. Br. 4 - 5, 7; P. R. Br. 5; HCFA Ex. 2.

11. Petitioner violated 42 U.S.C. 263a(i)(4) by recalibrating its equipment and retesting its proficiency testing samples based upon the results obtained from the testing of separate proficiency testing samples at

the San Juan Laboratory, irrespective of whether Petitioner reported the results or not.

12. It is irrelevant that Petitioner's technical consultant was unaware that his recalibration of Petitioner's analyzer and retesting of Petitioner's 1st quarter 1995 hematology proficiency testing samples, based on the dissimilarity in results between Petitioner's first white blood cell counts and those he had obtained at the San Juan Hospital laboratory, were prohibited by law.

13. A laboratory must not send proficiency testing samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. 42 C.F.R. 493.801(b)(4).

14. A referral of proficiency testing samples to another laboratory for analysis can occur where proficiency testing samples are physically carried or transferred from one laboratory to another for retesting. Decision at 19 - 23.

15. A referral of proficiency testing samples can occur where the proficiency testing samples are not moved from the laboratory, but are retested or otherwise rechecked based on information gained from another laboratory. Decision at 19 - 23.

16. Petitioner referred both its 2nd quarter 1994 hematology proficiency testing samples and its 1st quarter 1995 hematology proficiency testing samples to another laboratory, in each case the San Juan Hospital laboratory, for analysis.

17. "Intentionally referred" [as in "intentionally referred" its proficiency testing samples to another laboratory for analysis] requires not specific intent, but general intent, that is, an intent to act. No guilty knowledge, no culpability, no scienter is required. Motive is irrelevant. It is necessary merely that a person act deliberately, that is, not inadvertently.

18. Petitioner's lack of "deliberate fraud" and lack of "knowing and willful noncompliance with CLIA conditions," are irrelevant.

19. Petitioner's technical consultant's retesting, in the San Juan Hospital laboratory, of Petitioner's 2nd quarter 1994 hematology proficiency testing samples, as an "internal quality control measure," constitutes an intentional referral of Petitioner's proficiency testing samples to another laboratory for analysis.

20. Petitioner's technical consultant's recalibrating of Petitioner's analyzer and retesting of Petitioner's 1st quarter 1995 hematology proficiency testing samples, based on the dissimilarity in results between

Petitioner's first white blood cell counts and those he had obtained at the San Juan Hospital laboratory,
constitutes an intentional referral of Petitioner's proficiency testing samples to another laboratory for
analysis.

21. Petitioner, through the action of its technical consultant, intentionally referred its proficiency testing
samples to another laboratory for analysis during 2nd quarter 1994, in violation of 42 U.S.C. 263a(i)(4);
42 C.F.R. 493.801(b)(4) and 493.1840(b).

22. Petitioner, through the action of its technical consultant, intentionally referred its proficiency testing
samples to another laboratory for analysis during 1st quarter 1995, in violation of 42 U.S.C. 263a(i)(4);
42 C.F.R. 493.801(b)(4) and 493.1840(b).

23. The CLIA statute and applicable regulations require HCFA to revoke a laboratory's CLIA certificate
for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another
laboratory for analysis. 42 U.S.C. 263a(i)(4); 42 C.F.R. 493.801(b)(4) and 493.1840(b).

24. Neither I nor HCFA has the discretion in this case to revoke Petitioner's CLIA certificate for less than
the mandatory minimum period of one year, or to substitute any lesser sanction.

25. I affirm HCFA's one-year revocation of Petitioner's CLIA certificate, with concomitant cancellation of
Petitioner's Medicare payments for laboratory services.

Discussion

Two words, "intentionally" and "referred," require careful analysis in determining whether Petitioner
intentionally referred its proficiency testing samples to another laboratory for analysis. The meaning of
"intentionally" impacts both the 2nd quarter 1994 PT, and the 1st quarter 1995 PT. The meaning of
"referred" impacts only the 1st quarter 1995 PT.

I. Definitions of "Intentionally" under CLIA

[see Statute and Regulations above]

I conclude that "intentionally" is defined differently in CLIA for civil violations than for criminal
violations.

The word "intentionally" is found in both the civil section of CLIA and the criminal section of CLIA:

civil:

> Any laboratory that the Secretary determines intentionally refers [emphasis added] its proficiency testing samples to another laboratory for analysis . . . .

42 U.S.C. 263a(i)(4).

criminal:

> Any person who intentionally violates [emphasis added] any requirement of this section or any regulation promulgated thereunder . . . .

42 U.S.C. 263a(l).

Although the term "intentionally" is used in both the civil and criminal sections of CLIA, the term need not be accorded the same meaning in each of these sections. Upon careful analysis, I conclude that the term "intentionally refers" as it appears at 42 U.S.C. 263a(i)(4) indeed does not have the same meaning as the term "intentionally violates" which appears at 42 U.S.C. 263a(l). To begin with, the phrases are different in that one contains the word "refers" and one contains the word "violates." This is discussed more fully below.

A. Parties' arguments

[see Factual Background above]

Petitioner's arguments

Petitioner argues that "intentionally" [as in "intentionally referred its proficiency testing samples to another laboratory for analysis"] means that a lab intended to report another lab's PT results as its own. P. Br. 7, 13, 28. Regarding the 2nd quarter 1994 PT, Petitioner maintains that the referral was made to the San Juan Hospital laboratory for internal quality control measures, and Mr. LaGiglia mistakenly submitted the results obtained in the San Juan Hospital laboratory to the PT agency as Petitioner's PT results. Id. at 4, 14. Consequently, Petitioner argues, HCFA is without authority to revoke Petitioner's CLIA certificate because Petitioner did not manifest the requisite intent.

Petitioner urges consistent construction of the term "intentional" in the civil and criminal contexts, noting the "draconian" outcome of revocation. Id. at 18 - 28. Petitioner contends that the term "intentionally" in the civil context of CLIA should require "the deliberate motive of deceiving the testing agency by reporting the other labs's [sic] proficiency testing results as its own." P. Br. 18. Petitioner adds that "intentional" must be construed so that criminal penalties cannot be meted out upon a mere showing of "deliberate taking of action," without consideration of motive. Id. at 17 - 18.

Petitioner argues further that, although it may have violated some CLIA requirements, it did not do so knowingly and willfully. The regulation at 42 C.F.R. 493.2 defines "intentional violation" as "knowing and willful noncompliance with any CLIA condition." Petitioner contends that HCFA accordingly must establish that Petitioner's violation was knowing and willful, before HCFA can revoke Petitioner's CLIA certificate.

HCFA's arguments

HCFA urges consideration of the definition of "intentionally" [as in "intentionally referred its proficiency testing samples to another laboratory for analysis"] found in Long Medical Laboratory v. HCFA, DAB CR334 (1994), at 6. HCFA Br. 8 - 9. In Long, Administrative Law Judge Steven Kessel determined that "intentionally" should be given its common and ordinary meaning. Applying a dictionary definition of that term, Judge Kessel concluded that "when one acts intentionally, he or she acts deliberately," regardless of motivation. HCFA Br. 8 - 9.

To Petitioner's stated objective of "quality control" as the reason for referring its proficiency testing samples to the San Juan Hospital laboratory, HCFA responds as follows: "(P)roficiency testing is a test for which no second chance or 'quality control' is permitted." HCFA Br. 9.

HCFA further maintains that it is irrelevant whether Petitioner intended to report the results of the San Juan Hospital laboratory as Petitioner's results. The statute requires revocation of a CLIA certificate where a laboratory intentionally refers its proficiency testing to another laboratory for analysis. 42 U.S.C. 263a(i)(4). 42 C.F.R. 493.801(b)(4). The statute does not require also that a laboratory intentionally report the second laboratory's results as its own. HCFA Br. 10.

HCFA argues that the civil and criminal sections of CLIA are distinct and separate. CLIA contains sections dealing with the civil penalties that may be imposed against a laboratory for noncompliance with a CLIA condition [42 U.S.C. 263a(h) and (i)]; and a separate section providing criminal penalties for individuals who intentionally violate the CLIA statute or regulations [42 U.S.C. 263a(l)].

HCFA's position is that the criminal sanctions section of CLIA [42 U.S.C. 263a(l)] provides HCFA with the discretion to refer intentional violations of statutory requirements to the Department of Justice for criminal prosecution. HCFA R. Br. 7. HCFA maintains that Congress fully intended to provide HCFA

with the authority to impose a program sanction, e.g., revocation of the CLIA certificate, and, at the same time, have the discretion to refer the matter for criminal prosecution. Id. at 8.

B. Purpose of CLIA

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) require certification of all laboratories that perform clinical diagnostic tests on human specimens. The authority to enforce CLIA requirements is granted to the Secretary of Health and Human Services (Secretary). 42 U.S.C. 263a (esp. 263a(f)); 42 C.F.R. 493.1800; See Consumer Federation of America and Public Citizen v. U.S. Dept. of Health and Human Services, 83 F. 3d 1497 (D.C. Cir. 1996).

CLIA was established to address the issue of unacceptably high error rates at unregulated laboratories and the dangers to patients that these high laboratory error rates posed. H.R. Rep. No. 899 at 14, reprinted in 1988 U.S.C.C.A.N. at 3831; S. Rep. No. 561, 100th Cong., 2nd Sess. 3-4.

The importance of proficiency testing as a means of measuring and ultimately ensuring laboratory competence was noted by Congress as follows:

> The Committee's investigation focused particularly on proficiency testing because it is considered one of [the] best measures of laboratory performance. It is arguably the most important measure, since it reviews actual test results rather than merely gauging the potential for good results . . .
>
> Proficiency testing is a method of externally validating the level of a laboratory's performance. Proficiency testing is not currently conducted by HHS, but is conducted by private agencies. . . . The standard testing methodology currently in use involves sample test specimens being sent by mail to a laboratory by the proficiency testing agency. The laboratory then analyzes the samples and returns the results of the test to the proficiency testing organization. The proficiency testing organization typically calculates the mean of the test results, determines an acceptable range variation based on standard deviations from the mean, and reports the results to the lab.
>
> The major problems identified by the Committee were lax Federal oversight and direction, lack of proficiency testing for many analytes, inconsistent criteria for acceptable laboratory performance, and improprieties by laboratories in handling specimen samples.
>
> . . .
>
> A significant deficiency in the current proficiency testing regime is its inability to assure that

proficiency testing samples are treated like patient specimens. Samples are mailed to laboratories, and
although proficiency testing organizations recommend that tests be treated in the same manner as patient
samples, there was evidence that laboratories retest samples repeatedly to ensure satisfactory results and
send proficiency testing samples out to other laboratories for analysis. The only way to guarantee that
samples are treated by the same personnel, at the same speed, using the same equipment as patient
specimens is though [sic] blind or on-site proficiency testing. The committee learned, however, that such
testing can be quite expensive and may have to be used with discretion to assure proper processing of
specimens.

H.R. No. 899, reprinted in 1988 U.S.C.C.A.N. at 3828, 3836, 3837.

Thus, Congress, in enacting CLIA, was concerned about, among other things, laboratories that were
sending their proficiency testing samples to other laboratories for analysis or retesting to ensure a
satisfactory result. It is within this context that Congress authored the prohibition on intentional referrals
of proficiency testing, at 42 U.S.C.
263a(i)(4).

C. Definition of "intentionally," as in "intentionally refers"

"Intentionally" is not defined in the CLIA statute, but some assistance is found in the regulations.
"Intentional violation" is defined in the regulations as "knowing and willful noncompliance with any CLIA
condition." 42 C.F.R. 493.2 ("Definitions").

The phrase "intentional violation" does not appear elsewhere in the pertinent regulations, other than in the
definitions section, as just quoted, and as follows:

Section 353 also [p]rovides for imprisonment or fine for any person convicted of intentional
violation of CLIA requirements.

42 C.F.R. 493.1800(a)(3)(i).

The phrase "intentionally violating" appears in the pertinent regulations, also solely in connection with
criminal sanctions:

Criminal sanctions. Under section 353(1) of the PHS [Public Health Service] Act, an individual
who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

42 C.F.R. 493.1806(e).

After careful study of the pertinent portions of the statute and the regulations, I conclude that "intentional violation" is defined by the regulations for the sole purpose of clarifying the phrase "intentionally violates," which is found in the CLIA statute only in the criminal section [42 U.S.C. 263a(l)]. The "knowing and willful" requirement provided by the regulation is consistent with the element of criminal offenses known as "scienter," "culpability," or "guilty knowledge."

By providing a definition for "intentional violation", the authors of the regulations have explicitly provided guidance on how to interpret 42 C.F.R. 493.1800(a)(3)(i) and 493.1806(e). There is little doubt that, with respect to the imposition of criminal sanctions, in determining whether there was an intentional violation, the legal standard of "knowing and willful" is to be applied.

Thus, I agree with Petitioner to the extent that criminal penalties under CLIA cannot be meted out without a showing of "knowing and willful noncompliance" with a CLIA condition. I disagree with Petitioner's argument, however, that revocation is such a severe penalty that a similar standard regarding intent should apply to revocation as applies to criminal penalties.

Criminal convictions, particularly for persons who work in health care, trigger extremely serious consequences. It is reasonable to require proof of specific intent before subjecting a person to criminal penalties under CLIA. CLIA has clearly delineated two distinct types of penalties -- the first, directed at a laboratory and involving civil sanctions (regarding the laboratory's CLIA certificate, civil money penalties, costs and the like); -- and the second, directed at a person and involving criminal penalties (imprisonment or a fine or both). [See 42 C.F.R. 493.1806 for available sanctions.]

Under CLIA, a laboratory is subject to inspection and a variety of civil penalties for failing to comply with CLIA standards. 42 U.S.C. 263a(g), (h), (i). ["Principal sanctions," such as suspension, revocation, and limitation of the laboratory's CLIA certificate, are provided by 42 U.S.C. 263a(i). "Intermediate" or "alternative sanctions," such as directed plans of correction, civil money penalties, and onsite monitoring costs, are provided by 42 U.S.C. 263a(h).]
In sharp contrast are the CLIA penalties that are criminal in nature. 42 U.S.C. 263a(l). The potential penalties include imprisonment for up to one year and a fine or both. Even more serious, a repeat offender can be imprisoned for up to three years and fined or both.

The regulations go to the effort of defining "intentional violation" to ensure that sufficient scienter is proved before a person can be convicted of a criminal violation under CLIA. The fact that "intentional

violation" is specifically defined in the regulations [42 C.F.R. 493.2] suggests that the definition is different from its common and ordinary meaning, and in fact, it is.

Nowhere do the regulations define the term "intentionally referred," which is contained in the regulations at 42 C.F.R. 493.801(b)(4) and 493.1840(b). "Intentionally refers" is found in the statute at 42 U.S.C. 263a(i)(4). Neither Congress nor the Secretary chose to define or modify the word "intentionally" in the context of "intentionally referred its proficiency testing samples to another laboratory for analysis." Where "intentionally" is not specifically defined in the context of CLIA civil sanctions, one can infer that it should be given its common and ordinary meaning.

This conclusion is in accordance with that of Administrative Law Judge Steven Kessel in the case of Long Medical Laboratory v. HCFA, DAB CR334 (1994). Although in Long Petitioner admitted that it had intentionally referred proficiency testing samples for testing, Judge Kessel nonetheless determined that the word "intentionally" should be given its common and ordinary meaning. As stated in Long, "intention" is a determination to act in a certain way. Long, at 6 (citing Webster's New Collegiate Dictionary, 1975 ed., at 601). When one acts "intentionally," he or she acts deliberately, regardless of motivation. Long, at 6 - 9. Accordingly, I find that "intentionally referred" [as in "intentionally referred" its proficiency testing samples to another laboratory for analysis] requires not specific intent, but general intent, that is, an intent to act. No guilty knowledge, no culpability, no scienter is required. Motive is irrelevant. It is necessary merely that a person act deliberately, that is, not inadvertently.

In current practice, where proficiency testing samples are clearly marked, enabling the technician receiving them to know they are test materials, not patients' specimens, it is difficult to conceive of an inadvertent referral. If proficiency testing samples are referred to another laboratory for analysis, with the knowledge that they were proficiency testing samples, the referral can be expected to be intentional, that is, deliberate, not inadvertent. 6/

D. Further consideration of Petitioner's arguments regarding definition of "intentionally," as in "intentionally refers"

In further considering Petitioner's position regarding the definition of "intentionally," as in "intentionally refers," I begin with Petitioner's philosophical arguments. Petitioner asks for punishment to fit the "crime," stating that revocation and its consequences are "wildly disproportionate" penalties in relation to

Petitioner's conduct, where there was no intent to deceive, no motive to report falsely, no bad faith. P. R. Br. 1 - 4, 7 - 10, 12. "While Blanding [Petitioner] may have committed certain CLIA violations, it was not attempting to defraud through a pattern of improper referrals or seeking to conceal a substandard facility by using another lab to perform its PT." Id. at 9.

Petitioner shows that Congress provided a wide range of civil sanctions, arguing that less culpable noncompliance should be sanctioned less severely. Petitioner points out that Congress, in drafting CLIA, was disturbed by the lack of a flexible response to poor proficiency testing. P. Br. 10. Petitioner states also that Congress pointed to the need for lesser sanctions, including civil monetary penalties and corrective action plans, where a laboratory has either made a good faith effort to comply with the law or where the health of patients is not in immediate danger. Petitioner contends that, by imposing a one year revocation of its CLIA certificate, HCFA is applying the most severe sanction possible. 7/ Petitioner believes that, while it has made good faith efforts to correct the problems with its testing, it is being unduly penalized by HCFA's adherence to a rigid enforcement method which is contrary to the intent of Congress.

It is true that the alternative sanctions Congress provided, the "intermediate sanctions," may be applied in countless situations, whether or not those situations involve cheating in proficiency testing. Even the principal sanctions of suspension or limitation of a laboratory's CLIA certificate may be less severe than a one-year minimum mandatory revocation.

For example, failing to obtain satisfactory performance in proficiency testing, that is, having unacceptable error levels, may trigger a sanction less severe [or more severe] than a one-year revocation. Failing to test proficiency samples the same way a laboratory tests patients' specimens [42 C.F.R. 493.801, 493.801(b)] may be penalized by a sanction less severe [or more severe] than a one-year revocation [42 C.F.R. 493.1812, 493.1814]. Engaging in inter-laboratory communications pertaining to the results of proficiency testing sample(s) before the date the laboratory must report the results of its proficiency testing [42 C.F.R. 493.801(b)(3)] may be penalized by a sanction less severe [or more severe] than a one-year revocation [42 C.F.R. 493.1812, 493.1814]. In each of these situations, HCFA has discretion to impose a sanction less severe or more severe than a one-year revocation.

But where intentional referral of a laboratory's proficiency testing samples to another laboratory for analysis has occurred, there is no possibility of a less severe sanction than a one-year minimum mandatory

revocation. The statute itself specifies the sanction:

> Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year . . . .

42 U.S.C. 263a(i)(4).

Congress enacted an especially strong prohibition against intentionally referring proficiency testing samples to another laboratory for analysis, by requiring mandatory revocation for at least one year as the sanction. Clearly, Congress wanted the practice to stop.

Petitioner argues that, in order for it to have committed an "intentional referral" within the meaning of the statute and the regulations, Petitioner must have referred its tests to another laboratory with the intent of reporting such results as its own. P. Br. 7, 13, 28.

Petitioner's construction is unreasonable. As HCFA points out, Petitioner's interpretation of 42 U.S.C. 263a(i)(4) would make it almost impossible for HCFA to revoke a CLIA certificate pursuant to that provision, because HCFA would be required to prove a laboratory's "intent to submit another lab's PT results as its own." HCFA R. Br. 9.

HCFA points out also that Petitioner's interpretation of 42 U.S.C. 263a(i)(4) "would make it acceptable for a laboratory to refer its proficiency testing to another laboratory for analysis as Long as it did not intentionally report the second laboratory's results as its own. The effect of such an interpretation would be to endorse cheating on proficiency testing." HCFA R. Br. 3. "Indeed, Congress did not require false reporting because it anticipated that laboratories could simply retest their proficiency testing samples to improve their test scores after receiving the analysis from a second laboratory." Id. at 4.

Petitioner's insistence that referral be with the "intent to submit another lab's PT results as its own," is far too narrow a view of what constitutes an intentional referral. The statute requires revocation of a CLIA certificate where a laboratory intentionally refers its proficiency testing to another laboratory for analysis. 42 U.S.C. 263a(i)(4). 42 C.F.R. 493.801(b)(4) and 493.1840(b). The statute does not require also that a laboratory intentionally report the second laboratory's results as its own. HCFA Br. 10.

HCFA need only establish a general intent to act, and not, as Petitioner suggests, specific intent to report incorrect or improper test results. It is highly improbable that, within the framework of civil penalties

against an entity, where no loss of personal liberty is involved, Congress would require specific intent in order to establish a CLIA violation under the statute's civil penalty provisions. Here, a laboratory is subject to civil administrative sanctions for failure to comply with statutory requirements. [Even Petitioner concedes that criminal sanctions traditionally require proof of a greater degree of scienter and culpability on the part of the defendant. P. Br. 17.]

Regardless of motivation, Petitioner acted with the requisite general intent, that is, the intent to act, to trigger the penalty provisions of CLIA. Petitioner acted deliberately, that is, not inadvertently, in obtaining test results elsewhere. It is cheating to look at another's answer on a test, even if merely to confirm one's own answer. Anyone looking at answers different from his own would likely compare and analyze them before forming any intent about what to do with the other answers.

In summary, two definitions of "intentionally" [as in "intentionally referred its proficiency testing samples to another laboratory for analysis"] proposed by Petitioner must be rejected:

The first definition that must be rejected is "knowing and willful noncompliance," because that phrase is applicable in CLIA only to criminal sanctions.

The second definition that must be rejected is "with the intent to submit another lab's proficiency testing results as its own."

I find that "intentionally" as found in the civil section of CLIA means with general intent, regardless of motivation.

II. Definition of "Referred" under CLIA

[see Factual Background above]

As previously mentioned, the meaning of "referred" impacts only Petitioner's 1st quarter 1995 PT.

[With regard to the 2nd quarter 1994 PT, Petitioner acknowledges that Petitioner's 2nd quarter 1994 hematology PT samples were physically carried from Petitioner to the San Juan Hospital laboratory, where they were retested, as an "internal quality control measure." Thus, Petitioner acknowledges that Petitioner's 2nd quarter 1994 PT samples were "referred" to another laboratory for testing.]

A. Parties' arguments

Petitioner's arguments

Petitioner argues that it did not physically send its 1st quarter 1995 PT samples to another laboratory for analysis --these samples never left Petitioner-- and there consequently was no referral, and no violation sufficient to warrant revocation of Petitioner's CLIA certificate. P. Br. 7 - 8.

Petitioner argues further that regulatory language supports its position [P. Br. 7 - 8]:

> The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory.

42 C.F.R. 493.801(b)(4).

HCFA's arguments

HCFA contends that Petitioner is taking too narrow a view of the word referral, and ignoring the context in which the word is used within the CLIA statute and regulations. First, HCFA states that Petitioner's argument regarding whether or not it referred the 1st quarter 1995 PT samples is irrelevant when it is undisputed that Petitioner referred the 2nd quarter 1994 PT samples.

Second, HCFA argues that the facts regarding Petitioner's handling of the 1st quarter 1995 PT samples constitute a referral because the laboratory technician 1) tested Petitioner's proficiency testing samples at Petitioner; 2) compared the results to results he had obtained on PT samples at the San Juan Hospital laboratory and realized the results he had obtained on Petitioner's analyzer were erroneous; and 3) based on his discovery, recalibrated Petitioner's analyzer; and 4) retested the samples at Petitioner on the recalibrated analyzer and reported the results.

B. Definition of "referred"

HCFA's position is that a referral can occur without the proficiency testing samples ever being physically sent to another laboratory for analysis. In other words, Petitioner did not have to move or transfer the samples physically from Petitioner to another laboratory in order to commit a "referral" to another laboratory for analysis, within the meaning of the CLIA statute and regulations.

Petitioner concedes that Petitioner recalibrated its testing equipment and retested the PT samples, as a result of information the technician obtained from his testing of samples that were sent to the San Juan Hospital laboratory for proficiency testing. P. Br. 4, 7; P. R. Br. 5.

The word "refer" is defined by the Random House College Dictionary, revised ed. 1980, at 1108, as "to

direct the attention or thoughts of." The second definition is "to direct to a person, place, etc., for information or anything required."

Neither of these definitions would require Petitioner physically to have sent the PT samples to the San Juan Hospital laboratory (or to any other laboratory) for analysis. Under either of these definitions, Petitioner's recalibration of the equipment and retesting of the PT samples at Petitioner, based on information, results, or testing at another laboratory, suffices.

Were I to take Petitioner's argument to its logical conclusion, it would render the entire concept of proficiency testing meaningless. Under the scenario offered by Petitioner, a laboratory, from information it received from another laboratory, would be able to discover that its equipment had to be recalibrated, recalibrate its testing equipment, and retest the PT testing samples to enable it to pass the proficiency test.

A cardinal rule of statutory construction is to interpret the statute in such a way that no part is rendered meaningless. Petitioner's interpretation of the word "referral" as not including any proficiency testing sample that is not physically removed from a laboratory for retesting would do just that, that is, render meaningless the CLIA statutory provisions prohibiting referrals.

Also, under Petitioner's definition, a referral would not occur in an instance where a technician brought equipment to a lab in order to retest a PT sample that had already been tested on the laboratory's own equipment. Yet, this would be a referral, irrespective of whether the PT sample ever left the lab. The PT sample would be retested, and the results would change or be reaffirmed based on information discovered in the retesting.

In handling the 1st quarter 1995 PT samples, Petitioner's technical consultant knew something was wrong when he did not get similar results from Petitioner's and the San Juan Hospital laboratory's proficiency tests. He inferred from the discrepancy that something was wrong with Petitioner's analyzer. He then recalibrated Petitioner's analyzer and re-performed the proficiency testing, as a result of the information he had obtained in the testing of PT samples at the San Juan Hospital laboratory.

I find that, for a laboratory to have referred proficiency testing samples to another laboratory for analysis, it need not physically take or transfer its proficiency testing samples to another laboratory. The facts involving Petitioner's 1st quarter 1995 PT samples, where Petitioner, in effect, received a second opinion

from another laboratory with regard to Petitioner's PT samples, are sufficient for me to find that a referral of Petitioner's proficiency testing samples occurred, within the meaning of the CLIA statute and regulations. 42 U.S.C. 263a(i)(4); 42 C.F.R. 493.801(b)(4) and 493.1840(b). Furthermore, when the regulation cited by Petitioner is read as a whole, the wording "(t)he laboratory must not send PT samples or portions of samples to another laboratory . . . . " [42 C.F.R. 493.801(b)(4)] does not eliminate from consideration the other ways in which referral may be accomplished.

To use the terms of the Dictionary definition, Petitioner "directed" the samples "for information or anything required," to another laboratory for analysis. By retesting the samples based on information gleaned from the proficiency testing at the San Juan Hospital laboratory, Petitioner referred the samples. Thus, I find that Petitioner referred its 1st quarter 1995 PT samples to another laboratory for analysis, despite the fact that these samples were not removed from Petitioner.

III. HCFA Required to Revoke Petitioner's CLIACertificate for a One-Year Period

Petitioner acknowledges that its handling of CLIA samples was not in accordance with CLIA standards. P. Br. 6. Petitioner indicates that it has been diligent in its efforts to correct the problems and that, in any event, the deficiencies regarding its handling of PT samples do not warrant the revocation of its CLIA certificate for one year. According to Petitioner, Congress intended for a laboratory certificate to be revoked only in instances of the most serious misconduct. P. Br. 9.

The CLIA statute and applicable regulations require HCFA to revoke a laboratory's CLIA certificate for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another laboratory for analysis. 42 U.S.C. 263a(i)(4); 42 C.F.R. 493.801(b)(4) and 42 C.F.R. 493.1840(b).

Neither I nor HCFA has the discretion in this case to revoke Petitioner's CLIA certificate for less than the mandatory minimum period of one year, or to substitute any lesser sanction.

Conclusion

Petitioner intentionally referred its proficiency testing samples to another laboratory for analysis during 2nd quarter 1994 and 1st quarter 1995. Accordingly, Petitioner's CLIA certificate must be revoked for a one-year minimum mandatory period, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

Jill S. Clifton
Administrative Law Judge

1. CLIA refers to the Clinical Laboratory Improvement Amendments, enacted in 1988 (42 U.S.C. 263a).

2. Medicaid payments for laboratory services are also affected (42 C.F.R. 493.1809).

3. HCFA filed a Motion to Affirm with a supporting brief (HCFA Br.). HCFA's submissions were accompanied by HCFA Exhibits (HCFA Exs.) 1 through 10.

Petitioner filed a Motion to Reverse with a supporting brief (P. Br.).

HCFA filed a Reply brief (HCFA R. Br.).

Petitioner filed a Sur-Reply brief (P. R. Br.).

Petitioner did not object to any of HCFA's exhibits, and I admit HCFA Exs. 1 through 10 into evidence.
Petitioner did not submit any exhibits.

4. The State PT agency is the entity that surveyed Petitioner; Petitioner's proficiency testing results were processed by a separate entity which I refer to as the PT agency.

5. "Intermediate" civil sanctions, such as civil money penalties, are found in 42 U.S.C. 263a(h), and are alternative remedies to the "principal" civil sanctions of CLIA certificate suspension, revocation, or limitation, found in 42 U.S.C. 263a(i).

6. The inclusion by Congress of the word "intentionally" in the civil context may well be more significant in the case of "blind" proficiency testing, in which the laboratory technicians cannot tell the test samples from patients' specimens. [Patients' specimens of course may be referred to other laboratories.]

7. HCFA has imposed the minimum sanction specified by 42 U.S.C. 263a(i)(4).

Primary Care Medical Group, CR No. 439 (1996)

$05:Civil Money Penalty

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)
)
Primary Care Medical Group,) DATE: October 9, 1996
)
Petitioner,)
) v.)
Docket No. C-95-161
) Decision
No. CR439
Health Care Financing)
Administration.)
)
)

DECISION

I conclude that Petitioner, Primary Care Medical Group (a physician's office operating a laboratory), is subject to revocation of its CLIA 1/ certificate for a one-year minimum mandatory period, and to concomitant cancellation of Medicare 2/ payments for laboratory services.

In reaching this conclusion, I determine that the word "intentionally" is defined differently in CLIA for civil violations than for criminal violations.

PROCEDURAL BACKGROUND

Only civil violations are alleged in this case. By letters dated April 21, 1995 and May 23, 1995, the Health Care Financing Administration (HCFA) of the United States Department of Health and Human Services (DHHS) notified Petitioner that it was revoking Petitioner's CLIA certificate for one year and cancelling Petitioner's approval to receive Medicare payments for its laboratory services for one year. (In addition, Medicaid payments were no longer going to be available to the laboratory for the same period of time).

By letter dated July 19, 1995, Petitioner filed a request for hearing. On October 25, 1995, I held a hearing in San Francisco, California. Subsequently, the parties filed briefs. 3/ Based on the evidence and the law,

in light of the parties' arguments, I affirm HCFA's determination to revoke Petitioner's CLIA certificate for a one-year minimum mandatory period, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

ISSUES

There are two issues: 1) whether Petitioner intentionally referred its proficiency testing samples to another laboratory for analysis; and 2) whether Petitioner was otherwise deficient in meeting CLIA requirements.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Petitioner is a physician's office operating a laboratory, located in Madera, California.

2. Theodore Johnstone, M.D., is Petitioner's owner and laboratory director. Tr. 337; P. R. Br. 4.

3. Petitioner's laboratory did testing in the following areas: general chemistry (i.e., glucose, blood urea, nitrogen, creatinine, total protein, cholesterol); isoenzymes; hematology (complete blood counts and platelet counts); and microbiology (gonorrhea screening only). Tr. 22, 255.

4. The results obtained from Petitioner's laboratory tests were used in the treatment of Dr. Johnstone's patients.

5. A laboratory receives proficiency testing samples three times a year. Each testing is known as an "event," with the first "event" occurring in January. Tr. 52, 118-119.

6. Petitioner's laboratory is enrolled in an approved proficiency testing program, pursuant to 42 C.F.R. 493.801, conducted by the American Association of Bioanalysts (AAB).

7. Among the proficiency testing samples sent to Petitioner were hematology samples and chemistry enzyme samples.

8. Petitioner's hematology proficiency testing from the third testing event (i.e., 3rd quarter) of 1994 is at issue in this case. Tr. 119.

9. Petitioner's chemistry proficiency testing from the second testing event (i.e., 2nd quarter) of 1994 is also at issue in this case. Tr. 119.

10. David Dohi is a licensed medical technologist, who in September 1994 was working part-time at Petitioner [one day a week for two to three hours a day], full-time at the Madera Community Hospital

(community hospital), and part-time at the hospital in Chowchilla [on call every other weekend and on call Wednesday nights]. HCFA Ex. 4; Tr. 262-263.

11. Mr. Dohi's duties for Petitioner's laboratory included drawing blood, doing laboratory testing and reporting the results. HCFA Ex. 5; Tr. 262.

12. Mr. Dohi did the testing of Petitioner's laboratory's 3rd quarter 1994 hematology proficiency testing samples. Tr. 232-233.

13. Mr. Dohi did not do the testing of Petitioner's laboratory's chemistry proficiency testing samples from 2nd quarter 1994. Tr. 245.

14. With respect to the instruments to be used by Petitioner's laboratory on the proficiency test samples, Petitioner had indicated to the AAB that it would be using the hemacytometer for platelet counts, and the Cell-Dyn 400 for the other hematology tests. Tr. 274-275.

15. At the time relevant to these proceedings, Dorothy Maurer was employed by HCFA as a CLIA Laboratory Expert. She has a background as a medical technologist. Tr. 17, 21.

16. On February 28, 1995, Ms. Maurer conducted a survey of Petitioner's laboratory on behalf of HCFA for the purpose of determining whether Petitioner was in compliance with requirements imposed under CLIA (Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a), and the implementing regulations at 42 C.F.R. Part 493.

17. Pursuant to the survey, Ms. Maurer found three condition level deficiencies: (1) enrollment and testing of samples -- 42 C.F.R. 493.801; (2) patient test management -- 42 C.F.R. 493.1101; and (3) laboratory director -- 42 C.F.R. 493.1441.

18. Ms. Maurer testified that she found computer generated printouts from a Cell-Dyn 1600 among the 3rd quarter 1994 proficiency testing documentation in Petitioner's files. Tr. 37-40. These printouts, each of which is titled "Cell-Dyn 1600 Specimen Data Report," contained various hematologic values, including platelet counts. HCFA Ex. 2 at 2-7.

19. The computer generated printouts from the Cell-Dyn 1600 are evidence that Petitioner's hematology proficiency samples were analyzed on a Cell-Dyn 1600.

20. Petitioner does not have a Cell-Dyn 1600. It has a Cell-Dyn 400, which does not have the ability to count platelets nor can it generate computer printouts.

21. Mr. Dohi admitted that he had run tests on Petitioner's laboratory's 3rd quarter 1994 hematology proficiency testing samples on both the Cell-Dyn 400 at Petitioner's laboratory and the Cell-Dyn 1600 at the community hospital laboratory. Tr. 234, 239, 269-271, 287-288; HCFA Exs. 4, 5.

22. Mr. Dohi knew he was retesting Petitioner's laboratory's 3rd quarter 1994 hematology proficiency testing samples on the Cell-Dyn 1600 at the community hospital laboratory. Thus, Mr. Dohi's action was deliberate, not inadvertent.

23. Mr. Dohi stated that the reason he took Petitioner's laboratory's hematology proficiency testing samples to the community hospital laboratory and analyzed the samples on its Cell-Dyn 1600 was that he wished to verify the results he had obtained using Petitioner's Cell-Dyn 400 [he wanted to check and make sure his numbers were fairly accurate or within the ...ballpark]. HCFA Ex. 5, Tr. 239.

24. Mr. Dohi reported the platelet count results obtained from the Cell-Dyn 1600 printouts to the AAB for 3rd quarter 1994. Tr. 47, 286-287.

25. At Petitioner, platelet counts for patients are not done on a Cell-Dyn 1600.

26. Even though Petitioner reported platelet count values obtained from a Cell-Dyn 1600, Petitioner did not indicate on the AAB reporting form, as it was required to do, that it had used different equipment than what it had indicated it would use. Tr. 275.

27. Mr. Dohi testified that, at Petitioner, he used the hemacytometer to do the platelet counts. Tr. 238, 241, 244-245, 287.

28. Use of a hemacytometer is an appropriate and acceptable way to perform a platelet count. Tr. 115.

29. Mr. Dohi stated that he could not find the worksheet where he had written the platelet values that he had obtained using the hemacytometer. Tr. 286.

30. With the exception of the platelet count values, Petitioner submitted to the AAB the values obtained from using Petitioner's Cell-Dyn 400 for the hematology samples. Tr. 235.

31. A laboratory that obtains analysis of its proficiency testing samples from another laboratory, regardless of whether the laboratory reports to the proficiency testing agency its own results or the results obtained from the other laboratory, violates 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b).

32. By retesting its proficiency testing samples in the community hospital laboratory, irrespective of whether Petitioner reported the community hospital laboratory results, Petitioner violated 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b).

33. A laboratory must not send proficiency testing samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. 42 C.F.R. 493.801(b)(4).

34. Because neither Congress nor the Secretary has defined "intentionally" as used in the context of 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b), one can infer that the term is to be given its common and ordinary meaning.

35. The definition of "intention" is a determination to act in a certain way. Long, at 6 (citing Webster's New Collegiate Dictionary, 1975 ed., at 601). When one acts "intentionally", he or she acts deliberately. Long, at 6.

36. "Intentionally referred" [as in "intentionally referred" its proficiency testing samples to another laboratory for analysis] requires not specific intent, but general intent, that is, an intent to act. No guilty knowledge, no culpability, no scienter is required. Motive is irrelevant. It is necessary merely that a person act deliberately, that is, not inadvertently.

37. The fact that Mr. Dohi committed the act of referring Petitioner's proficiency testing samples to another laboratory for analysis, with the knowledge that the samples were proficiency testing samples, is sufficient evidence to show that Petitioner violated 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b). Long, at 6.

38. It is irrelevant that Mr. Dohi was unaware that his retesting of Petitioner's 3rd quarter 1994 hematology proficiency testing samples in the community hospital laboratory was prohibited by law.

39. Mr. Dohi's motive in referring Petitioner's proficiency testing samples to another laboratory for analysis is irrelevant under 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b).

40. To prove "intention" in the context of 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b), HCFA is not required to prove what Mr. Dohi was thinking when he took the proficiency samples to another laboratory and ran the tests there.

41. Petitioner intentionally referred its 3rd quarter 1994 hematology proficiency testing samples to another laboratory for analysis, in violation of 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b).

42. As laboratory director, Dr. Johnstone was responsible for the actions of Mr. Dohi in intentionally referring proficiency testing samples to another laboratory for analysis, and the fact that Dr. Johnstone had no knowledge of Mr. Dohi's intentional referral of proficiency testing samples to another laboratory for analysis is irrelevant.

43. Petitioner did not test its 3rd quarter 1994 hematology proficiency testing samples in the same manner as patient samples were tested.

44. Petitioner did not test its 2nd quarter 1994 chemistry proficiency testing samples in the same manner as patient samples were tested.

45. Petitioner did not test its 3rd quarter 1994 hematology proficiency testing samples using its routine methods.

46. With respect to the chemistry isoenzyme test samples, Ms. Maurer testified that they were run twice, evidenced by a worksheet on which was reported two results for each test. Tr. 43-46. There should have been only one set of answers.

47. Based on the evidence pertaining to the hematology proficiency testing [finding 21] and the chemistry proficiency testing [finding 46], Petitioner did not test its proficiency testing samples the same number of times that it tested patient samples. Tr. 54; HCFA Ex. 1 at 4-5.

48. Petitioner failed to document the date it ran the tests on the proficiency testing samples, when it received the samples, and that the tests were done there (at Petitioner's laboratory). Tr. 55, 59-60; HCFA Ex. 1 at 6.

49. Petitioner failed to maintain specimen logs with respect to the proficiency testing in chemistry and hematology. Tr. 55, 60.

50. Petitioner failed to identify the technologist performing the proficiency testing. HCFA Ex. 1 at 6; Tr. 55.

51. Petitioner failed to maintain copies of all proficiency testing records for 1994. HCFA Ex. 1 at 7.

52. Relevant proficiency testing documentation, including copies of the attestation statements for the hematology samples for the third event and the chemistry samples for the second event, were missing at the time of the survey of Petitioner. Tr. 40-41, 52-53.

53. Mr. Dohi did not dispute that some proficiency test documentation was missing at the time of the survey. Tr. 238.

54. Mr. Dohi stated that he could not find the worksheet where he had written the results obtained from the Cell-Dyn 400. He admitted he had no proof that he had run the samples on the Cell-Dyn 400. Tr. 271; see also Finding 29.

55. Petitioner's documentation for the second event 1994 for chemistry proficiency testing was incomplete. Ms. Maurer was unable to locate the printout with the chemistry results and could not document that the tests had been performed. Tr. 57, 80, 102.

56. Moreover, Ms. Maurer could locate only one set of answers on a printout, even though there were two sets of results on the worksheet. [All printouts are required to be kept.] Tr. 44, 57. Mr. Dohi was unable to find the documentation showing the other set of numbers. Tr. 123.

57. Dr. Johnstone and Mr. Dohi signed the attestation form accompanying the proficiency testing samples, and, by doing so, were attesting that the proficiency samples were tested in the same manner as patient samples. Tr. 204; HCFA Ex. 2 at 2.

58. Petitioner failed to meet the Condition for Enrollment and Testing of Samples, in violation of 42 C.F.R. 493.801.

59. The procedure manual maintained by Petitioner was inadequate, old, and outdated. Tr. 61, 84.

60. With respect to patient specimens, Petitioner did not have in place written policies and procedures to assure positive identification and adequate tracking of the specimens. Tr. 65-66; HCFA Ex. 1 at 9.

61. For all types of laboratory testing performed in a day, quality control should be conducted on that day for those tests. Tr. 67, 72.

62. Quality control in the area of hematology is performed for every eight hours of operation. Tr. 67.

63. Petitioner failed to perform quality control daily in hematology. Tr. 68; HCFA Ex. 8. Petitioner failed to perform and document two levels of hematology quality control materials each day of testing. HCFA Ex. 1 at 10.

64. Specifically, Petitioner failed to run hematology quality control on four of 18 days in February 1995,

when patients were tested. HCFA Ex. 8 at 1; HCFA Ex. 1 at 10. Petitioner performed quality control only
78 percent of the time in February 1995. Tr. 80.

65. Petitioner conducted gonorrhea screenings. Tr. 61-62, 255.

66. Petitioner did not have in place a tracking system for sending gonorrhea cultures to other labs. Tr. 64-
65; HCFA Ex. 1 at 9.

67. Petitioner's procedure manual did not contain written procedures for gonorrhea testing. Tr. 75.

68. The temperature chart on Petitioner's incubator, an instrument used in gonorrhea screenings, indicated
that the last time the temperature was documented (checked) was in November 1992. Tr. 63, 76; HCFA
Ex. 1 at 11.

69. Mr. Dohi admitted that the incubator was used for gonorrhea incubations and that results were reported
on the gonorrhea cultures. Tr. 278.

70. Mr. Dohi admitted that he was unaware that the incubator thermometer was broken until the survey.
Tr. 278.

71. Petitioner replaced the broken thermometer in March 1995. Tr. 259, 277; P. Ex. 5 at 48.

72. Mr. Dohi could not recall if he ever saw a positive culture. Tr. 278-279.

73. At the time of the survey, Petitioner did not have any culture media records with respect to gonorrhea
screening. Tr. 77; HCFA Ex. 1 at 12.

74. Petitioner failed to meet the Condition for Patient Test Management set forth at 42 C.F.R. 493.1101.

75. As laboratory director, Dr. Johnstone was responsible for the overall management and direction of
Petitioner in accordance with 42 C.F.R. 493.1445. 42 C.F.R. 493.1441.

76. Dr. Johnstone failed to ensure that Petitioner's laboratory's testing system in hematology provided
quality testing, as evidenced by the records showing that quality control was performed only 78 percent of
the required time in February 1995.

77. Dr. Johnstone failed to ensure that Petitioner's laboratory's proficiency testing samples were tested as
required under subpart H of 42 C.F.R. Part 493. See Finding 58. This failure is evidenced by the
following: proficiency tests on the hematology testing samples were run at two sites with two different

instruments, there were two sets of answers for the chemistry isoenzymes proficiency testing samples, and documentation containing chemistry results, as well as other documentation, was not available. Tr. 80; see HCFA Ex. 1 at 14.

78. Dr. Johnstone had the ultimate responsibility for ensuring that Petitioner's laboratory's proficiency testing was performed in accordance with the requirements set forth at 42 C.F.R. 493.801.

79. Dr. Johnstone failed to ensure that quality control and quality assurance programs were established and maintained in Petitioner's laboratory, and he failed to identify failures in quality as they occurred. 42 C.F.R. 493.1445(e)(5).

80. Petitioner's laboratory's procedure manuals did not have any documentation for doing quality control. Tr. 81; HCFA Ex. 1 at 15.

81. Dr. Johnstone failed to have in place a system by which to monitor the competency of Petitioner's laboratory employees. Tr. 82-83; HCFA Ex. 1 at 16; see also Finding 85.

82. Dr. Johnstone failed to ensure that Petitioner's laboratory procedure and policy manuals were current, complete and approved, especially regarding gonorrhea cultures and quality control. HCFA Ex. 1 at 17; Tr. 83-84.

83. Dr. Johnstone failed to assign in writing the duties and responsibilities involved in all phases of the patient testing process for Petitioner's laboratory's technical consultant, technical supervisor, and testing personnel. HCFA Ex. 1 at 17-18; Tr. 87-88.

84. Petitioner's laboratory last reviewed charts for completeness of laboratory work documentation on April 3, 1992. Tr. 84-86; HCFA Ex. 1 at 18-19.

85. Petitioner's laboratory did not have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence. Tr. 89; HCFA Ex. 1 at 19; see also Finding 81.

86. Petitioner failed to meet the Condition for Laboratory Director, in violation of 42 C.F.R. 493.1441.

87. HCFA's Notice, dated May 23, 1995, provided Petitioner with adequate notice that non-compliance with respect to the laboratory director condition, in violation of 42 C.F.R. 493.1441, would independently support revocation of Petitioner's CLIA certificate.

88. Petitioner's failure to meet the Condition for Laboratory Director forms an independent basis for

HCFA's revocation of Petitioner's CLIA certificate under 42 C.F.R. 493.1814(a)(2).

89. The CLIA statute and applicable regulations require HCFA to revoke a laboratory's CLIA certificate for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another laboratory for analysis. 42 U.S.C. 263a(i)(4); 42 C.F.R. 493.801(b)(4) and 493.1840(b).

90. Neither I nor HCFA has the discretion in this case to revoke Petitioner's CLIA certificate for less than the mandatory minimum period of one year, or to substitute any lesser sanction.

91. HCFA is required to cancel a laboratory's approval to receive Medicare payment for its services where the laboratory's CLIA certificate is revoked. 42 C.F.R. 493.1808(a) and 493.1842(a)(1).

92. I affirm HCFA's one-year revocation of Petitioner's CLIA certificate, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

DISCUSSION

The word "intentionally" requires careful analysis in determining whether Petitioner "intentionally referred" its proficiency testing samples to another laboratory for analysis. This is the key issue in this case, and I will

address it first; thereafter I will address the remaining alleged deficiencies. 4/

I. Intentional Referral of Proficiency Testing Samples to Another Laboratory for Analysis

A. Statute and Regulations

CLIA provides both civil sanctions and criminal sanctions:

Civil Sanctions

> Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in section (h) 5/ of this section.

42 U.S.C. 263a(i)(4).

Regulations which implement CLIA parallel the Act's requirement that the Secretary revoke 6/ a

laboratory's CLIA certificate where that laboratory improperly refers a proficiency testing sample to a reference laboratory:

> The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency testing samples from another laboratory for testing must notify HCFA of the receipt of those samples.

42 C.F.R. 493.801(b)(4).

> Adverse action based on improper referrals in proficiency testing. If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

42 C.F.R. 493.1840(b).

Criminal Sanctions

Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under Title 18, or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with Title 18, or both.

42 U.S.C. 263a(l).

The implementing regulations regarding such criminal violations provide:

> Definitions. Intentional violation means knowing and willful noncompliance with any CLIA condition.

42 C.F.R. 493.2.

> Section 353 also [p]rovides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements.

42 C.F.R. 493.1800(a)(3)(i).

Criminal sanctions. Under section 353(1) of the PHS [Public Health Service] Act, an individual who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

42 C.F.R. 493.1806(e).

B. Definitions of "Intentionally" under CLIA

I conclude that "intentionally" is defined differently in CLIA for civil violations than for criminal violations.

The word "intentionally" is found in both the civil section of CLIA and the criminal section of CLIA:

civil:

Any laboratory that the Secretary determines intentionally refers [emphasis added] its proficiency testing samples to another laboratory for analysis . . . .

42 U.S.C. 263a(i)(4).

criminal:

Any person who intentionally violates [emphasis added] any requirement of this section or any regulation promulgated thereunder . . . .

42 U.S.C. 263a(l).

Although the term "intentionally" is used in both the civil and criminal sections of CLIA, the term need not be accorded the same meaning in each of these sections. Upon careful analysis, I conclude that the term "intentionally refers" as it appears at 42 U.S.C. 263a(i)(4) indeed does not have the same meaning as the term "intentionally violates" as it appears at 42 U.S.C. 263a(l). To begin with, the phrases are different in that one contains the word "refers" and one contains the word "violates." This is discussed more fully below.

1. Factual background

Petitioner is a physician's office operating a laboratory, located in Madera, California. Theodore Johnstone, M.D., is Petitioner's owner and laboratory director. P. Br. 2, P. R. Br. 4. Petitioner's laboratory did testing in the following areas: general chemistry (i.e., glucose, blood urea, nitrogen, creatinine, total protein, cholesterol); isoenzymes; hematology (complete blood counts and platelet counts); and microbiology (gonorrhea screening only). Tr. 22, 255. The results obtained from Petitioner's laboratory tests were used in the treatment of Dr. Johnstone's patients.

Proficiency testing is designed to determine a laboratory's accuracy in doing testing for its patients. Each laboratory enrolls in a proficiency testing program and is sent specimens [proficiency samples] for testing, approximately three times a year. The specimens are clearly marked as proficiency testing samples, so the technician receiving them knows they are test materials, not patients' specimens. The laboratory that is being tested is required to test the

proficiency samples the same way it tests patients' specimens.

3rd Quarter 1994 Proficiency Testing Samples

Pursuant to 42 C.F.R. 493.801, Petitioner is enrolled in an approved proficiency testing program conducted by the American Association of Bioanalysts (AAB). P. Br. 3. On September 22, 1994, Petitioner's laboratory received certain hematology samples for testing. HCFA Ex. 2, P. Br. 3.

David Dohi is a licensed medical technologist who, in September 1994, was working part-time at Petitioner's laboratory [one day a week for two to three hours a day], full-time at the Madera Community Hospital (community hospital), and part-time at the hospital in Chowchilla [on call every other weekend and on call Wednesday nights]. HCFA Ex. 4; Tr. 262-263. Mr. Dohi's duties for Petitioner's laboratory included drawing blood, doing laboratory testing, and reporting the results. HCFA Ex. 5; Tr. 262.

On September 28, 1994, Mr. Dohi tested Petitioner's 3rd quarter 1994 hematology proficiency testing samples within Petitioner's laboratory, using Petitioner's laboratory equipment. [The evidence is unclear whether Mr. Dohi counted platelets at Petitioner. Tr. 92.] HCFA Ex. 2; Tr. 232-238; P. Br. 3.

On September 29, 1994, Mr. Dohi, on his own initiative and without the knowledge of Dr. Johnstone, took Petitioner's 3rd quarter 1994 hematology proficiency testing samples to the laboratory at the community hospital, where Mr. Dohi was also employed. Mr. Dohi retested Petitioner's hematology proficiency testing samples in the community hospital's laboratory, using the community hospital's laboratory equipment. Tr. 239, 246, 316-317; P. Br. 4.

The computer printouts obtained from the community hospital's Cell-Dyn 1600, as well as Mr. Dohi's admission that he ran the proficiency test samples on that instrument, constitute proof that Petitioner's hematology proficiency samples were analyzed at a laboratory other than Petitioner's, on an instrument other than Petitioner's own Cell-Dyn 400.

Mr. Dohi was unaware that his retesting of Petitioner's 3rd quarter 1994 hematology proficiency testing samples, at the community hospital's laboratory, was prohibited by law. Mr. Dohi's motive for retesting Petitioner's hematology proficiency testing samples at the community hospital's laboratory was to check the results he had obtained at Petitioner's laboratory. Tr. 239, 266-267. P. Br. 4.

Dr. Johnstone was unaware that Mr. Dohi had retested Petitioner's 3rd quarter 1994 hematology proficiency testing samples at the community hospital's laboratory until, during a survey of Petitioner's laboratory conducted on February 28, 1995, a CLIA Laboratory Expert employed by HCFA, Dorothy Maurer, told Dr. Johnstone so. Tr. 17, 21; P. Br. 6; P. R. Br. 4.

The survey of Petitioner's laboratory conducted by Ms. Maurer on behalf of HCFA on February 28, 1995, was done to determine whether Petitioner was in compliance with requirements imposed under CLIA. Ms. Maurer analyzed Petitioner's records concerning its performance of proficiency testing in the 2nd and 3rd quarters of 1994.

Ms. Maurer testified that, in examining the testing documentation relating to the hematology proficiency samples, she realized that she "had two sets of answers." Tr. 38. Although Petitioner has a Cell-Dyn 400 on the premises, Ms. Maurer stated that she found computer generated printouts from a Cell-Dyn 1600 among the 3rd quarter 1994 proficiency testing documentation in Petitioner's files. Tr. 37-40. Petitioner's Cell-Dyn 400 does not have the ability to count platelets nor can it generate computer printouts.

The computer printouts discovered by Ms. Maurer, each of which is titled "Cell-Dyn 1600 Specimen Data Report," contained various hematologic values, including platelet counts. HCFA Ex. 2 at 2-7. According to Ms. Maurer, it would not have been possible for Petitioner to have obtained these printouts from its own instrument, i.e., the Cell-Dyn 400.

The platelet count was the only Cell-Dyn 1600 result that was reported as if it had been Petitioner's result. With the exception of the platelet count values, Mr. Dohi submitted to the AAB the values obtained from using Petitioner's Cell-Dyn 400. Tr. 235. Mr. Dohi admitted that the platelet count values he reported to the AAB were those obtained from the Cell-Dyn 1600 at the community hospital's lab. Tr. 47, 286-287.

2. Parties' arguments

Petitioner's arguments

Petitioner responds to HCFA's citation of the Long case [see HCFA's arguments, infra]: "Long is simply incorrect insofar as it states that 'intentionally' is not defined in the applicable regulations. 42 C.F.R. Part 493, which contains

the regulations relied upon by HCFA as the basis for revoking Petitioner's CLIA certificate, states:

> As used in this part, unless the context indicates otherwise . . . .
>
> Intentional violation means knowing and willful noncompliance with any CLIA condition.

42 C.F.R. 493.2.

Petitioner argues that the definition of "intentional violation" found in at 42 C.F.R. 493.2 is to be applied to the terminology used in 42 C.F.R. 493.801(b)(4) and [493.]1840(b). P. Br. 7; P. R. Br. 3.

Petitioner argues further that revocation of a Petitioner's CLIA certificate pursuant to 42 C.F.R. 493.801(b)(4) and 493.1840 is improper unless Petitioner or its employees knowingly and willfully violated a CLIA condition. Petitioner adds that 42 C.F.R. 493.2 makes it clear that no intentional violation can occur without the putative offender's knowing and willful noncompliance with a legal duty imposed by the CLIA regulations. P. Br. 7.

Petitioner maintains that neither Petitioner nor any of its employees had a specific intent to violate a CLIA condition at the time Dohi verified the proficiency testing results obtained at Petitioner's laboratory. P. Br. 11. Moreover, Petitioner contends that Dr. Johnstone was unaware of Mr. Dohi's referral of proficiency testing samples until the survey and thus could not have intended to violate the CLIA regulation. P. Br. at 6.

HCFA's arguments

HCFA argues: "[T]he issue at hand is whether petitioner "intentionally referred" its proficiency samples to another facility, not whether there was an "intentional violation" of a CLIA condition. Although the elements necessary for proving whether there was an intentional referral may be similar to those for proving an intentional violation of a Condition, the definition itself is not controlling in making the determination in petitioner's case." HCFA R. Br. 2.

HCFA argues that criminal case standards, including the "'knowing and willful' elements," and "'specific intent' to do something which the law forbids," "should not be controlling on this administrative proceeding." HCFA R. Br. 2-3.

HCFA (HCFA Br. 23) quotes Long Medical Laboratory v. HCFA, DAB CR334 (1994):

> A laboratory contravenes the prohibition against referrals of proficiency tests by deliberately referring proficiency testing samples to another laboratory. Inadvertent referrals of such samples do not contravene the prohibition. The necessary elements of a violation consist of: (1) a referral by a laboratory to another laboratory of a proficiency testing sample, and (2) knowledge by the referring laboratory that the sample it is referring is a proficiency testing sample. If it is established that a laboratory has deliberately referred a proficiency testing sample to another laboratory, then that laboratory's motive for referring the sample is irrelevant. The Act and regulations do not distinguish between deliberate referrals that are motivated by good intentions and those which are motivated by some other purpose.

Long, supra, at 6.

HCFA continues: "With respect to the element of 'intent' that is contained in both the statute and regulation, the Administrative Law Judge [ALJ] in Long noted that while the term is not defined, 'it is apparent, from both the language of CLIA and the regulations, that it was intended that this term be given its common and ordinary meaning.' Long, supra, at 6. The ALJ then notes that in Webster's New Collegiate Dictionary, 1975 ed., at 601, 'Intention' is defined to mean a determination to act in a certain way. 'Intentional' or 'intentionally,' means to act by intention or design. Id. 'Thus, when one acts 'intentionally,' he or she acts deliberately.'" Long, supra, at 6. HCFA Br. 25-26. "[T]he knowledge element...is satisfied by showing that the referring laboratory knew the sample it was referring was a proficiency testing sample as opposed to a patient sample." HCFA R. Br. 3.

3. Purpose of CLIA

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), enacted by Congress, require certification of all laboratories that perform clinical diagnostic tests on human specimens. CLIA was established to address the issue of unacceptably high error rates at unregulated laboratories and the dangers to patients that these high laboratory error rates posed. H.R. Rep. No. 899, 100th Cong., 2d Sess. 14,

reprinted in 1988 U.S.C.C.A.N. at 3831; S. Rep. No. 561, 100th Cong., 2d sess. 3-4. Congress intended CLIA to establish a single set of standards to govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. See H.R. Rep. No. 899, 100th Cong., 2d Sess. 8, reprinted in 1988 U.S.C.C.A.N. at 3828. 7/

The authority to enforce CLIA requirements is granted to the Secretary of Health and Human Services (Secretary). Under CLIA, the Secretary is authorized to inspect clinical laboratories and, in effect, license them to perform tests. 42 U.S.C. 263a (esp. 263a(b) and 263a(f)); 42 C.F.R. 493.1800; See Consumer Federation of America and Public Citizen v. U.S. Dept. of Health and Human Services, 83 F. 3d 1497 (D.C. Cir. 1996).

The importance of proficiency testing as a means of measuring and ultimately ensuring laboratory competence was noted by Congress as follows:

> The Committee's investigation focused particularly on proficiency testing because it is considered one of [the] best measures of laboratory performance. It is arguably the most important measure, since it reviews actual test results rather than merely gauging the potential for good results . . .
>
> Proficiency testing is a method of externally validating the level of a laboratory's performance. Proficiency testing is not currently conducted by HHS, but is conducted by private agencies. . . . The standard testing methodology currently in use involves sample test specimens being sent by mail to a laboratory by the proficiency testing agency. The laboratory then analyzes the samples and returns the results of the test to the proficiency testing organization. The proficiency testing organization typically calculates the mean of the test results, determines an acceptable range variation based on standard deviations from the mean, and reports the results to the lab.
>
> The major problems identified by the Committee were lax Federal oversight and direction, lack of proficiency testing for many analytes, inconsistent criteria for acceptable laboratory performance, and improprieties by laboratories in handling specimen samples.
>
> . . .
>
> A significant deficiency in the current proficiency testing regime is its inability to assure that proficiency testing samples are treated like patient specimens. Samples are mailed to laboratories, and

although proficiency testing organizations recommend that tests be treated in the same manner as patient samples, there was evidence that laboratories retest samples repeatedly to ensure satisfactory results and send proficiency testing samples out to other laboratories for analysis. The only way to guarantee that samples are treated by the same personnel, at the same speed, using the same equipment as patient specimens is though [sic] blind or on-site proficiency testing. The committee learned, however, that such testing can be quite expensive and may have to be used with discretion to assure proper processing of specimens.

H.R. Rep. No. 899, 100th Cong., 2d Sess. 8, reprinted in 1988 U.S.C.C.A.N. at 3828, 3836, 3837.

Thus, Congress, in enacting CLIA, was concerned about, among other things, laboratories that were sending their proficiency testing samples to other laboratories for analysis or retesting to ensure a satisfactory result. It is within this context that Congress authored the prohibition on intentional referrals of proficiency testing. The Act mandates revocation of a CLIA certificate for improper referral of proficiency testing samples by a laboratory. It states that:

> Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year . . . .

42 U.S.C. 263a(i)(4).

4. Definition of "intentionally," as in "intentionally refers"

"Intentionally" is not defined in the CLIA statute, but some assistance is found in the regulations. "Intentional violation" is defined in the regulations as "knowing and willful noncompliance with any CLIA condition." 42 C.F.R. 493.2 ("Definitions").

The phrase "intentional violation" does not appear elsewhere in the pertinent regulations, other than in the definitions section, as just quoted, and as follows:

> Section 353 also [p]rovides for imprisonment or fine for any person convicted of intentional violation of CLIA requirements.

42 C.F.R. 493.1800(a)(3)(i).

The phrase "intentionally violating" appears in the pertinent regulations, also solely in connection with criminal sanctions:

Criminal sanctions. Under section 353(1) of the PHS [Public Health Service] Act, an individual
who is convicted of intentionally violating any CLIA requirement may be imprisoned or fined.

42 C.F.R. 493.1806(e).

After careful study of the pertinent portions of the statute and the regulations, I conclude that "intentional
violation" is defined by the regulations for the sole purpose of clarifying the phrase "intentionally violates"
which is found in the CLIA statute only in the criminal section [42 U.S.C. 263a(l)]. The "knowing and
willful" requirement provided by the regulation is consistent with the element of criminal offenses known
as "scienter," "culpability," or "guilty knowledge."

By providing a definition for "intentional violation", the authors of the regulations have explicitly provided
guidance on how to interpret 42 C.F.R. 493.1800(a)(3)(i) and 493.1806(e). There is little doubt that,
with respect to the imposition of criminal sanctions, in determining whether there was an intentional
violation, the legal standard of "knowing and willful" is to be applied. Criminal convictions, particularly for persons who work in health care, trigger extremely serious
consequences. It is reasonable to require proof of specific intent before subjecting a person to criminal
penalties under CLIA. CLIA has clearly delineated two distinct types of penalties -- the first, directed at a
laboratory and involving civil sanctions (regarding the laboratory's CLIA certificate, civil money penalties,
costs and the like); -- and the second, directed at a person and involving criminal penalties (imprisonment
or a fine or both). [See 42 C.F.R. 493.1806 for available sanctions.]

Under CLIA, a laboratory is subject to inspection and a variety of civil penalties for failing to comply with
CLIA standards. 42 U.S.C. 263a(g), (h), (i). ["Principal sanctions," such as suspension, revocation, and
limitation of the laboratory's CLIA certificate, are provided by 42 U.S.C. 263a(i). "Intermediate" or
"alternative sanctions," such as directed plans of correction, civil money penalties, and onsite monitoring
costs, are provided by 42 U.S.C. 263a(h).]

In sharp contrast are the CLIA penalties that are criminal in nature. 42 U.S.C. 263a(l). The potential
penalties include imprisonment for up to one year and a fine or both. Even more serious, a repeat offender
can be imprisoned for up to three years and fined or both.

The regulations go to the effort of defining "intentional violation" to ensure that sufficient scienter is
proved before a person can be convicted of a criminal violation under CLIA. The fact that "intentional
violation" is specifically defined in the regulations [42 C.F.R.

493.2] suggests that the definition is different from its common and ordinary meaning, and in fact, it is.

Nowhere do the regulations define the term "intentionally referred," which is contained in the regulations at 42 C.F.R. 493.801(b)(4) and 493.1840(b). "Intentionally refers" is found in the statute at 42 U.S.C. 263a(i)(4). Neither Congress nor the Secretary chose to define or modify the word "intentionally" in the context of "intentionally referred its proficiency testing samples to another laboratory for analysis." Where "intentionally" is not specifically defined in the context of CLIA civil sanctions, one can infer that it should be given its common and ordinary meaning.

This conclusion is in accordance with that of Administrative Law Judge Steven Kessel in the case of Long Medical Laboratory v. HCFA, DAB CR334 (1994). Although in Long Petitioner admitted that it had intentionally referred proficiency testing samples for testing, Judge Kessel nonetheless determined that the word "intentionally" should be given its common and ordinary meaning. As stated in Long, "intention" is a determination to act in a certain way. Long, at 6 (citing Webster's New Collegiate Dictionary, 1975 ed., at 601). When one acts "intentionally," he or she acts deliberately, regardless of motivation. Long, at 6 - 9. Accordingly, I find that "intentionally referred" [as in "intentionally referred" its proficiency testing samples to another laboratory for analysis] requires not specific intent, but general intent, that is, an intent to act. No guilty knowledge, no culpability, no scienter is required. Motive is irrelevant. It is necessary merely that a person act deliberately, that is, not inadvertently.

In current practice, where proficiency testing samples are clearly marked, enabling the technician receiving them to know they are test materials, not patients' specimens, it is difficult to conceive of an inadvertent referral. If proficiency testing samples are referred to another laboratory for analysis, with the knowledge that they were proficiency testing samples, the referral is intentional, that is, deliberate, not inadvertent. 8/

5. Further consideration of Petitioner's arguments regarding definition of "intentionally," as in "intentionally refers"

Mr. Dohi testified that he was the laboratory technologist who had run the tests on the hematology samples. Tr. 232-233. He admitted that he had tested the hematology proficiency test samples on both the Cell-Dyn 400 at Petitioner and on the Cell-Dyn 1600 at the lab at community hospital. Tr. 234-235, 239, 269-271, 287-288; HCFA Exs. 4, 5. Mr. Dohi stated that the reason he took the hematology test samples to the

community hospital's lab and analyzed the samples on the Cell-Dyn 1600 there, was that he wished to verify the results he had obtained using Petitioner's Cell-Dyn 400. HCFA Ex. 5.

Although I agree with HCFA that Mr. Dohi "should have known" that he was circumventing the purpose of proficiency testing by analyzing the samples at another laboratory, on different and more sophisticated instruments [HCFA R. Br. 5 - 6], I am persuaded that he did not know. His actions appear to me to be more the result of scientific curiosity than of any intent to violate the law. I agree with the following statement of Petitioner [P. Br. 11]:

> Neither Petitioner nor any of its employees had a specific intent to violate a CLIA condition at the time Dohi verified the proficiency testing results obtained at Petitioner's laboratory.

I agree with Petitioner that Mr. Dohi did not know that his action of retesting Petitioner's proficiency testing samples at another laboratory was prohibited by law, as his statements to Ms. Maurer, his statements of corrective action, and his testimony demonstrate. P. Br. 4, 12. Mr. Dohi still did not know his action was prohibited by law when, in May 1995, he wrote a Corrective Action Plan that included the potential of future retesting of Petitioner's proficiency testing samples at another laboratory! [P. Br. 12 - 14]. Also significant to me is that Mr. Dohi placed the Cell-Dyn 1600 printouts in Petitioner's files and did not purge them. P. Br. 4, 12.

Nevertheless, whether Mr. Dohi "should have known," and whether he had specific intent to violate a CLIA condition, are irrelevant to the issue at hand.

HCFA need only establish a general intent to act, and not, as Petitioner suggests, specific intent, as would be required in a criminal case. It is highly improbable that, within the framework of civil penalties against an entity, where no loss of personal liberty is involved, Congress would require specific intent in order to establish a CLIA violation under the statute's civil penalty provisions. Here, a laboratory is subject to civil administrative sanctions for failure to comply with statutory requirements.

To prove "intention" in the context of 42 U.S.C. 263a(i)(4), 42 C.F.R. 493.801(b)(4) and 493.1840(b), HCFA is not required to prove what Mr. Dohi was thinking when he took the proficiency samples to another laboratory and ran the tests there. The issue is whether Mr. Dohi's actions were intentional, i.e., deliberate (not inadvertent). The uncontroverted evidence in this case is that Mr. Dohi referred proficiency

test samples to another laboratory intentionally. Mr. Dohi has admitted doing so.

Regardless of motivation, Mr. Dohi acted with the requisite general intent to satisfy the civil penalty provision of CLIA, that is, the intent to act. Mr. Dohi acted deliberately, that is, not inadvertently, in obtaining test results elsewhere. It is cheating to look at another's answer on a test, even if merely to confirm one's own answer. Anyone looking at answers different from his own would likely compare and analyze them before forming any intent about what to do with one's own answers.

Mr. Dohi obtained platelet count values for Petitioner's proficiency testing samples from the Cell-Dyn 1600 at the community hospital's laboratory. The platelet count was the only item reported to AAB from Petitioner's retesting of its proficiency testing samples on the Cell-Dyn 1600 at the community hospital's laboratory. All of the remainder of Petitioner's hematology proficiency testing was reported as performed at Petitioner, on the Cell-Dyn 400. Whether or not a laboratory reports the information it has obtained from another laboratory's analysis of its proficiency testing samples, it is the obtaining of the analysis itself from the other laboratory which constitutes the intentional referral. Accordingly, I find that Petitioner intentionally referred its hematology proficiency testing samples to another laboratory for analysis, in violation of 42 C.F.R. 493.1840(b) and 493.801(b)(4). Petitioner has not disputed that a referral of proficiency testing samples occurred here. As stated above, Petitioner admits taking the proficiency test samples to the community hospital's laboratory and running the tests there on that hospital's Cell-Dyn 1600.

Congress enacted an especially strong prohibition against intentionally referring proficiency testing samples to another laboratory for analysis, by requiring mandatory revocation for at least one year as the sanction. Clearly, Congress wanted the practice to stop.

While the actions of Mr. Dohi and Dr. Johnstone may not have been as egregious as that of the petitioner in the Long case, they still contravened the purpose of the CLIA statute and regulations.

Where intentional referral of a laboratory's proficiency testing samples to another laboratory for analysis has occurred, there is no possibility of a less severe sanction than a one-year minimum mandatory revocation. The statute itself specifies the sanction:

> Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to

another laboratory for analysis shall have its certificate revoked for at least one year . . . .

42 U.S.C. 263a(i)(4).

II. Enrollment and Testing of Samples -- Condition

The laboratory must test its proficiency testing samples in the same manner as patients' specimens. 42 C.F.R. 493.801.

The enrollment and testing of samples condition includes the "testing of proficiency testing samples" standard. 42 C.F.R. 493.801(b). Within that standard is found the prohibition against intentional referral of proficiency testing samples to another laboratory for analysis. 42 C.F.R. 493.801(b)(4). The intentional referral issue has been discussed above. See pp. 11-24 supra.

Hematology proficiency testing

With respect to the 3rd quarter 1994 hematology proficiency testing results, HCFA alleges that Petitioner did not test the hematology samples using its routine method nor did it test the samples in the same manner or the same number of times as it tested patient samples.

I conclude that Petitioner's testing of the hematology samples on the Cell-Dyn 1600 at the community hospital violated its obligation to conduct its proficiency tests using the routine method, in the same manner and for the same number of times that it routinely performs patient tests. See 42 C.F.R. 493.801(b), (b)(1) and (b)(2).

Hemacytometer

Although there is no dispute that the reported platelet count values were obtained from the Cell-Dyn 1600 at the community hospital (Tr. 286-287), HCFA disputed Mr. Dohi's claim that he did use an instrument called a hemacytometer to count the platelets and that he ordinarily uses this at Petitioner. Ms. Maurer alleged that Mr. Dohi had informed her that he counted platelets using a "smear" technique, which would give an estimated number. 9/ Tr. 141. Ms. Maurer stated that she did not look to see if Petitioner had a hemacytometer because Mr. Dohi never told her he used one. Tr. 115. With respect to the "smear" method, Ms. Maurer expressed her opinion that no one had ever "put down an actual number on the smear method". She stated that "the smear method is simply for an estimate of the platelets. I had never heard of anybody else ever doing that." Tr. 144.

Mr. Dohi denied using the "smear" method, and stated that he used a hemacytometer to do the platelet counts. Tr. 238, 240, 287. He described using the hemacytometer as doing a "manual" platelet count. Tr. 241-242.

After reviewing the testimony of Ms. Maurer, Mr. Dohi, and Dr. Johnstone, I conclude that I am not able to make a satisfactory determination on what platelet counting method Petitioner routinely used (except that a Cell-Dyn 1600 was not routinely used).

Chemistry proficiency testing

With respect to the 2nd quarter 1994 chemistry proficiency testing results, HCFA alleges that Petitioner did not test the chemistry isoenzyme samples in the same manner or the same number of times as it tested patient samples. Ms. Maurer testified that the chemistry isoenzyme test samples were run twice. As proof of this, she stated that there was a worksheet on which Petitioner reported two sets of answers for each test. Tr. 43-46; HCFA Ex. 7 at 2. Ms. Maurer stated that there should have been only one set of answers. Moreover, although there were two sets of answers, Ms. Maurer could locate only one set of answers in the printout from the chemistry analyzer. Tr. 44, 57.

Mr. Dohi testified that he was not the technician who performed the testing on the chemistry samples. Tr. 245. He stated that he did not know why the tests were run twice. Tr. 245-246. Mr. Dohi was unable to find the documentation showing the other set of numbers. Tr. 123. Petitioner did not introduce any evidence to contradict Ms. Maurer, either at the hearing or in its briefs. I conclude that Petitioner's retesting of the chemistry isoenzyme samples violated its obligation to conduct its proficiency tests in the same manner and for the same number of times that it routinely performs patient tests.

Proficiency testing documentation

Ms. Maurer found also that relevant proficiency testing documentation, as required by 42 C.F.R. 493.801(b)(5), was either missing or incomplete at the time of the survey. She testified that copies of the attestation statements for the hematology samples for the third event and the chemistry samples for the second event were missing. Tr. 40-41, 52-53. Petitioner failed to document the date it ran the tests on the proficiency testing samples, when it received the samples, and that the tests were done there (at Petitioner's laboratory). Tr. 55, 59-60. See HCFA Ex. 1 at 6. Petitioner failed to maintain specimen logs with respect to the proficiency testing in chemistry and hematology. Tr. 55. Petitioner failed to maintain copies of all

proficiency testing records for 1994. HCFA Ex. 1 at 7. With respect to the second event for chemistry proficiency testing, Ms. Maurer testified that she was unable to locate the printout with the chemistry results and could not document that the tests had been performed. Tr. 57, 80, 102.

Mr. Dohi did not dispute that some proficiency test documentation was missing at the time of the survey. Tr. 238. He acknowledged that he could not find the worksheet where he had written the results obtained from Petitioner's Cell-Dyn 400. Tr. 271. Mr. Dohi admitted that he had no proof that he had run the samples on the Cell-Dyn 400. Tr. 271. Mr. Dohi admitted that he could not find the worksheet where he had written the platelet values that he had obtained using the hemacytometer. Tr. 238, 286. I conclude that HCFA has proven that Petitioner was deficient in its recordkeeping with respect to proficiency testing.

III. Patient Test Management -- Condition

The laboratory must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. 42 C.F.R. 493.1101.

With respect to the Patient Test Management Condition, Ms. Maurer alleged that Petitioner was deficient regarding documentation and recordkeeping, quality control, and its gonorrhea screening. In the area of documentation and recordkeeping, Ms. Maurer testified that Petitioner did not have specimen logs and had an inadequate and outdated procedure manual. Under 42 C.F.R. 493.1103(a), which is cited in HCFA Ex. 1, a "laboratory must have available and follow written policies and procedures for . . . conditions for specimen transportation." Ms. Maurer testified:

> [T]he procedure manual did not include any directives for handling of specimens at all. They did not have any directives at all on taking specimens to another laboratory for confirmation or further testing. There were no log sheets to follow a specimen that was transported elsewhere. I don't know how they kept track of them.

Tr. 61.

Ms. Maurer testified also that Petitioner's "procedure manual is old and outdated." Ms. Maurer stated that "when you change a procedure then you should take your old procedure out." Tr. 84. She discovered that the manual contained procedures that Petitioner was no longer doing. Id. In addition, Ms. Maurer

discovered that, although Petitioner was conducting gonorrhea screenings, its procedure manual did not contain any written procedures for this. Tr. 75. (I discuss Petitioner's deficient procedure manual further in my discussion regarding Petitioner's deficient practice in conducting gonorrhea screenings).

HCFA's evidence, including Ms. Maurer's testimony, establishes that Petitioner did not comply with the condition of participation for Patient Test Management set forth at 42 C.F.R. 493.1101.

Further support for Ms. Maurer's findings regarding Petitioner's deficient documentation is found in Petitioner's Exhibit 5. Petitioner, in this exhibit, attempts to show that it has implemented adequate recordkeeping and documentation systems. Tr. 250-259.

IV. Quality Control -- Standards

In the area of quality control, Ms. Maurer testified that, for all types of laboratory testing performed in a day, quality control should be conducted on that day for those tests. Tr. 67, 72, 74. The regulation requires that the laboratory must perform and document its control procedures using at least two levels of control materials each day of testing. 42 C.F.R. 493.1202(c)(4); HCFA Ex. 1 at 10. Quality control is conducted on a known sample, of which the testing results would already be known. Tr. 67, 74. By performing quality control, a laboratory is able to check that its equipment is operating properly and, also, that its technologist is using the proper procedures. Tr. 67, 74.

Ms. Maurer stated that quality control in the area of hematology is to be performed for every eight hours of operation. Tr. 67. She alleged that Petitioner failed to perform quality control daily in hematology. Tr. 68; HCFA Ex. 8. Specifically, I find that Petitioner failed to run hematology quality control on four of 18 days in February 1995, when patients were tested. HCFA Ex. 8 at 1; HCFA Ex. 1 at 10.

Gonorrhea screenings

Other deficiencies identified by Ms. Maurer related to the gonorrhea screenings conducted by Petitioner. Under the regulations, a laboratory must have available a written procedure manual for all of the tests it performs. 42 C.F.R. 493.1211(a). Ms. Maurer testified that, initially, she was unaware that Petitioner was even doing gonorrhea screening because there was no indication in the procedure manual that these tests were being done. Tr. 61-63. 10/ Ms. Maurer testified:

You're to have written procedures for all testing that you do. . . . The technologist should use the procedures. The procedure should be available so people know what you are doing in the laboratory, and how you are doing it, and the correct way, and the equipment that you're using.

Tr. 75.

The lack of written procedures meant that Petitioner had no way of ensuring that gonorrhea screenings would be subject to proper and uniform protocols. By failing to document the gonorrhea screening procedures in its procedure manual, Petitioner violated the regulatory requirement stated above. In addition, the lack of culture media records indicated to the surveyor that Petitioner had failed to follow proper control procedures for the culture media used for gonorrhea screening, resulting in a deficiency under 42 C.F.R. 493.1218(f)(1). Petitioner also was found deficient in the area of specimen transportation, as evidenced by the absence of a tracking system for when Petitioner sent gonorrhea cultures to other labs.

Ms. Maurer discovered also that the temperature chart on Petitioner's incubator indicated that the last time the temperature was checked and recorded was in 1992. Tr. 63, 76. See HCFA Ex. 1 at 11. In addition, the thermometer on the incubator was broken, a fact that was not discovered by anyone until the time of the survey. Tr. 278.

The regulations mandate that a laboratory "perform equipment maintenance and function checks . . . necessary for the proper test performance and test result reporting of equipment, instruments and test systems". 42 C.F.R. 493.1215. Petitioner's failure to notice the broken thermometer on the incubator, coupled with its failure to keep the temperature chart up-to-date, could have jeopardized the accuracy and reliability of the gonorrhea screening results. 11/ Petitioner admitted that the incubator was in use despite having a broken thermometer and that results were reported on cultures. Such inadequate maintenance and poor oversight of crucial laboratory instrumentation serves to underscore Petitioner's laxness in management. 12/

I find that Petitioner's deficiencies with respect to its gonorrhea screenings cannot be considered to be minor. It is apparent from Petitioner's violations that the manner in which it conducted its gonorrhea screenings was grossly inadequate and a cause for alarm. A likelihood existed that these violations could have adversely impacted the quality and reliability of the tests performed by Petitioner.

V. Quality Assurance -- Standards

The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results. 42 C.F.R. 493.1703(f). Petitioner last reviewed charts for completeness of laboratory work documentation on April 3, 1992. Tr. 84-86; HCFA Ex. 1 at 18-19.

The evidence establishes that Petitioner did not have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence. 42 C.F.R. 493.1713; Tr. 89; HCFA Ex. 1 at 19.

VI. Laboratory Director -- Condition

Notice

Before I discuss Petitioner's non-compliance with the condition of participation for Laboratory Director set forth at 42 C.F.R. 493.1441, I will address the preliminary issue of whether HCFA gave Petitioner adequate notice that this deficiency constitutes an independent basis for revocation of its CLIA certificate.

Petitioner argues that HCFA's Notice was deficient in that it did not state that HCFA had imposed the sanction of revocation in connection with a violation of the Laboratory Director condition. P. R. Br. 6. Petitioner contends that "HCFA asserted for the first time at the hearing . . . that Petitioner failed to meet . . . 42 C.F.R. 493.1441 and that this failure was the basis for revocation of Petitioner's CLIA Certificate." Id. at 7.

I am not persuaded by Petitioner's assertion that it did not receive adequate notice that its violation of the Laboratory Director condition was a basis for revocation. HCFA's Notice, dated May 23, 1995, states:

> . . .[T]he supplemental information you submitted by letters dated May 16 and May 17, 1995, not only reconfirm that your laboratory (see 42 C.F.R. 493.2) did in fact intentionally refer its proficiency testing samples to another laboratory for analysis, but your admissions therein regarding your failure to meet your overall management responsibilities as the director also further evidence your contravention of the CLIA condition at 42 C.F.R. 493.1441 - a violation which independently supports the revocation of your CLIA certificate under the terms of 42 C.F.R. 493.1814(a)(2).

Based on the language contained in the May 23, 1995 letter from HCFA to Petitioner, I find that HCFA did

allege that Petitioner's non-compliance with respect to the Laboratory Director condition would be a basis for revocation. The contents of the letters establish to my satisfaction that HCFA provided Petitioner with adequate notice concerning this issue. I conclude that HCFA's Notice, dated May 23, 1995, provided Petitioner with adequate notice that violation of 42 C.F.R. 493.1441 would independently support revocation of Petitioner's CLIA certificate under 42 C.F.R. 493.1814(a)(2). HCFA Br. 21-22; HCFA R. Br. 8. While it appears that HCFA's Notice, dated May 23, 1995, focused on Petitioner's alleged intentional referral of its proficiency testing samples as a basis for the imposition of sanctions, it is apparent that HCFA also was premising the sanction of revocation on the alleged violation of the laboratory director condition. (See passage quoted above.)

The Notice sufficiently informed Petitioner that the alleged intentional referral of proficiency samples and the alleged violation of the laboratory director condition were each independent grounds for the sanction of revocation.

Deficiencies

The laboratory must have a director who . . . provides overall management and direction in accordance with 493.1445 of this subpart. 42 C.F.R. 493.1441.

I find that Petitioner's deficiencies in proficiency testing, quality control, and documentation (including procedure manual) establish that Petitioner failed to comply with the condition of participation for Laboratory Director set forth at 42 C.F.R. 493.1441. With respect to these alleged deficiencies, Ms. Maurer testified:

> When you find that the conditions have not been met in such things as proficiency testing, for example, or quality control, and it has not been done properly, then you have to cite your laboratory director for failure to perform, and failure to see that it is being performed. It's up to him to look at the laboratory and to check those things.

Tr. 79.

In addition, Ms. Maurer testified that there was no evidence of any documentation showing that Dr. Johnstone was monitoring the competency of the laboratory employees. Tr. 82-83. Ms. Maurer stated also that Dr. Johnstone failed to ensure that the laboratory procedure and policy manuals were up-to-date and complete. Tr. 83-84; HCFA Ex. 1 at 17. Another deficiency identified by Ms. Maurer was Dr. Johnstone's

failure to assign in writing the duties and responsibilities involved in all phases of the patient testing process for the testing personnel. Tr. 87-88; HCFA Ex. 1 at 18. Ms. Maurer discovered also that Petitioner last reviewed charts for completeness of laboratory work documentation on April 3, 1992. Tr. 84-86.

It is evident from the foregoing deficiencies, many of which were previously described by Ms. Maurer in conjunction with her testimony concerning Petitioner's non-compliance with the conditions listed at 42 C.F.R. 493.801 and 493.1101, that Dr. Johnstone failed to supervise adequately Petitioner's operations and employees. As laboratory director, Dr. Johnstone was responsible for the overall operation and administration of Petitioner in accordance with 42 C.F.R. 493.1445. Part of that responsibility is to ensure that quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 42 C.F.R. 493.1445(e)(5). See sections IV. and V. above. Dr. Johnstone had a duty to keep apprised of the day-to-day operation of his laboratory and to exercise proper supervision over his employees. He was obligated also to familiarize himself with the applicable CLIA regulations. With respect to proficiency testing, Dr. Johnstone had the ultimate responsibility for ensuring that proficiency testing was performed in accordance with the requirements set forth at 42 C.F.R. 493.801. HCFA Br. 30; HCFA R. Br. 9-11.

A primary objective of the CLIA requirements is to provide the public with safe and reliable laboratory services. Congress, in enacting CLIA, intended to assure that clinical laboratories perform medical tests accurately and reliably.

I conclude from the deficiencies that Dr. Johnstone failed to carry out his duties as Laboratory Director, in violation of the Condition for Laboratory Director set forth at 42 C.F.R. 493.1441. Dr. Johnstone's failure to ensure that the proficiency testing samples were tested as required, and his failure to have adequate quality control and patient test management programs, demonstrate his neglect of his responsibilities as a laboratory director.

Petitioner's failure to meet the Condition for Laboratory Director forms an independent basis for HCFA's revocation of Petitioner's CLIA certificate under 42 C.F.R. 493.1814(a)(2).

VII. HCFA Required to Revoke Petitioner's CLIA Certificate for a One-Year Period

Enforcement of CLIA is intended to protect individuals served by laboratories against substandard testing, to safeguard the public against health and safety hazards which might result from noncompliance, and to motivate laboratories to comply with CLIA requirements. 42 C.F.R. 493.1804(a)(1) - (3).

The evidence establishes that Petitioner was out of compliance with the Conditions of Participation set forth at 42 C.F.R. 493.801 [Enrollment and Testing of Samples], 493.1101 [Patient Test Management], and 493.1441 [Laboratory Director].

The CLIA statute and applicable regulations require HCFA to revoke a laboratory's CLIA certificate for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another laboratory for analysis. 42 U.S.C. 263a(i)(4); 42 C.F.R. 493.801(b)(4) and 42 C.F.R. 493.1840(b).

Neither I nor HCFA has the discretion to revoke Petitioner's CLIA certificate for less than the mandatory minimum period of one year, or to substitute any lesser sanction. HCFA is required to cancel a laboratory's approval to receive Medicare payment for its services where the laboratory's CLIA certificate is revoked. 42 C.F.R. 493.1808(a) and 493.1842(a)(1).

CONCLUSION

Petitioner intentionally referred its proficiency testing samples to another laboratory for analysis during 3rd quarter 1994. Accordingly, Petitioner's CLIA certificate must be revoked for a one-year minimum mandatory period, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

Further, Petitioner's failure to meet the Condition for Laboratory Director forms an independent basis for HCFA's revocation of Petitioner's CLIA certificate.

Jill S. Clifton

Administrative Law Judge

1. CLIA refers to the Clinical Laboratory Improvement Amendments, enacted in 1988 (42 U.S.C. 263a).

2. Medicaid payments for laboratory services are also affected (42 C.F.R. 493.1809).

3. Petitioner's opening brief [Petitioner's "Post-Hearing Brief"] is cited as "P. Br." Petitioner's "Supplemental Brief" is cited as "P. R. Br."

HCFA's opening brief [HCFA's "Posthearing Memorandum"] is cited as "HCFA Br." HCFA's "Posthearing Reply Memorandum" is cited as "HCFA R. Br." I cite to the transcript as "Tr." (page).

4. The remaining alleged deficiencies relate to the enrollment and testing of samples condition, 42 C.F.R. 493.801; patient test management condition, 42 C.F.R. 493.1101; and laboratory director condition, 42 C.F.R. 493.1441.

5. "Intermediate" civil sanctions, such as civil money penalties, are found in 42 U.S.C. 263a(h), and are alternative remedies to the "principal" civil sanctions of CLIA certificate suspension, revocation, or limitation, found in 42 U.S.C. 263a(i).

6. Revocation is a civil sanction.

7. The Act defines a clinical laboratory to be a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

42 U.S.C. 263a(a).

8. The inclusion by Congress of the word "intentionally" in the civil context may well be more significant in the case of "blind" proficiency testing, in which the laboratory technicians cannot tell the test samples from patients' specimens. [Patients' specimens of course may be referred to other laboratories.]

9. According to Ms. Maurer, the use of a hemacytometer to perform a platelet count is an appropriate and acceptable method. Tr. 115. Ms. Maurer testified further that platelet counting is very difficult and that using a Cell-Dyn 1600 to count platelets would give a more accurate count than a hemacytometer. Tr. 142-144.

10. Ms. Maurer stated further that, because Petitioner was conducting gonorrhea screenings, it was required to undergo proficiency testing in this area. Tr. 62, 64, 79-80. I will not discuss whether or not Petitioner was required to undergo proficiency testing with respect to gonorrhea screening since HCFA did

not cite this as a deficiency in the HCFA 2567.

11. Mr. Dohi testified that he could not recall if he ever saw a positive culture. However, he conceded that "it is a possibility" that the reason he may not have seen a positive culture might be due to the fact that organisms were being killed due to incorrect incubator temperature. Tr. 278-279.

12. Petitioner pointed out at the hearing that it replaced the broken incubator thermometer following the survey.

Ward General Practice Clinic, DAB **CR451** (1996)

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 ¾ P. Ex. 1; Enc # 2A ¾ P Ex. 2; Enc # 2B ¾ P. Ex. 3; Enc # 3 ¾ P. Ex. 4; Enc # 4 ¾ P. Ex. 5; Enc # 5 ¾ 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.

_____

Steven T. Kessel
Administrative Law Judge

California Medical Associates Laboratory, DAB **CR476** (1997)

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.

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;

(2) to safeguard the general public against health and safety hazards that might result from laboratory activities; and

(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.

_____
Stephen J. Ahlgren
Administrative Law Judge

* * * Footnotes * * *

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.

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.

Ward General Practice Clinic, DAB No. 1624 (1997)

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	)	DATE: July 24, 1997
Ward General Practice Clinic,	)	Docket No. C-96-443
	)	Decision No. 1624
Petitioner,	)	
- v. -	)	
Health Care Financing Administration	)	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Ward General Practice Clinic (Petitioner) appealed a December 27, 1996 decision by Administrative Law Judge (ALJ) Steven T. Kessel. See Ward General Practice Clinic, DAB **CR451** (1996) (ALJ Decision). The ALJ affirmed the Health Care Financing Administration's (HCFA's) determination to impose sanctions against Petitioner pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The ALJ determined that Petitioner's failure to comply with CLIA requirements posed immediate jeopardy to patients and that Petitioner had not corrected outstanding deficiencies. Consequently, Petitioner's CLIA certification was revoked.

On appeal, Petitioner alleged three general errors of law and fact arguing that it had submitted a satisfactory plan of correction, that HCFA had erred by not allowing it to perform lower level testing and, thereby, continue participation in Medicare and Medicaid and that the ALJ mistakenly relied upon Petitioner's purported history of noncompliance in reaching his decision.

The record in this case consists of the record before the ALJ and the parties' submissions in connection with Petitioner's appeal. Based on the analysis below, we uphold the ALJ Decision in its entirety.

Statute and Regulations

CLIA (section 353 of the Public Health Service Act; 42 U.S.C. § 263a)

establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and requires a federal certification scheme to be applied to all such laboratories. See 42 C.F.R. § 493.1800(a)(2). CLIA certification of a laboratory is dependent upon whether the laboratory meets the conditions of coverage set out at 42 U.S.C. § 263a(f)(1)(E) and 42 C.F.R. §§ 493.1 et seq., in addition to other CLIA requirements. Each "condition," as set forth in the statute and regulations, represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. A laboratory's failure to comply with even a single condition represents a serious breakdown in one of the major health care delivery or safety systems of the laboratory, all of which are critical to ensuring the provision of acceptable health care services and essential for purposes of the laboratory's operations. See definitions of Certificate of compliance and Condition level deficiency at 42 C.F.R. § 493.2.

The CLIA statute and implementing regulations grant the Secretary broad enforcement authority to ensure that laboratories remain in compliance with CLIA requirements throughout the period of their CLIA certification. This enforcement authority includes the use of principal sanctions affecting the laboratory's ongoing operations (suspension, limitation, or revocation of the CLIA certificate) where the laboratory is out of compliance with one or more conditions of certification. Indeed, the CLIA statute expressly provides that the Secretary may suspend or limit the CLIA certificate prior to a hearing in some situations, and provides that an opportunity for a hearing in that instance must be provided on an expedited basis. 42 U.S.C. § 263a(i)(2). The legislative history discusses the purpose for pre-hearing sanctions as follows:

> The Committee included this prehearing exclusion to allow the Secretary the opportunity to respond promptly to situations in which a laboratory's failure to comply may sacrifice the integrity of test results. Where this occurs or where a laboratory's interference with the Secretary's ability to make a determination about laboratory quality occurs, it is imperative that the Secretary have the authority either to force prompt compliance or to move quickly to protect the public health. The Committee has been informed that, under current law, lengthy court proceedings and appeals may interfere with the Secretary's ability to stop a laboratory from operating irrespective of the seriousness of the violations. The bill's requirement of a prompt opportunity for a hearing is designed to limit the potential adverse effects on a laboratory of such a pre-hearing determination by the Secretary and to allow a timely airing of the issues.

H.R. Rep. No. 899, 100th Cong., 2nd Sess. 35 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3856.

The enforcement authority also includes the use of alternative sanctions, which include a directed plan of correction, state on-site monitoring, and civil money penalties. With respect to a directed plan of correction, the legislative history noted that:

> [A] directed plan of correction would be particularly appropriate

where a laboratory is out of compliance . . ., but where imposition of such a sanction in lieu of revocation, suspension or limitation would not place the health of patients in jeopardy.

Id. at 3854.

Moreover, the preamble to the final regulations states that alternative sanctions "offer laboratories the opportunity to come into compliance within a specified period of time instead of immediately having their CLIA certificates suspended, limited, or revoked, or their Medicare approval canceled." 57 Fed. Reg. 7223 (Feb. 28, 1992) (emphasis added).

The enforcement scheme in the regulations at 42 C.F.R. Part 493, Subpart R, affords HCFA broad discretion in selecting the appropriate sanction to meet particular deficiencies identified in surveys of the operations of the laboratories. Perhaps foremost among the factors HCFA must consider is whether the deficiencies pose an "immediate jeopardy." 1/ When a laboratory's deficiencies have been found to pose an immediate jeopardy, the enforcement scheme contemplates that HCFA will require the laboratory to take immediate action to remove the jeopardy. 42 C.F.R. § 493.1812. 2/ Further, the regulations specifically provide that the determination by HCFA that a laboratory's deficiencies pose immediate jeopardy is solely within HCFA's discretion and is not subject to further review. 42 C.F.R. § 493.1844(c)(6).

In order to fulfill its statutory obligation to ensure that clinical laboratories remain in compliance with CLIA requirements, HCFA contracts with state health departments to conduct on-site surveys of the laboratories to determine whether federal requirements are met. State surveyors conduct federal surveys of laboratories pursuant to the detailed rules in 42 C.F.R. Part 488 entitled "Survey and Certification Procedures." These regulations recognize that "surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance." 42 C.F.R. § 488.26(b)(3).

The preamble to the final regulations describes the respective roles of the state surveyors and HCFA:

> The surveyors . . . are laboratory professionals. They are trained extensively by both HCFA and their respective States in proper inspection techniques under CLIA. They use their professional judgment and expertise in making recommendations. . . . The surveyors' recommendations are reviewed by the supervisory staff of the State agency or other HCFA agents, and are further reviewed by the HCFA Regional Office (RO). The RO makes the final determination of compliance or noncompliance and imposes the sanction(s) that would in the opinion of the RO, most likely precipitate correction.

57 Fed. Reg. 7224 (Feb. 28, 1992).

BACKGROUND

The following facts are undisputed. Petitioner is a clinical laboratory in New Orleans, Louisiana. On July 18, 1996, the Louisiana Department of Health and Hospitals subjected Petitioner to a CLIA recertification survey. The survey found that Petitioner no longer met the requirements to perform testing
under CLIA due to deficiencies that represented immediate jeopardy to Petitioner's patients. ALJ Decision at 5; HCFA Exhibit (Ex.) 2, at 1.

On July 29, 1996, HCFA notified Petitioner of its concurrence with the survey findings. HCFA found the following conditions out of compliance:

Enrollment and Testing of Samples (42 C.F.R. § 493.801)

General Quality Control; Moderate Complexity or High Complexity Testing, or any combination of these Tests (42 C.F.R. § 493.1201)

Bacteriology (42 C.F.R. § 493.1227)

Routine Chemistry (42 C.F.R. § 493.1245)

Endocrinology (42 C.F.R. § 493.1247)

Urinalysis (42 C.F.R. § 493.1251)

Laboratories Performing Moderate Complexity Testing; Laboratory Director (42 C.F.R. § 493.1403)

Laboratories Performing High Complexity Testing; Laboratory Director (42 C.F.R. § 493.1441) and

Quality Assurance; Moderate Complexity or High Complexity Testing, or any combination of these Tests (42 C.F.R. § 493.1701).

HCFA Ex. 2, at 1.

Consequently, HCFA decided to --

(1) suspend Petitioner's CLIA certificate (effective August 10, 1996) pursuant to 42 C.F.R. § 493.1840(d)(2)(i);

(2) propose revocation of Petitioner's CLIA certificate pending a decision from an Administrative Law Judge, if an appeal is filed, as provided by 42 C.F.R. § 493.1840(e)(1); and

(3) cancel Petitioner's approval to receive Medicare payments for laboratory services, effective August 10.

HCFA Ex. 2, at 1.

HCFA notified Petitioner that failure to meet a condition of participation precluded a laboratory's participation under CLIA. HCFA indicated that if Petitioner submitted a plan of correction alleging credibly that it was complying with the CLIA requirements, Petitioner would be resurveyed. If the resurvey supported Petitioner's allegations of compliance, no sanctions would be imposed. Id. at 3.

Petitioner timely submitted a plan of correction to HCFA in which it alleged compliance with CLIA as of July 24, 1996. See HCFA Ex. 3. There, Petitioner admitted that it had not been complying with CLIA requirements, but declared that as of July 24 it was conducting only waived procedures and physician performed testing. 3/ Id.

On August 8, 1996, HCFA informed Petitioner that its plan of correction did not rectify the deficiencies identified in the recertification survey. HCFA noted that CLIA contained no provisions permitting a laboratory to perform only waived tests and PPM procedures in order to avoid the imposition of sanctions associated with a failure to comply with CLIA requirements. Consequently, HCFA stated its intention to impose the penalties described in its July 29 letter to Petitioner. See HCFA Ex. 4; see also HCFA Ex. 2. Petitioner timely appealed HCFA's sanctions to an ALJ.

The ALJ Decision upholding HCFA's sanctions is based on the following findings
of fact and conclusions of law (FFCLs):

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 imposition of 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.

ALJ Decision at 2-4.

Petitioner filed three exceptions to the ALJ Decision alleging generally that --

1. [The ALJ Decision at page 6 states] . . . the plan of correction does not explain how Dr. Ward [the laboratory Director] intended to correct the deficiencies that were identified . . . Agreeing not to do the failed procedures, and move to a lesser certificate, would certainly prevent doing procedures improperly in the future. . . [T]his is a combined error of fact and of law . . . .

2. [FFCL 6 contains] . . . a serious error of law . . . [by finding that it] . . . "is a matter of discretion whether a laboratory that has been found not to be complying with a clear [sic] 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." It is respectfully submitted that the handbook provided by the Dallas regional office, dated [M]arch, 1995 must be construed to . . . [allow] such voluntary withdrawal. . . .

3. The ALJ makes an error in relying upon a purported history of noncompliance to justify his decision. It is submitted that if a history is to be included, then the entire history of the Ward General Practice Clinics, under both certificates must be considered.

Petitioner's Brief (Br.) at 2-3.

ANALYSIS

The standard of review on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the record. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous.

As explained below, Petitioner's exceptions are without merit.

Plan of Correction Exception

Petitioner asserted that its proposal to discontinue the procedures cited as deficient in the survey comprised a more than adequate plan of correction. Petitioner noted that the tests to be performed under the plan of correction were low level and that the individual involved in the deficient procedures had been removed from the testing procedure. The low level tests would now be performed by Dr. Ward. Generally, Petitioner argued that this approach represented a reasonable business decision to downgrade the laboratory's certification rather than incurring whatever expenses might be associated with upgrading the laboratory to meet the standards for high level procedures. Petitioner's Br. at 3-4.

The ALJ addressed this argument in his decision. He reasoned that the fact that Petitioner converted the laboratory to waived tests and PPM procedures --

does not address the specific deficiencies identified by HCFA. . . I do not find that Petitioner corrected its deficiencies simply by ceasing to perform certain tests and procedures. The deficiencies . . . 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. . . Petitioner offers no assurance that it has corrected these pervasive and systematic failures merely by ceasing to perform certain tests.

ALJ Decision at 7-8.

Petitioner failed to provide any cogent basis for concluding that this analysis is erroneous. As the ALJ noted, Petitioner did not deny that the deficiencies cited in the recertification survey posed immediate jeopardy to patients. See ALJ Decision at 7. Moreover, Petitioner did not dispute the ALJ's finding that some of the deficiencies involved quality control procedures which affected laboratory's overall operation. These deficiencies would compromise Petitioner's ability to perform even the lower level tests. They could not be corrected by Petitioner's merely ceasing to perform higher level procedures that were also found to have deficiencies. This does not mean that Petitioner was not free to cease performing high level procedures. However, Petitioner clearly had to do something more to remove the inherent danger to patients posed by the deficiencies which affected its overall operation. 4/
Furthermore, Petitioner's argument ignores the fact that deficiencies were found in the PPM procedures. See ALJ Decision at 3 and 9. 5/ Thus, Petitioner's plan of correction was clearly unacceptable to the extent that it
proposed that Petitioner would continue performing PPM procedures.

Discretion as to Voluntary Withdrawal

Petitioner disputed FFCL 6, which states that 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.

Petitioner suggested that since the ALJ determined that the regulations were silent "as to whether a laboratory . . . 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 . . . ." (ALJ Decision at 5), the ALJ should have concluded that there was no bar to Petitioner converting its operations. Petitioner also argued that 42 C.F.R. § 493.807 and the CLIA Handbook (Petitioner Exhibit 5, at 3-4) 6/ specifically authorized it to cease performing high level tests in order to avoid HCFA's sanctions. Petitioner asserted that, since the sanctions imposed as a result of the CLIA deficiencies are punitive in nature, due process and equal protection require that the applicable regulations be construed so as to provide Petitioner the benefit of the doubt. 7/ Petitioner finally asserted that, at the very least, it should be afforded an opportunity "to undergo a second examination, or present a new plan of correction." Petitioner Br. at 4-6.

Petitioner's reliance on the regulation at 42 C.F.R. § 493.807(a) is misplaced. In pertinent part, the regulation indicates that a laboratory which --

> voluntarily withdraws its certification under CLIA . . . must . . . demonstrate sustained satisfactory performance on two consecutive proficiency testing

events . . . before HCFA will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test.

42 C.F.R. § 493.807(a) (emphasis added).

This regulation does nothing to limit HCFA's discretion. While the regulation appears to permit a laboratory to freely withdraw its certification to perform one or more tests, the regulation gives HCFA full discretion in determining whether the laboratory may be reinstated. Moreover, the regulation does not even suggest that by withdrawing its certification as to some tests, a laboratory may avoid sanctions for deficiencies which affect the overall safety of its testing program.

Further, the CLIA Handbook sections submitted by Petitioner provide nothing more than a general outline of the steps to be taken by a laboratory seeking reinstatement under CLIA. Effectively, they lay out the process described in 42 C.F.R. § 493.807 in simpler terms. Certainly, the Handbook does not commit HCFA to the particular course of action suggested by Petitioner.

Contrary to what Petitioner suggested, this is not a case of interpretation of an ambiguous regulation. The ALJ correctly concluded that the statute and regulations clearly authorize HCFA, in its discretion, to impose sanctions based on the findings it made here. As discussed above, Congress specifically granted HCFA wide-ranging enforcement powers in this area due to the potential threat to public welfare posed by laboratories failing to meet the standards set out in CLIA. See Center Clinical Laboratory, DAB No. 1526 (1995). These enforcement powers are available to HCFA in the face of a laboratory's failure to meet even a single condition. Id. at 4. Moreover, the sanctions Congress authorized are not punitive, but have different purposes. See 45 C.F.R. § 493.1804(a).

Finally, there is neither a statutory nor regulatory basis for Petitioner's suggestion that it be given another examination or chance to submit a new plan of correction. HCFA certainly cannot be found to have abused its discretion simply because it is unwilling to provide an opportunity for correction not provided for by law. Moreover, in view of HCFA's finding of immediate jeopardy, HCFA might reasonably have concluded that it was inadvisable for it to offer an additional opportunity for correction.

Alleged History of Noncompliance

The ALJ found that Petitioner had a history of noncompliance (FFCL 10). The ALJ then found reasonable HCFA's decision to deny approval to Petitioner to convert its operations to a lower level of testing, in lieu of imposition of 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 (FFCL 12).

Petitioner argued that the ALJ erred in relying on Petitioner's history of noncompliance. Petitioner did not dispute that if it had a history of noncompliance, that history would be relevant in determining whether sanctions were properly imposed. However, Petitioner asserted that there was "no real history of noncompliance by Ward General Practice Clinics." Petitioner alleged that it has held "two certificates for some time" and that the second of these certificates has been unchallenged and provides proof of Petitioner's ability to maintain the standards necessary for participation in Medicare and Medicaid. Petitioner Br. at 6.

Petitioner's argument has no merit. The ALJ's determination that Petitioner had a history of failing to comply with CLIA requirements was based on an unchallenged affidavit by the HCFA Region VI, Chief, Survey and Certification Review Branch. ALJ Decision at 8. The affiant stated:

> Two years ago [1994], the laboratory was found out of compliance with CLIA regulations. Because this was a physician office laboratory and the staff was not familiar with CLIA regulations, the state surveyor worked with the laboratory to help it achieve compliance. However, the laboratory did not maintain the compliance, instead the non-compliance escalated to an immediate jeopardy level.

HCFA Ex. 5, at Par. 9.

Petitioner pointed to nothing in the record before the ALJ, nor did it submit any additional evidence, which would refute this statement. Instead, Petitioner made vague references to satisfactory surveys in connection with its other license. However, even if there were no compliance-related issues surrounding Petitioner's other license, this does not obviate the fact that Petitioner had a history of noncompliance in terms of its operation of the laboratory in question here, which was directly relevant to HCFA's decision to deny approval for converting the laboratory's operation to a lower level of testing.

CONCLUSION

Based on the foregoing analysis, we sustain the ALJ Decision in its entirety. We affirm and adopt each of the FFCLs in the ALJ Decision.

_____
Judith A. Ballard

_____
M. Terry Johnson

_____
Donald F. Garrett
Presiding Board Member

* * * Footnotes * * *

1. "Immediate jeopardy" is defined in the regulations as:

> [A] situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public.

42 C.F.R. § 493.2.

2. Concerning sanctions in an immediate jeopardy situation the preamble to the final regulations states:

> If the deficiencies are determined to pose immediate jeopardy to the health and safety of individuals served by the laboratory . . ., the sanctions imposed will, of necessity, be more severe than those used in situations which are less threatening, and will consist of at least one principal sanction. When there is not immediate jeopardy, alternative sanctions rather than principal sanctions would be imposed first, thus allowing the laboratory a longer period of time to come into compliance.

57 Fed. Reg. 7224 (Feb. 28, 1992).

3. Petitioner's plan of correction did not explain the terms "waived procedures" and "physician performed testing." Consequently, the ALJ determined that Petitioner used these terms referring to "waived tests" and "provider-performed microscopy (PPM) procedures." CLIA regulations define waived tests as simple laboratory examinations and procedures, cleared by the Food and Drug Administration for home use, employing methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible and posing no reasonable risk of harm to a patient if performed incorrectly. 42 C.F.R. § 493.15. PPM procedures are tests of moderate complexity (42 C.F.R. § 493.5(a)(2)) involving a test performed personally by a physician, midlevel practitioner or dentist on a specimen obtained during a patient's visit. 42 C.F.R. § 493.19(b)(1) i-iii. ALJ Decision at 6. Examining the nature of PPM procedures as set out

in the regulations, the ALJ found that they were more than simple risk free tests. Rather, there existed a potential for harm to patients if the tests were not performed correctly. Moreover, the ALJ also recognized that Petitioner was found deficient in performing tests of moderate complexity. Id. at 6-7, 9.

4. The individual performing the deficient procedures was Dr. Ward's wife. HCFA Ex. 6, at Par. 3. However, Petitioner did not allege that Dr. Ward was unaware of these deficient procedures prior to the CLIA survey. Since he at least tacitly condoned the deficiencies, there is no assurance that the deficiencies would be corrected simply by his personally performing all the tests.

5. As HCFA noted in its brief, laboratories eligible to perform PPM examinations must meet "the applicable requirements in subpart C or subpart D, and Subparts F, H, J, K, and M and P" of Part 493. 42 C.F.R. § 493.19(e)(1); HCFA Br. at 3. The deficient conditions of participation relied on by HCFA and cited by the ALJ in FFCL 7 are found in 42 C.F.R. Part 493, Subparts H (§ 493.801), K (§§ 493.1201, 493.1227, 493.1245, 493.1247 and 493.1251), M (§§ 493.1403 and 493.1441) and P (§ 493.1701).

6. These two pages of the CLIA Handbook constituted pages 3 and 4 of Petitioner's Exhibit 5 before the ALJ. On appeal of the ALJ Decision, Petitioner resubmitted those pages as its Appeal Exhibits 1 and 2. We refer to these documents as identified by the ALJ.

7. Petitioner also protested the complete closure of its laboratory as violative of its inherent right to function outside the Medicare and Medicaid programs and interstate commerce. The legislative history of the CLIA Amendments demonstrates why the Amendments removed the prior exemption for laboratories that do not send specimens across State lines. Congress considered these laboratories "among the poorest performing . . . in the nation" and "a serious threat" to public health. For that reason "and because these laboratories purchase goods and services from entities outside their home states, . . . such laboratories necessarily affect interstate commerce." H.R. Rep. No. 899, 100th Cong., 2nd Sess., 13-14 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3834-35. Since we conclude that the CLIA statute and regulations clearly authorize closure of the laboratory under the conditions present here, Petitioner's assertions that the applicable legal provisions may be constitutionally void are beyond the scope of this Board's review.

Williams BioMedical Laboratory, DAB **CR487** (1997)

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Williams Bio Medical Laboratory,	)	Date: August 5, 1997
	)	
Petitioner,	)	
	)	
-v.-	)	Docket No. C-96-101
	)	Decision No. **CR487**
Health Care Financing Administration.	)	
	)	

DECISION

This case arises under the Clinical Laboratory Improvement Amendments of 1988 (referred to as "CLIA" or "the Act"), 42 U.S.C. § 263a and on implementing regulations in 42 C.F.R. Part 493. On November 28, 1995, the Health Care Financing Administration (HCFA) notified Williams Bio Medical Laboratory (WBML or Petitioner) that, based on a survey completed on October 26, 1995, deficiencies had been found in Petitioner's facility which remained uncorrected 12 months after having been identified originally in surveys dated August 4, 1994 and November 2, 1995. HCFA notified Petitioner also that it had failed to comply with an August 24, 1995 Directed Plan of Correction, which had required correction of all deficiencies by September 29, 1995. As a result, HCFA informed Petitioner that it had decided to revoke Petitioner's CLIA certificate and cancel all Medicare payments for services furnished by Petitioner. By letter dated December 2, 1995, Petitioner timely requested a hearing. 1/

This case was assigned initially to Administrative Law Judge Mimi Hwang Leahy. In a Ruling dated August 20, 1996, Judge Leahy granted partial summary judgment, based on HCFA's motion for summary judgment. Judge Leahy ruled that only two issues remained for hearing: (1) whether Petitioner had deficiencies that remained uncorrected over 12 months following the survey of August 4, 1994; and (2) whether Petitioner had failed to comply with the terms of the Directed Plan of Correction requiring that all deficiencies (whether condition-level or standard-level) be corrected by September 29, 1995. Specifically,

Judge Leahy ruled that, under the first issue, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that Petitioner failed to correct all standard-level and condition-level deficiencies from the August 4, 1994 survey. 42 C.F.R. §§ 493.1816(b), 493.1820, 498.1828(b)(2). Judge Leahy further ruled that, under the second issue, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that by September 29, 1995, Petitioner had even one standard-level deficiency that remained uncorrected from either of the two prior surveys. If HCFA prevails on either one of these two issues, then HCFA is entitled to prevail as a matter of law on its imposition of the sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), and 493.1842(a). Finally, Judge Leahy ruled that Petitioner must prevail on both issues for the sanctions imposed by HCFA, in the notice of November 28, 1995, to be set aside. Id.

On September 26, 1996, this case was reassigned to me. I scheduled a hearing to commence on February 11, 1997, solely on the issues remaining after Judge Leahy's ruling of August 20, 1996. However, on February 7, 1997, in a telephone prehearing conference, Petitioner withdrew its request for an in-person hearing, and requested instead that the case be heard based on an exchange of documentary evidence and briefs. After consideration, HCFA agreed to submit its case on briefs and documentary evidence, including declarations. 2/

I have considered the relevant evidence, the applicable law and the parties' arguments. Any argument or issue raised by the parties that is not specifically addressed in this decision I have rejected as either lacking in merit or irrelevant. I conclude that Petitioner has failed to prevail on either issue identified above. 3/ I conclude further that HCFA's determination to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare reimbursement for its services is authorized by CLIA and implementing regulations.

GOVERNING LAW

Congress enacted CLIA in order to guarantee that clinical laboratories perform medical tests accurately. CLIA was intended by Congress to establish a single set of standards which govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. See H.R. Rep. No. 899, 100th Cong., 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N. 3828-3836 (House Report).

CLIA authorizes the Secretary of the United States Department of Health and Human Services (Secretary) to

inspect clinical laboratories. The Act directs the Secretary to establish standards to assure that clinical laboratories certified by the Secretary perform tests that are valid and accurate. 42 U.S.C. § 263a(f)(1). Before a clinical laboratory can accept or solicit specimens, a clinical laboratory must first receive a certificate from the Secretary authorizing it to perform the specific category of tests which the laboratory intends to perform. 42 U.S.C. § 263a(b).

The Act provides for revocation of a CLIA certificate under specified circumstances. These include, among others things, failure of the laboratory's owner or operator to comply with standards issued by the Secretary, or failure by an owner or operator to abide by an intermediate sanction issued by the Secretary. 42 U.S.C. § 263a.

In addition to standards established by the Act, regulations are issued by the Secretary pursuant to CLIA that establish standards for certification, provide a framework for inspections, and provide for the imposition of sanctions in the event that laboratories fail to comply with the applicable standards.

Regulations provide for an enforcement process to assure that clinical laboratories comply with the requirements of CLIA and applicable regulations. Enforcement is intended to protect individuals served by laboratories against substandard testing, to safeguard the public against health and safety hazards which might result from noncompliance, and to motivate laboratories to comply with the CLIA requirements. 42 C.F.R. § 493.1804(a)(1)-(3).

Principal sanctions consist of remedies which HFCA may impose for any of the reasons set forth in section 263a(i)(1) of the Act. 42 C.F.R. § 493.1840(a). HCFA may impose principal sanctions where a laboratory has not complied with applicable standards or where the laboratory has not complied with an alternative sanction. 42 C.F.R. § 493.1840(a)(3), (7). Principal sanctions may include revocation of a laboratory's CLIA certificate and cancellation of its approval to receive Medicare payments for its services. 42 C.F.R. §§ 493.1806, 493.1807, 493.1840(a), 493.1842.

BURDEN OF PROOF

By notice letter of March 26, 1997, I afforded the parties the opportunity to file a supplemental brief addressing what effect, if any, the decision in the case of Hillman Rehabilitation Center, DAB 1611 (1997) might have on this case. Neither party availed itself of the opportunity. In Hillman, an appellate panel of the Departmental Appeals Board held that HCFA has an initial obligation to set forth the basis for its determinations

with sufficient specificity to allow the petitioner to respond (the obligation to make a prima facie case). To prevail, a petitioner must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with relevant statutory and regulatory provisions. Thus, under Hillman, the petitioner, not HCFA, bears the ultimate burden of persuasion. This case is governed by the burden of proof set forth in Hillman.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Judge Leahy's Ruling of August 20, 1996 sets forth 33 Findings of Fact and Conclusions of Law (FFCL). These are set out below. The rest of the FFCL pertain to the October 26, 1995 revisit survey and to the resultant November 28, 1995 notice letter issued by HCFA.

1. Pursuant to a CLIA survey conducted on August 3 and 4, 1994 by the California Department of Health Services (State agency), Petitioner was found to have various standard-level deficiencies as well as the following seven condition-level deficiencies:

a. Enrollment and testing (proficiency testing) samples (42 C.F.R. § 493.801);

b. Bacteriology (42 C.F.R. § 493.1227);

c. Laboratories performing high complexity testing; laboratory director (42 C.F.R. § 493.1441);

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

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

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

g. General quality control; moderate or high complexity testing, or both (42 C.F.R. § 493.1201).

HCFA Br. at 2-3; HCFA Ex. 1.

2. In response to the deficiencies found during the survey which was completed on August 4, 1994, Petitioner submitted a plan of correction which was found acceptable by HCFA's agent (the State agency), and a revisit survey was conducted. HCFA Ex. 3 at 1; HCFA Ex. 4 at 1.

3. The results of the revisit survey conducted on November 2, 1994, showed that Petitioner had five of the same condition-level deficiencies (FFCLs 1a to e) as noted during the August 1994 survey. HCFA Ex. 2, 4.

4. After having provided Petitioner with the opportunity to submit additional information or comments concerning the possible imposition of sanctions (HCFA Ex. 3, 4), HCFA notified Petitioner by letter dated August 24, 1995, that the following alternative sanctions were being imposed and that Petitioner had a right to appeal HCFA's determinations:

a. state on-site monitoring (42 C.F.R. § 493.1836);

b. a directed plan of correction (42 C.F.R. § 493.1832) to correct all designated deficiencies by September 29, 1995; and

c. the suspension of all Medicare and Medicaid (Social Security Act, § 1902(a)(9)(C); 42 C.F.R. § 440.30(c), 440.2(b)) payments for laboratory services (42 C.F.R. § 493.1828) effective September 8, 1995.

HCFA Ex. 5.

5. The directed plan of correction stated: "EXPECTED DATE OF CORRECTION FOR ALL DEFICIENCIES: On, or before September 29, 1995." HCFA Ex. 2 at 3.

6. Petitioner received HCFA's notice imposing the alternative sanctions and was aware that all deficiencies should be corrected by September 29, 1995. P. Br. at 2.

7. Petitioner did not request a hearing to contest the results of the above-mentioned August and November 1994 surveys, or to contest HCFA's imposition of alternative sanctions pursuant to those survey results. P. Br. at 2.

8. Petitioner verified that Medicare and Medicaid payments had stopped on September 8, 1995. P. Br. at 3.

9. Subsequent to the imposition of the alternative sanctions and prior to October of 1995, Petitioner changed its location and telephone number without providing HCFA with advance notice. Declaration of Franklin Barnes (HCFA Ex. 14); Petitioner's declaration "Reference to Franklin R. Barnes Declaration."

10. After ascertaining Petitioner's new address, HCFA conducted a scheduled revisit survey on October 26, 1995, and found that 21 standard-level deficiencies still remained uncorrected from the prior two surveys. HCFA Ex. 7.

11. Petitioner was closed in November and has remained

closed since then. P. Br. at 3.

12. Based on the October 26, 1995 survey, HCFA notified Petitioner by letter dated November 28, 1995 that, as a result of the deficiencies which remained uncorrected over the 12 months since the August 4, 1994 survey, as well as Petitioner's failure to comply with the terms of the Directed Plan of Correction requiring the correction of all deficiencies by September 29, 1995, HCFA was imposing the following principal sanctions:

a. revocation of Petitioner's CLIA certificate, effective 60 days after receipt of the notice letter unless a hearing is requested; and

b. cancellation of all Medicare payments for services furnished by the laboratory 15 days from Petitioner's receipt of the notice letter, in accordance with 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), and 493.1842(a).

HCFA Ex. 8.

13. Cancellation of Medicare payments under 42 C.F.R. § 493.1842 may be imposed before a hearing, and it terminates any Medicare payment sanctions, regardless of the original time frames. 42 C.F.R. § 493.1842(b), (c).

14. If a hearing is requested, the revocation of a CLIA certificate does not take effect unless and until there is a decision by an administrative law judge which upholds HCFA's revocation determination. 42 C.F.R. § 493.1840(e).

15. By letter dated December 2, 1995, Petitioner timely requested a hearing to contest the results of the October 26, 1995 survey.

16. By letters dated January 16, 1996 (HCFA Ex. 10) and March 15, 1996 (HCFA Ex. 11), HCFA notified Petitioner that it owed outstanding CLIA fees in the amount of $2549 and that Petitioner had a right to appeal the determination of outstanding fees and the imposition of the following sanctions for the nonpayment of CLIA fees:

a. revocation of Petitioner's CLIA certificate effective March 21, 1996, if a request for hearing was not received; and

b. cancellation of Medicare payments to Petitioner within 15 days of receiving the notice dated January 16, 1996.

HCFA Ex. 10, 11.

17. By letter dated March 28, 1996, HCFA informed Petitioner that, since HCFA had not received the outstanding fee payment or any request for hearing, Petitioner's CLIA certificate was revoked as of March 21, 1996 for the nonpayment of CLIA fees, which is an independent and separate basis from the reasons stated for revoking Petitioner's CLIA certificate in HCFA's notice of November 28, 1995. HCFA Ex. 13, 8.

18. The reasons provided by HCFA in its January 16, 1996 letter for imposing the sanctions of revocation of Petitioner's CLIA certificate and cancellation of all Medicare payments to Petitioner are separate and distinct from those HCFA set forth in its November 28, 1995 notice imposing the same sanctions against Petitioner. HCFA Ex. 13, 8.

19. Petitioner acknowledges that it had not paid the CLIA fees and that it has no basis for appealing the revocation of its CLIA certificate for that reason. P. Br. at 2-4.

20. Unappealed determinations are binding upon Petitioner and cannot be set aside in this proceeding. See, e.g., 42 C.F.R. § 498.20(b).

21. Petitioner may not dispute HCFA's findings of deficiencies from the survey which was completed on August 4, 1994. FFCL 7, 20.

22. Petitioner may not dispute HCFA's findings of deficiencies from the survey of November 2, 1994. FFCL 7, 20.

23. Petitioner may not dispute any of the sanctions HCFA imposed by notice dated August 24, 1995, which resulted from the surveys of August 3 and 4, 1994 and November 2, 1994. FFCL 7, 20.

24. The alternative sanction of a directed plan of correction, imposed by notice of August 24, 1995, and containing HCFA's directive for Petitioner to correct all deficiencies by September 29, 1995, did not give specific instructions on how Petitioner must make the corrections. HCFA Ex. 2.

25. Petitioner may not dispute HCFA's determination that it failed to pay its CLIA fees. FFCL 19, 20.

26. Petitioner may not dispute the sanctions HCFA imposed based on Petitioner's nonpayment of CLIA fees. FFCL 19, 20.

27. The only issues for hearing are whether, as determined by HCFA on the basis of the October 26, 1995 revisit survey;

a. Petitioner had deficiencies which remained uncorrected over the 12 months following the survey which was completed on August 4, 1994, and

b. Petitioner failed to comply with the terms of the Directed Plan of Correction requiring the correction of all deficiencies (whether condition-level or standard-level) by September 29, 1995.

FFCL 4, 7, 12, 17.

28. Under the issue identified in FFCL 27a, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that Petitioner had failed to correct all standard-level and condition-level deficiencies from the August 4, 1994 survey. 42 C.F.R. §§ 493.1816(b), 493.1820, 498.1828(b)(2).

29. Under the issue identified in FFCL 27b, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that, by September 29, 1995, Petitioner had even one standard-level deficiency which remained uncorrected from either of the two prior surveys. FFCL 5, 6, 20.

30. If relevant to either party's position on the issue identified in FFCL 27b, either party may submit evidence to prove whether Petitioner was closed for any period of time up to and including September 29, 1995.

31. The effective dates specified by HCFA in its November 28, 1995 notice for the imposition of sanctions are in accord with the requirements of the regulations. 42 C.F.R. §§ 493.1842(b), 493.1844(h)(2), 493.1844(d)(2).

32. If HCFA prevails on either one of the two issues identified above in FFCL 27, HCFA is entitled to prevail also as a matter of law on its imposition of the sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), and 493.1842(a).

33. Petitioner must prevail on both issues identified above in FFCL 27 in order to have me set aside the sanctions imposed by HCFA in the notice letter dated November 28, 1995 (revocation of Petitioner's CLIA certificate and cancellation of Medicare payments to Petitioner). Id.

34. By confirming letter dated October 10, 1995, HCFA notified Petitioner that an onsite CLIA revisit survey would be performed on October 26, 1995. HFCA Ex. 6.

35. On October 26, 1995, a second revisit survey was conducted by the State agency. HCFA Ex. 14, at 5, para. 17.

36. The purpose of this second revisit survey was to verify whether Petitioner had corrected all deficiencies identified in the surveys of August 4, 1994 and November 2, 1994, as required by the August 24, 1995 Directed Plan of Correction. HCFA Ex. 6.

The August 24, 1995 Directed Plan of Correction required that all deficiencies be corrected by September 29, 1995. HCFA Ex. 5.

37. The State agency found that numerous standard-level deficiencies identified during the prior surveys remained uncorrected, contrary to the terms of the August 24, 1995 Directed Plan of Correction. HFCA Ex. 14, at 5-6, para. 17.

38. As a result of the second revisit survey of October 26, 1995, HCFA now alleges that eight standard-level deficiencies remained uncorrected over 12 months following the August 4, 1994 survey. HCFA Ex. 7, 14, 15, 16, 17.

39. The 13 remaining deficiencies identified during the October 26, 1995 revisit survey, were later determined to be corrected, because HCFA subsequently verified that the laboratory was enrolled in a proficiency testing program at the time of the survey. HCFA Ex. 15, at 5-6, para. 10; HCFA Br. 2, at 13.

40. Petitioner failed to comply with 42 C.F.R. § 493.1103(a), which governs specimen submission and handling, by the second revisit survey on October 26, 1995.

41. Petitioner failed to comply with 42 C.F.R. § 493.1407(e)(5), which governs the responsibilities of the laboratory director to ensure that quality control and assurance programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur, by the second revisit survey on October 26, 1995.

42. Petitioner failed to comply with 42 C.F.R. § 493.1711, which governs quality assurance for moderate or high complexity testing for quality assurance and requires the laboratory to have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria, such as the relationship with other test parameters, when available within the laboratory, by the second revisit survey on October 26, 1995.

43. At the time of the revisit survey of October 26, 1995, eight standard-level deficiencies remained uncorrected over 12 months following the survey of August 4, 1994, as cited under D tags 3013, 6022, 6094, 7009, 7010, 7054, 7057, 7066. HCFA Ex. 7, 14, 15, 16, 17.

44. At the time of the revisit survey of October 26, 1995, the following eight standard-level deficiencies remained uncorrected in violation of the Directed Plan of Correction requiring the correction of all deficiencies (whether condition-level or standard-level) by September 29, 1995:

a. D tag 3013 concerning specimen submission, transportation and handling (42 C.F.R. §§ 493.1103(a) and 493.1445(e)(5));

b. D tag 6022 concerning the responsibilities of the laboratory director (42 C.F.R. § 493.1407(e)(5));

c. D tag 6094 also concerning the responsibilities of the laboratory director (42 C.F.R. § 493.1445(e)(5));

d. D tag 7009 concerning patient test management assessment (42 C.F.R. §§ 493.1103(a), 493.1445(e)(5), and 493.1703);

e. D tag 7010 also concerning patient test management assessment (42 C.F.R. §§ 493.1103(a) and 493.1703);

f. D tag 7054 concerning patient information and test results (42 C.F.R. §§ 493.1445(e)(5) and 493.1711(e));

g. D tag 7057 concerning communications (42 C.F.R. §§ 493.1445(e)(5) and 493.1715);

h. D tag 7066 concerning quality assurance records (42 C.F.R. §§ 493.1407(e)(5), 493.1445 (e)(5), and 493.1721);

HCFA Ex. 7, 14-17.

45. HCFA prevails, since it met its obligation to provide notice of its determinations regarding the October 26, 1995 survey, and since Petitioner failed to prove by a preponderance of the evidence that it had corrected all the deficiencies identified during the August 4, 1994 survey. The period of time between these two surveys is over 12 months. HCFA Ex. 7, 17; 42 C.F.R. §§ 493.1816(b), 493.1820, 493.1828(c)(2).

46. HCFA prevails, since it met its obligation to provide notice of its determinations, and since Petitioner failed to prove by a preponderance of the evidence that, by September 29, 1995, no condition or standard-level deficiencies remained uncorrected, a violation of the terms of the Directed Plan of Correction.

47. As a matter of law, HCFA prevails on its imposition of the sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. FFCL 1-46; 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), 493.1842(a).

DISCUSSION

The evidence and argument presented by Petitioner do not persuade me that, based on the results of the October 26, 1995 survey, Petitioner has proved that all the deficiencies identified by HCFA had been corrected. Petitioner, not HFCA, bears the ultimate burden of persuasion. Petitioner has not met this burden.

Specifically, Petitioner failed to comply with the standard governing Specimen Submission and Handling (42 C.F.R. § 493.1103(a)). This resulted in a deficiency cited as D tag 3013. This standard requires that a laboratory must have available and follow written policies and procedures for conditions for specimen transportation. Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported. HCFA determined that Petitioner failed to comply with this standard, based upon interviews conducted by the State agency with Petitioner's staff and upon the review of available procedure manuals. This failure was corroborated by Petitioner's general supervisor. HCFA Ex. 7, at 6; HCFA Ex. 17, at 1, para. 3. Petitioner attempts to refute this evidence by referring to P. Ex. 36, a document entitled "Quality Assurance Program-Phlebotomy-Specimen Collecting Procedure for Williams Bio Medical Laboratory." However, Petitioner cannot rely on this exhibit to show its compliance with the regulation, since P. Ex. 36 pertains only to specimen collection, and not to specimen transportation. In addition, P. Ex. 36 has no date or signature on it to show that it was in place at WBML at the time of the October 26, 1995 revisit survey. Obviously, the best evidence to demonstrate that the procedures were in place would be documentation showing they were in use. Petitioner, who would be in the best position to have such documentation, assuming such documentation was in use, did not offer such proof.

Consequently, I must conclude that no such documents exist and that the procedures were never in place. Petitioner claims also that this standard does not apply to it, since it does not transport specimens and all testing is done in house. However, 42 C.F.R. § 493.1103(a) is intended to "assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until the testing has been completed and the results reported." Clearly, section 493.1103(a) is referring to "in house" specimen transportation. Therefore, this regulation does apply to WBML, and WBML has failed to comply with it.

Petitioner failed also to comply with 42 C.F.R. § 493.1407(e)(5), which requires that a laboratory director of moderate complexity testing must ensure that quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. HCFA found deficiencies (D tags 6022 and 7066) under this standard based, in part, on the State agency's interviews with staff and review of quality control/quality assurance records, and based, in part, on a lack of documentation showing that quality assurance activities, including the identification of problems and corrective actions taken, had, in fact, occurred. HFCA Ex. 7 at 12-13 (D tag 6022) and 28-29 (D tag 7066); HCFA Ex. 15, 17. Petitioner relies on its P. Ex. 39-43 to show that it had quality control and assurance programs in place at the time of the October 26, 1995 survey. However, these exhibits consist of forms and checklists which are blank. There are no dates, signatures, or any other information to show that the required quality control/quality assurance programs were in place at the time of the survey. HFCA Ex. 16. The evidence offered by Petitioner thus does not prove that such a program was in place at the time of the October 26, 1995 survey.

The regulation at 42 C.F.R. § 493.1711(e) requires that for internal quality assurance, a laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria, such as its relationship with other test parameters when available. HCFA determined that, at the time of the surveys, WBML did not have such a mechanism. HCFA Ex. 7, at 24-25; HCFA Ex. 17. This resulted in a deficiency cited as D tag 7054.

Petitioner attempts to refute this by relying on P. Ex. 45, 46, 49, and 51. P. Ex. 45 is a form on which tests are ordered. There is no place on this form to record results. P. Ex. 46 appears to be a form on which results are reported. This form does provide a normal range for each test, but it does not provide a mechanism to identify and evaluate patient test results that are inconsistent with relevant criteria such as patient age,

sex, diagnosis, distribution of test results, or relationship with other test parameters, when available. Therefore, these two exhibits do not demonstrate compliance with this regulation.

P. Ex. 49 is a communication log between the laboratory director or clinical consultant and clients or facilities. This form shows blanks to be filled in with the date, time, who was spoken to, patient name, subject of communication, and resolution. There are also blanks to be filled in to identify the individual initiating the communication and the individual who reviews the completed form. A note at the bottom of the form says that the form should be turned in to the Quality Assurance Committee. However, this form does not indicate how or when it should be used. There is no indication what the triggering circumstance would be to initiate communication. Further, the form does not provide a mechanism to identify and evaluate patient test results that are inconsistent with relevant criteria.

P. Ex. 51 is part of a document entitled "Quality Assurance" (P. Ex. 50), and it states:

> (f) Standard. The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with clinically relevant criteria such as--
>
> 1) Patient's age;
> 2) Sex;
> 3) Diagnosis of pertinent clinical data;
> 4) Relationship with other test parameters.

This document simply repeats the wording of the regulation. It states that the laboratory "must have" a mechanism to identify and evaluate patient test results that appear to be inconsistent with relevant criteria. It does not state that the laboratory has identified such a mechanism, nor does it show that such a mechanism was being used by WBML.

P. Ex. 49 and 51 contain no dates, signatures, or other identifying information indicting that any of the procedures reflected there had been adopted by the laboratory, or were in place, at the time of the October 26, 1995 survey. Nor had these exhibits been provided to HCFA previously, either in response to the deficiencies identified during any of the three surveys or at the time Petitioner requested a hearing. HFCA Ex. 16. Further, even assuming that these documents were present in the laboratory at the time of the October 26, 1995 survey, they fail to identify any mechanism in place at that time to assure that the regulation was being carried out.

The remaining uncorrected deficiencies, for which

Petitioner has submitted no acceptable documentation to refute the evidence introduced by HCFA, include: deficiencies based on the failure of the laboratory director to establish and maintain quality control and quality assurance programs in order to assure the quality of laboratory services provided and to identify failures as they occur (42 C.F.R. § 493.1445(e)(5), D tags 6094, 7009, 3013, 7054, 7057, 7066); deficiencies based on the failure to have an ongoing mechanism for monitoring and evaluating the systems required under subpart J of 42 C.F.R. Part 493, Patient Test Management (42 C.F.R. §§ 493.1103 and 1703, D tags 7009, 7010); a deficiency based on a failure to have in place a system to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations (42 C.F.R. § 493.1715, D tag 7057); and a deficiency based on the failure to maintain documentation of all quality assurance activities, including problems identified and corrective actions taken (42 C.F.R. § 493.1721, D tag 7066). HCFA determined that these deficiencies existed based on interviews conducted by the State agency with WBML's staff, including WBML's general supervisor, a review of the quality assurance records, and the finding of a lack of documentation where required. HCFA Ex. 7, 15, 17. In addition, HCFA provided declarations from the surveyor, Franklin R. Barnes, and from a laboratory consultant employed by HCFA, Esther-Marie Carmichael. HCFA Ex. 14-17. These declarations support the existence of the deficiencies at WBML.

Petitioner relies on its exhibits to show that it had overcome these remaining deficiencies prior to the revisit survey of October 26, 1995 (P. Ex. 39-43 and 49). These exhibits consist of forms and checklists that are blank. None of these exhibits show that Petitioner had the required quality assurance or other systems in place at the time of the October 26, 1995 survey. This showing does not meet the burden of persuasion required by Hillman.

CONCLUSION

Petitioner had deficiencies which remained uncorrected over 12 months following the August 4, 1994 survey. Further, Petitioner failed to comply with the terms of the August 24, 1995 Directed Plan of Correction requiring that all deficiencies, whether condition-level or standard-level, be corrected by September 29, 1995.

HCFA may impose principal sanctions where a laboratory fails to correct deficiencies within 12 months of the day of the inspection or where it fails to comply with an alternative sanction, such as a Directed Plan of Correction. 42 C.F.R. §§ 493.1816(b), 493.1840(a)(7). Thus, as a matter of law, HCFA prevails on its imposition

of sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), 493.1842(a).

_____
Edward D. Steinman
Administrative Law Judge

* * * Footnotes * * *

1. Petitioner's CLIA certificate was subsequently revoked on separate and independent grounds, effective March 21, 1996, as a result of Petitioner's failure to pay required CLIA fees. Petitioner acknowledges that it did not pay the required fees and that it did not appeal its revocation based on this failure to pay required CLIA fees. Unappealed determinations are binding and cannot be set aside in this proceeding. Administrative Law Judge Mimi Hwang Leahy's August 20, 1996 Ruling in this case (ALJ Ruling), Findings of Fact and Conclusions of Law (FFCL) 17-20.

2. Petitioner's exhibits 1-6, 8-25, 25A, 26-28, and 18 attachments (P. Att. 1-18) were accepted into the record by Judge Leahy. Subsequently, Petitioner submitted a copy of its brief in opposition to HCFA's motion for summary judgment, which was labeled exhibit 1 (and which was previously submitted to Judge Leahy); a declaration ("Reference to Franklin R. Barnes Declaration"), which was labeled exhibit 2 and which I have remarked as P. Ex. 29; and a revised response to the October 26, 1995 revisit survey, which was labeled exhibit 3 and which I have remarked as P. Ex. 30. At the same time, Petitioner submitted 23 attachments. I am discarding part of the second set of attachments, attachments 1-18, because these attachments are duplicates of P. Att. 1-18 which were accepted into the record by Judge Leahy. Petitioner submitted five new attachments (P. Att. 19-23). I am re-marking P. Att. 1-23 as P. Ex. 31-53, to conform with Civil Remedies Division practice. I am discarding the brief Petitioner submitted as exhibit 1, as it is of record already.

HCFA had previously submitted HCFA exhibits 1-15 in support of its motion for summary judgment. Judge Leahy accepted those exhibits into the record. Following Judge Leahy's ruling, HCFA submitted a brief in support of the revocation of Petitioner's CLIA certificate, and 17 exhibits (HCFA Ex. 1-8 and 10-18). I am discarding part of the second set of exhibits, HCFA Ex. 1-8 and 10-15, because these exhibits are duplicates of exhibits already in the record. HCFA submitted three new exhibits (HCFA Ex. 16-18). In order to decide the case before me, I am receiving into the record those exhibits that were not

previously admitted as exhibits: P. Ex. 29-53 and HCFA Ex. 16-18.

The parties have submitted several briefs, some referred to above. Those submitted to Judge Leahy include the brief accompanying HCFA's motion for summary judgment (HCFA Br.), Petitioner's brief in response to this motion (P. Br.), and HCFA's response brief (HCFA Resp. Br.). Before me, HCFA submitted a brief in support of the revocation of Petitioner's CLIA certificate (HCFA Br. 2) and Petitioner submitted a summary letter in response (P. Let.).

3. Petitioner sought to raise other issues in its brief. Specifically, Petitioner claimed that the deficiencies cited in the November 2, 1994 survey were incorrect. Petitioner alleges that it did not receive the letter dated March 30, 1995, from the California Department of Health Services (State agency) which notified WBML that, as a result of the November 2, 1994 survey, four condition-level deficiencies were still out of compliance. This letter further stated that the State agency would recommend to HCFA that alternative sanctions be imposed. However, even if all Petitioner's claims are true, as Judge Leahy found, Petitioner still received HCFA's notice imposing alternative sanctions, and was aware that all deficiencies had to be corrected by September 29, 1995. ALJ Ruling, FFCL 6. Petitioner did not request a hearing to contest the results of the August and November 1994 surveys, or to contest the imposition of alternative sanctions pursuant to those surveys. ALJ Ruling, FFCL 7. Judge Leahy ruled that Petitioner may not dispute HCFA's findings of deficiencies from the survey of November 2, 1994, because unappealed determinations are binding on Petitioner and cannot be set aside in this proceeding. ALJ Ruling, FFCL 7, 20.

Petitioner also submitted a declaration with reference to the declaration of Franklin R. Barnes, the State agency surveyor (P. Ex. 29). This declaration relates to procedural points that are not relevant to the issues before me. In her August 20, 1996 Ruling, Judge Leahy ruled that the issues raised by WBML, other than the issues referred to above, were beyond the scope of Petitioner's remaining hearing rights, since WBML had failed to appeal any of HCFA's prior sanctions.

Thyroid Specialty Laboratory, DAB **CR501** (1997)

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Thyroid Specialty Laboratory,	) Date: October 21, 1997	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-96-336
	)	Decision No. **CR501**
Health Care Financing Administration.	)	
	)	

DECISION

By this decision, I order the revocation of Thyroid Specialty Laboratory's (Petitioner) certification under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, for a period of one year, as proposed by the Health Care Financing Administration (HCFA). 1/ By operation of law, this decision also has the effect of affirming HCFA's determination to cancel Medicare payments to Petitioner for all tests. 42 C.F.R. §§ 493.1808(a), 493.1842(a) and (b).

As relevant to the facts of this case, CLIA specifies as follows:

> Any laboratory that the Secretary [of Health and Human Services] determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year ....

42 U.S.C. § 263a(i)(4).

The regulations promulgated by the Secretary to implement the foregoing statutory mandate state in relevant part:

> The laboratory must not send PT [proficiency test] samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year.

42 C.F.R. § 493.801(b)(4). See also 42 C.F.R. § 493.1840(b).

In addition, the regulations require HCFA to impose the sanction

of canceling a laboratory's approval to receive Medicare payments whenever HCFA takes action to revoke the laboratory's CLIA certificate. 42 C.F.R. § 493.1842(a). HCFA must cancel Medicare payments concurrently with its determination to revoke the laboratory's CLIA certificate. 42 C.F.R. § 493.1808(a). Notwithstanding the contrary provisions applicable to HCFA's decisions to revoke a CLIA certificate (42 C.F.R. § 493.1840(e)), HCFA may effectuate the cancellation of Medicare payments in advance of the laboratory's exercising its hearing rights. 42 C.F.R. § 493.1842(b).

By letter dated April 30, 1996, HCFA provided notice that it intended to revoke Petitioner's CLIA certificate for one year due to the unlawful referral of certain proficiency testing samples. In addition, HCFA stated that, Petitioner's approval to receive Medicare payments was being canceled effective May 15, 1996. Petitioner filed a timely request for hearing. I held an in-person evidentiary hearing 2/ in St. Louis, Missouri, on February 13, 1997. Both parties have filed post-hearing briefs 3/ summarizing their legal theories and their view of the evidence of record.

I. ANALYSIS OF FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Uncontested Background Facts and Law

Petitioner does not disagree with HCFA's assertion that Petitioner received its CLIA certification on August 31, 1994, pursuant to an application submitted on September 1, 1992. 4/ HCFA Br. at 2. Nor does Petitioner dispute HCFA's description of Petitioner as a small reference laboratory 5/ which conducted tests of moderate complexity during the relevant periods of time. Id. Petitioner acknowledges that, in order to maintain its CLIA certificate, it was required to analyze proficiency testing samples and report the results to a testing service for grading each year. P. Br. at 6.

As explained through unrefuted witness testimony, HCFA, an agency of the Department of Health and Human Services (HHS), approves certain companies to administer proficiency tests under CLIA. Three times each year, these approved testing companies send out proficiency test samples to be analyzed by each laboratory. (A set of five testing samples are sent out to each laboratory for each test period.) The laboratories then perform the tests and submit their results on forms provided by the testing services. The testing services grade the results and report them to HCFA. To remain certified under CLIA, a laboratory must maintain a minimum score of 80% (i.e., provide correct answers for four out of the five test samples) for each of the three annual proficiency test "events." Tr. 16-17.

Proficiency testing samples are sent to laboratories for testing without any indication of their potential results. Because HCFA inspects CLIA certified laboratories only once every two years, HCFA uses the outcomes of the proficiency tests to monitor on a more regular basis the quality of a laboratory's work, as if the work were being performed on its patient specimens. Therefore,

it is necessary for a laboratory to analyze proficiency test samples on its own, in the same manner as it would analyze its patient specimens. Tr. 17-19.

The above-described testimony introduced by HCFA is consistent with the regulations, which specify that, as a condition of participation under CLIA, a laboratory must enroll in an approved proficiency testing program and must conduct the proficiency tests in the same manner it tests patient specimens. 42 C.F.R. § 493.801. Further, each laboratory performing tests of moderate or high complexity must successfully participate in a HCFA-approved proficiency test program each year, or be subject to sanctions. 42 C.F.R. § 493.803.

The regulations emphasize that in testing proficiency test samples, a laboratory must "examine or test, as applicable, the proficiency testing samples that it receives from the proficiency testing program in the same manner as it tests patient specimens." 42 C.F.R. § 493.801(b). The proficiency test samples "must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods" (42 C.F.R. § 493.801(b)(1)), and "[t]he laboratory must test samples the same number of times it routinely tests patient samples." 42 C.F.R. § 493.801(b)(2). Under CLIA requirements, the laboratory director and the analyst must also sign an attestation statement provided by the proficiency testing program to document that the proficiency test samples were tested in the same manner as patient specimens. 42 C.F.R. § 493.801(b)(5).

Accordingly, I adopt the following as uncontroverted background findings of fact and conclusions of law:

1. Pursuant to an application submitted on September 1, 1992, Petitioner was certified as being in compliance with CLIA requirements on August 31, 1994.

2. During the period in controversy, Petitioner was a small reference laboratory conducting moderate complexity tests under its CLIA certificate.

3. As a CLIA certified laboratory during the period in controversy, Petitioner was required to participate successfully in the performance of proficiency tests under a testing program which was approved by HHS and which met the requirements established by regulation. 42 C.F.R. § 803.

4. Proficiency tests are designed to determine a laboratory's accuracy in performing tests for its patients. Tr. 19.

5. While enrolled in a proficiency testing program, Petitioner, like other CLIA certified laboratories, was sent proficiency test samples for analysis approximately three (3) times each year. Tr. 19.

6. During the period in controversy, Petitioner, like all other laboratories enrolled in HHS-approved proficiency testing programs, was required to examine or test proficiency samples in the same manner it tested patients' specimens. 42 C.F.R. § 493.801.

7. During the period in controversy, Petitioner, like all other laboratories enrolled in HHS-approved proficiency testing programs, was required to have its laboratory director and analyst sign an attestation statement to certify that the proficiency samples were tested by the laboratory in the same manner as it tested its patient specimens. 42 C.F.R. § 493.801 (b)(5).

B. Proof of the Violations Committed by Petitioner

1. The Statutory Elements

I adopt the legal analysis of Administrative Law Judge Steven Kessel and Administrative Law Judge Jill Clifton in concluding, as they have, that a violation under 42 U.S.C. § 263a(i)(4) can be established on proof that:

a. a proficiency test sample has been referred for analysis by one laboratory to another laboratory, and

b. the referring laboratory had knowledge that the sample it was referring was a proficiency test sample.

Long Medical Laboratory, DAB CR334 (1994) (Judge Kessel); Primary Care Medical Group, DAB CR439 (1996) (Judge Clifton). I agree also with their conclusion that ordinary, dictionary meanings must be given to the words "intentional" or "intentionally," as used in 42 U.S.C. § 263a(i)(4) and the Secretary's implementing regulations. Therefore, I will also construe "intentional" or "intentionally" in this case to mean that the proscribed actions were taken deliberately, pursuant to a determination to act in a certain way, and without regard to the nature of the motive for the actions. I, too, am of the view that the knowledge element of 42 U.S.C. § 263a(i)(4) and its corresponding regulations can be satisfied by showing that the referring laboratory knew the sample it was referring was a proficiency test sample, not a patient specimen. Primary Care Medical Group, DAB CR439 at 17 (quoting Long Medical Laboratory, DAB CR334).

Given the above-specified elements of proof, it is not necessary for HCFA to establish also that the referrals resulted in actual, objectively verifiable cheating by the referring laboratory by the use of methods such as the copying of the other laboratory's results, the double-checking or comparing of its own results against those of the other laboratory, or the alteration of its results based on the other laboratory's analysis. 6/ Nor is it necessary in order for HCFA to establish a violation, that HCFA prove that the laboratory had specifically intended to violate CLIA through the referral of proficiency test samples.

2. Evidence that Petitioner's Proficiency Testing Samples were Referred to Another Laboratory for Analysis

In this case, there is no dispute that referrals of proficiency tests samples took place. Petitioner admits that, during two proficiency testing periods in 1995, a total of five proficiency test samples were sent to Corning Laboratory. P. Br. at 16. During the June 1995 testing event, two of Petitioner's five proficiency samples (test samples C-3 and C-5) were referred to Corning Laboratory. Tr. 136; P. Ex. 32. Then, for the October 1995 testing event, three of Petitioner's five proficiency samples (test samples C-1, C-2, and C-5) were also referred to Corning Laboratory. Id. HCFA has not alleged violations with respect to the referrals of other proficiency test samples or for other testing periods preceding the April 1996 survey. 7/

The referrals of the five proficiency test samples were made on the same days that Petitioner performed its own tests on the same samples. HCFA Ex. 3; P. Ex. 32 (summary of Petitioner's other exhibits). June 15, 1995, is the date on which Petitioner performed its own tests for the June testing cycle, and the date on which two of those proficiency testing samples were referred to Corning Laboratory. October 25, 1995, is the date on which Petitioner performed its own tests for the October testing cycle, and the date on which three of those proficiency testing samples were referred to Corning Laboratory.

On the issue of whether the referrals herein were made for the purpose of having another laboratory analyze the test samples, 8/ HCFA's witness opined that there exists no other reason to make a referral of proficiency test samples to another laboratory. Tr. 60 - 61. In fact, the requisition forms in evidence confirm that Petitioner's proficiency test samples were repeatedly sent to Corning Laboratory for the specific purpose of having that laboratory perform the requested analysis. For the two proficiency test samples sent to Corning Laboratory during the June 1995 testing event, Petitioner's agent or employee completed two separate requisition forms (one for sample C-3 and one for sample C-5) for Corning Laboratory to perform the analysis of those samples. P. Ex. 3, 4. Three additional requisition forms specifying the analysis to be done by Corning Laboratory were filled out by Petitioner's agent or employee during October of 1995, when three more proficiency test samples from that testing event (samples C-1, C-2, and C-5) were sent to Corning Laboratory. P. Ex. 22-24.

The parties' evidence on Corning Laboratory's responses to those requisition forms further establish that the proficiency testing samples were referred for analysis. Corning Laboratory issued separate reports for each of the five proficiency samples it tested. Tr. 45; P. Ex. 32. At approximately 3:00 p.m. on June 16, 1995, Corning Laboratory delivered its reports on the two June proficiency samples to Petitioner. Tr. 52, 62. At approximately 3:00 p.m. on October 26, 1995, Corning Laboratory delivered its reports on the three October proficiency samples to Petitioner. Tr. 52, 57-59. 9/

3. Evidence on the Identity and Authority of the Individual who is Alleged by Petitioner to have Referred its Proficiency Testing Samples to Another Laboratory

The parties agree that on June 16, 1995 (the same day on which Corning Laboratory delivered its results to Petitioner), Petitioner signed the form attesting to its results for the June 1995 proficiency tests. Tr. 56. The parties agree also that on October 27, 1995 (one day after the delivery of Corning Laboratory's test results), Petitioner signed the form attesting to its results for the October 1995 proficiency tests. Id. The signed attestation form contained the following statement:

> The undersigned analyst attests that the samples were tested in the same manner as patient samples.

HCFA Ex. 3 at 32.

The attestation forms were signed by Petitioners' Laboratory Director, who did not perform any of the proficiency tests in 1995 and who claims to have had no knowledge of the referrals to Corning Laboratory until well after their occurrence. Id; Tr. 160, 198, 221. Petitioner contends that its Laboratory Director was not aware of the referrals until the surveyor brought the matter to his attention during the survey conducted on April 9, 1996. Tr. 136. The contention that the Laboratory Director lacked contemporaneous knowledge of the referrals raises the question of who had made the referrals, and whether that person had acted with the authority to bind Petitioner.

On these two issues, the relevant evidence shows that during 1995, only three people were employed by Petitioner: Marilyn Banes, Petitioner's Office Manager; Dr. Bahartur Premachandra, Ph.D., Petitioner's founder, sole proprietor, and Laboratory Director; and Stacey Abernathy, a part-time employee who performed all of Petitioner's laboratory tests. Tr. 43, 145 - 47, 169, 179, 183. Petitioner referred to Ms. Abernathy as its "Laboratory Technician." Tr. 183. However, it stipulated that there exists no licensure requirements for the work performed by Ms. Abernathy. Under CLIA, individuals such as Ms. Abernathy are called "Testing Personnel." Tr. 185. Like others having the designation of "Testing Personnel," Ms. Abernathy was given some on-the-job training in order to perform laboratory tests and analyses for her employer. 10/ Tr. 183, 190. She was given the freedom to set her own hours and to do however much work was needed during whatever periods were convenient to her. Tr. 148.

Dr. Premachandra, Petitioner's founder, sole owner, and Laboratory Director, testified that it was Stacey Abernathy, Petitioner's Testing Personnel in 1995, who filled out the requisition forms and referred the five proficiency test samples to Corning Laboratory for analysis. Tr. 206. Neither party called her to testify at the hearing, even though it is likely that her whereabouts could have been ascertained despite her departure from Petitioner's employment. (For example, she has

kept in touch with Petitioner's Office Manager, Ms. Banes, through the use of Christmas cards and by submitting Ms. Banes' name as a job reference. Tr. 147-48.) Both of Petitioner's remaining employees in 1995, Ms. Banes and Dr. Premachandra, have denied making the referrals in dispute. HCFA has not introduced evidence to show that Ms. Banes or Dr. Premachandra made those referrals. Therefore, I am constrained to proceed by accepting as true that Petitioner's only other employee in 1995, its Testing Personnel, took the actions attributed to her by Petitioner.

Petitioner argues that the Testing Personnel inadvertently referred the proficiency test samples under a random quality control procedure in place for patient samples. P. Br. at 24-25. As relevant to the issue of whether the Testing Personnel had the authority to act for Petitioner during the relevant periods of time, Dr. Premachandra testified that, when discussing the random quality control procedure, he had given the Testing Personnel the discretion to send to another laboratory "whatever they [sic] want to send on a random basis." Tr. 189. He had provided the Testing Personnel with no guidelines on the concept of "random." Tr. 189-90. He testified that he did not check on the referrals that were made "randomly" by the Testing Personnel at whatever intervals she chose; he did not set any limits or goals on the number of referrals to be made "randomly;" nor did he establish any intervals or quantities for these "random" referrals he authorized. Id.; Tr. 219.

Dr. Premachandra testified also that he instructed the Testing Personnel to "handle" all samples in the same manner, including referring them to another laboratory under the so-called "random" referral procedures he said he had created. 11/ Tr. 191, 194, 199-200. Even though he alleged that he did not intend for his instructions to mean that the Testing Personnel should refer any proficiency test samples to another laboratory under the "random" referral process (id.), I do not find his allegation credible or material. 12/ By his own admission, the Testing Personnel received from him the authority to refer "whatever they [sic] want to send on a random basis." Tr. 189. Additionally, Dr. Premachandra admitted to having never issued any instructions until after the April 1996 survey to preclude the referrals of proficiency test samples to another laboratory. Tr. 200, 217; See Tr. 157. 13/

The testimony given by Marilyn Banes, Petitioner's Office Manager, also proves that the Testing Personnel had authority and discretion to make referrals of proficiency test samples on behalf of Petitioner. She testified that she had recorded the proficiency test results on the reports returned to the testing service. Tr. 151. She testified that, at the time she was recording the proficiency test results from Petitioner's own data, she saw the requisition forms to Corning Laboratory and became aware that certain proficiency samples had been referred out. Tr. 156. (Her responsibilities included book-keeping, maintaining Petitioner's accounts receivable, and issuing disbursements for Petitioner. Tr. 146.) She knew that the requisitions to Corning Laboratory were for the testing of

proficiency test samples, and not patient specimens, because the requisition forms contained the proficiency test numbers instead of patient names. Tr. 165. She even saw the results from Corning, though she denies having studied them, understood them, or given them any effect. Tr. 154, 164. She testified that she had no knowledge of, and no interest in, why the proficiency test samples were referred to Corning Laboratory. Tr. 155. According to the Office Manager, her awareness of these referrals, and their results from Corning Laboratory, did not cause her to discuss the matter with Dr. Premachandra at or around the time she was completing the proficiency test reports. Tr. 155. Instead, she merely placed the requisition forms and reports from Corning Laboratory in a file denoted as "Proficiency Testing." Tr. 165.

The foregoing evidence shows that Ms. Banes, in her capacity as Petitioner's Office Manager, knew of the referrals at issue, as well as the outcomes of those referrals, at about the time those events occurred. The evidence shows also that she recognized the Testing Personnel's authority to make the referrals of proficiency testing samples, in that she did not react as if anything was amiss when she saw the requisition forms and Corning Laboratory's reports. For example, as Petitioner's Office Manager, she did nothing to disavow those referrals for Petitioner. Nor did she see a need to bring those referrals of the proficiency testing samples to the Laboratory Director's attention. In sum, all of the evidence points to the conclusion that, even assuming that the Testing Personnel had done all that Ms. Banes and Dr. Premanchandra had attributed to her, the Testing Personnel had been given the authority in 1995 to act for Petitioner, at her own discretion, in referring to another laboratory for analysis whatever she wished (patient specimens or proficiency test samples), in whatever quantity she wished, and at whatever interval she wished. Therefore, the actions attributed to the Testing Personnel by Dr. Premachandra and Ms. Banes are binding on Petitioner, as are the legal consequences of those actions.

4. Evidence of Petitioner's Knowledge that the Referrals were of Proficiency Test Samples, not Patient Specimens

With respect to the remaining issue of whether the referrals were made knowingly or intentionally, the evidence shows that Petitioner, through its Testing Personnel, had knowledge that the referrals were of proficiency test samples, and not of patient specimens. HCFA's witness testified that proficiency test samples were recognizable as such and had an appearance that was distinct from patient specimens. Tr. 20. Dr. Premachandra, Petitioner's Laboratory Director, agreed. Tr. 208, 217, 218. Dr. Premachandra noted that Petitioner's patient specimens were kept in tubes, while proficiency test samples came to Petitioner in vials. Tr. 208. Dr. Premachandra testified also that the colors of the tubes (for patient samples) and vials (for proficiency test samples) were different. Id.

According to Dr. Premachandra's description of the laboratory's practices in 1995, Petitioner's Office Manager would have received a box of the proficiency test samples from a delivery man and then placed the entire box -- unopened -- in the laboratory's refrigerator. Tr. 220-21. The Testing Personnel would later open the box and remove the proficiency testing samples in order to perform the necessary analysis. Tr. 221. From the foregoing activities, the Testing Personnel would have known which samples were part of the proficiency tests. Tr. 221.

Proof that the referrals were made intentionally consists also of the evidence showing that, in the course of making the referrals at issue, the Laboratory Technician had ample and repeated additional opportunities to realize that proficiency test samples were being sent to Corning Laboratory. I have noted the parties' apparent agreement that the referrals of proficiency test samples were made on June 15, 1995 and October 25, 1995 -- the same days on which the Testing Personnel also performed the proficiency tests in-house for Petitioner. P. Ex. 32. Since on the same days, the same person used the same proficiency testing samples to perform the tests in-house as well as to make the referrals, she would have realized that she was not referring patient specimens in those instances.

In addition, as described by the Laboratory Director, Petitioner's procedure for sending samples to Corning Laboratory entailed placing each sample and corresponding requisition form in a separate plastic bag for delivery to Corning Laboratory. Tr. 210. 14/ Therefore, in order to refer samples C-3 and C-5 of the June 1995 testing period, the Testing Personnel would have had to have generated two separate requisition forms, placed the two proficiency test samples in two separate bags, matched the requisition forms with their corresponding vials, and placed each requisition form in the correct bag. The same steps would need to have been taken by the Testing Personnel to effectuate the referrals of proficiency samples C-1, C-2, and C-5 of the October 1995 testing period. Therefore, even if the Testing Personnel had failed to notice that the vials she took from the laboratory's refrigerator were sent by the proficiency testing service and did not have the same appearance or container as Petitioner's patient specimens, her taking of this many steps to effectuate each of the five referrals would have caused her to realize that she was sending proficiency test samples to Corning Laboratory for analysis.

It is also significant that Petitioner performed only about 2,000 tests a year. Tr. 90. Assuming 150 work days per year, since Petitioner's Testing Personnel worked part-time, Petitioner only averaged 13 samples a day. Such a low volume of samples, along with the difference in appearance of the proficiency samples, would have made it obvious that the Testing Personnel should have been aware that she was dealing with proficiency samples.

HCFA's witness noted also that the manner in which the requisition forms were filled out provides further proof that the referrals were made intentionally and with knowledge that

proficiency test samples were being sent to another laboratory for analysis. The requisition forms used by Petitioner in this case contained several questions which should be answered when patient specimens are being referred for testing by another laboratory. Tr. 32. The requisition forms asked for information such as the patient's name, sex, age, insurance company, date of birth, physician's name, and the date on which the specimen was collected. Id.; e.g., HCFA Ex. 3 at 12. When the proficiency test samples were being referred to Corning Laboratory using these requisition forms, the answers to these patient-specific questions were left blank. Id. The requisition forms used to transmit the proficiency test samples to Corning show only the identifier of the test samples being sent, with the date of the referral provided as the date on which the specimen was allegedly collected. Id. Thus, this evidence shows also that the Laboratory Technician knew she was referring proficiency test samples.

By virtue of her authority to make referrals at her discretion on behalf of Petitioner, the Testing Personnel's knowledge that the samples she referred were proficiency test samples (and not patient specimens) must also be imputed to Petitioner.

5. Relevant Findings and Conclusion

Based on the foregoing evidence and analysis, I find and conclude as follows:

8. A violation under 42 U.S.C. § 263a(i)(4) may be established on proof that:

a. a proficiency test sample has been referred for analysis by one laboratory to another laboratory, and

b. the referring laboratory had knowledge that the sample it was referring was a proficiency test sample instead of a patient specimen.

9. A total of five proficiency test samples sent to Petitioner for the June and October testing cycles of 1995 were referred to Corning Laboratory.

10. Petitioner's five proficiency test samples were referred for the purpose of having Corning Laboratory analyze them.

11. Petitioner alleged, and HCFA did not dispute, that the five proficiency test samples were referred to Corning Laboratory by the individual employed as Petitioner's Testing Personnel in 1995.

12. Before the five proficiency test samples were referred to Corning Laboratory, Petitioner's Laboratory Director and sole owner had given Petitioner's Testing Personnel the authority and

discretion to make referrals of patient specimens as well as proficiency testing samples on behalf of Petitioner.

13. While preparing reports for the proficiency test service in June and October of 1995, Petitioner's Office Manager became aware that proficiency test samples had been referred to Corning Laboratory for analysis.

14. In June and October of 1995, when she became aware that the referrals of Petitioner's proficiency test samples had been made, Petitioner's Office Manager took no action on behalf of Petitioner to repudiate or disavow those referrals.

15. In 1995, Petitioner's Office Manager recognized and acknowledged the Testing Personnel's authority to refer proficiency testing samples to another laboratory for analysis.

16. Whether or not Petitioner's Laboratory Director had contemporaneous knowledge of the referrals at issue, Petitioner is bound by its Testing Personnel's actions and knowledge in having referred the five proficiency samples to another laboratory for analysis.

17. On June 15, 1995, Petitioner, through its Testing Personnel, knew that it was referring to Corning Laboratory two proficiency testing samples instead of two patient specimens.

18. On October 25, 1995, Petitioner, through its Testing Personnel, knew that it was referring to Corning Laboratory three proficiency testing samples instead of three patient specimens.

19. The referrals of five proficiency test samples in 1995 were made by Petitioner intentionally, within the meaning of 42 U.S.C. § 263a(i)(4) and the corresponding regulations.

C. Invalidity of Petitioner's Affirmative Defenses

1. Summary of the Affirmative Defenses

Petitioner asserted as an affirmative defense that the five proficiency samples were referred to Corning Laboratory through an inadvertent mistake on the part of Petitioner's Testing Personnel, who misunderstood Dr. Premachandra's instructions to "handle the proficiency samples in the same manner as patient samples" as meaning that proficiency test samples should be included for referrals as part of a "quality control random testing procedure." P. Br. at 24; Tr. 135-36. Petitioner contended also that the referrals of proficiency samples were

unintentional, in that Dr. Premachandra, who admits to having "unknowingly and inadvertently caused the situation which led to this action," was merely trying to follow the law by directing the "Laboratory Technician"/"Testing Personnel" "to treat" the proficiency samples like all patient samples. P. Br. at 25. According to Petitioner, the Testing Personnel took Dr. Premachandra's directives literally and without bad intent. Id.

In related arguments, Petitioner contends also that it never analyzed Corning Laboratory's results, and, therefore, the "for analysis" requirement of the statute and regulations was never satisfied in this case. P. Br. at 30-31.

I reject Petitioner's affirmative defenses for the reasons which follow.

2. The Immateriality of the Nature of the Motives and Specific Intent

I have already ruled above that the test for intent under 42 U.S.C. § 263a(i)(4) and its corresponding regulations is whether the referring laboratory knew that it was referring proficiency test samples instead of patient specimens to another laboratory for analysis. I have ruled also that "intentional" under the statute and regulations relevant to this case means only that the acts were done deliberately or with a determination to act in a certain way. Proof that the referring laboratory knew that it was referring proficiency test samples (as opposed to patient specimens) satisfies the intent requirement of 42 U.S.C. § 263a(i)(4) and the corresponding regulations.

For these reasons, it is immaterial whether Dr. Premachandra and the Testing Personnel were without bad motive or without specific intent to violate the law when they chose to take the various actions which resulted in these proceedings. Moreover, Dr. Premachandra's state of mind cannot absolve Petitioner of liability, since he denies having had any prior or contemporary knowledge of the referrals, he denies having made any of the referrals in this case, and the Testing Personnel to whom he has attributed the referrals had the authority to refer the samples on behalf of Petitioner.

3. The Inadequacy of Proof in Support of Petitioner's Affirmative Defenses Based on Good Motive and Specific Intent (if relevant)

Additionally, even if I were to consider relevant Dr. Premachandra's motives or intent at the time he authorized the Testing Personnel to make referrals on Petitioner's behalf, I would conclude that the facts fail to support Petitioner's contention that his actions were inadvertent or taken by mistake. Even if I were to consider relevant also the Testing Personnel's motives or specific intent at the time she made the referrals of proficiency testing samples, I would conclude that the evidence is insufficient to support Petitioner's contention that its

actions were motivated by and intended for the testing of patient specimens under Petitioner's "quality control" procedures. I will discuss these conclusions below, along with my corollary conclusions that the evidence fails to establish the existence of a bona fide "quality control" program in 1995, and that the only reason why Petitioner had set up the referral process under review in this action was to enable the Testing Personnel to perform independent verifications of any or all test results attained in Petitioner's facility by comparing them against those results provided by another laboratory on request.

a. The evidence does not show that Petitioner's Laboratory Director had acted unintentionally, as that term is defined for purposes of this action.

Whereas Petitioner alleges that Dr. Premachandra "unknowingly and inadvertently caused the situation which led to this action" (P. Br., 25), the evidence shows that Dr. Premachandra gave instructions and authorizations to the Testing Personnel pursuant to choices he had under circumstances which required the exercise of due deliberation in his capacity as Petitioner's founder, sole owner, and Laboratory Director. In these positions Dr. Premachandra clearly had the choice of setting any procedures he felt to be appropriate for Petitioner to perform the proficiency tests necessary for maintaining its CLIA certificate. Setting up those procedures for the June and October, 1995 test events were especially important for Petitioner since, as I noted above, Petitioner was certified under CLIA on August 31, 1994, but did not enroll in a proficiency test program for the first test period of 1995.

However, as the evidence I have noted above shows, Dr. Premachandra made the decision not to reserve the referral decisions for himself and not to monitor closely the referral decisions made by another. He decided to delegate the referral responsibility to the Testing Personnel who was not only working part-time on a widely variable schedule, but who also did not need to have more than minimal on-the-job training to perform her work. He chose to make a plenary delegation of referral responsibilities to the Testing Personnel without providing for routine, after-the-fact reviews of her referral choices, and without specifying for her what she may or may not refer to another laboratory under the law.

The evidence introduced by Petitioner leads me to conclude also that Dr. Premachandra chose to direct that all proficiency test samples be "handled" in the same manner as patient specimens, despite the fact that the relevant statute and regulations specify very clearly that the proficiency test samples must be tested by Petitioner on its own and without referrals, in the same manner that Petitioner tests patient specimens on its own and without referrals. I find nothing in the statute and regulations which would have led Dr. Premachandra or anyone else in his position to conclude that proficiency testing samples should be "handled" or "treated" in the same manner as patient

specimens for referrals to another laboratory for analysis. See Footnote 11. As Petitioner's founder, sole owner, and Laboratory Director, Dr. Premachandra had the knowledge, incentive, opportunity, and authority to issue instructions which would have prohibited the referrals of proficiency test samples to another laboratory for analysis.

Also significant is the fact that in both June and October of 1995, Dr. Premachandra had the opportunity, incentive, and duty to inquire into the manner in which all of Petitioner's proficiency testing samples from these two test events had been "handled" by the Testing Personnel before he signed the two attestation forms required by law. He would have been in a position to take remedial steps to avoid the imposition of sanctions by HCFA if he had chosen to find out about the referrals of the proficiency test samples before he signed the attestation forms. Instead, the evidence indicates that he chose to sign these forms and remain ignorant of the referrals now at issue until the April 1996 survey was being conducted.

For the foregoing reasons, even if I were to consider relevant Dr. Premachandra's motives or state of mind at the time Petitioner considers significant for its affirmative defense, the facts would still lead me to conclude that he had acted intentionally, as I have defined the term under 42 U.S.C. § 263a(i)(4). Those of Dr. Premachandra's actions referenced by Petitioner were taken deliberately by him, with a determination to act in a certain way, in situations which required him to make choices on Petitioner's behalf.

b. The evidence does not show that the referrals of proficiency test samples were made to evaluate the quality of Petitioner's work on patient specimens under a "quality control" program for patient specimens.

I have already concluded that Petitioner, through its Testing Personnel, knew that it was referring proficiency testing samples instead of patient specimens to Corning Laboratory. I reached this conclusion based on the preponderance of the evidence. The evidence of record provided no support for Petitioner's intimation that the proficiency test samples might have been mistaken for patient specimens when the referrals were made to Corning Laboratory.

However, even if Petitioner's affirmative claim of inadvertence now makes relevant the issue of Dr. Premachandra's specific intent when he set up the procedures for the Testing Personnel to make referrals at her discretion, Petitioner has not proven the truth of its contentions that Dr. Premachandra intended that only patient specimens be referred "randomly" for internal quality control purposes, or that there existed a bona fide internal quality control program which depended on the "random" referrals described by Petitioner. Nor has Petitioner proven for its affirmative defense the Testing Personnel's good intentions or thoughts. As I will discuss in greater detail below, what Dr. Premachandra described for Petitioner was, at best, the

procedures which were set up to enable the sole Testing Personnel employed in 1995 to double-check, on her own, any test results she had obtained in-house by requesting analysis from another laboratory; the specific end result intended by these procedures was the comparison of these two sets of results to ascertain if they are in accord.

As indicated by HCFA's witness during the hearing, it would make no fiscal sense for a small laboratory like Petitioner to use its own money to refer out specimens as a self-created quality control program when it was already participating in a federally mandated quality control program (the proficiency tests) three times each year, which resulted in Petitioner's being evaluated on its testing of samples equalling almost one percent of those patient specimens it routinely tests each year. 15/ Tr. 90. For background purposes, I take notice also that the regulations detail the Quality Assurance procedures that each laboratory must maintain as a condition of participation under CLIA. 42 C.F.R. Part 493, subpart P. A Quality Assurance program under CLIA must evaluate the effectiveness of the laboratories' policies and procedures, identify and correct problems, assure the accurate, reliable, and prompt reporting of test results, and assure the adequacy and competency of the staff. 42 C.F.R. § 493.1701. A Quality Assurance program under the regulations depends on the assumption of responsibilities and oversight by the laboratory's management, as well as the routine maintenance of records under the program. What Petitioner has alleged to be its voluntary "quality control" program via "random referrals" appears to have nothing in common with the process or goals of the similarly named procedures required for participation under CLIA.

What Petitioner alleges to be its "quality control" program by "random referrals" consisted of no more than a delegation to its sole Testing Personnel (who performed all of the tests for Petitioner) to make as many or as few referrals as she wished on whichever days she chose (Tr. 189), at a cost to her employer of approximately $20 per single test referred out (Tr. 218), without her employer's keeping track of the referrals actually made by week, month, year, or costs (Tr. 219), so that the same Testing Personnel could then compare the results of referrals with the results she had attained in-house (Tr. 191) -- usually without the Laboratory Director's knowledge or input 16/ -- in order to determine whether there were problems with the test results she had obtained. I do not find credible that the purpose of the "random" referral process described by Petitioner was to assess the quality of the testing work performed by its sole Testing Personnel, since this same Testing Personnel not only selected what she referred out in order to double-check her own results, but she was charged also with notifying the Laboratory Director only if she perceived a "big variation" between her results and the results returned from her referrals. See Tr. 187, 191. The evidence does not establish that the referral process Petitioner described for 1995 had any purpose other than to enable Petitioner's Testing Personnel to double-check whichever of her own test results she selected, for whatever reasons she

may have had. The evidence is clear that, whenever referrals have been made by the Testing Personnel, Petitioner expected the Testing Personnel to compare, on Petitioner's behalf, the results she obtained in-house with those obtained by another laboratory under the referral process. Tr. 191.

Therefore, if the Testing Personnel's motive and specific intent is relevant to Petitioner's affirmative defense, I would conclude on the basis of the above-discussed evidence that the evidence fails to support Petitioner's argument that the referrals of the proficiency test samples resulted from the Testing Personnel's adherence to certain "quality control" procedures set up to evaluate her work on patient specimens. I note in addition that there exists no testimony or first-hand account of the relevant events from the Testing Personnel herself in this case. Petitioner has attributed certain good motives and specific intent to her in making its affirmative arguments. These attributions do not suffice as credible proof -- especially when the greater weight of the evidence establishes that she knew she was referring proficiency test samples under a process which was specifically set up to enable her to check any of her results against those she requested from another laboratory.

c. Petitioner did not prove that, by its Testing Personnel, it did not analyze or intend to analyze the results received from Corning Laboratory.

Another of Petitioner's affirmative arguments is that no violation has been proven by HCFA because there is no evidence of Petitioner's intent to analyze the results it received from Corning Laboratory, and Petitioner did not, in fact, analyze Corning Laboratory's results. If I have not yet made clear in other parts of this Decision, I now make explicit my holding that, for liability to attach under 42 U.S.C. § 263a(i)(4) or the regulations promulgated thereunder, HCFA need not prove that Petitioner had a specific intent to analyze the results of tests performed by another laboratory on Petitioner's proficiency test samples. After it is established that one laboratory has referred proficiency test samples to another laboratory for analysis, HCFA need not prove also that the referring laboratory actually analyzed (or intended to analyze) the results returned by the other laboratory pursuant to the referral. I have construed the "for analysis" language of the statute and regulations to mean that the proficiency test samples were referred to another laboratory to perform an analysis of them; I have rejected Petitioner's legal interpretation that "for analysis" means the referring laboratory must study the results sent by the other laboratory. Therefore, I find immaterial the issue of whether Petitioner performed or intended to perform an analysis of Corning Laboratory's results before it filed its reports with the proficiency testing service.

However, even if the factual merits of Petitioner's contention needed to be evaluated in the context of Petitioner's assertion that the referrals of proficiency samples were made by mistake or with no improper intent, I would conclude that the evidence does not support the truth of Petitioner's assertion that it never

analyzed or intended to analyze the results from Corning Laboratory. Petitioner's contention is based solely on the fact that its Office Manager, who recorded the proficiency test results for Petitioner, testified at hearing that she did not make use of the results from Corning Laboratory. P. Br. at 31. (HCFA did not stipulate to the truth of those asserted facts during hearing or in its briefs. 17/) The Office Manger's testimony, even though uncontradicted, is not dispositive on the issues of whether Petitioner, by another of its employees in 1995, intended to compare (or had actually compared) Petitioner's results with those from Corning Laboratory.

The evidence previously discussed in this Decision shows that, under the procedures described by Petitioner, Petitioner expected its Testing Personnel to compare the test results she obtained in-house against the results returned from any referrals she made. Petitioner did not call the Testing Personnel to testify about her actions or intentions. The record before me does not contain adequate evidence for concluding, as Petitioner urges, that the Testing Personnel referred the proficiency test samples to Corning Laboratory to analyze with Petitioner's authorization and at Petitioner's expense, but the Testing Personnel never intended to study Corning Laboratory's results on behalf of Petitioner.

Additionally, Petitioner has never established that no analysis of the Corning Laboratory results had been done by the Testing Personnel before the Office Manager prepared the report for the proficiency testing service. Petitioner, by its Office Manager, could not set forth any specifics of the Testing Personnel's work schedule during 1995. See, e.g., Tr. 148. Since there is no evidence concerning the Testing Personnel's whereabouts on the days that Corning Laboratory delivered its reports to Petitioner, Petitioner has not ruled out the Testing Personnel's opportunity to analyze the Corning Laboratory results on behalf of Petitioner. Given the evidence showing that the intended purpose of Petitioner's referral procedures was for the Testing Personnel to compare the results she obtained in-house with those she received from another laboratory, Petitioner has not ruled out the likelihood that the Testing Personnel had decided to retain the in-house results until after having reviewed Corning Laboratory's reports.

The Office Manager testified only that she had recorded the proficiency test results for Petitioner by use of the documents left by the Testing Personnel in a designated tray. Tr. 149. However, she did not allege any knowledge of what was done by the Testing Personnel or anyone else before the data she copied was left in the designated tray and before she had an opportunity to copy them onto the proficiency test report forms. The Office Manager's testimony merely seeks to prove that she herself did not do what the Testing Personnel could have done and was expected to do for Petitioner under the referral procedures in place.

4. Relevant Findings and Conclusions

Based on the evidence and reasons discussed in this section, I find and conclude as follows with respect to Petitioner's affirmative defenses:

20. Petitioner's evidence and arguments on good motives and lack of specific intent to violate 42 U.S.C. § 263a(i)(4) are not material.

21. Even if material, Petitioner's evidence relating to its Laboratory Director's intent does not prove that the referrals of five proficiency samples in this case were made unintentionally, or inadvertently, as those terms are construed in the context of 42 U.S.C. § 263a(i)(4).

22. Even if material, the truth of Petitioner's arguments concerning its Testing Personnel's good motives and mistakes under a "quality control" program for only patient specimens has not been established by the evidence.

23. It is immaterial whether Petitioner had performed or intended to perform an analysis of Corning Laboratory's results before it filed its reports with the proficiency testing service.

24. Even if material, the truth of Petitioner's assertion that it never analyzed or intended to analyze the results from Corning Laboratory has not been established by the evidence.

25. The purpose of the alleged "quality control" referral procedures set up by Petitioner was for Petitioner, by its Testing Personnel, to compare the results it obtained in-house with those results obtained from another laboratory pursuant to referrals.

26. Under the alleged "quality control" referral procedures described by Petitioner, Petitioner, by its Testing Personnel, routinely compared the results she obtained for Petitioner in-house with those she obtained from another laboratory pursuant to referrals.

II. CONCLUSION

I order the revocation of Petitioner's CLIA certificate. In so doing, I issue also the following formal conclusions to resolve the ultimate issues before me, based on the legal authorities and evidence discussed above:

27. Petitioner has violated 42 U.S.C. § 263a(i)(4) and the regulations promulgated thereunder by the Secretary of HHS.

28. Pursuant to 42 U.S.C. § 263a(i)(4) and 42 C.F.R. §§ 493.801(b)(4), 493.1840(b), I uphold HCFA's determination to revoke Petitioner's CLIA certificate for one year.

29. Pursuant to 42 C.F.R. § 493.1842(a), 493.1808(a), and 493.1842(b), I uphold also HCFA's cancellation of Medicare payments for all tests performed by Petitioner.

Mimi Hwang Leahy
Administrative Law Judge

* * * Footnotes * * *

1. Because a timely request for hearing was filed by Petitioner, HCFA was precluded from effectuating its proposal to revoke Petitioner's CLIA certificate until a hearing decision is issued in HCFA's favor. 42 C.F.R. § 493.1840(e).

2. During the hearing, I received into evidence Petitioner's exhibits 1-20 (P. Ex. 1-20) and 22-32 (P. Ex. 22-32). Petitioner's exhibit 33 was not admitted into evidence on the basis of relevancy and because it was submitted after the deadline date for submitting proposed exhibits.

HCFA submitted three proposed exhibits (HCFA Ex. 1-3). Petitioner objected to HCFA Ex. 1 and 2. In my Ruling of February 5, 1997, I determined that certain parts of those exhibits should be deleted by HCFA, since those parts do not relate to the allegedly intentional referral of proficiency testing samples. HCFA resubmitted expurgated exhibits 1 and 2. During the hearing, I received into evidence HCFA Ex. 1-3.

3. Petitioner's post-hearing briefs will be designated as "P. Br." and "P. Reply;" HCFA's briefs will be designated as "HCFA Br." and "HCFA Reply." I cite to the transcript as "Tr."

Petitioner submitted four attachments (P. Att. 1-4) along with its post-hearing brief and one attachment along with its reply brief. At the conclusion of the in-person hearing I closed the evidentiary portion of the proceedings. Tr. 222. The attachments submitted by Petitioner with its briefs are not in evidence and have not been considered by me.

4. Petitioner was established as a laboratory in 1992. Tr. 145, 179.

5. A "reference laboratory" is a laboratory which receives specimens for analysis from physicians and laboratories which do not perform their own testing. Tr. 15.

According to the documents reviewed by HCFA, Petitioner was performing only about 2,000 tests each year. Tr. 90. Petitioner also introduced testimony to show that its physical plan

consisted of only four rooms: an office for the Director, an office for the Office Manager, a storage room, and the laboratory. Tr. 181.

6. An earlier version of the regulations published at 42 C.F.R. § 493.801(b)(4) stated that the laboratory's CLIA certificate would be revoked for at least one year if it referred proficiency test samples to another laboratory "and submits the other laboratory's results as their own." 42 C.F.R. § 493.801(b)(4)(1992). However, this subsection of the regulation was subsequently changed, to delete the reference to the submission of another laboratory's results. Under the version of the regulation applicable to this case, Petitioner's certificate must be revoked for at least one year even if its referrals of proficiency test samples did not also lead to the submission of the other laboratory's results. 42 C.F.R. § 493.801(b)(4)(1995).

Petitioner herein asserted that it did not compare its own proficiency test results with those received from another laboratory, nor did it substitute another laboratory's results for its own. Tr. 136. HCFA did not allege as part of its case-in-chief that Petitioner compared its results with another laboratory's results. Tr. 116. The documentary evidence of record does not show that the results of another laboratory had been placed on Petitioner's proficiency test reports.

7. HCFA's allegations resulted from the following circumstances: during the first testing period of 1995, Petitioner was not enrolled in any proficiency testing program, as was required by CLIA; additionally, when the survey was conducted during early April 1996, Petitioner had just completed the first (March) set of proficiency tests for 1996. Tr. 130-132. The HCFA official testifying at hearing did not know whether the surveyor had available for review any information from the testing service concerning Petitioner's proficiency tests for March 1996. Tr. 131.

8. The relevant statutory language is, "Any laboratory that . . . intentionally refers its proficiency testing samples to another laboratory for analysis . . ." 42 U.S.C. § 263a(i)(4). The implementing regulations specify that "[t]he laboratory must not send PT samples . . . to another laboratory for any analysis which it is certified to perform in its own laboratory." 42 C.F.R. § 493.801(b)(4). I read the foregoing as meaning that the referrals must be made for the purpose of having the other laboratory analyze the proficiency test samples. I agree with HCFA that the words "for analysis", "refer to the reason for the referral, in other words what the reference laboratory is requested to do with the samples, not what the referring laboratory does with the results." HCFA Reply at 2.

However, Petitioner interprets the "for analysis" language of the statute as requiring HCFA to prove that Petitioner had analyzed the results provided by Corning Laboratory. See P. Br. at 30-31. According to Petitioner, HCFA must show that Petitioner made the referrals with the intent that Petitioner would analyze the test results obtained from the referrals in the sense that it would compare its results on the proficiency samples to those obtained from Corning Laboratory or that it would otherwise use the

results obtained from Corning Laboratory. I reject Petitioner's legal interpretation for being contrary to the plain language of the statute and implementing regulations.

To the extent Petitioner's use of the Corning Laboratory results has bearing on Petitioner's affirmative defense, I will evaluate elsewhere in this Decision the relevant facts asserted by Petitioner.

9. Because Petitioner's counsel claimed surprise upon hearing that Corning Laboratory had informed HCFA's witness of the actual delivery time of the relevant reports, I provided Petitioner's counsel with the opportunity to further explore the matter with Corning Laboratory and, thereafter, to assert whatever disputes of fact as may be appropriate. After conversing with Corning Laboratory during a recess, Petitioner's counsel indicated that it was not disputing the delivery time of the reports, as earlier recounted by HCFA's witness.

10. Given the stipulation concerning Ms. Abernathy's training and classification under CLIA, I will refer to her as the "Testing Personnel" herein.

11. Contrary to what has been implied by Petitioner, the instructions allegedly given by Dr. Premachandra are not in accord with the law. In attempting to justify the instructions, Petitioner contended that "federal regulations require laboratories to treat proficiency samples in the same manner as patient samples." P. Br. at 11. Petitioner's contention is not correct. The relevant statute and regulations quoted in this Decision make clear that a laboratory is limited to testing proficiency test samples on its own, in-house, and without referrals to another laboratory for analysis; additionally, the manner in which the laboratory tests proficiency samples on its own and in-house must be the same as when it tests patients samples in-house and on its own. These limitations are not consistent with Dr. Premanchandra's broad-based instructions to "handle" or "treat" proficiency test samples like all patient specimens. The statute and regulations do not permit any laboratory to "treat" or "handle" the proficiency test samples in the same manner as patient specimens for the purpose of making referrals to another laboratory for analysis.

12. I discuss in a separate section below my rejection of Petitioner's affirmative arguments based on Dr. Premachandra's descriptions of his intent when he established the "random" referral process.

13. Petitioner's Office Manager, who denied having used Corning Laboratory's results when she completed the proficiency test reports, testified also that she did not know or could not remember from what source she had acquired the understanding, in 1995, to report only the proficiency test results attained by Petitioner itself. Tr. 157-158.

14. I find the procedures relevant because no evidence was presented by either party to suggest that different steps were taken in the referrals of June or October of 1995.

15. Petitioner's recorded test volume was just over 2,000 tests per year. It received five samples to test for each of the three proficiency test cycles.

16. Dr. Premachandra testified that he would be told only of "big variations" between Petitioner's own results and the

results attained by another laboratory. Tr. 191. If a big variation existed, he would be told by the Testing Personnel or the Office Manager and then consider the situation. Id.

17. During the hearing, HCFA made clear that, for its case in chief, it was not contending that Petitioner had compared its results with Corning Laboratory's results; however, if Petitioner presented evidence as an affirmative defense that no comparisons were made by Petitioner, then HCFA reserved the right of rebuttal. Tr. 116-19.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

Date: March 31, 1998
In the Case of:
Eugene R. Pocock, M.D.,
Petitioner,
- v. -
Health Care Financing Administration.
Docket No. C-97-024
Decision No. **CR527**

DECISION

For the reasons stated below, I conclude that Petitioner, Eugene R. Pocock, M.D. (Petitioner), was an "operator" as that term is defined in 42 C.F.R. § 493.2. Consequently, the Health Care Financing Administration's (HCFA) determination to prohibit Petitioner from owning or operating a laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed.

I. Background

A. Applicable law and regulations

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), 42 U.S.C. § 263a, were enacted by Congress to ensure that the results of tests performed in clinical laboratories, including those tests performed in physicians' office laboratories, are reliable and accurate. See H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N., 3828, 3829. The statute provides as follows:

> [n]o person may solicit or accept materials derived from the human body for laboratory[(1)] examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

42 U.S.C. § 263a(b).

CLIA '88 was intended by Congress to establish one set of standards which would govern all suppliers of laboratory services, including those which supply laboratory services to Medicare beneficiaries. See 1988 U.S.C.C.A.N., at 3829, 3843.

The statute directed the Secretary of the United States Department of Health and Human Services (Secretary) to issue regulations to implement various provisions set out in CLIA '88, including standards to assure consistent performance of valid and reliable laboratory examinations by laboratories issued a certificate under the Act. 42 U.S.C. § 263a(f)(1). The Secretary's regulations implementing CLIA '88 are found in 42 C.F.R. Part 493.

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.

Finally, under 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), no person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation own or operate (including serve as laboratory director - see 42 C.F.R. § 493.2) a laboratory.

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in Hillman Rehabilitation Center, DAB No. 1611 (1997). Under Hillman, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that Petitioner failed to comply with participation requirements. Petitioner has the burden of proving, by a preponderance of the evidence, that it complied substantially with participation requirements.[(2)] In determining whether HCFA has met its burden of establishing a prima facie case, I may consider rebuttal evidence offered by Petitioner that HCFA's evidence is neither credible or relevant to the issue

of Petitioner's compliance with the participation requirements or that the weight of the evidence establishes that the regulatory deficiency alleged by HCFA did not occur. Hillman Rehabilitation Center, DAB CR500, at 3-8 (1997). If I conclude that the preponderance of the evidence establishes that such circumstances exist, then I will find that HCFA has not met its burden of establishing a prima facie case (but rather its case is based on unsubstantiated allegations) and Petitioner will not be obligated to prove that it was substantially complying with the participation requirements.[3]

B. History of this case

In July 1996, the California Department of Health Services, Laboratory Field Services (State agency), initiated an investigation of WML based on a complaint that WML had fabricated test results. Tr. 42.[4] The investigation was expanded into a full survey, which was completed on August 16, 1996. Tr. 43, 44, 46. The State agency examiners determined that WML failed to meet ten of the required CLIA conditions of participation. The examiners determined also that the problems identified during the survey presented immediate jeopardy to the health and safety of patients served by WML. WML at the time of the survey was certified under CLIA (based on an accreditation from the College of American Pathologists (CAP)) to perform the following testing: histopathology, cytology, parasitology, bacteriology, hematology, chemistry, special chemistry, and immunohematology. It served as a reference laboratory for physicians' offices, hospitals, and other entities. Tr. 45. WML had reported to the State agency that it performed testing in bacteriology, mycology, parasitology, virology, syphilis serology, general immunology, routine chemistry, urinalysis, toxicology, hematology, ABO & Rh Group, antibody ID, compatibility testing, histopathology, and cytology. HCFA Ex. 31.

By notice dated September 11, 1996 (Notice), HCFA informed Petitioner and WML that WML remained out of compliance with the ten conditions previously specified in an earlier August 21, 1996 letter (HCFA Ex. 15) and that immediate jeopardy had not been removed.[5] See HCFA Ex. 16. HCFA stated further that the following sanctions, which had been proposed in that August 21, 1996 letter, would be imposed: suspension of the laboratory's CLIA certificate effective September 16, 1996; revocation of the laboratory's CLIA certificate; and cancellation of the laboratory's approval to receive Medicare payments for its services performed on or after September 16, 1996. HCFA stated also that payment under the Medicaid program would no longer be available to the laboratory for any laboratory services performed on or after September 16, 1996, should these sanctions occur. Furthermore, HCFA informed Petitioner and WML that, under revocation, the present owner or operator (including director) would be prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. Lastly, HCFA directed Petitioner and WML to submit a list of names and addresses of all physicians, providers, suppliers, and other clients who had used some or all of its services from December 1, 1994 to the present date.

Petitioner submitted a request for hearing dated September 12, 1996 and WML submitted a request for hearing dated September 13, 1996. During a telephone prehearing conference that I held on October 25, 1996, I informed the parties that my office had docketed the hearing request of Petitioner as a separate case. Counsel for HCFA raised the issue of whether Petitioner, as an individual, had standing, and thus, appeal rights, to contest HCFA's sanctions. I informed counsel for HCFA that HCFA could brief this issue and that both counsel for Petitioner and counsel for WML could file responses. HCFA filed a Motion to Dismiss Request for Hearing by Petitioner. Petitioner filed a response brief in which he opposed HCFA's motion. HCFA filed a reply brief.

I issued a ruling dated March 3, 1997. In my ruling, I determined that Petitioner is an affected party and has a right to a hearing under 42 C.F.R. § 498.40, which flows from the sanctions imposed by HCFA against WML.[6] Accordingly, I denied HCFA's Motion to Dismiss Petitioner's hearing request. Furthermore, in my ruling, I stated that the scope of Petitioner's hearing rights encompasses the following issues:

1) whether or not Dr. Pocock is an "operator" as defined in the regulations; (see infra pp. 28-34)

2) whether any of the laboratory activities which are alleged to be deficiencies were in violation of federal regulatory standards for a laboratory; (see infra pp. 34-37)

3) whether any of the alleged deficiencies, if proven, are subject to sanctions; (see infra pp. 36-37)

4) whether any of the alleged deficiencies occurred while Dr. Pocock was an operator, assuming he is found to be an operator. (see infra pp. 37-38)

Prior to my issuing the March 3, 1997 ruling, WML, through counsel, withdrew its request for hearing by letter dated February 25, 1997. In an order/ruling dated May 20, 1997, I dismissed the action involving WML pursuant to 42 C.F.R. § 498.68 with the understanding that WML had waived its right to any further review of the sanctions imposed by HCFA which were set forth in HCFA's September 11, 1996 letter. I stated in my order/ruling that Petitioner's hearing request, however, remained before me. I addressed HCFA's argument that two of the four issues which I set out in my March 3, 1997 ruling were rendered moot as a result of WML's withdrawal of its hearing request. I ruled that WML's actions had not rendered any issues moot with respect to Petitioner's case. The alleged deficiencies cited by HCFA continued to remain "alleged" and unadjudicated as to Petitioner. I found that WML's withdrawal of its hearing request did not constitute an implicit validation of HCFA's findings of deficiencies. Consequently, all four issues which I set forth in my March 3, 1997 ruling remained valid as they related to Petitioner.

As a result of WML's withdrawal of its hearing request, and my order dismissing its case, revocation of WML's laboratory CLIA certificate took effect on June 5, 1997.[7] HCFA Br., at 1, 11.[8]

I held a hearing in this case in Los Angeles, California, from June 23-27, 1997. At the hearing, I received and admitted into evidence HCFA's exhibits 1, 2, and 4-40 (HCFA Exs. 1, 2, 4-40) and Petitioner's exhibits 1-12, 14-17 (P. Exs. 1-12, 14-17). HCFA Ex. 3 was withdrawn. I rejected P. Ex. 13.

The parties filed posthearing briefs and response briefs.

I base my decision in this case on the governing law, the evidence I received at hearing, and on the parties' arguments as expressed in their briefs. Any arguments raised by the parties but not specifically addressed in this decision have been rejected. I use the following format for my decision. The numbered paragraphs, as well as the subsection headings, set out in bold face are findings and the descriptive text under each numbered paragraph and/or subsection heading is my rationale for such finding.

II. Discussion

1. The record amply supports that Petitioner was the laboratory director of WML for CLIA purposes for all aspects of the operation of WML.

Petitioner and his partner, Dr. Arthur Williams, and their corporation, Consulting Pathologists Medical Group, Inc., became associated with WML in February 1996. See Tr. 1217. Petitioner's main assertion is that, although he did assume the role of laboratory director of WML for State purposes, he was never at any time the laboratory director for CLIA purposes. Furthermore, Petitioner asserts that, as the director, he was only responsible for the anatomical testing section of the laboratory.

I find, contrary to Petitioner's assertions, that the record amply supports that Petitioner was the laboratory director of WML for CLIA purposes for all aspects of the operation of WML.

At the outset, it is abundantly clear from this record that Petitioner's past experience as a laboratory director under CLIA put him in a position where he knew or should have known of the requirements of the statute and regulations and the consequences arising from failure to abide by the conditions of participation set forth in 42 C.F.R. § 493 et. seq. Prior to February 1996, Petitioner had been the CLIA director at the laboratory for Foothill Presbyterian Hospital (Foothill).[(9)] Tr. 1067, 1068, 1205. Petitioner testified that, at Foothill, he was the primary director under CLIA for the whole laboratory and had responsibility for both the clinical and anatomical pathology areas. Tr. 1067, 1068, 1108, 1121, 1216, 1217.[(10)]

As the CLIA director at Foothill, Petitioner's responsibilities included the oversight of quality control with respect to all laboratory testing and oversight of patient test management and quality assurance. Tr. 1121, 1122. Petitioner stated that he has an "understanding" of the CLIA requirements in each of the aforementioned areas. Tr. 1122. Petitioner testified that he was cognizant of the fact that he was the CLIA director of Foothill because Foothill "asked [him] to be CLIA director" and he filled out an initial CLIA application designating himself as the director. Tr. 1205, 1206, 1209. Petitioner stated also that he was listed as the laboratory director of Foothill on the laboratory's State license. Tr. 1108.

Petitioner testified also that he had been the CLIA laboratory director for Physicians Clinical Laboratory (PCL) and was also listed as its director on the State license.[(11)] Tr. 1205. With respect to PCL, Petitioner stated that he was added on as the CLIA director after the CLIA license had already been issued to the laboratory. Tr. 1206, 1217. Although Petitioner could not recall if he had filled out a form adding him as CLIA director, he testified that "[i]t was clear that those would be my responsibilities," and PCL "asked [him] for permission to become a CLIA director." Tr. 1206, 1207.

Based on Petitioner's past experience as a CLIA director at other laboratories, Petitioner should have been aware of CLIA requirements and the responsibilities of being a CLIA director. Indeed, Petitioner acknowledged that he is familiar with the CLIA requirements with respect to directing a laboratory. Tr. 1120. Petitioner gave further testimony that by February 1996, when he became associated with WML, he was familiar with the responsibilities of a CLIA director because he had previously been a director. Tr. 1217.

The record reflects that Petitioner's corporation, Consulting Pathologists Medical Group, Inc., entered into a contractual agreement with WML effective February 6, 1996. P. Ex. 1. Petitioner testified that he and Dr. Williams were primarily motivated to enter into the contract for financial reasons and did not see it as a money-losing contract. Tr. 1059, 1098, 1099. Petitioner stated that he and Dr. Williams saw an affiliation with WML as a means to "expand [their] business" and thereby increase their revenue. Tr. 1056. In particular, Petitioner and Dr. Williams hoped that doing business with WML would potentially result in "pull through" business for their own corporation. Tr. 1096. Petitioner testified that by "pull through" business, he was referring to the situation where a physician's office would, under an health maintenance organization (HMO) contract, send laboratory tests to a laboratory but would also send testing for their private insurance paying patients to the laboratory as well. Tr. 1096; see 877, 878. The laboratory would, in essence, be "pulling through" private business through the HMO. Id.[(12)]

Prior to signing their contract with WML, Petitioner and Dr. Williams made only a cursory check of WML's operations.[(13)] They visited WML on two occasions. Tr. 1100. On one of their visits, according to Petitioner and Dr. Williams, they took a quick, self-guided tour of WML. Tr. 872, 1100, 1101. At no time did they speak to any testing personnel or laboratory managers or inquire into any quality control or quality assurance procedures used by WML. Tr. 1101, 1102. Apparently, the desire to expand their patient base and increase revenue for their corporation was a stronger influence on Petitioner and Dr. Williams than making reasonable checks on WML's operations prior to their agreement to be directors of WML.

It is evident also from the record that Petitioner failed to make reasonable inquiries of past laboratory directors of WML. Petitioner testified that Dr. William R. Starke, a pathologist who had been a former director of WML, had called him in February or March 1996 and informed him that he and his partner, Dr. Craig L. Fischer, had problems getting paid by Mr. Watson under their contractual agreement. Tr. 1117-1119. Petitioner stated that he was aware that Mr. Watson was severing WML's contractual relationship with Drs. Fischer and Starke, and accordingly, felt that Dr. Starke was calling him out of "sour grapes." Tr. 1118. At no time did Petitioner feel concerned or make any inquiries with Drs. Fischer or Starke as to why their contract with WML had ended. While it may not have been of great necessity for Petitioner to have inquired further, by doing so, Petitioner at least would have had a better understanding of how Mr. Watson conducted the business aspect of WML's operations.*(14)*

2. Petitioner's assertion that he was not the CLIA director of WML is contradicted by the documentary evidence.

The record contains a copy of an "Application for Renewal of Clinical Laboratory License" which was signed by Petitioner and submitted to the State agency. HCFA Ex. 32. According to this document, the current license of WML was to expire on December 31, 1995 and the renewal fee of $768.00 was due January 1, 1996.*(15)* The current directors listed on this renewal application are "Douglas W. Andorka MD" and "Craig L[.] Fischer MD." However, at the bottom of this application, Petitioner's name is printed on the line given for "Director's Printed/Typed Name" and his apparent signature appears on the line given for "Director's Verification Signature of No Changes." Id.*(16)* Mr. Watson's name is nowhere listed as director on this document.

In a letter dated September 1, 1995, addressed to the State agency, Dr. Andorka states that he is notifying it that he "will no longer be the Laboratory Director of [WML] as of September 1, 1995." HCFA Ex. 40.

Accordingly, by December 31, 1995, there had been changes with respect to the directorship of WML and these changes had been brought to the attention of the State of California. Dr. Andorka had resigned and was no longer affiliated with WML and Petitioner had come "on board" as co-medical director of WML for State purposes.

Also in evidence is a copy of the Clinical Laboratory License, effective January 1, 1996, issued by the State agency to WML. HCFA Ex. 38. The expiration date on the license is December 31, 1996. The "Owner(s)" is listed as "Watson Medical Laboratories, Inc." and the "Director(s)" are listed as "Craig L[.] Fischer MD," "Arthur H[.] Williams MD", and "Eugene R[.] Pocock MD." Id.*(17)*

In a letter dated February 6, 1996, written by Mr. Watson to Alice Brydon at the State agency, Mr. Watson stated that Drs. Williams and Pocock "will be added as Medical Directors of Watson Medical Laboratories, Inc., effective today, February 6, 1996." Watson signed the letter and under his name is the title "President/C.E.O." HCFA Ex. 30. In another letter written to Alice Brydon, also dated February 6, 1996, Dr. Williams states "[t]his letter is to formally notify yourself and Laboratory Field Services that myself, Arthur H. Williams, M.D., and my partner, Eugene R. Pocock, M.D.[,] will be added as Medical Directors of Watson Medical Laboratory, . . . effective today, February 6, 1996." HCFA Ex. 35.

The record contains also a letter dated February 9, 1996 from Dr. Starke to the State agency. Dr. Starke wrote "[e]ffective immediately, 9 February, Doctors Craig L. Fischer and the undersigned have resigned as the Medical Laboratory Directors for Watson Medical Laboratories . . . ." HCFA Ex. 39.

Thus, based on HCFA Exs. 30, 35, and 39, after Dr. Starke and Dr. Fischer resigned on February 9, 1996, Petitioner and Dr. Williams were the only laboratory directors (for State purposes) remaining at WML. The State agency was put on notice by the correspondence described above that a change of directorship had occurred at WML and that the only directors affiliated with WML, as of February 9, 1996, were Petitioner and Dr. Williams.

On August 16, 1996, Petitioner and Dr. Williams jointly sent a letter to the State agency stating that they "have resigned as Medical Directors of Laboratories as of this date, August 16, 1995 [sic]." P. Ex. 5, at 1. Both Petitioner and Dr. Williams signed this letter.

The record contains further documentary evidence that indicates that, despite Petitioner's protestations to the contrary, Petitioner acted as the laboratory director of WML and was overseeing the operation of WML. In February 1996, Petitioner completed and returned to the State agency a form which sought information regarding the laboratory's cytology services. HCFA Ex. 29. The questions on the form were intended to be completed by whomever was WML's laboratory director. Id.*(18)* At the end of it, Petitioner printed and apparently signed his name on the lines designated for the laboratory director.*(19)* The form was dated February 16, 1996. In signing this form, Petitioner signed as the sole director of WML. Accompanying this document is a list of the names and addresses of personnel employed to read cytology slides at WML. Petitioner's and Dr. Williams' names and addresses appear on the list. At the bottom of each page of the list (the list consists of ten names on two pages), Petitioner has signed on the signature line provided for the "laboratory director." Id. The pages are dated February 16, 1996.

Petitioner apparently signed another document titled "Laboratory Testing Report," which was dated February 16, 1996 and submitted to the State agency. HCFA Ex. 31.*(20)* The purpose of this form was for WML to indicate the "specialties/subspecialties" in which it was currently testing. Petitioner's signature appears on the line designated for the "director" and wrote in the word "Director" as his title. Mr. Watson signed on the line provided for the "owner" and identified himself as "CEO/President." At the hearing, I questioned Petitioner regarding HCFA Ex. 31:

Q: Isn't it a fair statement that a recipient of this particular document, HCFA Exhibit 31, could assume from reading the document that the laboratory director of Watson Medical Laboratories Inc. on February 16th, 1996 was [Petitioner]?

A: The state director, yes. . . .
Q: But on this particular document, there's only one reference to director. Would you agree with that?
A: Yes, I do.
Q: And the only director of this laboratory mentioned on this document is [Petitioner].
A: That is true.
Tr. 1147, 1148.
Nowhere on HCFA Ex. 31 is there any indication that Mr. Watson is a laboratory director or that he is representing himself to be a director. By signing this form, Petitioner signed as the director of both the clinical and anatomical areas of WML.[(21)]
Furthermore, the record contains two completed laboratory personnel reports. HCFA Exs. 2, 37. HCFA Ex. 37 is a report dated February 16, 1996, which lists all the names of WML's laboratory personnel, their work shifts and workdays, their California license numbers, and their functions. On this report, Petitioner's name is listed, and his functions are denoted to be that of director, general supervisor, and technical supervisor. HCFA Ex. 37, at 1. Dr. Fischer's and Dr. Williams' names are also listed, and their functions are also denoted to be that of director, general supervisor, and technical supervisor. Id. at 2, 3. Paul Watson's name appears on this form as well and he is listed as being a technical supervisor and technologist. Id. at 3. Nowhere on this document is it indicated that Mr. Watson is the director of WML.
At the bottom of each page of HCFA Ex. 37, Petitioner's signature appears on the signature line for the laboratory director.[(22)] No one else's signature appears on the report as the laboratory director.
Petitioner gave testimony that he filled out HCFA Ex. 37 "as a state laboratory director." Tr. 1218, 1219. He testified that "there is no clear designation" on HCFA Ex. 37 as to which of the three directors listed would have been designated as the CLIA director. Tr. 1226. Petitioner stated that "[a]ny one of the three could have signed this form." Id. He acknowledged that, on the form, Mr. Watson was not designated as a director for any purposes, either State or federal. Tr. 1219; see Tr. 1218. Petitioner testified further that when he signed the form, he believed that Mr. Watson was the "primary CLIA director." Tr. 1218.
I questioned Petitioner concerning HCFA Ex. 37:
Q: When you signed HCFA Exhibit 37, did you read that document?
A: Again, your Honor, I can't recall whether I read it. . . . This is again the first week and there is a learning curve . . . at this time I felt that I could take the information as to be true and therefore I signed it under those conditions. . . .
Q: So the information on this document as reflected on page 3 is that Mr. Watson is not director, correct?
A: That is correct.
Tr. 1221, 1222.
Q: Who did you think was going to be ultimately responsible for the actions of the lab based on this document, HCFA Exhibit 37?
A: I can't base it on these documents. I have to base it on the testimony of those that work there and what we were told.
Tr. 1223.
Finally, the other laboratory personnel report, which is titled "Laboratory Personnel Report (CLIA)" [CLIA personnel report], is dated August 6, 1996 and was completed during the survey of WML. HCFA Ex. 2. This report lists the names of WML's employees, their positions, work shifts, and whether they are qualified to do moderate or high complexity testing. Petitioner's name is the only person designated on this personnel report as the director. Id. at 2. Petitioner is designated as being the director in the specialties of immunohematology, histopathology, and cytology. Id.; see HCFA Ex. 34.[(23)] In addition to the position of director, Petitioner is also denoted as holding the positions of clinical consultant and technical consultant in all three of the aforementioned specialties and is listed as a technical supervisor in immunohematology and histopathology.[(24)] HCFA Ex. 2. On the same form, Mr. Watson is denoted as being a technical supervisor in the specialties of diagnostic immunology, chemistry, and hematology. Id. at 3; see HCFA Ex. 34. Nowhere is it indicated on the form that Mr. Watson is the director over any of the testing specialties. I note that Dr. Williams' name does not appear on this personnel report and he is not listed as holding any position with WML. At the bottom of the report, in the space for the laboratory director's signature, Petitioner has apparently signed his name and dated the report "8-6-96."[(25)] The certification above Petitioner's signature indicates: "CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY, TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M." HCFA Ex. 2.
42 C.F.R. § 493.1351 states that Subpart M "consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests." Petitioner, by signing this form, was identifying himself as the only director of WML and attesting that he was the only person qualified to function as the laboratory director for WML with respect to such testing.
In his posthearing brief, Petitioner points out that this personnel directory (HCFA Ex. 2) "does not list him as the director of all areas of the laboratory, but rather only the director of the areas which fall into the anatomical area of WML." P. Br., at 10. However, Petitioner contradicts himself in his response brief, stating that "HCFA Exhibit 2 . . . designates [Petitioner] as director of two areas of the lab falling under the anatomical section of the lab and one area falling under the clinical section." P. R. Br., at 1.

Based on Petitioner's own statement, then, his directorship of WML did cover both the anatomical and clinical sections of WML. Moreover, based on the testimony of Esther-Marie Carmichael, who is a laboratory consultant with HCFA, immunohematology is a specialty for which Petitioner alone possessed the directorship qualifications under CLIA. This establishes further that Petitioner was the director of more than just the anatomical section of WML.
Ms. Carmichael, when questioned about Petitioner's functions with respect to the specialty of immunohematology, first explained that immunohematology "includes . . . antibody identification and compatibility testing. And transfusion service," which all have to do with blood. Tr. 1310. Ms. Carmichael testified that immunohematology is a clinical area of laboratory testing. Tr. 1312. Moreover, under CLIA, only a medical doctor is permitted to serve as laboratory director over this specialty. Tr. 1310. Ms. Carmichael stated further that, in the State of California, a bioanalyst who was licensed prior to September 1, 1992, could also be a director over immunohematology under CLIA. Tr. 1310-1311. After September 1, 1992, in California, a bioanalyst, to serve in that position, would have to be board certified in one of the specialties designated by CLIA. Tr. 1311. According to Ms. Carmichael, to qualify as a technical supervisor over immunohematology under CLIA, the individual must be a medical doctor in order to perform the compatibility testing associated with transfusions. Tr. 1311. Ms. Carmichael stated that Mr. Watson could not have met the qualifications of technical supervisor because "[h]e's not an M.D," nor could he have met the qualifications of director because "he wasn't a bioanalyst." Id. Ms. Carmichael testified that, for WML to be certified to perform immunohematology testing, it was necessary to have Petitioner act as the supervisor for that specialty because of the CLIA requirements. Id.
Petitioner himself gave testimony that "immunohematology has to do with blood banking, the tests for typing of blood and similar issues." Tr. 1160. He stated that these tests are part of the clinical testing area of the laboratory. Tr. 1161. Petitioner testified that compatibility testing is one of the specialties in immunohematology and acknowledged that the laboratory testing report (HCFA Ex. 31), which he had signed as the Director, indicated this category as being one of WML's testing areas. Tr. 1161. Petitioner testified further that he "believe[s]" he can do immunohematology testing and compatibility testing. Id.
As I stated above, the CLIA personnel report indicates that Petitioner holds the positions of director, clinical consultant, technical consultant, and technical supervisor in the specialty of immunohematology. HCFA Ex. 2, at 2. Because immunohematology is a clinical area of testing, there can be little doubt that Petitioner served as the director, for CLIA purposes, of both anatomical and clinical testing at WML.
Moreover, notwithstanding his claim that he did not supervise the clinical area of the laboratory (Tr. 1164), Petitioner testified that, as co-director for State purposes, he considered it appropriate to respond to questions that came up in the clinical testing section of the lab. Tr. 1163, 1164. Petitioner acknowledged that he signed proficiency testing from the clinical part of the laboratory "[o]n rare occasions when Doctor Watson didn't." Tr. 1164.
Petitioner makes the assertion that he signed the CLIA personnel report when "Watson was absent." P. Br., at 10. Petitioner contends, in effect, that the reason he signed the form was because there was no one else around at WML during the survey who could have signed it and Mr. Watson was not available. Id. at 2. Petitioner's argument is misdirected. Even if Mr. Watson had been present during the survey of WML, he could not have signed the CLIA personnel report. The report specifically requires the signature of the laboratory director and Mr. Watson did not hold this position. The CLIA personnel report lists Mr. Watson as holding the position of technical supervisor. Id. at 3. A technical supervisor is a distinct and separate position from that of laboratory director and does not in any way carry with it the duties and responsibilities of a director. Also, as I stated above, Dr. Williams' name nowhere appears on this report. Thus, of all the WML personnel listed in the report, Petitioner was the only employee who could have legally signed it as the laboratory director, and he did.
The record contains also a July 25, 1996 letter from CAP to WML regarding a complaint. P. Ex. 4, at 1. The letter was addressed to Petitioner and stated that CAP was aware of a "complaint alleging improper practices in your laboratory that could affect patient care." Id. The letter requested Petitioner to "submit current policies and procedures" regarding certain areas in order to enable CAP to investigate the complaint. Id. In a letter to CAP dated August 22, 1996, Petitioner and Dr. Williams responded to the July 25, 1996 letter. P. Ex. 4, at 4. In the letter they stated that they "have been medical directors of Watson Medical Labs, Inc., since February of 1996." Id. They explained their relationship with WML and recent troubles experienced by WML. At the end of the letter, Petitioner and Dr. Williams requested that WML "be removed from the Laboratory Accreditation program" and stated also that they had resigned as "Medical Directors" of WML effective August 16, 1996. Id. at 5.
Based on a review of all the records sent to the State of California concerning the laboratory directors of WML from February 6, 1996 onward and of the CLIA documents provided by WML during the survey of July-August 1996, Petitioner's name appears as either co-director or sole director of WML. There are no documents of record demonstrating a contrary conclusion.
As is evident from his testimony, Petitioner attempts to play down any significance of his having signed HCFA Ex. 37. However, the fact remains that, on each page, Petitioner signed his name on the laboratory director's signature line. Petitioner by this time was familiar with CLIA requirements and would have known that one individual would be ultimately responsible for the actions of WML. I find not credible Petitioner's claim that he should not be considered the director for CLIA purposes.
Based on the testimony of Ms. Carmichael, HCFA, to determine who holds the position of CLIA director at a laboratory, relies on the information supplied by laboratories to the State agency and on HCFA form 209 (i.e., HCFA

Ex. 2--the CLIA personnel report) which is completed and signed by the laboratory director during the CLIA survey reflecting the roles of existing personnel of the laboratory. HCFA does not have a specific document that a laboratory director completes when he or she agrees to assume that position or when there is a change in directorship. Tr. 606, 608.

It thus strains credulity to say that Petitioner did not believe that he was signing the various documents discussed above as the director for CLIA purposes. The record plainly shows that Petitioner signed documents as the "director" of WML. Petitioner had to know that he could and would be held accountable under the CLIA regulations. I am not persuaded by Petitioner's assertions that Mr. Watson, and not he, was the laboratory director of WML. Petitioner testified that he believed that his "responsibilities was to conduct anatomic pathology. That was a service that [Mr. Watson] wanted from us." Tr. 1061. However, I find that Petitioner accepted full responsibility as laboratory director for all testing services completed by WML, including clinical and anatomical. Consequently, as laboratory director (i.e. operator), he assumed responsibility for compliance with CLIA conditions of participation.

3. The employment contract between Dr. Williams and Petitioner and WML further establishes that Petitioner was assuming full co-directorship of the laboratory.*(26)*

In addition to the documents discussed above, the contract between Mr. Watson/WML and Petitioner's incorporated pathology group (P. Ex. 1) is another key piece of evidence demonstrating that Petitioner was the **sole** director of the entire laboratory and not just the anatomical section of WML and that Mr. Watson was **not** the director over the entire laboratory. To begin with, the contract states on its face that WML was to retain the services of Petitioner and Dr. Williams "to provide medical direction and supervision of certain of its clinical laboratory facilities" and to perform "certain pathology services." P. Ex. 1, at 1. Moreover, Petitioner and Dr. Williams agreed in their contract with Watson/WML that they "would ensure adherence to all applicable Title 22, CAP policies, and all Federal and other governing regulations and standards that apply to laboratory services." Id. at 2.

4. Petitioner's arguments that the employment contract is invalid are rejected for the reasons set forth below.

(a). The evidence of record does not support Petitioner's assertion that the employment contract was induced through the fraud and deceit of Mr. Watson and therefore is invalid.

Despite the contractual language, Petitioner contends that this contract did not make him the operator/director of WML. P. Br., at 7. Petitioner alleges that he was induced into the contract "through fraud and deceit on the part of Paul Watson." Id. at 7, 8. Petitioner's allegations of fraud pertain to Mr. Watson's apparent willful misrepresentation of his educational background and qualifications. Petitioner contends that Mr. Watson held himself out as a licensed Ph.D. bioanalyst who was the director of WML. Id. at 5. Petitioner argues that, as a bioanalyst, Mr. Watson would be qualified to be a laboratory director for CLIA purposes. Id.*(27)* Furthermore, Petitioner contends that Mr. Watson deceitfully led Petitioner and Dr. Williams into believing that WML had received CAP accreditation through an on-site survey in December 1995. Id. at 7. Additionally, Petitioner argues that Mr. Watson had orally changed the terms of the contract so that the "printed contract was wholly inconsistent with the expected performance of responsibilities and duties" of Petitioner as laboratory director. Id. at 8. The cornerstone of Petitioner's argument is that Mr. Watson was qualified as a bioanalyst to be the laboratory director of WML. Despite this assertion, there is no evidence of record demonstrating that Mr. Watson had the necessary educational background to be qualified as a bioanalyst. See supra p. 16; see also infra pp. 24-25. Additionally as will be discussed more fully below, Petitioner never really ascertained the exact nature of Mr. Watson's qualifications to be a laboratory director prior to or while he was associated with WML. Of greater significance is the fact that the specific contractual terms do not indicate that Mr. Watson was to have any role as laboratory director.

Regarding the CAP accreditation, the evidence of record indicates that numerous deficiencies in the operation of WML were cited at a December 15, 1994 on-site inspection of WML. HCFA Ex. 36. The CAP inspection report cited deficiencies in such areas as quality assurance, quality control, and procedure manual contents. See Id. Following its submission of corrective action, WML was found to meet the standards of accreditation. Because WML apparently did receive accreditation in December 1994, I found somewhat puzzling Petitioner's contention that he was deceitfully led to believe that WML had received CAP accreditation through an on-site survey in December 1995.*(28)* While Petitioner contends he was misled as to the findings of the CAP survey, he did admit that he never asked to see the CAP inspection report.*(29)* Tr. 1054, 1055.

(b). Petitioner did not exercise due diligence in attempting to discern the qualifications of Mr. Watson to be a laboratory director or whether he was in fact a state laboratory director prior to entering into the employment contract with WML.

I find that whatever erroneous perception that may have been generated by Mr. Watson as to his qualifications was influenced to a significant degree by Petitioner's own lack of effort to verify the alleged claims of Mr. Watson. The record reflects that Petitioner made no attempts to verify Watson's claim that he was a bioanalyst. Tr. 1103, 1104. Rather than making inquiries himself about Mr. Watson, Petitioner relied on an investigation conducted by Dr. Williams. Tr. 1055, 1056, 1103. Dr. Williams confined his inquiry into the background of Mr. Watson to: speaking to the other pathologists in his group and asking them whether their friends had heard of Mr. Watson and asking various hospital laboratory managers about Mr. Watson's reputation in the community. Tr. 942. Dr. Williams testified that members of his pathology group had not heard of Mr. Watson. Tr. 942.

Petitioner himself admitted that he never saw any documents signed by Mr. Watson as either "Dr. Watson" or "Paul Watson, Ph.D." nor did he ever ask to see documentation indicating he was a Ph.D. bioanalyst. Tr. 1104, 1141, 1053.

Moreover, Petitioner testified that he never saw anything that stated that Mr. Watson was the laboratory director of WML. Tr. 1132, 1164. I questioned Petitioner on this subject:
Q: Doctor, during the entire time that you were affiliated with [WML] did you ever see any written documentation that bore Mr. Watson's signature as the laboratory director?
A: No, I did not.
Tr. 1132.
Petitioner never checked with the State agency regulating laboratories to determine what Mr. Watson's status was with respect to the position of laboratory director. The record fails to show that as of February 2, 1996, Mr. Watson had a current license from the State of California as a laboratory director as required under 42 C.F.R. §§ 493.1405(a), and 493.1443(a). Petitioner should have been aware that Mr. Watson never indicated in any regulatory document going to the State of California for licensing purposes or submitted for CLIA purposes that he was a bioanalyst, medical director, or laboratory director. In fact, Mr. Watson, in signing the letter of February 6, 1996, notifying the State agency that Drs. Williams and Pocock would be added as Medical Directors of WML, gave his title as "President/C.E.O." HCFA Ex. 30. The licenses are a matter of public record and their contents could have been verified easily by contacting the State agency. As I discussed above, there is no documentation concerning WML establishing that Mr. Watson was the director of WML. Tr. 1219. Ms. Carmichael testified that she reviewed the State file on WML and there was nothing in the file to indicate that Mr. Watson was the laboratory director during the time Petitioner was involved with WML. see Tr. 582.

(c). Whether the employment contract was dated or not at the time it was signed by Petitioner and Dr. Williams is not material to the validity of the contract.

Dr. Williams contended that he and Petitioner submitted a signed but undated contract to Mr. Watson as a proposal. Tr. 1027, 1028, 1031. He testified that Mr. Watson may have put the dates in. Tr. 1027. The contractual document offered by Petitioner and accepted in the record contains dates by the signatures of Petitioner, Dr. William and Mr. Watson.[(30)] P. Ex. 1. The exact timing when those dates were inserted is not clear from this record. It is clear that prior to this hearing there is no indication that Petitioner ever questioned the legality of the contract.

(d). The employment contract was prepared by Dr. Williams, Petitioner's contractual partner, and was drawn from other agreements under which their corporation had agreed to be the laboratory director for all services.

It is difficult to accept Petitioner's claim of fraud when Dr. Williams wrote the contract himself. Dr. Williams testified that he wrote the contract based on other agreements that his corporation had with other laboratories. Dr. Williams stated that, at the four laboratories where he is the CLIA director, his contracts state that he would be directing all laboratory functions, both anatomic pathology and clinical testing. Tr. 931, 940.

(e). There is no credible evidence of record that Mr. Watson orally modified the written employment contract.

I find further that Petitioner's claim that Mr. Watson made an oral modification to the contract is unconvincing and not credible. Petitioner contended that Mr. Watson subsequently modified the contract orally at the end of February 1996, informing Petitioner and Dr. Williams that they would only be responsible for the anatomical testing portion of the laboratory. P. Br., at 7; see Tr. 1018, 1019, 1030-1032. There is no evidence of record to support such an allegation other than the verbal statements of Petitioner and Dr. Williams. Also, Petitioner's and Dr. Williams' allegations that there was an oral understanding between themselves and Mr. Watson that Mr. Watson would be responsible for the clinical portion of WML is contradicted by the written contract.[(31)]

Second, even if there is an exception to the parol evidence rule for contracts procured by fraud in the inducement of the contract, Petitioner has failed to demonstrate such fraud when the contract was entered. Arguably, if Petitioner actually believed that Mr. Watson would be responsible for the clinical portion of the laboratory, then I must question why the contract was not drafted to reflect that intention. The provisions of the contract clearly reflect the opposite result. Third, even under Petitioner's scenario, he would be responsible for laboratory practices that involved anatomical testing activities. Thus, any deficiencies in this area would be his responsibility and he would be held accountable.

The record establishes that Petitioner and Dr. Williams were eager to enlarge their patient base and entered into an agreement with Mr. Watson hoping that, if not now, but later, they would be responsible for both the clinical and anatomical areas of WML. Dr. Williams stated that he hoped that he and Petitioner would be able in the future to also provide clinical pathology services at WML and thought that at some point in time, as a result of increased business, Mr. Watson would ask him and Petitioner "to assume responsibility for the clinical laboratory." Tr. 951; See Tr. 879, 954. Thus, it is evident that at the very least, Petitioner and Dr. Williams intended to assume responsibility for all areas of WML in the future. While this might have been their intent, the facts of this case demonstrate that at the time the contract was executed and for the duration of Petitioner's association with WML he was the only person who was qualified to be a laboratory director under State and federal law.

5. Mr. Watson did not the possess the requisite credentials to be a laboratory director either under State law or the applicable CLIA regulations.

Based on the record, despite what Mr. Watson may have told his subordinates at WML and even what he told Petitioner, there is no evidence that Mr. Watson possessed the requisite qualifications to be the laboratory director of WML. Under the CLIA regulations, 42 C.F.R. §§ 493.1405(a) and 493.1443(a), for moderate and high complexity testing, the laboratory director must possess a current license as a laboratory director issued by the State where the

laboratory is located. The record demonstrates that Mr. Watson was not licensed in the State of California as a laboratory director. Under California law, Section 1283 of the California Business and Professions Code, "[i]t is unlawful for any person to conduct, maintain, or operate a clinical laboratory unless he is a duly licensed physician and surgeon or is duly authorized to so under the provisions of this chapter." A person could be issued a clinical laboratory bioanalyst's license under Section 1260 of the Code if he or she possessed at least a master's degree in one of the biological sciences, from a reputable institution, had a minimum four years' experience as a licensed clinical laboratory technologist, and successfully passed written and oral examinations conducted by the State agency. See HCFA Br., at 3 and attachment.

Mr. Newbold, the State examiner, stated that it was his understanding that Mr. Watson was the owner of WML (Tr. 212) and that he was never led to believe at any time during the survey that Mr. Watson was the laboratory director. He testified that he had researched State records but they contained no evidence that Mr. Watson was a laboratory director. Tr. 54, 55. Rather, the records showed that Mr. Watson was a clinical laboratory scientist and that he did not have a bioanalyst license. Id; Tr. 255. Mr. Newbold testified that Mr. Watson did not have the requisite background to be eligible in California to be a CLIA director. Tr. 255, 256. Moreover, Mr. Newbold had not seen "anything in the laboratory to indicate that [Mr. Watson] was a laboratory director." Tr. 55.

The record supports that Mr. Watson worked for WML as a technical supervisor besides being the owner of the laboratory. HCFA Ex. 2. The record is clear that Mr. Watson never was a State laboratory director for WML, either prior to Petitioner's involvement with WML or thereafter.

6. Petitioner held himself out to others as being the CLIA laboratory director of WML.

In addition to the documents discussed above, Petitioner's own actions contradict his assertion that he was not the director of WML for CLIA purposes. Petitioner was the primary person functioning as director of WML. Tr. 1122. According to Dr. Williams' testimony, Petitioner was "the one who oversaw the daily function" of WML since he lived closer to WML than Dr. Williams. Tr. 889, 958. Petitioner was on the premises of WML "at least one or two days a week" from February until approximately the end of March/early April 1996. Tr. 1122.[(32)] As I discussed above, Petitioner did respond to questions that came up in the clinical testing section of WML and did sign proficiency testing from the clinical section of the laboratory "[o]n rare occasions when Doctor Watson didn't." Tr. 1163, 1164.

According to Mr. Newbold, it was his understanding during the survey that Petitioner was the laboratory director for CLIA purposes. Tr. 52. He stated that, during the survey, he was informed by staff personnel that Petitioner was the director and that Petitioner was on vacation. Tr. 144, 145, 153, 262. Mr. Newbold testified that he had no reason to believe Petitioner was not the director and that "[n]o one ever told us that anybody else was the director." Tr. 145; see Tr. 153.

With respect to the CLIA personnel report (HCFA Ex. 2), Mr. Newbold testified that this form is to be signed by the laboratory director, who would be taken to be the director for CLIA purposes. Tr. 143. Mr. Newbold stated that he had handed the document to one of the employees, Mr. Edwards, who then returned it to him on the last day of the survey after getting Petitioner's signature. Tr. 53, 141. Mr. Newbold testified that Mr. Edwards represented to him that Petitioner was the appropriate person to sign the form for CLIA purposes. Tr. 53.[(33)]

At the exit conference, Petitioner was present and did not give any indication to Mr. Newbold that he was not the director. See Tr. 153, 154. Petitioner did not deny having overall responsibility for the laboratory's quality assurance program. Tr. 203. According to Mr. Newbold, during the exit conference, either Petitioner or Dr. Williams stated to him that they had not had time to "fix" all the problems in the laboratory prior to the survey and that "they were working on cytology, cleaning that up, and they hadn't gotten to the clinical portion." Tr. 266. Mr. Newbold testified also that it was his understanding that Petitioner and Dr. Williams "were the laboratory directors under the state system." Tr. 218. This he determined from examining various correspondence sent by the laboratory to the State agency. Mr. Watson was not present at the exit interview. Tr. 239.

Upon receipt of the HCFA Form 2567 setting forth the deficiencies identified by the State agency, Petitioner took action to remove the immediate jeopardy status from WML. Petitioner signed WML's plan of correction in the box indicated for the laboratory director's signature.[(34)] P. Ex. 7, at 3. He gave his title on the plan of correction as "Former Medical Director, Watson Medical Laboratory, Inc." Id.; see P. Ex. 5. The corrective measures outlined in WML's plan of correction consisted of closing WML on August 16, 1996, the day of the exit conference, and notifying clients of the possibility of erroneous test results. Petitioner never advised HCFA at any time of his belief that he was a director for State purposes only. It is evident that Petitioner thus took an active role on behalf of WML in dealing with the deficiencies identified by the State agency examiners.

Moreover, Mary Jew, a health insurance specialist with HCFA, testified that, in telephone conversations she had with Dr. Williams following the survey, she referred to Petitioner as being the "CLIA director." Tr. 772. Ms. Jew stated that she clarified to Dr. Williams that "for CLIA purposes, he [i.e., Dr. Williams] was not responsible or would suffer any consequences." Tr. 772, 773. Ms. Jew stated that she had "a conversation with Mr. Newbold and he advised me that [Petitioner] was the director." Tr. 773. Ms. Jew stated that the fact that Petitioner had signed the plan of correction reinforced her understanding that he was the director for CLIA purposes. Tr. 775.

7. The absence of a specific document signed by Petitioner stating that he accepted the responsibility of being the laboratory director of WML for CLIA purposes does not overcome the other evidence of record that he was the CLIA laboratory director.

One of Petitioner's principal arguments in this case against him being the laboratory director is the fact that he never signed any document where he affirmatively acknowledged that he would accept the responsibility of being the CLIA laboratory director of WML. He further relies on HCFA Ex. 38, the copy of WML's State Clinical Laboratory License, stating that his name does not appear on it alone, but is "preceded by two other physicians." P. Br., at 11.[(35)] Petitioner argues that the absence of a "C.L.I.A. certificate with [Petitioner's] name or signature" further evidences that he was not the CLIA director of WML. Id. at 11.

Petitioner's argument here is directed to the issue of whether he knowingly signed any documentation that could be construed that he was the CLIA director of WML. Relying on the testimony of Dr. Hilborne who indicated that he has been the co-director of several laboratories, and has encountered situations where there have been co-directors who were separately responsible for clinical and anatomical operations and who reported to a single director who was responsible for the entire operation of the laboratory for CLIA purposes, Petitioner contends he had a similar role at WML reporting to Mr. Watson, who was the principal director, on anatomic pathology issues only. Id. at 10, 11.

He further argues that his name as co-director of WML for State purposes does not render him a laboratory director for CLIA purposes. Id. Reaching this conclusion, Petitioner concludes that none of the deficiencies found while he was affiliated with WML occurred while he was a CLIA director/operator. Id. I have previously addressed much of Petitioner's arguments relating to whether he was a CLIA director/operator elsewhere in this decision, supra pp. 9-26. I conclude that such evidence supports the fact that Petitioner was an operator (which encompasses laboratory director) as that term is defined under the CLIA regulations. See infra pp. 28-34. I also find, contrary to Petitioner's assertion, that the cited deficiencies occurred while he was the CLIA laboratory director. See infra pp. 37-38.

I will agree with Petitioner that it would have been helpful if HCFA had a specific document which had to be signed by the current CLIA director and which was maintained by the State or HCFA for each CLIA-certified laboratory. Unfortunately, neither HCFA nor the State of California had such a document. But the absence of any such documentation does not relieve Petitioner of the responsibility of being a CLIA director if, on the whole, the evidence of record supports such a conclusion. Such evidence has been previously recited and I have so found.

8. Petitioner meets the definition of "operator" as that term is defined in 42 C.F.R. § 493.2.

The principal sanction affecting Petitioner as an individual is that, as an owner or operator, he would be prohibited from owning or operating another laboratory for two years as a result of the revocation of the CLIA certificate of WML. 42 U.S.C. § 263(a); 42 C.F.R. § 493.1840(a)(8). I have concluded that Petitioner was the laboratory director, for CLIA purposes, of WML. See supra pp. 6-28. Petitioner thus fell within the definition of "operator" as that term is defined in 42 C.F.R. § 493.2.

The regulation at 42 C.F.R. § 493.2 defines the term "operator" as "the individual . . . who oversee[s] all facets of the operation of a laboratory and who bear[s] primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory." The term includes a director of the laboratory "if he or she meets the stated criteria."[(36)]

I wish to note here that, based on the legislative history, Congress intended, in appropriate circumstances, for both the owner and operator of a laboratory to be sanctioned, in addition to the laboratory itself. In support of this interpretation is the following:

[t]he Committee intends that an owner or operator whose conduct has precipitated a revocation not be allowed simply to begin operating a new or existing laboratory during the period of revocation, when such person bore ultimate responsibility for the conduct giving rise to the revocation. The Committee does not intend this provision to limit in any way other provisions of corporate or other law which would otherwise restrict such operation, but to clarify that a revocation runs against an owner or operator, not merely against the laboratory.

See P.L. 100-578, 102 Stat. 2903, H.R. No. 100-899, p. 35, reprinted in 6 U.S.C.C.A.N. 3828, 3856 (1988).

The congressional committee thus recognized that a laboratory's owner or operator has "ultimate responsibility" for the conduct of a laboratory and should be sanctioned as well in the event of a laboratory's CLIA certificate revocation. Petitioner, in his role as the laboratory director of WML, did have "ultimate responsibility" for the conduct of the laboratory. Petitioner was the CLIA director, whether he intended to be or not, and was the primary person in charge of the operations of WML. As such, Petitioner was an "operator" and thus was subject to any sanction that might result in the event of WML's certificate revocation.

Citing 42 C.F.R. § 493.1403, Petitioner contends that he did not provide the "overall management and direction in accordance with § 493.1407." P. Br., at 2. Petitioner does admit that he meets the qualification requirements of 42 C.F.R. § 493.1405.[(37)] Id. However, he argues that Mr. Watson did the hiring, firing, and laying off of employees at WML. In support of this broad statement, Petitioner cites the testimony of Ms. Lee Ann Nichols, the chief operating officer of WML, that Mr. Watson directed the clinical testing section of the laboratory and did the hiring and firing of personnel doing clinical laboratory work. Tr. 629; P. Br., at 3.

Petitioner attempts to use the regulatory requirement contained in 42 C.F.R. § 493.1407 that the laboratory director be responsible for the overall operation and administration of the laboratory, including the employment of personnel, to demonstrate the he was not a director. P. Br., at 2. This argument is without merit.

Accepting the fact that Petitioner did not actually hire the personnel who performed the laboratory work, it was his responsibility under the regulations to be sure that the persons hired met the regulatory standards. Failure to ensure compliance did not mean he was not a CLIA director, but meant only that he was not in compliance with these regulatory requirements. HCFA alleged such failures in the HCFA Form 2567. See HCFA Ex. 1, at 61-65, 79-81.

Similarly, if Petitioner allowed Mr. Watson to direct the management of the clinical area of the laboratory (e.g., verify and release results, order reagents, supervise the laboratory manager, and handle all correspondence with the State of California, see Tr. 651), he did so at his peril considering the CLIA requirements. Petitioner had or should have been familiar with the CLIA requirements from his previous experience as a CLIA director at other laboratories. The regulations are clear on their face as to the responsibilities of the CLIA director.

It would be expected that, as owner of WML, Mr. Watson probably had final say on the operation of the laboratory. However, this does not affect Petitioner's status as operator/director for CLIA purposes. CLIA holds the owners and operators jointly and severally liable and the two-year sanction is applied to both.

It is undisputed in this record that Mr. Watson had no responsibility for the anatomical portion of the laboratory and that Petitioner was the one responsible for this area of the laboratory. Moreover, there is nothing in these regulations that permits a bifurcation of CLIA directorship responsibility between the clinical portion of a laboratory and the pathology portion where the laboratory has only one CLIA certificate. See Tr. 711, 712. Ms. Carmichael testified directly on this point:

Q: Does HCFA have any provision for having separate laboratory directors who are -- the anatomical testing and another laboratory direct the clinical testing in a laboratory?

A: Under a single certificate, no.

Q: In other words, if the laboratory has one certificate, one CLIA number, they can only have one director?

A: That's right.

Q: Would it be possible for them to have two separate laboratories, two separate certificates, and have two directors?

A: They could have two separate certificates, yes.

Q: But were [sic] both anatomical testing and clinical testing are done under the umbrella of a single laboratory certificate and a single laboratory -- is there any provision for two directors?

A: No, and that's addressed in the preamble to the regulations that were published on February 20th of 1992.

Tr. 582, 583.

Q: So in this case would it have been permissible for . . . [Petitioner] to be a director only with respect to pathology, in the case of Watson Laboratories?

A: No.

Q: And why is that?

A: Because once you accept the directorship of a CLIA laboratory, it's for the whole laboratory.

Tr. 585.

Petitioner under the CLIA regulations would have had no authority to grant management responsibility to Mr. Watson for the clinical section of the laboratory while alleging that he himself maintained management responsibility for only the anatomical testing portion of the laboratory. Moreover, if this was a condition imposed by Mr. Watson on Petitioner, Petitioner had no authority under the CLIA regulations to accept such a bifurcation.

The argument, at P. Br., at 3, that Mr. Watson did not permit Petitioner to perform his duties as CLIA director is equally unpersuasive. As an example of this restriction of duties, Petitioner points to Mr. Watson's failure to gave Petitioner the communication that a negative report (HCFA Ex. 23) about the laboratory services provided by WML had been generated for MedPartners/Mullikin, Inc. (MM). It is Petitioner's position that if Petitioner had gotten this report he would have known about the clinical deficiencies found by Dr. Hilborne. While I would agree that failing to have and read this report may have hampered Petitioner's ability to discover the deficiencies occurring in the clinical testing area, the record is abundantly clear that Petitioner did not undertake reasonable steps to acquaint himself with the clinical laboratory portion of WML even though he was responsible for it. He failed to check with the prior directors, Drs. Fischer and Starke, as to why they were leaving the laboratory. When rumors of gross clinical deficiencies came to the attention of Petitioner, he believed that they arose from the bankruptcy action between Mr. Watson and MM. No effort was undertaken by Petitioner to inquire as to the legitimacy of the allegations of clinical deficiencies. Tr. 1071, 1072. The same applies for allegations in the declaration of Pam Fitzgerald, HCFA Ex. 26, and the report by Dr. Hilborne, HCFA Ex. 23. While the declaration and report may have been under seal by the Bankruptcy Court Judge (see Tr. 640), it is not clear how long they were under seal. See Tr. 846. Nor did Petitioner make any effort to contact these persons to determine the specifics of the allegations. Petitioner simply chose to ignore these allegations.[(38)] Finally, the statements by Ms. Nichols that Mr. Watson in her opinion was the "medical director" and owner of WML is not dispositive of these issues for CLIA purposes. See Tr. 634.

Since WML was doing clinical and anatomical testing for its clients, and the laboratory was never separated for CLIA purposes, the only individual who was qualified under the CLIA regulations to be the director for all aspects of the laboratory was Petitioner and not Mr. Watson. This circumstance gives validity to the written contract as to what Petitioner and Mr. Watson actually intended and makes the assertions of split responsibility to be a subterfuge created as a means to avoid responsibility under CLIA. I have no doubt that Mr. Watson, being the owner of the laboratory, had a great deal to say about what happened in all aspects of the laboratory's operations. Considering the allegations of major deficiencies in the clinical portion of the laboratory, it is also quite possible that Mr. Watson tried to keep Petitioner from involving himself in the clinical laboratory operations. Such activity by Mr. Watson does not absolve Petitioner from his responsibility under CLIA to provide overall management and direction of the laboratory. If Mr. Watson would not allow Petitioner to carry out his CLIA responsibilities, then Petitioner should have promptly resigned and notified the State agency and HCFA. This he did not do. To the contrary, he allegedly allowed Mr.

Watson to breach the written agreement, did not delve into clinical laboratory operations which were alleged to be violative of the regulations and permitted this unlawful circumstance to continue for several months with untold adverse impact on patient care until it was discovered in the July-August 1996 survey. Even accepting for argument purposes Petitioner's assertion that Mr. Watson was the laboratory director of WML for clinical operations, Petitioner through communications to the State agency and in the CLIA documents held himself out as the CLIA director of WML.

WML had one CLIA certificate. Tr. 788. Because of this, as discussed above, there could only be one CLIA director. The record amply supports that Petitioner was laboratory director of WML for CLIA purposes for all aspects of the operation of WML. Therefore, any individual sanction under the CLIA regulations for deficiencies identified at WML while Petitioner was laboratory director applies to him.

Petitioner contends also that former pathologists who were designated as laboratory directors of WML were only to perform duties associated with the anatomical area of WML. P. Br., at 4, 5. To support this statement, Petitioner cites the testimony of Dr. Fischer who never "felt" he was in charge of the clinical area of WML nor did he believe he was the CLIA director. What Dr. Fischer believed to be his responsibility when he was affiliated with WML is irrelevant. What is controlling is what responsibilities are imposed on a laboratory director by CLIA and the State agency, not what a particular individual who was acting in the capacity of CLIA director or State laboratory director believed his or her responsibilities to be. The responsibilities are imposed by regulation and failure to realize the regulatory ramifications of being designated as a laboratory director does not alter the legal obligations imposed.

It is the responsibility of an individual who voluntarily agrees to be a laboratory director for State purposes and signs all CLIA documents as laboratory director to know what his or her obligations are under State and federal law. There is no evidence that anyone forged Petitioner's name to the documents I have discussed above. See supra pp. 9-24. Congress imposed duties on the laboratory director by regulation. He cannot escape responsibility for being a CLIA director after the fact of a negative survey with imposition of sanctions by claiming he was a director for State purposes only. Under his argument there would be no CLIA director. If that was the case, then WML could not lawfully operate.

Based on Petitioner's familiarity with CLIA, he had to know that there was no bifurcation of responsibilities under the regulations. This issue was clarified in the preamble to HCFA's regulations implementing the CLIA amendments of 1988 where in responding to a commenter's suggestion that the definition of "laboratory" be clarified to distinguish between a pathology laboratory and a clinical laboratory, it is stated:

[t]he term laboratory, which is defined at section 353(a) of the PHS [Public Health Service] Act, encompasses both clinical and anatomical services, as well as any facility that performs examination of clinical or pathological materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. The law does not make a distinction between a pathology laboratory and a clinical laboratory, but treats every laboratory equally for the purpose of defining a laboratory.

57 Fed. Reg. 7013 (1992); HCFA R. Br., at 5.

Similarly, 42 U.S.C. 263a(a) does not distinguish between anatomical and clinical portions of a laboratory when that term is defined. Therefore, when Petitioner signed the written contract to be co-medical director for all laboratory services, he was agreeing to be responsible for CLIA purposes. He agreed, among other things, to be responsible for (1) reviewing and developing all laboratory policies and procedures; (2) ensuring quality assurance processes in all areas; (3) ensuring adherence to all applicable federal and State regulations and policies applicable to laboratory services; (4) supervising and implementing control and standardization of procedures; (5) supervising directly and indirectly all laboratory employees responsible for implementing and carrying out procedures and policies; and (6) ensuring that there are a sufficient number of qualified pathologists to be available to provide all specialty services required for patient care and reasonable client satisfaction. P. Ex. 1, at 2; HCFA R. Br., at 6. The contractual provisions make clear that Petitioner is responsible for all areas of WML, clinical and anatomical. Moreover, many of these areas which he specifically assumed responsibility for under the contract became subject to deficiencies cited in the July-August 1996 survey of WML. See HCFA Ex. 1. Any oral changes to the agreement, if there were any, bifurcating the responsibility between Petitioner and Mr. Watson would have no meaning under the CLIA regulations.

9. Petitioner either has admitted to the deficiencies cited during the July-August 1996 survey or failed to show by preponderance of the evidence that WML was in substantial compliance with the conditions of participation for laboratories certified under CLIA.

As discussed above, I have found that Petitioner was the laboratory director of WML. HCFA, in its brief, has pointed out that WML's CLIA certificate was revoked on June 5, 1997. The revocation of WML's certificate means that the issue of whether the deficiencies cited in the HCFA Form 2567 did exist has been, in effect, rendered moot.[(39)] Additionally, as a result of WML's certificate revocation, the CLIA regulations prohibit its present owner or operator (which includes a director) from owning or operating (or directing) a laboratory for two years from the date of the revocation. 42 C.F.R. § 493.1840(a)(8). Because I have concluded that Petitioner was WML's laboratory director, it follows that this prohibition applies outright to him.

Although I do not necessarily need to consider whether the record supports HCFA's assertions that deficiencies existed at WML in light of the fact that WML's certificate was revoked, nevertheless, I have evaluated the evidence regarding the deficiencies and have independently concluded that the deficiencies occurred as alleged at WML.

The State survey team determined that the following nine CLIA conditions of participation were out of compliance: 42 C.F.R. § 493.1101 (Patient Test Management); 42 C.F.R. § 493.1201 (General Quality Control); 42 C.F.R. § 493.1403 (Laboratory Director--Moderate Complexity Testing); 42 C.F.R. § 493.1409 (Technical Consultant--Moderate Complexity Testing); 42 C.F.R. § 493.1421 (Testing Personnel); 42 C.F.R. § 493.1441 (Laboratory Director--High Complexity Testing); 42 C.F.R. § 493.1447 (Laboratory Technical Supervisor); 42 C.F.R. § 493.1487 (Testing Personnel); 42 C.F.R. § 493.1701 (Quality Assurance). See HCFA Ex. 1.

At the hearing, Petitioner's counsel explained exactly which deficiencies cited in the HCFA Form 2567 (HCFA Ex. 1) Petitioner was contesting. Petitioner's counsel stated that Petitioner was contesting tag D3056 on pp. 13-15; tag D4030 on p. 22; tag D4038 on pp. 22-23; tag D4043 on pp. 23-25; tag D4066 on pp. 27-28; tag D4182 on pp. 41-42; tag D4327 on pp. 47-48; tag D4343 on p. 49; tag D4360 on p. 50; tag D4373 on pp. 50-52; tag D4382 on p. 52; tag D6093 (subsection b only) on p. 77; tag D6103 (subsection a only) on p. 82; tag D6128 on pp. 86-87; tag D6131 on p. 87; tag D6140 on pp. 87-88; and tag D6167 on p. 89. Tr. 705-709. These deficiencies have to do with failures at the standard-level of the CLIA regulatory requirements, which fall under CLIA conditions.

Despite his enumerating the deficiencies that he was contesting, Petitioner did not introduce any evidence to specifically rebut them. Moreover, Petitioner attempts to make a distinction between clinical and anatomical deficiencies. Instead of responding to the deficiencies identified in the clinical area of WML which were cited in the HCFA Form 2567, Petitioner claims he cannot speak to these deficiencies since he was not responsible for that portion of the laboratory's operation and no information relating to that area was shared with him. P. Br. at 9. Petitioner does concede that clinical deficiencies of "drylabbing, failure to conduct proficiency testing, and reported non-licensed personnel performing clinical lab tests may have been of a serious enough nature to have created immediate jeopardy." P. Br., at 9. However, he contends that jeopardy was corrected when WML was closed following the survey. Id.

As to the anatomical area of WML, where Petitioner admits that he was responsible for the operation of laboratory testing, Petitioner contends there were "only minor deficiencies," such as "failure to list the address of the certified lab, Foothill Presbyterian, as the site where the cytology slides were tested and read," which HCFA did not contend imposed immediate jeopardy to patients. P. Br., at 9. He further contends that other deficiencies in the anatomical section of WML, such as "procedure manuals not being signed, and quality assurance documentation of special stains not being present," were quickly and easily correctable and would not have resulted in HCFA sanctions. Id. at 10. Apparently, Petitioner is arguing that such deficiencies in the anatomical area would not support the two-year sanction imposed upon him by HCFA. In response, HCFA properly points out that WML as a laboratory for CLIA certification purposes is considered as a whole. HCFA R. Br., at 17. HCFA further argues, and I agree, that the anatomical deficiencies cited in the HCFA Form 2567, particularly those relating to the lack of quality assurance, failure to maintain accurate test reports and records reflecting where the tests were read, and the failure of the laboratory director to review and approve procedure manuals were significant deficiencies of such a character that they met the test for a certification of non-compliance under 42 C.F.R. § 488.24(b). Id.

Petitioner thus failed to introduce any evidence to counter the evidence offered by HCFA during the hearing regarding the specific deficiencies cited in the HCFA Form 2567. Petitioner raised no factual arguments that these deficiencies did not occur. His explanations and attempts to minimize the nature of the deficiencies have no merit and do not excuse his conduct as laboratory director.

10. The laboratory activities at WML which were alleged to be deficiencies were in violation of federal regulatory standards under CLIA, and, had revocation of WML's certificate not been effectuated on June 5, 1997, there would be a basis to revoke WML's certificate.

For purposes of brevity, I will incorporate and adopt HCFA's discussion of the deficiencies at pages 12-50 of its posthearing brief into my decision. For each of the alleged deficiencies cited in HCFA Form 2567, I find that HCFA has presented a prima facie case that the deficiency existed. The record will reflect that Petitioner has not offered any rebuttal evidence to HCFA's prima facie case and has not contested any of the nine CLIA conditions of participation cited in the HCFA Form 2567 that were found to be out of compliance. Thus, I find that HCFA has proven that Petitioner has violated nine CLIA conditions of participation.[(40)]

Because these deficiencies were in existence during the July-August 1996 survey of WML, I find that the revocation of WML's certificate is well supported by the record in this case. Had the revocation not been effectuated on June 5, 1997, there would be a basis to revoke WML's certificate. Consequently, the sanction of prohibiting Petitioner from owning or operating a laboratory for two years in accordance with statutory and regulatory authority flows from that revocation and is well justified.

11. The deficiencies cited in the HCFA Form 2567 occurred while Petitioner was an operator/director of WML.

I have reviewed the record to determine whether the deficiencies occurred while Petitioner was a CLIA director, that is, from February 6, 1996 until August 16, 1996. I find that many of the deficient practices cited began before Petitioner's tenure with WML but continued after his becoming the laboratory's director. What is clear in this record is that Petitioner made minimal efforts to ensure that the practices of WML conformed with CLIA regulations. Many of the deficiencies were easily discernible and measures could have been taken to ensure compliance. The issuance of laboratory results without ever conducting the necessary testing could have been discovered by comparing the test results with the underlying testing data. Obviously, if there is no indication that the underlying tests were done, then the test results must be false. However, Petitioner did not initiate any examination of the procedures of WML to

ensure compliance with CLIA, even in the anatomical area where he admits he was responsible. For example, he never stopped to review WML practices to ensure that the proper manuals were in place. The deficiencies in the anatomical area reflect the absence of any significant effort to ensure quality assurance and quality procedures as required by CLIA regulations. The record demonstrates that Petitioner did not meet his responsibility as laboratory director even for the anatomical area.

III. Conclusion

The evidence of record establishes that Petitioner was the CLIA laboratory director of WML during his affiliation with WML beginning in February 1996 until its closure in August 1996. Petitioner's arguments that Mr. Watson was the laboratory director for clinical operations and ultimately was responsible for all operations of the laboratory do not comport with the record.

While neither HCFA nor the State agency had a specific form designating the laboratory director for CLIA purposes, the documents submitted by WML to the State agency prior to the survey and those submitted to the State examiners during the survey establish that Petitioner was functioning in that position. That conclusion is further supported by Petitioner's actions while being associated with WML. Petitioner's belated protestations, after sanctions against him were proposed, that he did not intend to be the CLIA laboratory director are self-serving and irrelevant. The CLIA regulations are clear that there can be only one laboratory director who is responsible for all operations, both clinical and anatomical, if such testing is conducted at the laboratory.

Petitioner having familiarity with CLIA regulations from his past experience as a CLIA laboratory director for other laboratories prior to being associated with WML either knew or should have known the consequences of his actions while performing laboratory services at WML. Claims that he was misled or fraudulently induced into contracting with WML by Mr. Watson are specious. He did not exercise due care in verifying Mr. Watson's qualifications or determining whether Mr. Watson was a laboratory director for State purposes. Mr. Watson was not qualified under State or federal law to be the laboratory director of WML.

Additionally, Petitioner either submitted or allowed to be submitted on his behalf, forms which designated him as a State laboratory director of WML. At the time of the survey in July-August 1996, he and Dr. Williams were the only State laboratory directors still affiliated with WML. It was agreed between them that Petitioner would be principally responsible for the operations of WML. Petitioner was present during the survey and signed the documentation as the CLIA laboratory director for WML. The evidence establishes that Petitioner was the CLIA laboratory director of WML for the period of February to August 1996. He held himself out as such whether he intended to do so or not.

Petitioner fell within the definition of "operator" as that term is defined in 42 C.F.R. § 493.2. Congress by statute and HCFA through the CLIA regulations ensure the health and safety of recipients of laboratory testing by imposing obligations on the laboratory operator [director] to make sure that such testing meets all federal regulatory standards; this, Petitioner failed to do. The deficiencies cited in the HCFA Form 2567, which Petitioner does not specifically contest, were of such character as to substantially limit WML's capacity to furnish adequate care or which adversely affected the health and safety of patients. 42 C.F.R. § 488.24(b). Based on the record in this case, there would be a basis to revoke WML's CLIA certificate had that not been effectuated on June 5, 1997. Consequently, HCFA's determination to prohibit Petitioner from owning or operating a laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed.

Edward D. Steinman
Administrative Law Judge

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1. CLIA defines a "laboratory" or a "clinical laboratory" as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. See 42 U.S.C. § 263a(a).

2. As to whether Petitioner is an operator (the director) of a laboratory for CLIA purposes, HCFA bears the responsibility to come forth with evidence to establish a prima facie case and bears the ultimate burden of proving by the preponderance of the evidence that Petitioner is the laboratory director of Watson Medical Laboratories, Inc. (WML).

3. In a recent decision, an appellate panel of the Departmental Appeals Board reiterated that the burden of persuasion set forth in Hillman applies only where the evidence proffered by both sides is "in equipoise." Oak Lawn Pavilion, Inc., DAB No. 1638, at 16-17 (1997). In such cases, the burden of persuasion would be on Petitioner. Here, Petitioner never explicitly challenged the factual allegations that supported the revocation of WML's CLIA certificate.

4. I cite to the transcript of the hearing as "Tr." (page number).

5. HCFA's Notice to WML stated that WML was out of compliance with ten CLIA conditions. However, at the hearing, counsel for HCFA stated that the letter was incorrect because WML was not out of compliance with the Condition for General Supervisor, 42 C.F.R. § 493.1459. Therefore, WML was in noncompliance with nine, rather than ten, CLIA conditions. HCFA's Notice; HCFA Ex. 15; Tr. 5.

6. As indicated later in my decision, WML had previously withdrawn its request for hearing and I issued an Order of Dismissal. The effect of that dismissal was to put into effect against WML the sanctions set forth in the August 21, 1996 letter and reaffirmed in the September 12, 1996 letter. See 42 C.F.R. § 493.1844(d)(2).
7. Upon further consideration of the effect of the revocation of WML's certificate, I have concluded that such action would provide HCFA with the right to sanction WML's owner and/or operator. Thus, the principal issue in this case is whether Petitioner was an operator of WML at the time the deficiencies occurred which led to the revocation of the certificate.
8. Petitioner's opening brief is cited as "P. Br." Petitioner's response brief is cited as "P. R. Br." HCFA's opening brief is cited as "HCFA Br." HCFA's response brief is cited as "HCFA R. Br."
9. The transcript does not appear to contain the dates of Petitioner's laboratory directorship at Foothill. However, P. Ex. 2 lists Petitioner's hospital affiliations and "1982 - present" is handwritten next to "Foothill Presbyterian Hospital." I note that Petitioner testified that he is not currently the CLIA director of Foothill. Tr. 1119.
10. Petitioner testified that his specialty is clinical and anatomic pathology and that he is board certified in both. Tr. 1045.
11. The transcript does not appear to contain the dates of Petitioner's laboratory directorship at PCL, nor does P. Ex. 2 list PCL anywhere. It would appear from the testimony of Dr. Williams that both he and Petitioner were active with PCL (and its predecessor Damon Reference Laboratories) from the early 1990's until the demise of PCL due to bankruptcy in 1996. Tr. 861-866, 1205.
12. Petitioner and Dr. Williams were also aware of the possibility that WML might get a large contract with an HMO in Las Vegas, Nevada, which would have been an additional expansion opportunity for their corporation. Tr. 874, 1098.
13. Similarly, Dr. Williams on behalf of himself and Petitioner made only a cursory effort to determine the bona fides of Mr. Watson's claimed credentials. See infra pp. 20-21.
14. Dr. Fischer's testimony portrayed both himself and Dr. Starke as believing that they were the directors for only the anatomical testing portion of WML. While Petitioner, had he inquired further of Drs. Fischer and Starke, may not have gained much information regarding the clinical portion of WML, he at least would have gained some knowledge of Mr. Watson's business dealings.
15. Mr. Newbold testified that this was an application for the renewal of WML's State license. Tr. 152.
16. Petitioner did not deny that his signature appeared on the document. He testified, "[i]t looks like mine, I don't recall filling this out. It's been a long time ago." Tr. 1169; see Tr. 1164, 1165.
17. It would appear from the evidence of record that this license was issued after February 1996 but made retroactive as of January 1, 1996.
18. The form starts out with "Dear Laboratory Director." HCFA Ex. 29, at 1.
19. When asked by HCFA counsel if it was his signature that appeared on page 2 of HCFA Ex. 29, Petitioner testified, "[i]t could be." Petitioner admitted that the signature looked like his signature and did not have any reason to doubt that it was not his signature. Tr. 1138, 1139.
20. HCFA counsel asked Petitioner, "[a]t the bottom would you dispute that that could be your signature?" Petitioner responded, "I would not dispute that it could be my signature." Tr. 1141, 1142. Petitioner later confirmed that he did sign the form. Tr. 1143.
21. At the hearing, Dr. Hilborne described the distinction between anatomical versus clinical pathology as follows:
[a]natomic generally includes the areas of surgical pathology, cytology, autopsy pathology, and related anatomic services. Clinical pathology includes the majority of the other testing disciplines, conventionally, microbiology, blood bank, chemistry, and hematology. And other areas like microbiology and so on.
Tr. 716.
22. Petitioner testified that he did not recall signing HCFA Ex. 37 but admitted that the name at the bottom of the pages does appear to be his. Petitioner then testified "I would imagine any director could have signed this and I signed it." Tr. 1194.
23. Mr. Newbold testified that HCFA Ex. 2 was not filled out properly. He stated that the identification of specialties was not applicable for the position of director but only applied to technical consultants or technical supervisors. Tr. 147, 148. Mr. Newbold testified that he would have just expected to see a check mark denoting that Petitioner was the director. Tr. 261. Based on Mr. Newbold's testimony, then, HCFA Ex. 2 was not filled out properly. Despite the failure of the State agency examiner to bring this discrepancy to Petitioner's attention during the survey, Petitioner's attempt to limit his director

responsibilities to the areas identified is not compelling. In my judgment, the controlling fact was that no other individual was indicated as director for the non-anatomical areas of the laboratory. Also, Petitioner signed the report as the laboratory director. Consequently, a fair reading and implication from this report is that Petitioner is responsible for all areas of the laboratory.
24. Mr. Newbold testified that immunohematology does not fall into the anatomical pathology area but histopathology and cytopathology do. Tr. 234.
25. Petitioner testified that he did not recollect signing HCFA Ex. 2 or filling it out. Tr. 1090; see Tr. 1087, 1088, 1092. I questioned Petitioner, "[s]o you're not denying that you did, you just don't have any recollection, present recollection. Is that your statement?" Petitioner's response was "[y]es." Tr. 1090. Petitioner testified that the writing in the completed portion of the document, other than the signature portion, did not appear to be his and he did not recognize it as belonging to anyone he knew. Tr. 1088; see Tr. 1091. It appears that another employee of WML, Gerald Edwards, completed the textual portion of the document. Tr. 659, 661.
26. As will be discussed infra p. 25, it was agreed between Dr. Williams and Petitioner that Petitioner would be the responsible person for their corporation relating to the directorship responsibilities of WML.
27. I assume counsel for Petitioner is referring to 42 C.F.R. § 493.1405(b)(3), which states that one is qualified to be a laboratory director if one holds an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution. In addition to holding the required degree, one must also satisfy either 42 C.F.R. § 493.1405(b)(3)(i) or (ii).
28. Based on the letter from CAP dated September 19, 1996, I must assume that there was no survey of WML and CAP accreditation in December 1995. The CAP accreditation was based on the December 15, 1994 on-site survey.
29. The CAP inspection report contains numerous deficiencies in both the clinical and anatomical areas of WML. Dr. Lee Hilborne, director for quality management services at UCLA Medical Center, testified that a newly designated laboratory director should be proactive in reviewing the procedures of the laboratory, including the review of prior CAP inspection reports, to ensure that they were in compliance with applicable CLIA regulations. Tr. 686, 725-729. No such proactive approach was employed by Petitioner.
30. Petitioner testified that he "[didn't] recall signing the contract, but that could be my signature." Tr. 1095.
31. Under the parol evidence rule, evidence of prior agreements which contradicts the terms of an integrated written agreement may not be introduced. See Restatement (Second) of Contracts §§ 209, 213 (1981). Where a document appears on its face to be complete and unambiguous, it is presumed to be integrated. Id. at § 209(3). However, an agreement prior to or contemporaneous with the adoption of a writing is admissible in evidence to establish, inter alia, illegality, fraud, or duress. See Id. at § 214(d). In California, the parol evidence rule is codified in the Code of Civil Procedure, section 1856. Subdivision (a) of that section states:
[t]erms set forth in a writing intended by the parties as a final expression of their agreement with respect to such terms as are included therein may not be contradicted by evidence of any prior agreement or of a contemporaneous oral agreement.
Subdivision (g) of section 1856 provides:
[t]his section does not exclude other evidence of the circumstances under which the agreement was made or to which it relates, as defined in Section 1860, or to explain an extrinsic ambiguity or otherwise interpret the terms of the agreement, or to establish illegality or fraud.
Cal. Civ. Proc. Code § 1856 (a), (g).
Although Petitioner is not seeking to rescind the contract in the matter before me, he is attempting to minimize the effect of the express terms of the contract by arguing that it was invalid. I find that the contract between Petitioner, Dr. Williams, and Mr. Watson/WML appears to be a completely integrated written agreement which embodies the full nature of Petitioner's contractual relationship with WML. For this reason, the terms of the contract may not be contradicted by any extrinsic evidence, oral or written. Moreover, because I have concluded that there was no fraud in the procurement of the contract, the fraud exception to the parol evidence rule is inapplicable.
32. Petitioner indicated that when he was not at WML, that Dr. Rogers, another pathologist with Petitioner's corporation, was the primary pathologist who served WML. Tr. 1122, 1123. Having a backup pathologist does not negate the inference that can be drawn from Petitioner's role at WML as laboratory director. The director can have other pathologists working at the laboratory and still be the CLIA director.

33. Mr. Newbold never ascertained whether or not the signature was, in fact, that of Petitioner. Tr. 142. My review of this record would reflect that it is either Petitioner's signature or that Petitioner authorized someone to sign it on his behalf.
34. The plan of correction was attached to a letter to HCFA written by Petitioner and Dr. Williams, dated August 28, 1996. P. Ex. 7, at 1-2. In this letter, Petitioner and Dr. Williams stated that they became Medical Directors of WML in February 1996.
35. The copy of WML's State Clinical Laboratory License lists, on the right-hand side, from top to bottom, the directors as being "Craig L[.] Fischer MD;" "Arthur H[.] Williams MD;" and "Eugene R[.] Pocock MD." HCFA Ex. 38.
36. I assume "stated criteria" is referencing the laboratory director qualifications and responsibilities as set forth in 42 C.F.R. §§ 493.1405 and 493.1407 in the regulations rather than any criteria for director under any given State regulation.
37. The sections of the regulations referenced by Petitioner pertain to laboratories performing moderate complexity testing. Because WML also performed high complexity testing, the requirements set forth at 42 C.F.R. §§ 493.1443 and 493.1445 (laboratory director qualifications and responsibilities for laboratories performing high complexity testing) equally apply.
38. Petitioner testified that he saw Dr. Hilborne's report for the first time at the hearing. Tr. 1176.
39. The only way that such revocation could arguably not apply to Petitioner is if the deficiencies occurred and were corrected prior to his becoming the CLIA director. The record does not support such a finding. See infra pp. 37, 38.
40. [40] I make no findings as to the issue of immediate jeopardy. HCFA correctly points out that the issue of immediate jeopardy is not a matter of which I have authority to hear since it is not an "initial determination." See 42 C.F.R. § 493.1844(c)(6); HCFA R. Br., at 17.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

Date: February 16, 1999
In the Case of:
BAN Laboratories,
Petitioner,
- v. -
Health Care Financing Administration.
Docket No. C-97-418
Decision No. **CR576**

DECISION

I decide that the Health Care Financing Administration (HCFA) is authorized to impose principal and alternative remedies against Petitioner, BAN Laboratories, based on Petitioner's failure to comply with conditions of certification under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). I sustain the remedies imposed by HCFA. As a matter of law, my decision means that Petitioner's authority to participate under CLIA is revoked.

I. BACKGROUND

A. Governing law

I decide this case pursuant to regulations that are contained in 42 C.F.R. Part 493 (CLIA regulations). The CLIA regulations implement sections or parts of sections 1846, 1861(e), 1861(j), 1861(s)(13), and 1902(a)(9) of the Social Security Act, along with section 353 of the Public Health Services Act. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations authorize HCFA or its designee (such as a State survey agency) 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). HCFA may also impose **alternative** sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against the laboratory. 42 C.F.R. § 493.1810(e). A laboratory may make an allegation of compliance once it believes it has corrected the deficiencies. HCFA will verify whether the deficiencies have been corrected if it finds the allegation of compliance to be

credible and will lift alternative sanctions effective as of the correction date. Id. However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted based on self-correction of deficiencies and an allegation of compliance by the laboratory.

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 that upholds 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). A suspension automatically becomes a revocation of the laboratory's CLIA certificate in a case 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. 42 C.F.R. § 493.1844(d)(4).

An immediate jeopardy determination is not appealable. 42 C.F.R. § 493.1844(c)(6). Thus, a laboratory that has been found to be posing immediate jeopardy to patients may appeal the findings of condition-level deficiencies which are the basis for the imposition of remedies against it, but not HCFA's determination that these deficiencies pose immediate jeopardy to patients. Nor may a laboratory appeal a determination by HCFA not to reinstate a suspended laboratory where HCFA has concluded that the reason for the suspension has not been removed or that there is insufficient assurance that the reason will not recur. 42 C.F.R. § 493.1844(c)(3).

B. Background facts and procedural history

Petitioner is a clinical laboratory in Dallas, Texas. It is in the business of performing laboratory tests that are referred to it by physicians. On March 31, 1997, Petitioner was surveyed by the Texas Department of Health, a State survey agency acting as HCFA's designee, in order to determine whether Petitioner was in compliance with CLIA conditions of certification. The surveyors concluded that Petitioner was not complying with 15 specific conditions of certification. HCFA Exhibit (Ex.) 1.

On April 3, 1997, HCFA notified Petitioner that it concurred in these findings. HCFA Ex. 2. It advised Petitioner further that it had concluded that the deficiencies that were identified at the March 1997 survey were so severe as to pose immediate jeopardy to the health and safety of patients. Id. HCFA advised Petitioner that, effective April 15, 1997, it would impose principal sanctions, which included suspension of Petitioner's CLIA certificate. Id. HCFA advised Petitioner further that the suspension would become a revocation of Petitioner's CLIA certificate if an administrative law judge issued a decision which upheld HCFA's determination. Id.

HCFA's notice to Petitioner invited Petitioner to correct its deficiencies and to submit a credible allegation of compliance to HCFA. HCFA Ex. 2. It is unclear from the text of HCFA's notice whether HCFA meant that Petitioner could submit an allegation of compliance in order to have HCFA rescind the principal sanctions that it had imposed.

See id. As I discuss above, at Part A of this section, the regulations do not afford a noncompliant laboratory the opportunity to submit an allegation of compliance in order to have principal sanctions rescinded. But, on April 11, 1997, Petitioner sent a letter to HCFA in which it stated that its owner would "insure that the necessary procedures to bring the laboratory into compliance in response to the deficiencies . . . will be achieved as of 4/11/97." HCFA Ex. 3. The letter listed six corrective actions that the laboratory would undertake in order to attain compliance. Id.

Petitioner requested an administrative hearing and the case was assigned to me for a hearing and a decision. I conducted an initial prehearing conference at which Petitioner's counsel advised me that Petitioner believed it had corrected its deficiencies and wished to have its laboratory resurveyed for compliance with CLIA conditions. I advised the parties then that I had no authority to direct HCFA to resurvey Petitioner. The parties agreed to stay the case while they discussed possible settlement.

HCFA's Dallas Regional Office reviewed Petitioner's April 11, 1997 letter and found the allegations of compliance that Petitioner made in the letter not to be credible. HCFA Ex. 5 at 4. Evidently, based on this review, and in response to the request that Petitioner made at the initial prehearing conference in this case, HCFA decided that it would not request the Texas Department of Health to resurvey Petitioner. On April 13, 1998, HCFA sent Petitioner a letter advising it of its determination. HCFA Ex. 4. HCFA did not furnish me directly with a copy of that letter.

Neither party contacted me to apprise me of the state of settlement negotiations or to request that I activate this case. In the summer of 1998, I became concerned that the case had remained stayed for an extended period without any advice from the parties. Therefore, I convened a prehearing conference. At the conference, the parties advised me that they intended to litigate the case based on written submissions. I established a schedule for the parties to file briefs and proposed exhibits.

HCFA timely submitted its brief and six proposed exhibits. Petitioner submitted documents which were not organized as a brief and exhibits in accordance with the directions that I had given to the parties. I returned these items to Petitioner and directed that it resubmit them in correct form. After a lapse of some weeks without an additional submission by Petitioner, I issued an order to show cause asking Petitioner to explain why the case should not be dismissed for abandonment. Subsequently, I received a written submission from Petitioner dated December 29, 1998. The submission includes statements which are in the nature of assertions of fact and arguments and 40 proposed exhibits.

I note that Petitioner's final submission to me was sent by B. Antiquene Nichols, who, in various communications, describes herself to be either the owner or the administrative director of Petitioner. Petitioner had been represented by an attorney, Alfonzo R. Greenidge. All of my communications with Petitioner had been directed to counsel. It is unclear why Ms. Nichols made Petitioner's final submission to me or why Mr. Greenidge is no longer in contact with me. He has not formally withdrawn as counsel.

In any event, I am accepting Petitioner's submission as its brief and proposed exhibits in this case. I conclude that the case is now ready for a decision on the merits. Petitioner has not objected to my receiving into evidence the six proposed exhibits which were submitted by HCFA. HCFA has not objected to my receiving into evidence the 40

proposed exhibits which were submitted by Petitioner. I receive into evidence HCFA's Exhibits 1 - 6 and Petitioner's Exhibits (P. Exs.) 1 - 40.

II. ISSUE, FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Issue

The issue in this case is whether HCFA is authorized to impose sanctions against Petitioner based on Petitioner's failure to comply with CLIA conditions of certification.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each of my Findings in detail.

1. As of March 31, 1997, Petitioner was not complying with CLIA conditions of certification.

HCFA established a prima facie case that, as of March 31, 1997, Petitioner was not complying with CLIA conditions of certification. The evidence which establishes HCFA's prima facie case consists of the report of the March 31, 1997 survey of Petitioner. HCFA Ex. 1. It consists additionally of the affidavit of Nancy Dominy, one of the surveyors who performed the March 31, 1997 survey of Petitioner. HCFA Ex. 6.

Petitioner has supplied commentary concerning the March 31, 1997 survey findings. This commentary is provided in two documents, one entitled "Statement of Deficiencies" and the other bearing a heading on the first page which reads "I. Exit Conference." This commentary contains unsworn allegations of fact. To be fair to Petitioner, I have treated this commentary as if it were an affidavit by Ms. Nichols, Petitioner's owner and administrator. I find that the commentary does not rebut the essential allegations of the surveyors. Indeed, in some critical respects, it admits to those allegations.

I have elected not to discuss each and every finding of deficiency that the surveyors made. In this Finding, I discuss the condition-level deficiencies that were identified by the surveyors. The report of the March 31, 1997 survey of Petitioner is 154 pages in length. HCFA Ex. 1. Many of the deficiencies that are identified in that report are not cited as being condition-level deficiencies.

I sustain each of the findings of condition-level deficiency made by the surveyors, although it is unnecessary for me to sustain each and every finding of a condition-level deficiency in order to conclude that HCFA is authorized to impose principal and alternative remedies against Petitioner. Under the applicable regulations, the presence of even **one** condition-level deficiency is sufficient to authorize HCFA to impose principal and alternative remedies. 42 C.F.R. § 493.1806(a).

HCFA's prima facie case of condition-level noncompliance was not rebutted by Petitioner with respect to the following conditions of certification:

a. Proficiency testing (42 C.F.R. §§ 493.801, 493.803, 493.839, and 493.849)

The conditions governing proficiency testing (in particular 42 C.F.R. §§ 493.801 and 493.803) require that a laboratory enroll in and successfully complete proficiency testing. The regulations do not allow laboratories to be exempted from the enrollment and successful completion requirements. The surveyors found that Petitioner was deficient in meeting these conditions in that it failed to enroll in or complete proficiency testing. The surveyors found that Petitioner had a history of non-compliance with proficiency testing requirements. HCFA Ex. 6 at 2-3. Furthermore, they found that Petitioner failed to enroll in proficiency testing for the year 1997.

Petitioner does contradict directly the surveyors' findings. It asserts that a surveyor had told it in March 1996, that it was not mandatory prior to 1996 that it enroll in proficiency testing. Petitioner's Commentary -- Statement of Deficiencies at 1. Petitioner admits that it had not enrolled in proficiency testing for 1997 but attributes this failure by it to a freeze that HCFA had allegedly placed on Petitioner's funds in December 1996. Id. Petitioner's assertions do not rebut the surveyors' findings. To the contrary, Petitioner admits to the central element of their findings which is that, as of March 31, 1997, Petitioner was not enrolled in a regulation-mandated proficiency testing program. The regulations do not suggest that a laboratory may justify not enrolling in proficiency testing on the ground that exigent financial circumstances impeded its enrollment.

b. Patient test management (42 C.F.R. § 493.1101)

The condition of certification which governs patient test management requires that a laboratory which performs tests of moderate or high complexity employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. The condition requires further that such a system must assure optimum patient specimen integrity and positive identification of specimens throughout the testing process and must meet applicable testing standards. 42 C.F.R. § 493.1101.

The surveyors concluded that Petitioner failed in numerous respects to comply with this condition. Among other things, they found that Petitioner: failed to perform tests timely; used compromised specimens for performing tests; altered test results, thereby altering the true values recorded on tests; and reported results for tests that were not performed. The surveyors concluded that Petitioner's failure to comply with the condition caused actual harm to patients. HCFA Ex. 6 at 3-4.

Petitioner has not rebutted persuasively these conclusions. In its commentary, Petitioner asserts that it did not fail to maintain all testing or patient records. Petitioner's Commentary - Statement of Deficiencies at 2. However, the surveyors did not conclude that Petitioner failed to maintain **all** testing or patient records. Their conclusion was that Petitioner failed to maintain a system to assure that tests were performed properly. Petitioner's other assertions similarly fail to address the central allegations of noncompliance made by the surveyors. See id.

c. General quality control (42 C.F.R. § 493.1201(a),(b))

The regulation which governs general quality control requires a laboratory to establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of the tests it provides. 42 C.F.R. § 493.1201(b). A laboratory is obligated to meet applicable quality control standards. Id.

The surveyors concluded that Petitioner manifested pervasive and ongoing quality control failures. HCFA Ex. 1 at 65; HCFA Ex. 6 at 4. They identified condition-level quality control failures in several areas. HCFA Ex. 1 at 65-66. These failures were documented in detail in the report of the March 31, 1997 survey of Petitioner. Id. Petitioner did not rebut the surveyors' conclusions. Petitioner merely asserts, without explanation, that it "performed quality control procedures for all areas of testing during 1996 and 1997." Petitioner's Commentary - Statement of Deficiencies at 6.

d. Routine chemistry quality control (42 C.F.R. § 493.1245)

The regulation which governs routine chemistry quality control establishes specific quality control criteria with which a laboratory must comply. 42 C.F.R. § 493.1245. The surveyors concluded that Petitioner failed to perform and document control procedures correctly. HCFA Ex. 1 at 127-129; HCFA Ex. 6 at 4. The surveyors found that, as a result, aberrant testing results were not identified and communicated to patients' physicians. Id.

Petitioner has not responded directly or persuasively to these findings. It asserts that its instruments were validated when they were installed and that calibrations of instruments were performed along with other instrument checks. Petitioner's Commentary - Statement of Deficiencies at 9. This assertion does not refute or, in the main, even address the surveyors' findings of noncompliance with quality control requirements as of the date of the survey.

e. Additional conditions of certification with which Petitioner did not comply (42 C.F.R. §§ 493.1239, 493.1247, 493.1249, 493.1253, 493.1409, 493.1441, 493.1447, 493.1701)

The surveyors made findings of additional condition-level deficiencies at Petitioner. These consisted of the following:

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

ii. Endocrinology and toxicology (42 C.F.R. §§ 493.1247, 493.1249);

iii. Hematologyy (42 C.F.R. § 493.1253);

iv. Personnel (42 C.F.R. §§ 493.1409, 493.1441, 493.1447);

v. Quality assurance (42 C.F.R. § 493.1701).

HCFA Ex. 6 at 4-6.

I find that Petitioner did not rebut these findings of deficiencies. Petitioner's explanations essentially amount to general assertions that equipment was calibrated or that requisite personnel were on duty. However, they fail to address the very explicit findings of failures to comply with laboratory certification requirements that the surveyors issued. For example, the surveyors found that the following personnel conditions were not met - director, high complexity; technical supervisor; and technical consultant. Additionally, the surveyors found that the persons functioning in those capacities failed to perform the technical supervision and overall management necessary to prevent the pervasive and ongoing failures that were identified during the survey of Petitioner. HCFA Ex. 1 at 137-138; HCFA Ex. 6 at 5; 42 C.F.R. § 493.1409. Petitioner's response to these findings is essentially that it had the requisite personnel on duty in 1997. Petitioner's Commentary - Statement of Deficiencies at 9. This assertion begs the question of whether the supervisory personnel were discharging the technical supervision and overall management responsibilities that are established under the conditions of participation.

As another example, the surveyors found that Petitioner failed to meet the specific requirements for hematology testing. HCFA Ex. 1 at 133-134; HCFA Ex. 6 at 5; 42 C.F.R. § 493.1253. Petitioner's response to these findings by the surveyors is essentially to assert that instruments were validated when installed and calibrations were performed along with other instrument checks. Petitioner's Commentary - Statement of Deficiencies at 9. This explanation by Petitioner merely is a general assertion that instruments were calibrated. It does not address or respond to the specific findings of deficiencies that the surveyors identified.

2. HCFA is authorized to impose principal and alternative remedies against Petitioner.

The presence of one or more condition-level deficiencies as of March 31, 1997, authorizes HCFA to impose principal and alternative remedies against Petitioner. 42 C.F.R. § 493.1806. These remedies may include any of the remedies that HCFA determined to impose against Petitioner, including suspension of Petitioner's CLIA certificate. As I discuss above, that suspension becomes a revocation effective with my decision that Petitioner manifested condition-level deficiencies.

I do not address the question of whether the condition-level deficiencies manifested by Petitioner posed immediate jeopardy to patients. As I discuss above, at Part I.A. of this decision, I have no authority to consider whether a condition-level deficiency poses immediate jeopardy.

3. Petitioner was not denied due process.

Petitioner makes two arguments to assert that it was denied due process by HCFA. First, Petitioner argues that representatives of the Texas Department of Health did not hold a proper and complete exit conference with Petitioner at the close of the March 31, 1997 survey of Petitioner. Second, Petitioner asserts that it should have been resurveyed prior to April 15, 1997, inasmuch as it had submitted allegedly credible allegations of compliance to HCFA prior to that date. I find both of these arguments to be without merit.

There is no provision in the regulations governing laboratories which compels HCFA or its designee to conduct an exit conference with a laboratory at the completion of a survey of that laboratory. See 42 C.F.R. § 493.1773. Notwithstanding, I would be concerned if Petitioner had shown that it was deprived of notice by HCFA or by the Texas Department of Health of the findings of deficiencies or the basis for those findings. However, Petitioner has not pointed to anything which would establish that it was deprived of adequate notice of these findings.

Petitioner's assertion to the contrary, its submission to HCFA of allegations of compliance did not trigger a duty on HCFA's part to assure that Petitioner was resurveyed. As I discuss above, at Part I.A. of this decision, a laboratory is entitled to a resurvey only as to ***alternative***, and not to ***principal***, remedies. But, HCFA's determination to suspend Petitioner's CLIA certificate is an invocation of a ***principal*** remedy. Under no circumstance would Petitioner be entitled to a resurvey to determine whether the remedy should be rescinded. Furthermore, a laboratory may qualify for a resurvey to determine whether an alternative remedy should be rescinded where it has submitted a ***credible*** allegation of compliance to HCFA. Here, HCFA determined that Petitioner's allegation of compliance was not credible.

Steven T. Kessel
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF Melvin C. Murphy, M.D., P.C.,
Petitioner,
Date: 1999 April 30 - v. - Health Care Financing
Administration.
Docket No. C-98-497
Decision No. CR590 **DECISION**

DECISION ENTERING SUMMARY DISPOSITION IN FAVOR OF THE HEALTH CARE FINANCING ADMINISTRATION

Petitioner, Melvin C. Murphy, M.D., P.C., moved for summary disposition in this case. The Health Care Financing Administration (HCFA) made a cross motion for summary disposition. I conclude that there are no material facts which are in serious dispute. Based on these facts and on the applicable law, I find that Petitioner failed to comply with the Clinical Laboratory Improvement Amendments of 1988, section 353 of the Public Health Services Act, 42 U.S.C. § 263(a) (CLIA), and with implementing regulations published at 42 C.F.R. Part 493, by intentionally referring proficiency tests to another laboratory. Based on that finding, I grant HCFA's cross motion for summary disposition. I sustain a revocation of Petitioner's CLIA certificate for a minimum period of one year. Additionally, I sustain HCFA's determination to cancel approval for Petitioner to receive Medicare payment for all laboratory services for a period of one year.

I had scheduled an in-person hearing to take place in this case beginning on June 7, 1999. There is no need for the hearing in light of my decision to enter summary disposition in favor of HCFA. Consequently, I cancel the scheduled hearing.

I. BACKGROUND

A. Procedural history and background facts

Petitioner is a medical practice located in Southfield, Michigan, which also has a CLIA certified laboratory. Petitioner is owned and operated by Melvin C. Murphy, M.D.. On June 29, 1998, HCFA notified Petitioner of HCFA's determination to cancel the laboratory's approval to receive Medicare payments for one year and to revoke Petitioner's CLIA certification. HCFA Ex. 2. HCFA advised Petitioner that it had based its determination to impose sanctions against Petitioner pursuant to CLIA on findings that Petitioner referred proficiency testing samples or portions of samples to another laboratory for analysis, and failed in other respects to comply with CLIA requirements. Id. at 2.

Petitioner requested a hearing. The case was assigned to me for a hearing and a decision. Petitioner moved for summary disposition. HCFA then cross moved for summary disposition. Petitioner submitted two exhibits (P. Ex. 1 and P. Ex. 2) with its motion and submitted a third exhibit (P. Ex. 3) with its brief in opposition to HCFA's cross motion. HCFA submitted 15 exhibits (HCFA Ex. 1 - HCFA Ex. 15) with its cross motion. I am receiving P. Ex. 1 - P. Ex. 3 and HCFA Ex. 1 - HCFA Ex. 15 into evidence.

However, I base my decision to enter summary disposition in favor of HCFA only on those facts which I discuss below.

B. Governing law

This case involves allegations that by Petitioner failed to comply with the requirements of CLIA and with implementing regulations. Central to my decision in this case is a provision of CLIA at 42 U.S.C. § 263(a)(4)(I) which states that:

Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its [CLIA] certificate revoked for at least one year . . . .

This section of CLIA is implemented in regulations at 42 C.F.R. § 493.1840(b). Additionally, 42 C.F.R. § 493.1842(a)(1) provides that HCFA shall cancel a laboratory's approval to receive Medicare reimbursement for its services if HCFA determines to suspend or revoke the laboratory's CLIA certificate. The remedy of revocation may not go into effect until after the laboratory against whom the remedy is imposed has the opportunity for a hearing and a decision by an administrative law judge. The remedy of cancellation of approval to receive reimbursement may go into effect prior to a hearing and a decision by an administrative law judge. 42 C.F.R. § 493.1842(b).

ISSUES

The issue in this case is whether Petitioner, a CLIA certified laboratory, intentionally referred proficiency testing samples to another laboratory for analysis. In its notice letter to Petitioner, HCFA raised additional issues regarding whether Petitioner complied with CLIA conditions of certification. HCFA Ex. 2. I do not address these additional issues here inasmuch as they involve controverted questions of material fact. It is unnecessary for me to resolve these additional issues in order for me to decide whether Petitioner intentionally referred proficiency testing samples to another laboratory for analysis.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I make findings of fact and conclusions of law (Findings) to support my decision that Petitioner intentionally referred proficiency testing samples to another laboratory for analysis. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. I base my decision in this case on material facts that are not in dispute.

The standard for imposing summary disposition is well established. Summary disposition is appropriate only where the disposition is made based on material facts that are not in dispute. Summary disposition cannot be made where material facts are controverted because due process considerations require an evidentiary hearing in order to decide controverted facts. Where inferences are made from facts which are averred to support a motion those inferences must be made in a manner that is most favorable to the party that opposes the motion.

However, it is not sufficient for a party simply to aver that it disputes allegations of facts in order to avoid possible entry against it of summary disposition. Where a party seeking summary disposition asserts material facts as the basis for its motion, the opposing party, if it disputes those facts, must deny the asserted facts credibly in order to

establish a dispute as to those facts. It will not suffice for a party to assert merely that it "disputes" facts or that it is without a basis to admit them or deny them.
The facts on which I base this decision are not in dispute. The facts on which I rely as stated in the following Findings are facts which Petitioner either admits or which Petitioner has not denied credibly. Some of the material facts in this case are facts which Petitioner has averred, either directly in affidavits which Petitioner submitted, or through briefs which Petitioner's counsel submitted on his behalf.

2. Petitioner's laboratory director referred proficiency testing samples to another laboratory for analysis.

In 1992, Petitioner contracted with Dr. Gurcharan Gagneja to serve as Petitioner's laboratory director. P. Ex. 1 at 2. Dr. Gagneja served in that capacity until March, 1998. Id. Dr. Gagneja's duties as Petitioner's laboratory director included conducting patient tests and operating the laboratory. Id. The responsibility to perform proficiency tests was implicit in Dr. Gagneja's duties as laboratory director. Id.
Dr. Gagneja spent only part of his time onsite at Petitioner. Dr. Gagneja managed another laboratory in California. P. Ex. 1 at 2. In January, 1995, Dr. Gagneja acquired the Clinical Laboratory of Hemet, California (Hemet laboratory). HCFA Ex. 5. He has served as the director of the Hemet laboratory. Dr. Murphy was aware of Dr. Gagneja's California duties. P. Ex. 1 at 2. Dr. Murphy paid for Dr. Gagneja's air fare so that Dr. Gagneja could travel from California to Michigan to perform his duties as laboratory director in Michigan. Id. Dr. Murphy was aware that Dr. Gagneja was taking materials from Petitioner to California. P. Ex. 1 at 3. Dr. Gagneja preferred to work with particular brands of equipment or leased equipment. Id. at 3.
On November 19 - 27, 1996, examiners from the State of California, Department of Health Services Laboratory Field Services Branch (California State Agency) conducted an investigation of the Hemet laboratory. Id. The examiners photocopied documents from Dr. Gagneja's office at the Hemet Laboratory. HCFA Ex. 4 at 3. The examiners concluded that Dr. Gagneja was performing proficiency tests at the Hemet laboratory for both Petitioner and the Hemet laboratory.
The documents that the examiners discovered during the course of their investigation of the Hemet laboratory included proficiency testing records for both the Hemet laboratory and Petitioner, some of which were commingled. HCFA Ex. 4 at 3. The proficiency test results for Petitioner included test results for the third testing event in 1995 and the first, second, and third testing events for 1996. Id. at 4. The documents that the examiners discovered in Dr. Gagneja's office included an envelope which contained proficiency tests results for Petitioner's third quarter of 1995. Id. These test results were accompanied by a Federal Express label that was addressed to Petitioner from the testing service. Id. Dr. Gagneja admitted that he was doing the proficiency testing for Petitioner. Id. at 4.
The examiners subsequently found additional evidence which convinced them that Dr. Gagneja was performing proficiency testing at the Hemet laboratory for both the Hemet laboratory and Petitioner. For example, for the third quarter of 1995, both laboratories produced identical scores for all five proficiency testing samples of Digoxin that they tested. HCFA Ex. 5 at 5. There was a high degree of identity between test results for Petitioner and the Hemet laboratory for all three testing events in 1996. Id. at 6 - 9. The examiners discovered a tape in the Hemet laboratory which contained the Digoxin test

sample results for the third quarter of 1995 for both Petitioner and the Hemet laboratory. Id. The tape was dated October 10, 1995. In fact, the testing service did not ship to Petitioner test samples for proficiency testing for the third quarter of 1995 until October 17, 1995. Id.

From the aforesaid evidence, HCFA asks that I infer that Dr. Gagneja took proficiency testing samples from Petitioner to the Hemet laboratory and performed proficiency tests for Petitioner at the Hemet laboratory. Petitioner does not dispute any of the aforesaid evidence. Nor does Petitioner argue strongly that it would be unreasonable for me to infer from this evidence that Dr. Gagneja performed proficiency tests for Petitioner at the Hemet laboratory. Petitioner asserts, however, that the evidence permits reasonable inferences leading to a conclusion that Dr. Gagneja did not do proficiency testing for Petitioner at the Hemet laboratory. Petitioner argues that, if reasonable inferences that are favorable to Petitioner may be drawn from the evidence, then those inferences must be drawn.

Petitioner asserts merely that it "appears that the proficiency tests for . . . [Petitioner's] laboratory were performed in Southfield as . . . [Dr. Murphy] originally intended. Petitioner's Brief in Response to HCFA's Motion for Summary Disposition (Petitioner's response) at 6. Petitioner argues additionally that the presence of proficiency testing results from Petitioner at the Hemet laboratory can be explained reasonably by the fact that Dr. Gagneja served as laboratory director for both laboratories. "[I]f the actor is a director for both laboratories, materials could easily surface in the other laboratory without comparison." Petitioner's response at 7. Finally, Petitioner argues that the facts adduced by the California State Agency which show a high degree of identity between test results for Petitioner and the Hemet laboratory do not necessarily lead to the conclusion that Dr. Gagneja performed tests for both laboratories at the Hemet laboratory.

Petitioner's arguments notwithstanding, there is only one *reasonable* inference that may be drawn from the evidence offered by HCFA. That is that Dr. Gagneja performed proficiency tests for Petitioner at the Hemet laboratory. I find other possible explanations for the presence of Petitioner's proficiency test results in Dr. Gagneja's Hemet laboratory office to be so far-fetched as to be not reasonable. I reach my conclusion that the evidence adduced by HCFA shows that Dr. Gagneja performed proficiency tests for Petitioner at the Hemet laboratory for the following reasons:

• The presence at the Hemet laboratory of commingled test results for both Petitioner and the Hemet laboratory strongly suggests that proficiency tests for both laboratories were performed at the Hemet laboratory.

• Petitioner has offered no affirmative evidence to show that proficiency tests for Petitioner were actually performed onsite at Petitioner. The absence of any evidence to show that proficiency tests for Petitioner were performed at Petitioner supports the evidence adduced by HCFA which suggests that these tests were performed at the Hemet laboratory.

• Moreover, evidence offered by Petitioner concerning the whereabouts of proficiency test results supports the inference that Dr. Gagneja referred samples from Petitioner to the Hemet laboratory for testing. Petitioner confirms that Dr. Gagneja maintained results of Petitioner's proficiency tests at the Hemet laboratory. Dr. Murphy avers that he searched for the results of 1995 and 1996 proficiency tests and found the test results to

be "missing." Petitioner's Brief in Support of Motion for Summary Disposition at 5. According to Dr. Murphy, he contacted Dr. Gagneja to ask Dr. Gagneja whether he had the test results. Id. at 5 - 6. Dr. Murphy avers that Dr. Gagneja denied having the results, but asserted to Dr. Murphy that HCFA had "confiscated these materials when it raided the Hemet Laboratory in 1996." Id. at 6.

• While it is true that Dr. Gagneja *could* have innocently commingled results from proficiency tests performed at Petitioner with results of tests performed at the Hemet laboratory, the fact that Dr. Gagneja served as director for both Petitioner and the Hemet laboratory in and of itself does not suggest any innocent reason for his commingling proficiency test results, particularly since the statute and regulations so explicitly require proficiency testing to be done independently and separately.

• Petitioner speculates that Dr. Gagneja transported proficiency testing results from Petitioner to the Hemet laboratory so that Dr. Gagneja could respond to questions from employees of Petitioner while Dr. Gagneja was in California. I find this explanation for Dr. Gagneja's actions to be beyond the realm of reasonable possibility. Proficiency testing results, however, must be completed and the results submitted within approximately two weeks from the date the testing service ships the samples to Petitioner. There would have been no reason for Dr. Gagneja to transport test results to California if, in fact, proficiency testing had been done onsite at Petitioner consistent with the requirements of CLIA because, given the short turn-around time, the tests would have been completed and the results submitted to the testing service by personnel onsite at Petitioner. HCFA Ex. 4 at 5.

• There is, however, a logical reason why Dr. Gagneja would have performed proficiency testing at the Hemet laboratory for both Petitioner and the Hemet laboratory. That is that Dr. Gagneja wanted to assure that the results of his proficiency testing for the two laboratories were consistent.

• The only reasonable inference that may be drawn from the high degree of identity between proficiency test results from Petitioner and proficiency test results from the Hemet laboratory is that Dr. Gagneja was testing samples for both laboratories at the Hemet laboratory and was manipulating test results to assure a high degree of identity. Petitioner notes several possible alternative explanations for these results which, if accepted, would lead to the conclusion that the test results' identity was coincidental and not intentional. I do not find that these alternative explanations are reasonable. The degree of overlap among test results and, in particular, the fact that Dr. Gagneja had developed test results for Petitioner *even before test samples were mailed to Petitioner for testing by the testing service* leads only to the inference that Dr. Gagneja performed all of the tests at one location and manipulated the test results.

There is no serious dispute as to the credibility of the witnesses whose statements are the basis for my conclusion that Dr. Gagneja performed proficiency tests for Petitioner at the Hemet laboratory. There is no need for me to take the testimony of these witnesses in person. Petitioner has not asserted that the credibility of the California State agency examiners could be shaken by cross examination. Dr. Gagneja's in-person testimony is unnecessary to support a conclusion that he performed proficiency tests for Petitioner at the Hemet laboratory. Petitioner has not asserted that Dr. Gagneja would provide in-person testimony that would challenge the material facts that are offered by HCFA. Nor has Petitioner asserted a need to present via in-person testimony

any evidence beyond the contents of the two affidavits which Dr. Murphy submitted and, which I accept as truthful for purposes of deciding whether to impose summary disposition. See P. Ex. 1; P. Ex. 3.

3. The actions of Petitioner's laboratory director are a violation of CLIA's prohibition against a laboratory intentionally sending proficiency testing samples to another laboratory for testing.

The only reasonable conclusion that may be drawn from the undisputed material facts is that Petitioner's laboratory director, Dr. Gagneja, knowingly and willfully transported proficiency samples from Petitioner to the Hemet laboratory so that he could test those samples at the Hemet laboratory. Such conduct by Dr. Gagneja violates CLIA's prohibition against intentionally referring proficiency testing samples from a laboratory to another laboratory for testing. 42 U.S.C. § 263(a)(4)(I); 42 C.F.R. § 493.1840(b).

4. Petitioner is responsible under CLIA for the unlawful actions of its laboratory director.

Petitioner argues that it may not be held responsible under 42 U.S.C. § 263(a)(4)(I) and 42 C.F.R. § 493.1840(b) because there is nothing in the facts or the applicable law which would permit holding Petitioner - as opposed to Dr. Gagneja - responsible for the intentional and unlawful acts of Dr. Gagneja. Petitioner asserts that if Dr. Gagneja transported proficiency testing samples from Petitioner to the Hemet laboratory for testing, he did so without its or Dr. Murphy's permission or knowledge. Moreover, according to Dr. Murphy, Dr. Gagneja lacked both the express and implied authority in his capacity as laboratory director to engage in unlawful conduct. Petitioner asserts that, under principles of State law governing agency, it may not be held liable for the unauthorized acts of Dr. Gagneja.

I disagree with Petitioner's analysis. Contrary to Petitioner's arguments, the issue of Petitioner's responsibility under CLIA is not resolved by principles of State agency law. Petitioner has responsibility under CLIA to comply with all CLIA requirements. Petitioner bears that responsibility regardless whether it or Dr. Murphy authorizes or is aware of conduct by its employees. If the laboratory director fails to execute properly Petitioner's obligation to comply with CLIA requirements then it is Petitioner's duty to assure that the requirements are met.

The statute and applicable regulations which implement CLIA make the laboratory responsible for the actions of its employees where the employee has intentionally referred its proficiency testing samples to another laboratory for analysis. 42 C.F.R. § 493.1840(b). Petitioner assumed responsibility for all the actions of its employees and its agents. Petitioner is liable for Dr. Gagneja's intentional referral of proficiency testing samples for testing from Petitioner to the Hemet laboratory. For purposes of this decision I accept as true Dr. Murphy's assertion that he did not authorize Dr. Gagneja to transport proficiency testing samples to the Hemet laboratory for testing. P. Ex. 1 at 3. I also accept as true Dr. Murphy's assertion that in his capacity as owner of Petitioner, he was unaware that Dr. Gagneja may have transported proficiency testing samples to the Hemet laboratory for testing. Id. Nevertheless, Petitioner is not excused by these facts from liability for the actions of Dr. Gagneja.

Petitioner had a statutory duty to assure that proficiency tests were being performed onsite and not elsewhere. It had an additional duty to maintain test records onsite. 42 C.F.R. § 493.801(b)(5). Petitioner may not evade its responsibility to comply with the

requirements of CLIA on the grounds that Dr. Murphy delegated responsibility to operate the laboratory to Dr. Gagneja and then assert that Dr. Murphy was unaware of Dr. Gagneja's actions. DAB CR527 at 20 - 21.

Moreover, although Dr. Murphy may not have authorized Dr. Gagneja's conduct, nor have been aware of it, it is not entirely accurate to characterize Dr. Murphy as being an innocent victim of Dr. Gagneja's actions. Dr. Murphy knew that Dr. Gagneja had the opportunity to perform proficiency tests for Petitioner at the Hemet laboratory. Also, there were facts available to Dr. Murphy that should have alerted him to the likelihood that Dr. Gagneja was performing proficiency tests for Petitioner at another location. Petitioner's employment relationship with Dr. Gagneja allowed Dr. Gagneja to divide his time between the Hemet laboratory and Petitioner. Dr. Murphy knew that Dr. Gagneja was transporting to the Hemet laboratory materials from Petitioner. The fact that Dr. Gagneja was performing work for Petitioner off-premises certainly should have alerted Dr. Murphy to the possibility that some of the off-premise work might include testing proficiency samples. The fact that Dr. Gagneja was performing proficiency tests for Petitioner at some other location should have been evident to Dr. Murphy from the fact that proficiency test results were not present onsite.

ANALYSIS

Steven T. Kessel
Administrative Law Judge

FOOTNOTES

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF Eugene A. Shaneyfelt, M.D., Petitioner Date: 1999 May 27 - v. - Health Care Financing
Administration Docket No. C-98-351
Decison No. **CR597 DECISION**

For the reasons explained below, I conclude that the Health Care Financing Administration (HCFA) was authorized under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[(1)] to revoke the certificate of waiver for Petitioner's office laboratory. I reach this conclusion because I find that HCFA has established that Petitioner is prohibited from owning or operating a laboratory for two years because he was the director -- and, thus, an "operator" -- of Buffalo Island Lab (Buffalo), located in Manila, Arkansas, whose CLIA certificate was revoked on April 11, 1998.

Factual Background

HCFA asserted the following facts, which Petitioner did not deny. During the period January 8-14, 1998, the Arkansas Department of Health (State Agency) conducted an initial certification survey of Buffalo, which was physically located inside Petitioner's clinic.[(2)] HCFA Ex. 1, ¶¶ 3, 4.[(3)] The HCFA Form 209, Laboratory Personnel Report, completed for Buffalo on the first day of the survey, lists only two employees: Petitioner and Joe Pierce. HCFA Ex. 1, Attachment A, at 1. The form lists Petitioner as Director and Clinical Consultant of Buffalo. Id. Petitioner's signature appears at the bottom of that form. Id.

At the conclusion of the survey, the State Agency concluded that Buffalo was out of compliance with CLIA conditions of participation. The State Agency transmitted to HCFA a copy of the HCFA Form 2567, Statement of Deficiencies, containing its findings regarding Buffalo. After reviewing the Statement of Deficiencies, HCFA determined that sanctions should be imposed against Buffalo. Accordingly, in letters dated February 9, 1998 and February 17, 1998, HCFA notified Buffalo that the sanctions of suspension of the lab's CLIA certificate, cancellation of its approval to receive Medicare payments, and, ultimately, revocation of the lab's CLIA certificate would be imposed. HCFA Ex. 3, Attachment A.

Both the February 9 and February 17 letters contain the following explanation of the consequences if Buffalo's CLIA certificate were revoked:

> Under revocation, the laboratory will be required to cease all operations. In addition, 42 CFR 493.1840(a)(8), will prohibit the present owner and operator from owning or operating a laboratory for two years from the date of revocation. Since Dr. Shaneyfelt is the operator (director) of Buffalo Island, this regulation would cause Dr. Shaneyfelt's other laboratory certificate, (CLIA # 04D0468059) to be revoked.

Id. at 2, 7. The letters were addressed to both Petitioner and Joe Pierce. The return receipt for the February 9 letter appears to have been signed by Joe Pierce on February 11, 1998. Id. at 5. The return receipt for the February 17 letter appears to have been signed by an individual named Judy Burks on February 17, 1998. Id. at 10.

By letter dated February 6, 1998, Joe Pierce stated that Buffalo was ceasing operations as of that date. HCFA Ex. 3, Attachment B. HCFA received that letter on February 18, 1998. HCFA Ex. 3, ¶ 9. Neither Joe Pierce nor Petitioner filed a request for a hearing to contest the revocation of Buffalo's CLIA certificate. Id. at ¶ 10.

By letter dated May 21, 1998, HCFA notified Petitioner that the CLIA certificate of waiver for his in-office lab would be revoked and its approval to receive Medicare payments would be cancelled. Petitioner timely requested a hearing, and the case was assigned to me for a hearing and decision. The parties agreed that the case could be decided on the basis of written submissions without the need for an in-person hearing.

Applicable Law and Regulations

The applicable regulations define the term "operator" as follows:

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes --
>
> (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2.

Additionally, 42 C.F.R. § 493.1840(a)(8)(e), provides:

> HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator . . .
>
> Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked . . . .

The regulations also provide that "HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation." 42 C.F.R. § 493.1840(e)(1).

The regulations provide that if a laboratory requests a hearing before an administrative law judge, the revocation will not be implemented unless and until the judge issues a decision upholding HCFA's determination. On the other hand, if the lab does not request a hearing, HCFA's determination becomes final.

Petitioner's Arguments

Petitioner does not dispute that Buffalo's CLIA certificate was revoked. Nor does he dispute that he was the director of Buffalo. He does state that he did not operate the lab, but that he "allowed the lab's owner to use [his] name for director." In essence, it appears Petitioner is arguing that he should not be subject to the two-year ban on owning or operating a lab because he was not an "operator" of Buffalo, as that term is defined in the regulations. Petitioner also asserts that neither he nor Joe Pierce received any warnings of the impending sanctions.

ISSUES

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Effective April 11, 1998, HCFA revoked the CLIA certificate of Buffalo Island Lab.

2. Petitioner was the director of Buffalo Island Lab.
3. Petitioner failed to contest HCFA's determination that, as director of Buffalo Island Lab, he was an "operator," subject to the two-year ban on owning or operating a CLIA laboratory required by 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).
4. HCFA's determination that Petitioner was an "operator" of Buffalo Island Lab is final and no longer subject to review.
5. Even if HCFA's determination that Petitioner was an "operator" of Buffalo Island Lab remained open to challenge in this proceeding, I would conclude that HCFA proved by the preponderance of the evidence that Petitioner was an "operator".
6. Pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), Petitioner is prohibited from owning or operating a clinical laboratory for a period of two years from the revocation of Buffalo Island Lab's CLIA certificate.
7. HCFA was authorized to revoke the CLIA certificate of waiver for Petitioner's office laboratory.

DISCUSSION

There is really no dispute that Petitioner was the director of Buffalo Island Lab, a lab whose CLIA certificate was revoked. Thus, it would appear that the two-year prohibition against owning or operating a lab found at 42 C.F.R. § 493.1840(a)(8) applies to him. In the present proceeding, Petitioner argues that he was director of Buffalo in name only, i.e., he did not have any operational authority at Buffalo. However, the nature of Petitioner's relationship to Buffalo is no longer open to challenge in this proceeding. If Petitioner wished to assert that he was not the director of Buffalo or that, even if he was the director, he did not meet the regulatory definition of an "operator", he should have requested a hearing to contest HCFA's imposition of sanctions against Buffalo. HCFA made plain in its February 1998 notice letters that it viewed Petitioner as an "operator" of Buffalo and that, if Buffalo's CLIA certificate were revoked, HCFA would seek revocation of the CLIA certificate for Petitioner's in-office lab. I have held in Eugene R. Pocock, M.D., DAB CR527 (1998), that a laboratory director is an affected party who has a right to request a hearing, pursuant to 42 C.F.R. § 498.40, to contest HCFA's determination to revoke the CLIA certificate of the laboratory which he or she directs. Because Petitioner did not challenge HCFA's revocation of Buffalo's CLIA certificate, that determination became final. Petitioner has waived his right to challenge HCFA's conclusion that he was an "operator" of Buffalo by failing to appeal from HCFA's determination revoking Buffalo's CLIA certificate.

I do not find credible Petitioner's assertion that neither he nor Joe Pierce received notice of HCFA's determination revoking Buffalo's CLIA certificate or of their right to appeal that determination. HCFA has produced copies of the return receipt cards for the February 9 and February 17, 1998 notice letters. One of the receipt cards appears to have been signed by Joe Pierce. The other appears to have been signed by Judy Burks. The record does not reveal the relationship of Judy Burks to Buffalo. However, Petitioner has offered no proof that Ms. Burks is unknown to him or was otherwise unauthorized to receive mail on behalf of Buffalo. I conclude that the documents offered by HCFA prove that it is more likely than not that the notice letters were received. Petitioner has offered no evidence that would rebut HCFA's showing. The notice letters explicitly stated that revocation of Buffalo's CLIA certificate would lead to revocation of the CLIA certificate of waiver for Petitioner's in-office lab. The notice letters also

provided clear instructions on how to file a request for a hearing before an ALJ. For these reasons, I conclude that Petitioner had ample notice of the consequences of his failure to request a hearing to contest HCFA's determination as to Buffalo. I therefore find no unfairness in holding that Petititioner waived his right to contest HCFA's determination that he was an "operator" of Buffalo Island Lab.

However, even if Petitioner's right to contest HCFA's finding that he was an "operator" of Buffalo were not foreclosed in this proceeding, I would conclude that HCFA has proved that Petitioner was an "operator" of Buffalo. HCFA has introduced documents from Buffalo which appear to have been signed by Petitioner. Petitioner has not denied that the signature on these documents is his.

In particular, the HCFA Form 209, Laboratory Personnel Report, completed for Buffalo lists Petitioner as Director and Clinical Consultant of Buffalo. HCFA Ex. 1, Attachment A, at 1. It appears that the signature on the Personnel Report is Petitioner's. Further, Ms. Treadwell, one of the State Agency surveyors who conducted the survey at Buffalo, states in her affidavit that Petitioner introduced himself as Buffalo's director, and that he signed the Personnel Report. HCFA Ex. 1, ¶ 4. Petitioner has introduced no evidence that would rebut Ms. Treadwell's affidavit.

In addition, other documents contained in Attachment A to Ms. Treadwell's affidavit appear to be operating records of Buffalo which also contain Petitioner's signature. Significantly, Petitioner appears to have signed a certification in connection with Buffalo's proficiency testing in which he attests that the proficiency testing samples were tested in the same manner as patient samples. HCFA Ex. 1, Attachment A, at 6. Petitioner also appears to have signed and initialed "Monthly Consultation Checklists" dated March 16, 1997 and May 20, 1997. Id. at 3, 4. The checklists indicate that Petitioner performed such tasks as "Review of Quality Control," "Review of Maintenance Records," and "Review of Proficiency Test Results." Petitioner neither objected to the authenticity of these documents nor offered any proof to contradict them.

HCFA has offered an affidavit supported by documentary evidence as proof that Petitioner was an "operator" of Buffalo Island Lab. Petitioner has offered nothing more than a broadly worded denial, which is not even in the form of an affidavit. The parties agreed that I should decide this case on the basis of the written record, without an in-person hearing. The standard of proof is a preponderance of the evidence. I conclude that HCFA's evidence is more credible than that of Petitioner. The documentary evidence produced by HCFA supports HCFA's contention that Petitioner, as laboratory director of Buffalo, exercised sufficient operational authority to qualify as an "operator." In light of the evidence adduced by HCFA, Petitioner's denial of responsibility appears self-serving and lacks credibility.

ANALYSIS

CONCLUSION

I conclude that HCFA was authorized to revoke the CLIA certificate of waiver for Petitioner's in-office lab because Petitioner was an "operator" of Buffalo Island Lab, whose CLIA certificate was revoked. I reach this conclusion primarily because Petitioner failed to contest the revocation of Buffalo's CLIA certificate and thus the issue of Petitioner's status as an "operator" is foreclosed in this proceeding. However, even if I

were to make a de novo determination as to whether Petitioner was an "operator" of Buffalo, I would conclude that HCFA had proved, by a preponderance of the evidence, that Petitioner was such an "operator."

JUDGE

Edward D. Steinman
Administrative Law Judge

FOOTNOTES

1. The CLIA provisions are codified at 42 U.S.C. § 263a.
2. In addition to Buffalo, Petitioner maintained a small in-office lab for performing routine tests.
3. HCFA offered three exhibits (HCFA Exs. 1 - 3). Petitioner did not object to the admission of these exhibits. I have received in evidence HCFA Exs. 1 - 3. HCFA Exs. 1 and 3 include attachments. Attachment A to HCFA Ex. 1 is not separately paginated. I have paginated HCFA Ex. 1, Attachment A, which includes pages 1 - 7. Similarly, Attachment A to HCFA Ex. 3 is not separately paginated. I have paginated HCFA Ex. 3, Attachment A, which includes pages 1 - 10. Petitioner did not offer any exhibits.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF Eugene A. Shaneyfelt, M.D., Petitioner Date: 1999 May 27 - v. - Health Care Financing
Administration Docket No. C-98-351
Decison No. **CR597 DECISION**

For the reasons explained below, I conclude that the Health Care Financing Administration (HCFA) was authorized under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[(1)] to revoke the certificate of waiver for Petitioner's office laboratory. I reach this conclusion because I find that HCFA has established that Petitioner is prohibited from owning or operating a laboratory for two years because he was the director -- and, thus, an "operator" -- of Buffalo Island Lab (Buffalo), located in Manila, Arkansas, whose CLIA certificate was revoked on April 11, 1998.

Factual Background

HCFA asserted the following facts, which Petitioner did not deny. During the period January 8-14, 1998, the Arkansas Department of Health (State Agency) conducted an initial certification survey of Buffalo, which was physically located inside Petitioner's clinic.[(2)] HCFA Ex. 1, ¶¶ 3, 4.[(3)] The HCFA Form 209, Laboratory Personnel Report, completed for Buffalo on the first day of the survey, lists only two employees: Petitioner and Joe Pierce. HCFA Ex. 1, Attachment A, at 1. The form lists Petitioner as Director and Clinical Consultant of Buffalo. Id. Petitioner's signature appears at the bottom of that form. Id.

At the conclusion of the survey, the State Agency concluded that Buffalo was out of compliance with CLIA conditions of participation. The State Agency transmitted to HCFA a copy of the HCFA Form 2567, Statement of Deficiencies, containing its findings regarding Buffalo. After reviewing the Statement of Deficiencies, HCFA determined that sanctions should be imposed against Buffalo. Accordingly, in letters dated February 9, 1998 and February 17, 1998, HCFA notified Buffalo that the sanctions of suspension of the lab's CLIA certificate, cancellation of its approval to receive Medicare payments, and, ultimately, revocation of the lab's CLIA certificate would be imposed. HCFA Ex. 3, Attachment A.

Both the February 9 and February 17 letters contain the following explanation of the consequences if Buffalo's CLIA certificate were revoked:

> Under revocation, the laboratory will be required to cease all operations. In addition, 42 CFR 493.1840(a)(8), will prohibit the present owner and operator from owning or operating a laboratory for two years from the date of revocation. Since Dr. Shaneyfelt is the operator (director) of Buffalo Island, this regulation would cause Dr. Shaneyfelt's other laboratory certificate, (CLIA # 04D0468059) to be revoked.

Id. at 2, 7. The letters were addressed to both Petitioner and Joe Pierce. The return receipt for the February 9 letter appears to have been signed by Joe Pierce on February 11, 1998. Id. at 5. The return receipt for the February 17 letter appears to have been signed by an individual named Judy Burks on February 17, 1998. Id. at 10.

By letter dated February 6, 1998, Joe Pierce stated that Buffalo was ceasing operations as of that date. HCFA Ex. 3, Attachment B. HCFA received that letter on February 18, 1998. HCFA Ex. 3, ¶ 9. Neither Joe Pierce nor Petitioner filed a request for a hearing to contest the revocation of Buffalo's CLIA certificate. Id. at ¶ 10.

By letter dated May 21, 1998, HCFA notified Petitioner that the CLIA certificate of waiver for his in-office lab would be revoked and its approval to receive Medicare payments would be cancelled. Petitioner timely requested a hearing, and the case was assigned to me for a hearing and decision. The parties agreed that the case could be decided on the basis of written submissions without the need for an in-person hearing.

Applicable Law and Regulations

The applicable regulations define the term "operator" as follows:

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes --
>
> (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2.

Additionally, 42 C.F.R. § 493.1840(a)(8)(e), provides:

> HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator . . .
>
> Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked . . . .

The regulations also provide that "HCFA does not revoke any type of CLIA certificate until after an ALJ hearing that upholds revocation." 42 C.F.R. § 493.1840(e)(1).

The regulations provide that if a laboratory requests a hearing before an administrative law judge, the revocation will not be implemented unless and until the judge issues a decision upholding HCFA's determination. On the other hand, if the lab does not request a hearing, HCFA's determination becomes final.

Petitioner's Arguments

Petitioner does not dispute that Buffalo's CLIA certificate was revoked. Nor does he dispute that he was the director of Buffalo. He does state that he did not operate the lab, but that he "allowed the lab's owner to use [his] name for director." In essence, it appears Petitioner is arguing that he should not be subject to the two-year ban on owning or operating a lab because he was not an "operator" of Buffalo, as that term is defined in the regulations. Petitioner also asserts that neither he nor Joe Pierce received any warnings of the impending sanctions.

ISSUES

1. Effective April 11, 1998, HCFA revoked the CLIA certificate of Buffalo Island Lab.
2. Petitioner was the director of Buffalo Island Lab.
3. Petitioner failed to contest HCFA's determination that, as director of Buffalo Island Lab, he was an "operator," subject to the two-year ban on owning or operating a CLIA laboratory required by 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).
4. HCFA's determination that Petitioner was an "operator" of Buffalo Island Lab is final and no longer subject to review.
5. Even if HCFA's determination that Petitioner was an "operator" of Buffalo Island Lab remained open to challenge in this proceeding, I would conclude that HCFA proved by the preponderance of the evidence that Petitioner was an "operator".
6. Pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), Petitioner is prohibited from owning or operating a clinical laboratory for a period of two years from the revocation of Buffalo Island Lab's CLIA certificate.
7. HCFA was authorized to revoke the CLIA certificate of waiver for Petitioner's office laboratory.

DISCUSSION

There is really no dispute that Petitioner was the director of Buffalo Island Lab, a lab whose CLIA certificate was revoked. Thus, it would appear that the two-year prohibition against owning or operating a lab found at 42 C.F.R. § 493.1840(a)(8) applies to him. In the present proceeding, Petitioner argues that he was director of Buffalo in name only, i.e., he did not have any operational authority at Buffalo. However, the nature of Petitioner's relationship to Buffalo is no longer open to challenge in this proceeding. If Petitioner wished to assert that he was not the director of Buffalo or that, even if he was the director, he did not meet the regulatory definition of an "operator", he should have requested a hearing to contest HCFA's imposition of sanctions against Buffalo. HCFA made plain in its February 1998 notice letters that it viewed Petitioner as an "operator" of Buffalo and that, if Buffalo's CLIA certificate were revoked, HCFA would seek revocation of the CLIA certificate for Petitioner's in-office lab. I have held in Eugene R. Pocock, M.D., DAB CR527 (1998), that a laboratory director is an affected party who has a right to request a hearing, pursuant to 42 C.F.R. § 498.40, to contest HCFA's determination to revoke the CLIA certificate of the laboratory which he or she directs. Because Petitioner did not challenge HCFA's revocation of Buffalo's CLIA certificate, that determination became final. Petitioner has waived his right to challenge HCFA's conclusion that he was an "operator" of Buffalo by failing to appeal from HCFA's determination revoking Buffalo's CLIA certificate.

I do not find credible Petitioner's assertion that neither he nor Joe Pierce received notice of HCFA's determination revoking Buffalo's CLIA certificate or of their right to appeal that determination. HCFA has produced copies of the return receipt cards for the February 9 and February 17, 1998 notice letters. One of the receipt cards appears to have been signed by Joe Pierce. The other appears to have been signed by Judy Burks. The record does not reveal the relationship of Judy Burks to Buffalo. However, Petitioner has offered no proof that Ms. Burks is unknown to him or was otherwise unauthorized to receive mail on behalf of Buffalo. I conclude that the documents offered by HCFA prove that it is more likely than not that the notice letters were received. Petitioner has offered no evidence that would rebut HCFA's showing. The notice letters explicitly stated that revocation of Buffalo's CLIA certificate would lead to revocation of

the CLIA certificate of waiver for Petitioner's in-office lab. The notice letters also provided clear instructions on how to file a request for a hearing before an ALJ. For these reasons, I conclude that Petitioner had ample notice of the consequences of his failure to request a hearing to contest HCFA's determination as to Buffalo. I therefore find no unfairness in holding that Petititioner waived his right to contest HCFA's determination that he was an "operator" of Buffalo Island Lab.

However, even if Petitioner's right to contest HCFA's finding that he was an "operator" of Buffalo were not foreclosed in this proceeding, I would conclude that HCFA has proved that Petitioner was an "operator" of Buffalo. HCFA has introduced documents from Buffalo which appear to have been signed by Petitioner. Petitioner has not denied that the signature on these documents is his.

In particular, the HCFA Form 209, Laboratory Personnel Report, completed for Buffalo lists Petitioner as Director and Clinical Consultant of Buffalo. HCFA Ex. 1, Attachment A, at 1. It appears that the signature on the Personnel Report is Petitioner's. Further, Ms. Treadwell, one of the State Agency surveyors who conducted the survey at Buffalo, states in her affidavit that Petitioner introduced himself as Buffalo's director, and that he signed the Personnel Report. HCFA Ex. 1, ¶ 4. Petitioner has introduced no evidence that would rebut Ms. Treadwell's affidavit.

In addition, other documents contained in Attachment A to Ms. Treadwell's affidavit appear to be operating records of Buffalo which also contain Petitioner's signature. Significantly, Petitioner appears to have signed a certification in connection with Buffalo's proficiency testing in which he attests that the proficiency testing samples were tested in the same manner as patient samples. HCFA Ex. 1, Attachment A, at 6. Petitioner also appears to have signed and initialed "Monthly Consultation Checklists" dated March 16, 1997 and May 20, 1997. Id. at 3, 4. The checklists indicate that Petitioner performed such tasks as "Review of Quality Control," "Review of Maintenance Records," and "Review of Proficiency Test Results." Petitioner neither objected to the authenticity of these documents nor offered any proof to contradict them.

HCFA has offered an affidavit supported by documentary evidence as proof that Petitioner was an "operator" of Buffalo Island Lab. Petitioner has offered nothing more than a broadly worded denial, which is not even in the form of an affidavit. The parties agreed that I should decide this case on the basis of the written record, without an in-person hearing. The standard of proof is a preponderance of the evidence. I conclude that HCFA's evidence is more credible than that of Petitioner. The documentary evidence produced by HCFA supports HCFA's contention that Petitioner, as laboratory director of Buffalo, exercised sufficient operational authority to qualify as an "operator." In light of the evidence adduced by HCFA, Petitioner's denial of responsibility appears self-serving and lacks credibility.

ANALYSIS

CONCLUSION

I conclude that HCFA was authorized to revoke the CLIA certificate of waiver for Petitioner's in-office lab because Petitioner was an "operator" of Buffalo Island Lab,

whose CLIA certificate was revoked. I reach this conclusion primarily because Petitioner failed to contest the revocation of Buffalo's CLIA certificate and thus the issue of Petitioner's status as an "operator" is foreclosed in this proceeding. However, even if I were to make a de novo determination as to whether Petitioner was an "operator" of Buffalo, I would conclude that HCFA had proved, by a preponderance of the evidence, that Petitioner was such an "operator."

JUDGE

Edward D. Steinman
Administrative Law Judge

FOOTNOTES

1. The CLIA provisions are codified at 42 U.S.C. § 263a.
2. In addition to Buffalo, Petitioner maintained a small in-office lab for performing routine tests.
3. HCFA offered three exhibits (HCFA Exs. 1 - 3). Petitioner did not object to the admission of these exhibits. I have received in evidence HCFA Exs. 1 - 3. HCFA Exs. 1 and 3 include attachments. Attachment A to HCFA Ex. 1 is not separately paginated. I have paginated HCFA Ex. 1, Attachment A, which includes pages 1 - 7. Similarly, Attachment A to HCFA Ex. 3 is not separately paginated. I have paginated HCFA Ex. 3, Attachment A, which includes pages 1 - 10. Petitioner did not offer any exhibits.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF Edison Medical Laboratories, Inc., Petitioner Date: 1999 June 7 - v. - Health Care Financing
Administration Docket No. C-99-095
Decision No. **CR599 DECISION**

I decide that the Health Care Financing Administration (HCFA) is authorized to impose remedies against Petitioner, Edison Medical Laboratories, Inc., including suspension of Petitioner's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). As a matter of law, my decision means that Petitioner's CLIA certificate is revoked.

I. BACKGROUND

A. Background facts

Petitioner is a clinical laboratory that is located in Edison, New Jersey. On November 20, 1998, HCFA notified Petitioner that Petitioner had been found to be deficient in meeting nine conditions of participation under CLIA at a survey that had been conducted of Petitioner by the New Jersey Department of Health and Senior Services (New Jersey Department of Health). Petitioner was told that the extent and nature of these deficiencies was such as to pose immediate jeopardy to Petitioner's clients. HCFA advised Petitioner that, as a consequence of these findings, and as a consequence of Petitioner's failure to submit to HCFA a credible allegation of compliance with CLIA

conditions, Petitioner would be subject to suspension of its CLIA certificate and cancellation of its approval to receive Medicare payments. Petitioner was advised that it had a right to a hearing before an administrative law judge to contest HCFA's determinations.

Petitioner filed a timely request for a hearing. In its request, Petitioner asked that the hearing be expedited. The case was assigned to me for a hearing and a decision. I agreed to hold an expedited hearing. I conducted an in-person hearing in this case in North Brunswick Township, New Jersey, on February 2 - 4, 1999. In this decision, I refer to the transcript of the hearing held on February 2, 1999, as "Tr. 2/2 at page number"; the transcript of the hearing held on February 3, 1999, as "Tr. 2/3 at page number"; and the transcript of the hearing held on February 4, 1999, as "Tr. 2/4 at page number."

At the in-person hearing, I received into evidence from HCFA exhibits consisting of HCFA Exhibits (HCFA Ex.) 1 - 119. Tr. 2/2 at 20. I received into evidence from Petitioner exhibits consisting of Petitioner Exhibits (P. Ex.) 1 - 84. Following the hearing, Petitioner submitted the certification of Amy C. Grossman, Esq., accompanied by what Petitioner identified as Exhibits "A" through "E." These exhibits consist of: Exhibit A - a Departmental Appeals Board (DAB) appellate panel decision in the case of Center Clinical Laboratory, DAB No. 1526 (1995); Exhibit B - a DAB administrative law judge's (ALJ) decision in the case of Center Clinical Laboratory, DAB CR411 (1996); Exhibit C - a DAB appellate panel decision in the case of Ward General Practice Clinic, DAB No. 1624 (1997); Exhibit D - an article regarding alpha fetoprotein concentrations in maternal serum, with reference to race and body weight; and Exhibit E - an article regarding clinical chemistry, theory, analysis, and correlation. I am not receiving these exhibits into evidence, as they were submitted after the conclusion of the evidentiary hearing in this case. However, to the extent that Petitioner has utilized the DAB decisions delineated as exhibits as authority for its arguments, I have considered them.

The following witnesses testified on behalf of HCFA at the in-person hearing:

- *Gerda Duffy* (Tr. 2/2 at 30 - 231). Ms. Duffy is employed by the New Jersey Department of Health. Currently, she manages the CLIA inspection program for the New Jersey Department of Health. Id. at 31. Ms. Duffy is a chemist and a medical technologist. Id. at 35. Ms. Duffy participated in the survey of Petitioner. Id. at 37.

- *Joan Mikita* (Tr. 2/2 at 231 - 264); Tr. 2/3 at 46 - 108. Ms. Mikita is employed by the New Jersey Department of Health as a microbiologist and as a quality assurance officer and a clinical laboratory evaluator. Tr. 2/2 at 232. Ms. Mikita participated in the survey of Petitioner. Id. at 234.

- *Ingo Kampa, Ph.D.* (Tr. 2/3 at 5 - 29). Dr. Kampa is a clinical biochemist. Id. at 5.

- *Donald L. Warkentin, Ph.D.* (Tr. 2/3 at 30 - 46). Dr. Warkentin is a clinical chemist and a clinical biochemist. Id. at 31.

The following witnesses testified on behalf of Petitioner at the in-person hearing:

- *Sam J. Lichtenfeld* (Tr. 2/3 at 113 - 140). Mr. Lichtenfeld has been employed by Petitioner since July, 1997, as an associate laboratory director. Id. at 114. He is a licensed bioanalytical laboratory director. Id.

• *Nilda Bawalan* (Tr. 2/3 at 140 - 160). Ms. Bawalan has been employed by Petitioner since the last week of July, 1998, as a general supervisor. Id. at 142. Her experience includes 25 years' experience as a medical technologist. Id. at 142 - 143.

• *Thirumalai Madhavan, M.D.* (Tr. 2/3 at 160 - 186). Dr. Madhavan is board certified in anatomic and clinical pathology. Id. at 161. Currently, he is Petitioner's laboratory director. Id. at 163.

• *Albert Grey* (Tr. 2/3 at 186 - 214). Mr. Grey is employed as a clinical applications specialist by Dade Behring, a manufacturer of laboratory equipment. Id. at 186 - 187.

• *Ratilal Kapadia, Ph.D.* (Tr. 2/3 at 215 - 231). Dr. Kapadia is a chemist. Id. at 217. He has been employed by Petitioner since July, 1996. Id. at 218.

• *Ranjit Jani* (Tr. 2/3 at 232 - 239). Mr. Jani is employed by Petitioner as a technical supervisor and as a bench technician for microbiology. Id. at 233.

• *Zwannah Dukuly, M.D.* (Tr. 2/4 at 244 - 257). Dr. Dukuly is an associate director of Petitioner. Id. at 246. His duties include being in charge of Petitioner's cytology operations. Id.

• *Harshad Patel, Ph.D.* (Tr. 2/4 at 257 - 323). Dr. Patel is a biochemist. He is Petitioner's general supervisor, president, and 100% stockholder. Id. at 258, 318.

• *Gopinatha Mallya* (Tr. 2/4 at 324 - 334). Mr. Mallya is employed by Petitioner as a laboratory manager. Id. at 325.

B. Governing law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as general requirements which must be met in order that a laboratory qualify under CLIA. For example, under 42 C.F.R. § 493.1201 (general quality control for tests of moderate or high complexity), the condition of participation is stated to include the requirement that a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each testing method to assure the accuracy and reliability of patient test results and reports.

Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of

participation. For example, under 42 C.F.R. § 493.1202 (standards for moderate or high complexity testing or both), specific requirements are set forth which govern the way such moderate or high complexity tests must be performed by a laboratory.

The CLIA regulations authorize HCFA or its designee (such as the New Jersey Department of Health) 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 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 the laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). HCFA may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against the laboratory. 42 C.F.R. § 493.1810(e). A laboratory may make an allegation of compliance once it believes it has corrected the deficiencies. HCFA will verify whether the deficiencies have been corrected if it finds the allegation of compliance to be credible and will lift alternative sanctions effective as of the correction date. Id. However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted based on self-correction of deficiencies and an allegation of compliance by the laboratory. Nor is HCFA obligated to accept as credible a laboratory's allegation of compliance. The determination to accept or not to accept a noncompliant laboratory's allegation of compliance is a matter of discretion for HCFA to exercise.

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 that upholds 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 after HCFA gives notice of its determination and in advance of a hearing and decision by an administrative law judge. 42 C.F.R. § 493.1844(d)(2)(ii). A suspension automatically becomes a revocation of the laboratory's CLIA certificate in a case where an administrative law judge upholds 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. 42 C.F.R. § 493.1844(d)(4)(ii).

A laboratory that has been found to pose immediate jeopardy to patients may appeal the finding or findings of condition level deficiencies which are the basis for the imposition of remedies against that laboratory. But, the laboratory may not appeal

HCFA's determination that the deficiencies pose immediate jeopardy to patients. 42 C.F.R. § 493.1844(c)(6). Nor may a laboratory appeal a determination by HCFA not to rescind a suspension of that laboratory based on the laboratory's allegations of compliance where HCFA has concluded that the reason for the suspension has not been removed or that there is insufficient assurance that the reason for the suspension will not recur. 42 C.F.R. § 493.1844(c)(3).

The standard of proof that is employed at a hearing concerning HCFA's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. HCFA has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by HCFA. Hillman Rehabilitation Center, DAB No. 1611 (1997).

ISSUES

The issue in this case is whether Petitioner failed to comply with one or more conditions of participation in CLIA, thereby giving HCFA the authority to suspend Petitioner's CLIA certificate and cancel its approval to receive Medicare payments.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I make findings of fact and conclusions of law (Findings) to support my decision to sustain HCFA's determination to suspend Petitioner's CLIA certificate. I set forth each Finding below as a separate heading. I discuss each of my Findings in detail.

1. Petitioner failed to provide laboratory services in a manner that complied with accepted standards for quality.

The assertion which lies at the heart of HCFA's determination that Petitioner failed to comply with nine specific CLIA conditions is that Petitioner failed, in numerous ways, and egregiously, to provide laboratory services in a manner that complied with accepted standards for quality. HCFA asserts that Petitioner's performance was so deficient as to endanger the health and safety of the individuals whose laboratory specimens Petitioner tested. According to HCFA, Petitioner's derelictions in providing quality services included the following:

> • Many of the test results that Petitioner obtained and reported to physicians or patients by testing specimens on a device known as a nephelometer were not technically possible. That Petitioner would report such test results means either that Petitioner's management and staff were grossly incompetent or that the results were falsified. HCFA's Posthearing Brief at 18.
>
> • Petitioner's staff incompetently performed tests in other areas, including low density lipoprotein testing, alpha fetoprotein testing, and indirect immunofluorescent antibody testing. HCFA's Posthearing Brief at 27.

Petitioner concedes that there may have been minor problems in its operations. But, it asserts that these problems all were easily correctable and were, in fact, corrected by Petitioner. It denies that it manifested quality problems which posed any dangers to the health or safety of patients.

As I discuss above, at Part I.B. of this decision, it is the Petitioner's burden to prove, by a preponderance of the evidence, that it is not deficient, assuming that HCFA establishes a prima facie case of deficiency in Petitioner's operations. It is apparent from the evidence in this case that Petitioner failed to meet its burden with respect to HCFA's allegations of deficient performance. Indeed, the overwhelming evidence in this case is that Petitioner's operations were deficient. The evidence plainly establishes that Petitioner was grossly incompetent in the way that it conducted laboratory tests to the extent that patients were at risk from Petitioner's performance of these tests.

a. Petitioner was deficient in its conduct of nephelometer tests.

A nephelometer is a device used by a clinical laboratory to perform specific tests on patient specimens. Tr. 2/2 at 51. Among the tests which are performed by a nephelometer is a test designed to determine a patient's levels of prealbumin. Id. at 54 - 55. Prealbumin results may be an important indicator of a patient's nutritional status. Id. Another test performed by a nephelometer is the transferrin test. Transferrin tests are used to differentiate between different types of anemia in a patient. Id. at 56 - 57.

When the New Jersey Department of Health surveyors analyzed nephelometer test results that were maintained by Petitioner, they discovered that the recorded results of many tests were identical. Tr. 2/2 at 65. Results on a large number of tests were replicated out to two decimal places. Id. at 66; HCFA Ex. 75 - 83.

The only reasonable conclusion that may be drawn about the veracity of the replicating nephelometer test results that Petitioner generated is that they do not reflect actual test values. In the credible opinion of HCFA's expert, Dr. Kampa, these results are "bogus." Tr. 2/3 at 8. Dr.Warkentin opined credibly that he had never seen nephelometer results such as those produced by Petitioner in his 25 years of work as a clinical biochemist. Id. at 39.

Replicated nephelometer test results such as those manifested by Petitioner are not technically possible. Normally, samples that are tested by a nephelometer would produce different results - depending on the contents of each sample - which, if graphed, would distribute themselves in the form of a bell curve. Tr. 2/2 at 75 - 77; Tr. 2/3 at 9 - 10, 35. It is not within the realm of reasonable statistical probability that test results within a set of results taken from different samples would duplicate each other. There is no reasonable statistical possibility that large groups of results of nephelometer test results taken from different specimens produced by different individuals would be identical out to two decimal places.

Petitioner has offered no persuasive evidence to show that the nephelometer test results that it generated were valid results. Petitioner's own witness, Mr. Grey, a technical advisor (clinical applications specialist) for the manufacturer of Petitioner's nephelometer device, could not explain how a nephelometer could produce the results that were generated by Petitioner. Tr. 2/3 at 203, 206 - 207.

HCFA suggests that Petitioner may have deliberately falsified nephelometer test results. I do not find that the evidence in this case establishes that Petitioner intentionally falsified nephelometer test results. The evidence is inconclusive as to how Petitioner obtained the obviously false replicated results. But, I do find that Petitioner was at least negligent in allowing the replicated results to be generated and communicated. Assuming that Petitioner did not generate the aberrant nephelometer results intentionally, the fact that the nephelometer tests produced obviously false replicated

data put Petitioner on notice that something was amiss. Petitioner should have recognized that the nephelometer test results were aberrant and should have made reasonable efforts to determine the cause of the problem. Tr. 2/2 at 83; Tr. 2/3 at 8 - 9, 34 - 35. And, under no circumstances, should Petitioner have communicated the false nephelometer results to patients or their physicians.

Petitioner's deficient conduct in its management of nephelometer tests is both that it permitted such obviously false test reports to be generated and that it did nothing to investigate the source of the false reports. Many of the nephelometer test results that Petitioner provided to physicians and their patients were worse than worthless. Not only were these results false, but they could have misled physicians into misdiagnosing their patients' medical conditions. Petitioner had a duty, which it failed to exercise, to assure that such misleading results were not communicated.

Petitioner asserts that, on at least one occasion, its employee identified and investigated replicating nephelometer results and ordered that tests be repeated to assure that results were correct. Petitioner's Reply Brief at 5. As support for this contention, Petitioner relies on some handwritten notations that someone made on test report documents. See P. Ex. 23 at 279, 282, 286. The documents in question do suggest that someone observed a pattern of replicating test results. See Id. But, they do not suggest that Petitioner made any meaningful systematic efforts either to ascertain the reason for the replicating results or to assure that they did not recur.

Petitioner argues that the false test results constituted only a small portion of a much larger universe of test results. Petitioner's Reply Brief at 6 - 7. Petitioner would have me conclude that it should be absolved of its responsibility to assure that false nephelometer test results were not disseminated because it arguably would have been difficult to distinguish the false results from those which were not false. I do not accept this argument. Petitioner's duty is to assure that *accurate* test results are generated and reported. Indeed, the principal purpose of CLIA is to assure that clinical laboratories discharge this duty. Petitioner was obligated to assure that only accurate nephelometer test results were generated or reported irrespective of the volume of results it was generating or the possibility that false replicating results could have been detected only with close scrutiny.

Petitioner argues that no harm was occasioned by its communication of false nephelometer test results. It asserts that these results probably were accurate even if they clustered around certain numbers. Petitioner argues that the replicated test results might have been the consequence of a "glitch" in a version of the software that is utilized by Petitioner's nephelometer to perform tests. Petitioner's Posthearing Brief at 16 - 17. Petitioner's theory is that the software might have "binned" test results (clustered results around specific numbers). According to Petitioner, the software may have assigned repeating values to test results which were very close to, but which varied to an insignificant degree from, the repeating values. Therefore, according to Petitioner, the nephelometer test results were valid even if they were "binned," because they were very close to actual test results.

I find this argument not to be persuasive. Indeed, it is fanciful. It is based on the testimony of Petitioner's general supervisor, Dr. Patel. Tr. 2/4 at 284 - 285. Dr. Patel's testimony was, essentially, speculative. He offered no foundation for his opinion. Dr. Patel offered no evidence which would show how the software at issue would produce

"binned" test results. Moreover, Dr. Patel's testimony was contradicted by the testimony offered on Petitioner's behalf by Mr. Grey. And, it was contradicted by the results of nephelometer tests performed by Petitioner using the allegedly suspect software that were not "binned." HCFA Ex. 49 at 11.

b. Petitioner was deficient in conducting other tests.

Petitioner's deficient performance of nephelometer tests was not an isolated instance of failure by Petitioner to conduct tests in compliance with accepted standards. The weight of the evidence in this case is that Petitioner was not competent in its performance of other tests in addition to nephelometer tests.

i. Alpha fetoprotein testing

Alpha fetoprotein testing is performed in the 15th to 19th weeks of a woman's pregnancy in order to determine whether abnormalities, such as spina bifida or Down's Syndrome, are present in the fetus. Tr. 2/2 at 130 - 131, 135. Obviously, the results of an alpha fetoprotein test are of great importance to a prospective mother and to her physician. An adverse result may lead to termination of a pregnancy. Moreover, it is often critically important that the test be performed promptly and that the results of the test be communicated expeditiously. Id. at 131.

The critical calculation which must be performed in an alpha fetoprotein test is a calculation known as the "multiple of the median" or "MoM." A MoM is, essentially, a value which is used to describe what a "normal" alpha fetoprotein test result would be. Tr. 2/2 at 134. Test results are compared against the MoM in order to determine the extent to which they comport with or deviate from the MoM value. Id. at 135. A wide discrepancy between a test result and the MoM value signals an abnormal test result. There is no single MoM value that may be used to measure the results of all alpha fetoprotein tests. Each test method used produces a different MoM. Tr. 2/2 at 135, 138; HCFA Ex. 93 at 4, 7, 13. And, the MoM changes for each test depending on the week of gestation of the woman whose specimen is being tested. Tr. 2/2 at 135, 138.

Petitioner was manifestly incompetent in its performance of alpha fetoprotein testing. Petitioner was careless in calculating test results. It reported results incorrectly or in ways that were misleading. And, it did not report results timely. These lapses potentially put expectant mothers and their unborn fetuses at great risk for harm.

Petitioner's lapses in its alpha fetoprotein testing included the following:

- In at least four instances, Petitioner inaccurately calculated the MoM. Tr. 2/2 at 144 - 146. These miscalculations produced inaccurate test results which Petitioner communicated to physicians.

- In reporting test results, Petitioner often left out pertinent data or gave misleading information. Petitioner, on occasion, reported incorrect MoMs with test results. Tr. 2/2 at 153 - 155; HCFA Ex. 3 at 44.

- In nine instances, Petitioner did not report test results timely. Tr. 2/2 at 163 - 166; HCFA Ex. 92 at 39, 41, 61, 64; HCFA Ex. 3 at 42. In one instance involving a specimen from a woman in her 19th week of gestation, Petitioner did not perform an alpha fetoprotein test on the specimen until three days after Petitioner received the specimen. Tr. 2/2 at 163, 165 - 166; HCFA Ex. 92 at 48.

Petitioner asserts that it did not inaccurately calculate MoMs. It contends that the New Jersey Department of Health surveyors failed to consider that Petitioner was using software to calculate MoMs which incorporated special factors which take into consideration the weight, race and diabetic status of the woman whose specimen is tested. Petitioner's Posthearing Brief at 22. Petitioner argues that its MoM calculations are accurate when these special factors are taken into account.

This argument is not persuasive. The New Jersey Department of Health surveyors found originally that Petitioner had incorrectly calculated the MoM in 13 instances. The surveyors reviewed their findings after Petitioner advised them that it was using software which took into account the weight of the women whose specimens were tested. Taking weight into consideration, the surveyors found that Petitioner's calculations were inaccurate in four instances. Tr. 2/2 at 144 - 146. Petitioner has not established these four calculations to be accurate. It has not shown how the "special" factors of race and diabetic status would establish these four calculations to be accurate.

Furthermore, Petitioner has not offered credible evidence to rebut the evidence adduced by HCFA which shows that Petitioner's performance of alpha fetoprotein tests was deficient in other respects. Petitioner has not rebutted evidence that Petitioner reported alpha fetoprotein test results late, or performed tests untimely, or supplied inaccurate or misleading information with test results.

ii. Low density lipoprotein testing

Low density lipoprotein (LDL) testing is done by a clinical laboratory to measure the quantity of a form of cholesterol in a patient's blood. LDL test results are important to physicians and their patients because they are an important indicia of the possible presence of coronary artery disease. For that reason, it is important that LDL tests be performed accurately.

At issue are direct LDL tests performed by Petitioner, where LDL is measured by testing patient blood specimens. See Tr. 2/2 at 107 - 108. Petitioner's LDL test results were unreliable for the following reasons:

- Petitioner repeated nearly all of its LDL tests. Tr. 2/2 at 109; HCFA Ex. 88 at 15. Repetition of a test by a laboratory does not in and of itself show that the laboratory is not testing specimens accurately. In fact, repetition of a test may show that the laboratory is cautious or that it is being diligent in ferreting out suspect test results. However, Petitioner repeated virtually all of its LDL testing. I infer from the high rate with which Petitioner repeated its LDL tests that Petitioner was almost never confident that the results it was obtaining on LDL tests were accurate.

- Rather than provide assurance that tests were being performed accurately, Petitioner's repeat testing raised additional questions about the likely inaccuracy of its LDL tests. There was a very high bias in repeat test results - a large percentage of the repeat tests were either all lower than or higher than original test results - a degree of variation that would not reflect normal analytical variation between original results and repeat results. Tr. 2/2 at 112 - 113, 115 - 116; HCFA Ex. 39 at 1; HCFA Ex. 40 at 1; HCFA Ex. 88 at 15.

Petitioner argues that it performed repeat LDL testing because at times there were problems with centrifuging specimens which resulted in cloudy specimens. Tr. 4/4 at 292 - 295; Petitioner's Posthearing Brief at 28 - 29. This explanation makes sense only if nearly all of Petitioner's initial LDL testing was done incorrectly, given the very high rate at which Petitioner retested specimens for LDL. That hardly constitutes reassurance that Petitioner did its LDL tests consistent with prevailing quality standards. Petitioner argues also that it passed proficiency tests for high density lipoproteins (HDL). Petitioner's Reply Brief at 8 - 9. HDL is another form of cholesterol. Petitioner reasons that, if it performed satisfactorily on proficiency tests for HDL, then its overall cholesterol testing must be satisfactory. I do not accept this argument. The fact that Petitioner may have passed a proficiency test does not derogate from the evidence gathered by the New Jersey Department of Health which shows Petitioner's overall failure to use acceptable testing techniques in its LDL testing.

iii. Indirect immunofluorescent antibody testing

Indirect immunofluorescent antibody (IFA) testing (also called immunofluorescent antibody testing) is a technique that is designed to detect the presence in a patient's blood of viral or other types of infections such as herpes, measles, or syphilis. Tr. 2/2 at 235 - 237. IFA tests are important diagnostic tools. Erroneous IFA test results pose a potential for significant harm to patients. Tr. 2/3 at 72 -73.

IFA testing seeks to find the presence of an infection by determining whether a patient's blood contains antibodies to a known disease agent. Tr. 2/2 at 235 - 236. The test is performed by adding an antigen (a specific disease agent) to a specimen of blood and then testing the blood to see if antibodies have combined with the antigen. Id. at 237 - 238. The antibody-antigen combination, assuming it is present, is made to fluoresce. Id. at 238. Test results are established by observing under a microscope the patterns and intensity of the fluorescence. Id.

The results of IFA tests may be affected by a number of variable factors. For that reason, the tests must be done with great precision and controlled carefully. For example, the volume of blood that is being tested must be measured carefully, because the amount of antibodies present, and, hence, the quantity of the disease agents, is affected by the volume of blood that is tested. Test results are affected by the temperatures at which testing materials are stored. Tr. 2/2 at 246 - 247. Test results are also affected by the amount of time that a reaction is given to take place. Tr. 2/3 at 68. The persuasive evidence in this case is that Petitioner's IFA testing was highly unreliable because Petitioner failed to properly control its IFA test methodology. Tr. 2/3 at 71. The credible testimony of Ms. Mikita is that:

> All the indicators - all the principal steps in the procedures were not adhered to . . . [T]he incubation, the wash procedures, the initial specimen screening dilution was not correct for most of the procedures. The interpretation of these results . . . the interpretation of the slides could not be made correctly . . . [T]here were errors on the test reports.

Id. at 71 - 72. Ms. Mikita also observed that Petitioner's plan of correction for its IFA testing contained errors, which, if implemented, would continue to make Petitioner's IFA testing unreliable. Id. at 72.

Among the errors that were present in Petitioner's IFA testing procedures were the following:

• Petitioner failed to screen IFA test results for fluorescence in a darkened room. Tr. 2/2 at 239 - 240.

• Petitioner's testing records failed to grade test results for fluorescence even though the degree of fluorescence in a specimen is an important factor in reading the results of an IFA test. Tr. 2/2 at 243 - 244. Rather, Petitioner merely noted results as being positive or negative.

• Petitioner failed to store IFA testing materials in a manner that was consistent with the instructions issued by the manufacturers of these materials. Tr. 2/2 at 244 - 245. For example, Petitioner stored working IFA test kits at minus fifteen degrees despite the manufacturer's instructions that the kits be stored at two to eight degrees. Id. at 245 - 248.

• Petitioner failed to incubate slides properly. Tr. 2/2 at 250 - 252; HCFA Ex. 3 at 33; HCFA Ex. 33 at 2, 5 - 8.

• Petitioner failed to wash test slides properly. Tr. 2/2 at 254 - 255.

• Petitioner failed to maintain accurate records of its testing procedures. Tr. 2/2 at 255 - 256, 263 - 264.

• Petitioner failed to perform or to interpret properly various of its IFA tests. For example, Petitioner incorrectly diluted the specimens that it tested for thyroglobulin/microsomal antibodies. Tr. 2/2 at 258 - 260. As another example, Petitioner failed to correctly dilute specimens for the DNA IFA test. Tr. 2/3 at 47 - 48. In another instance, Petitioner failed to correctly dilute specimens for the herpes simplex types 1 and 2 IFA tests. Id. at 51 - 52. In yet another instance, Petitioner failed to properly perform the Measles IFA test. Id. at 53 - 54. And, in its plan of correction, Petitioner offered a "correction" that in fact was an additional error in the way that this test would be conducted. Id. at 55- 56.

Petitioner asserts that, to the extent that it was deficient in performing IFA testing, it corrected these deficiencies. Petitioner avers that it has established a dark room for reviewing IFA slides for fluorescence. It asserts, additionally, that it had its staff retrained in IFA testing by representatives of the companies that manufacture and distribute IFA test materials. Petitioner's Reply Brief at 13.

The fact that Petitioner has taken corrective action concerning the way it conducts its IFA testing does not vitiate my conclusion that Petitioner committed errors in its IFA testing procedures. Indeed, to some extent, Petitioner's corrective actions support my conclusion. For the most part, the evidence that HCFA offered concerning Petitioner's IFA testing procedures stands unrebutted by Petitioner.

2. Petitioner failed to comply with condition level requirements of participation in CLIA.

HCFA told Petitioner in its determination notice to Petitioner that it had found Petitioner not to be complying with nine enumerated condition level requirements of participation in CLIA. In its posthearing brief, HCFA asserts that Petitioner was in fact not complying with 10 condition level requirements. It notes that the statement of deficiencies, which

had been sent to Petitioner by the New Jersey Department of Health, listed 10, and not nine, condition level deficiencies.

I have opted to consider the evidence only as it pertains to the nine conditions that were cited in HCFA's notice letter. The question of whether Petitioner was in fact deficient in complying with a tenth condition raises due process and notice considerations that are not necessary for me to decide here. The preponderance of the evidence strongly supports my conclusion that Petitioner was not complying with the nine conditions that were cited in the notice letter. That evidence justifies the imposition of the remedies that HCFA determined to impose. Indeed, the presence of just *one* condition level deficiency in Petitioner's operations justifies the imposition of the remedies that HCFA determined to impose. 42 C.F.R. § 493.1806.

I have reviewed HCFA's allegations of noncompliance in light of my Finding that Petitioner was not providing laboratory services in a manner which complied with accepted standards of quality. Finding 1. I have also reviewed HCFA's allegations in light of additional evidence that addresses some of the specific conditions that are at issue.

Petitioner makes a general argument in opposition to HCFA's assertions of noncompliance with condition level CLIA requirements that it has been certified as a clinical laboratory by the College of American Pathologists (CAP). Petitioner asserts that the evidence adduced by HCFA should be weighed against CAP's determination that Petitioner has satisfied its requirements. Petitioner reasons that it cannot be found to be seriously deficient inasmuch as CAP did not find serious deficiencies in Petitioner's operations.

I am not persuaded that CAP's certification of Petitioner overcomes the very specific and strong evidence of noncompliance with conditions of participation that HCFA presented. I find nothing in CAP's certification that rebuts directly this evidence. Moreover, the CLIA certification process is not subordinate to, nor does it defer to, whatever accreditation or certifications may be made by private organizations.

Petitioner acknowledges that it may have failed to comply with some standards of participation. It asserts that in no instance did these admitted standard level deficiencies rise to the level of a condition level deficiency. I have considered whether Petitioner failed to comply with conditions of participation or merely failed to comply with standards of participation. I conclude that, in those instances where standard level deficiencies were identified by the New Jersey Department of Health surveyors, such deficiencies were so egregious and pervasive as to create overall condition level deficiencies in Petitioner's operations.

a. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1201.

The condition level requirement that is stated at 42 C.F.R. § 493.1201 provides, among other things, that a clinical laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method utilized by the laboratory to assure the accuracy and reliability of patient test results and reports. I find that Petitioner failed to comply with this requirement in the following respects.

• Petitioner failed to follow meaningful quality control protocols for nephelometer testing. That is evidenced by Petitioner's failure to detect replicating results and to assure that such results did not recur.
• Petitioner failed to follow meaningful quality control protocols for other types of tests. That is made manifest by the way in which Petitioner conducted alpha fetoprotein tests and other types of tests, as I have discussed above, at Finding 1.

b. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1441.

The condition level requirement that is stated at 42 C.F.R. § 493.1441 provides, among other things, that a laboratory must have a director who provides overall management in accordance with the requirements that are stated at 42 C.F.R. § 493.1445. That regulation provides that a laboratory director is responsible for the overall operation and administration of the laboratory. These responsibilities include the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately, and proficiently, and assure that applicable regulations are complied with.
It is evident from the regulation that the laboratory director assumes responsibilities for assuring that a laboratory meets CLIA requirements. A systemic failure by a laboratory to meet these requirements is evidence from which I may infer that the laboratory director is failing to discharge his or her responsibilities.
Petitioner's laboratory directors failed to discharge their obligations under 42 C.F.R. §§ 493.1441 and 493.1445. There plainly were systemic failures by Petitioner, as I discuss above, at Finding 1, to meet accepted standards of quality.

c. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1447.

The condition level requirement that is stated at 42 C.F.R. § 493.1447 states that a laboratory must have a technical supervisor who meets prescribed qualification requirements and who provides technical supervision in accordance with the requirements of 42 C.F.R. § 493.1451. This regulation, 42 C.F.R. § 493.1451, states that a technical supervisor is responsible for resolving technical problems and insuring that remedial actions are taken whenever test systems deviate from a laboratory's established performance specification. Additionally, the regulation requires that a technical supervisor assure that test results are not reported until all corrective actions have been taken and that test systems are functioning correctly.
Petitioner failed manifestly to comply with this requirement. That is made evident by Petitioner's failures, discussed at Finding 1, to: identify and address problems with nephelometer and other tests; to take remedial actions to deal with these problems; and to assure that inaccurate test results were not reported.

d. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1459.

The condition level requirement that is stated at 42 C.F.R. § 493.1459 states that a laboratory must have one or more general supervisors who meet specified qualification requirements and who provide general supervision in accordance with the requirements of 42 C.F.R. § 493.1463. This regulation, 42 C.F.R. § 493.1463, provides that a

laboratory must have one or more general supervisors who provide day-to-day supervision of testing personnel and the reporting of test results. Moreover, 42 C.F.R. § 493.1461 provides that a general supervisor works under the direction of the laboratory director and the supervision of the technical supervisor.

Petitioner's wholesale failure to comply with generally accepted standards of quality is evidence from which I infer that Petitioner was failing to provide acceptable general supervision of laboratory activities. That conclusion is reinforced by the New Jersey Department of Health surveyors' findings that Petitioner's supervisors were not able to answer their questions about laboratory operations. Tr. 2/2 at 46 - 48. The answers that the supervisors gave the surveyors in response to their questions is strong evidence that the supervisors were not aware of what was going on under their ostensible authority. For the most part, the supervisors responded to the surveyors' questions by averring that the actual testing was performed at times when the supervisors were not on duty.

e. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1701.

The condition level requirement for participation that is stated at 42 C.F.R. § 493.1701 directs a laboratory that performs moderate or high complexity testing to establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the laboratory's testing program. The requirement provides that a laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the laboratory's staff. The requirement directs a laboratory to, as may be necessary, revise policies and procedures based upon the results of its evaluations.

There was a wholesale failure by Petitioner to monitor, evaluate the quality of, and address deficiencies in its testing program. That is made evident by the numerous quality failures, discussed above at Finding 1, that the New Jersey Department of Health surveyors identified in Petitioner's operation. One example, Petitioner's failure to monitor and evaluate the quality of its testing program, is apparent in the numerous quality deficiencies that were present in Petitioner's IFA testing program. Finding 1.b.iii.

f. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1241.

The condition level requirement that is stated at 42 C.F.R. § 493.1241 requires that, in order to meet the condition level requirements for general immunology, a laboratory must comply with the requirements that are stated at 42 C.F.R. §§ 493.1201 - 493.1221. The referred-to regulations establish requirements for performance of immunology testing.

Petitioner failed to comply with these requirements. That is apparent from my discussion at Finding 1. For example, 42 C.F.R. § 493.1215 requires that a laboratory perform equipment maintenance and function checks that include any electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports. I infer from the evidence relating to Petitioner's nephelometer

test results that Petitioner failed to perform equipment function checks of its nephelometer equipment. Petitioner as much as admits that when it avers that the replicating test results that were produced by its nephelometer equipment were as a consequence of a software "glitch."

As another example, 42 C.F.R. § 493.1205 requires a laboratory to utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports. Petitioner failed systematically to comply with this requirement. That is plain from the many quality failures in its conduct of IFA testing and nephelometer testing.

The requirements that are stated at 42 C.F.R. §§ 493.1201 - 493.1221 are standards of participation and not conditions. However, my conclusion that Petitioner failed to comply with these standards is not a conclusion that Petitioner failed to comply with standards only. The degree of noncompliance manifested by Petitioner was so pervasive as to comprise a failure to comply with the overall condition stated in 42 C.F.R. § 493.1241.

g. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1245.

The condition of participation governing the performance of routine chemistry testing that is stated at 42 C.F.R. § 493.1245 requires a laboratory to comply with the requirements of 42 C.F.R. §§ 493.1201 - 493.1221. The routine chemistry requirements largely duplicate the immunology requirements which I discuss above, at Finding 2.f. Petitioner manifested the same poor quality in the area of routine chemistry testing that it manifested in the area of general immunology. That is evident, for example, from the many examples of poor quality that Petitioner demonstrated in its LDL testing.

h. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.801.

The condition of participation that is stated at 42 C.F.R. § 493.801 requires a clinical laboratory to enroll in an approved proficiency testing program. The condition establishes as standards the criteria which must be adhered to by a clinical laboratory in its performance of proficiency testing. 42 C.F.R. § 493.801(a), (b).

Petitioner failed in several respects to comply with the standards established for proficiency testing. I find these failures to be so extensive and serious as to constitute a failure by Petitioner to comply with the overall condition established by 42 C.F.R. § 493.801. Petitioner's compliance failures included the following:

- Petitioner failed to assure that the person who did proficiency testing was an employee who routinely performed testing at Petitioner as is required by 42 C.F.R. § 493.801(b)(1). The analyst-employee of Petitioner who acknowledged doing proficiency testing for IFA specimens worked during daytime hours, whereas routine IFA testing was done by Petitioner at night. Tr. 2/3 at 100 - 102; HCFA Ex. 3 at 2. This lapse by Petitioner made meaningless its IFA proficiency testing. The whole point of such testing was to have the employees who did routine IFA testing demonstrate their proficiency. It is irrelevant that someone other than those employees might be able to test IFA specimens proficiently.

- Petitioner's directors signed statements attesting that proficiency testing specimens had been tested in the same manner as routine test specimens. However, that was not the case,

as is demonstrated by the way in which Petitioner's employees performed proficiency testing for IFA specimens. HCFA Ex. 3 at 2.

In the plan of correction that Petitioner submitted in response to the findings that were made by the New Jersey Department of Health surveyors, Petitioner asserted that the surveyors' findings that proficiency tests were not being conducted by the laboratory employees who performed routine tests on patients' specimens comprised "the exception and not the rule." HCFA Ex. 3 at 2. According to Petitioner, employee absences accounted for the occasional performance of a proficiency test by an employee other than the employees who performed routine tests on patient specimens. Id.; Petitioner's Posthearing Brief at 10 - 11.

I am not persuaded from this explanation that Petitioner complied with the requirements of 42 C.F.R. § 493.801 by assuring that the employees who did tests also performed proficiency tests. Petitioner has not provided affirmative proof in this case to satisfy me that proficiency tests were always performed by the employees who performed routine tests on patients' specimens.

i. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1101.

The condition of participation that is stated at 42 C.F.R. § 493.1101 requires a clinical laboratory that performs moderate or high complexity tests to employ and maintain a system that provides for proper patient specimen preparation, proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. The standards which recite the particular requirements of the condition are stated at 42 C.F.R. §§ 493.1103 - 493.1111. Petitioner failed pervasively to comply with these standards to the extent that it failed to comply with the overall condition of participation.

Petitioner's compliance failures include the following deficiencies:

•Petitioner failed to comply with the requirement that a laboratory perform tests only at the written or electronic request of an authorized person. 42 C.F.R. § 493.1105; Tr. 2/2 at 168 - 171; HCFA Ex. 3 at 7 - 8; HCFA Ex. 117 at 1 - 5, 11 - 12. On numerous occasions, Petitioner performed a test for the presence of Lyme disease where such test had not been requested by the patient's physician. Id.

•Petitioner failed to comply with the requirement that a laboratory maintain a record system that insures that patient specimens are reliably identified as they are processed and tested to assure that accurate test results are reported. 42 C.F.R. § 493.1107. For example, some of Petitioner's work records had control results recorded on them and were signed and dated by a supervisor - to signify that work had been done properly - before tests actually were performed. Tr. 2/3 at 84 - 85; HCFA Ex. 3 at 8 - 9; HCFA Ex. 100. As another example, the work record that Petitioner generated for ANA testing on July 10, 1998, showed that tests had been performed on seven patients' specimens. In fact, on that date Petitioner had performed 11 ANA tests. HCFA Ex. 3 at 9; HCFA Ex. 101 at 1- 2.

3. HCFA is authorized to impose principal remedies against Petitioner.

The presence of one or more condition level deficiencies in Petitioner's operations authorizes HCFA to impose principal remedies against Petitioner. 42 C.F.R. § 493.1806. These remedies may include suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare payments. Furthermore, as I discuss above, that suspension becomes a revocation effective with my decision that Petitioner manifested condition level deficiencies.

I do not address the question of whether the condition level deficiencies manifested by Petitioner posed immediate jeopardy to patients. As I discuss above, at Part I.B. of this decision, I have no authority to consider whether a condition level deficiency poses immediate jeopardy.

ANALYSIS

CONCLUSION

JUDGE
Steven T. Kessel
Administrative Law Judge

FOOTNOTES

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF Edison Medical Laboratories, Inc., Petitioner Date: 1999 June 7 - v. - Health Care Financing
Administration Docket No. C-99-095
Decision No. **CR599 DECISION**

I decide that the Health Care Financing Administration (HCFA) is authorized to impose remedies against Petitioner, Edison Medical Laboratories, Inc., including suspension of Petitioner's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). As a matter of law, my decision means that Petitioner's CLIA certificate is revoked.

I. BACKGROUND

A. Background facts

Petitioner is a clinical laboratory that is located in Edison, New Jersey. On November 20, 1998, HCFA notified Petitioner that Petitioner had been found to be deficient in meeting nine conditions of participation under CLIA at a survey that had been conducted of Petitioner by the New Jersey Department of Health and Senior Services (New Jersey Department of Health). Petitioner was told that the extent and nature of these deficiencies was such as to pose immediate jeopardy to Petitioner's clients. HCFA advised Petitioner that, as a consequence of these findings, and as a consequence of Petitioner's failure to submit to HCFA a credible allegation of compliance with CLIA conditions, Petitioner would be subject to suspension of its CLIA certificate and cancellation of its approval to receive Medicare payments. Petitioner was advised that it had a right to a hearing before an administrative law judge to contest HCFA's determinations.

Petitioner filed a timely request for a hearing. In its request, Petitioner asked that the hearing be expedited. The case was assigned to me for a hearing and a decision. I agreed to hold an expedited hearing. I conducted an in-person hearing in this case in North Brunswick Township, New Jersey, on February 2 - 4, 1999. In this decision, I refer to the transcript of the hearing held on February 2, 1999, as "Tr. 2/2 at page number"; the transcript of the hearing held on February 3, 1999, as "Tr. 2/3 at page number"; and the transcript of the hearing held on February 4, 1999, as "Tr. 2/4 at page number."

At the in-person hearing, I received into evidence from HCFA exhibits consisting of HCFA Exhibits (HCFA Ex.) 1 - 119. Tr. 2/2 at 20. I received into evidence from Petitioner exhibits consisting of Petitioner Exhibits (P. Ex.) 1 - 84. Following the hearing, Petitioner submitted the certification of Amy C. Grossman, Esq., accompanied by what Petitioner identified as Exhibits "A" through "E." These exhibits consist of: Exhibit A - a Departmental Appeals Board (DAB) appellate panel decision in the case of Center Clinical Laboratory, DAB No. 1526 (1995); Exhibit B - a DAB administrative law judge's (ALJ) decision in the case of Center Clinical Laboratory, DAB CR411 (1996); Exhibit C - a DAB appellate panel decision in the case of Ward General Practice Clinic, DAB No. 1624 (1997); Exhibit D - an article regarding alpha fetoprotein concentrations in maternal serum, with reference to race and body weight; and Exhibit E - an article

regarding clinical chemistry, theory, analysis, and correlation. I am not receiving these exhibits into evidence, as they were submitted after the conclusion of the evidentiary hearing in this case. However, to the extent that Petitioner has utilized the DAB decisions delineated as exhibits as authority for its arguments, I have considered them. The following witnesses testified on behalf of HCFA at the in-person hearing:

• *Gerda Duffy* (Tr. 2/2 at 30 - 231). Ms. Duffy is employed by the New Jersey Department of Health. Currently, she manages the CLIA inspection program for the New Jersey Department of Health. Id. at 31. Ms. Duffy is a chemist and a medical technologist. Id. at 35. Ms. Duffy participated in the survey of Petitioner. Id. at 37.

• *Joan Mikita* (Tr. 2/2 at 231 - 264); Tr. 2/3 at 46 - 108. Ms. Mikita is employed by the New Jersey Department of Health as a microbiologist and as a quality assurance officer and a clinical laboratory evaluator. Tr. 2/2 at 232. Ms. Mikita participated in the survey of Petitioner. Id. at 234.

• *Ingo Kampa, Ph.D.* (Tr. 2/3 at 5 - 29). Dr. Kampa is a clinical biochemist. Id. at 5.

• *Donald L. Warkentin, Ph.D.* (Tr. 2/3 at 30 - 46). Dr. Warkentin is a clinical chemist and a clinical biochemist. Id. at 31.

The following witnesses testified on behalf of Petitioner at the in-person hearing:

• *Sam J. Lichtenfeld* (Tr. 2/3 at 113 - 140). Mr. Lichtenfeld has been employed by Petitioner since July, 1997, as an associate laboratory director. Id. at 114. He is a licensed bioanalytical laboratory director. Id.

• *Nilda Bawalan* (Tr. 2/3 at 140 - 160). Ms. Bawalan has been employed by Petitioner since the last week of July, 1998, as a general supervisor. Id. at 142. Her experience includes 25 years' experience as a medical technologist. Id. at 142 - 143.

• *Thirumalai Madhavan, M.D.* (Tr. 2/3 at 160 - 186). Dr. Madhavan is board certified in anatomic and clinical pathology. Id. at 161. Currently, he is Petitioner's laboratory director. Id. at 163.

• *Albert Grey* (Tr. 2/3 at 186 - 214). Mr. Grey is employed as a clinical applications specialist by Dade Behring, a manufacturer of laboratory equipment. Id. at 186 - 187.

• *Ratilal Kapadia, Ph.D.* (Tr. 2/3 at 215 - 231). Dr. Kapadia is a chemist. Id. at 217. He has been employed by Petitioner since July, 1996. Id. at 218.

• *Ranjit Jani* (Tr. 2/3 at 232 - 239). Mr. Jani is employed by Petitioner as a technical supervisor and as a bench technician for microbiology. Id. at 233.

• *Zwannah Dukuly, M.D.* (Tr. 2/4 at 244 - 257). Dr. Dukuly is an associate director of Petitioner. Id. at 246. His duties include being in charge of Petitioner's cytology operations. Id.

• *Harshad Patel, Ph.D.* (Tr. 2/4 at 257 - 323). Dr. Patel is a biochemist. He is Petitioner's general supervisor, president, and 100% stockholder. Id. at 258, 318.

• *Gopinatha Mallya* (Tr. 2/4 at 324 - 334). Mr. Mallya is employed by Petitioner as a laboratory manager. Id. at 325.

B. Governing law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as general requirements which must be met in order that a laboratory qualify under CLIA. For example, under 42 C.F.R. § 493.1201 (general quality control for tests of moderate or high complexity), the condition of participation is stated to include the requirement that a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each testing method to assure the accuracy and reliability of patient test results and reports.

Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. For example, under 42 C.F.R. § 493.1202 (standards for moderate or high complexity testing or both), specific requirements are set forth which govern the way such moderate or high complexity tests must be performed by a laboratory.

The CLIA regulations authorize HCFA or its designee (such as the New Jersey Department of Health) 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 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 the laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). HCFA may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against the laboratory. 42 C.F.R. § 493.1810(e). A laboratory may make an allegation of compliance once it believes it has corrected the deficiencies. HCFA will verify whether the deficiencies have been corrected if it finds the allegation of compliance to be credible and will lift alternative sanctions effective as of the correction date. Id. However,

the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted based on self-correction of deficiencies and an allegation of compliance by the laboratory. Nor is HCFA obligated to accept as credible a laboratory's allegation of compliance. The determination to accept or not to accept a noncompliant laboratory's allegation of compliance is a matter of discretion for HCFA to exercise.

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 that upholds 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 after HCFA gives notice of its determination and in advance of a hearing and decision by an administrative law judge. 42 C.F.R. § 493.1844(d)(2)(ii). A suspension automatically becomes a revocation of the laboratory's CLIA certificate in a case where an administrative law judge upholds 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. 42 C.F.R. § 493.1844(d)(4)(ii).

A laboratory that has been found to pose immediate jeopardy to patients may appeal the finding or findings of condition level deficiencies which are the basis for the imposition of remedies against that laboratory. But, the laboratory may not appeal HCFA's determination that the deficiencies pose immediate jeopardy to patients. 42 C.F.R. § 493.1844(c)(6). Nor may a laboratory appeal a determination by HCFA not to rescind a suspension of that laboratory based on the laboratory's allegations of compliance where HCFA has concluded that the reason for the suspension has not been removed or that there is insufficient assurance that the reason for the suspension will not recur. 42 C.F.R. § 493.1844(c)(3).

The standard of proof that is employed at a hearing concerning HCFA's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. HCFA has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by HCFA. Hillman Rehabilitation Center, DAB No. 1611 (1997).

ISSUES

The issue in this case is whether Petitioner failed to comply with one or more conditions of participation in CLIA, thereby giving HCFA the authority to suspend Petitioner's CLIA certificate and cancel its approval to receive Medicare payments.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I make findings of fact and conclusions of law (Findings) to support my decision to sustain HCFA's determination to suspend Petitioner's CLIA certificate. I set forth each Finding below as a separate heading. I discuss each of my Findings in detail.

1. Petitioner failed to provide laboratory services in a manner that complied with accepted standards for quality.

The assertion which lies at the heart of HCFA's determination that Petitioner failed to comply with nine specific CLIA conditions is that Petitioner failed, in numerous ways, and egregiously, to provide laboratory services in a manner that complied with accepted standards for quality. HCFA asserts that Petitioner's performance was so deficient as to endanger the health and safety of the individuals whose laboratory specimens Petitioner tested. According to HCFA, Petitioner's derelictions in providing quality services included the following:

> • Many of the test results that Petitioner obtained and reported to physicians or patients by testing specimens on a device known as a nephelometer were not technically possible. That Petitioner would report such test results means either that Petitioner's management and staff were grossly incompetent or that the results were falsified. HCFA's Posthearing Brief at 18.
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> • Petitioner's staff incompetently performed tests in other areas, including low density lipoprotein testing, alpha fetoprotein testing, and indirect immunofluorescent antibody testing. HCFA's Posthearing Brief at 27.

Petitioner concedes that there may have been minor problems in its operations. But, it asserts that these problems all were easily correctable and were, in fact, corrected by Petitioner. It denies that it manifested quality problems which posed any dangers to the health or safety of patients.

As I discuss above, at Part I.B. of this decision, it is the Petitioner's burden to prove, by a preponderance of the evidence, that it is not deficient, assuming that HCFA establishes a prima facie case of deficiency in Petitioner's operations. It is apparent from the evidence in this case that Petitioner failed to meet its burden with respect to HCFA's allegations of deficient performance. Indeed, the overwhelming evidence in this case is that Petitioner's operations were deficient. The evidence plainly establishes that Petitioner was grossly incompetent in the way that it conducted laboratory tests to the extent that patients were at risk from Petitioner's performance of these tests.

a. Petitioner was deficient in its conduct of nephelometer tests.

A nephelometer is a device used by a clinical laboratory to perform specific tests on patient specimens. Tr. 2/2 at 51. Among the tests which are performed by a nephelometer is a test designed to determine a patient's levels of prealbumin. Id. at 54 - 55. Prealbumin results may be an important indicator of a patient's nutritional status. Id. Another test performed by a nephelometer is the transferrin test. Transferrin tests are used to differentiate between different types of anemia in a patient. Id. at 56 - 57.

When the New Jersey Department of Health surveyors analyzed nephelometer test results that were maintained by Petitioner, they discovered that the recorded results of many tests were identical. Tr. 2/2 at 65. Results on a large number of tests were replicated out to two decimal places. Id. at 66; HCFA Ex. 75 - 83.

The only reasonable conclusion that may be drawn about the veracity of the replicating nephelometer test results that Petitioner generated is that they do not reflect actual test values. In the credible opinion of HCFA's expert, Dr. Kampa, these results are "bogus." Tr. 2/3 at 8. Dr.Warkentin opined credibly that he had never seen nephelometer results such as those produced by Petitioner in his 25 years of work as a clinical biochemist. Id. at 39.

Replicated nephelometer test results such as those manifested by Petitioner are not technically possible. Normally, samples that are tested by a nephelometer would produce different results - depending on the contents of each sample - which, if graphed, would distribute themselves in the form of a bell curve. Tr. 2/2 at 75 - 77; Tr. 2/3 at 9 - 10, 35. It is not within the realm of reasonable statistical probability that test results within a set of results taken from different samples would duplicate each other. There is no reasonable statistical possibility that large groups of results of nephelometer test results taken from different specimens produced by different individuals would be identical out to two decimal places.

Petitioner has offered no persuasive evidence to show that the nephelometer test results that it generated were valid results. Petitioner's own witness, Mr. Grey, a technical advisor (clinical applications specialist) for the manufacturer of Petitioner's nephelometer device, could not explain how a nephelometer could produce the results that were generated by Petitioner. Tr. 2/3 at 203, 206 - 207.

HCFA suggests that Petitioner may have deliberately falsified nephelometer test results. I do not find that the evidence in this case establishes that Petitioner intentionally falsified nephelometer test results. The evidence is inconclusive as to how Petitioner obtained the obviously false replicated results. But, I do find that Petitioner was at least negligent in allowing the replicated results to be generated and communicated. Assuming that Petitioner did not generate the aberrant nephelometer results intentionally, the fact that the nephelometer tests produced obviously false replicated data put Petitioner on notice that something was amiss. Petitioner should have recognized that the nephelometer test results were aberrant and should have made reasonable efforts to determine the cause of the problem. Tr. 2/2 at 83; Tr. 2/3 at 8 - 9, 34 - 35. And, under no circumstances, should Petitioner have communicated the false nephelometer results to patients or their physicians.

Petitioner's deficient conduct in its management of nephelometer tests is both that it permitted such obviously false test reports to be generated and that it did nothing to investigate the source of the false reports. Many of the nephelometer test results that Petitioner provided to physicians and their patients were worse than worthless. Not only were these results false, but they could have misled physicians into misdiagnosing their patients' medical conditions. Petitioner had a duty, which it failed to exercise, to assure that such misleading results were not communicated.

Petitioner asserts that, on at least one occasion, its employee identified and investigated replicating nephelometer results and ordered that tests be repeated to assure that results were correct. Petitioner's Reply Brief at 5. As support for this contention, Petitioner relies on some handwritten notations that someone made on test report documents. See P. Ex. 23 at 279, 282, 286. The documents in question do suggest that someone observed a pattern of replicating test results. See Id. But, they do

not suggest that Petitioner made any meaningful systematic efforts either to ascertain the reason for the replicating results or to assure that they did not recur.
Petitioner argues that the false test results constituted only a small portion of a much larger universe of test results. Petitioner's Reply Brief at 6 - 7. Petitioner would have me conclude that it should be absolved of its responsibility to assure that false nephelometer test results were not disseminated because it arguably would have been difficult to distinguish the false results from those which were not false. I do not accept this argument. Petitioner's duty is to assure that *accurate* test results are generated and reported. Indeed, the principal purpose of CLIA is to assure that clinical laboratories discharge this duty. Petitioner was obligated to assure that only accurate nephelometer test results were generated or reported irrespective of the volume of results it was generating or the possibility that false replicating results could have been detected only with close scrutiny.
Petitioner argues that no harm was occasioned by its communication of false nephelometer test results. It asserts that these results probably were accurate even if they clustered around certain numbers. Petitioner argues that the replicated test results might have been the consequence of a "glitch" in a version of the software that is utilized by Petitioner's nephelometer to perform tests. Petitioner's Posthearing Brief at 16 - 17. Petitioner's theory is that the software might have "binned" test results (clustered results around specific numbers). According to Petitioner, the software may have assigned repeating values to test results which were very close to, but which varied to an insignificant degree from, the repeating values. Therefore, according to Petitioner, the nephelometer test results were valid even if they were "binned," because they were very close to actual test results.
I find this argument not to be persuasive. Indeed, it is fanciful. It is based on the testimony of Petitioner's general supervisor, Dr. Patel. Tr. 2/4 at 284 - 285. Dr. Patel's testimony was, essentially, speculative. He offered no foundation for his opinion. Dr. Patel offered no evidence which would show how the software at issue would produce "binned" test results. Moreover, Dr. Patel's testimony was contradicted by the testimony offered on Petitioner's behalf by Mr. Grey. And, it was contradicted by the results of nephelometer tests performed by Petitioner using the allegedly suspect software that were not "binned." HCFA Ex. 49 at 11.

b. Petitioner was deficient in conducting other tests.

Petitioner's deficient performance of nephelometer tests was not an isolated instance of failure by Petitioner to conduct tests in compliance with accepted standards. The weight of the evidence in this case is that Petitioner was not competent in its performance of other tests in addition to nephelometer tests.

i. Alpha fetoprotein testing

Alpha fetoprotein testing is performed in the 15th to 19th weeks of a woman's pregnancy in order to determine whether abnormalities, such as spina bifida or Down's Syndrome, are present in the fetus. Tr. 2/2 at 130 - 131, 135. Obviously, the results of an alpha fetoprotein test are of great importance to a prospective mother and to her physician. An adverse result may lead to termination of a pregnancy. Moreover, it is often critically important that the test be performed promptly and that the results of the test be communicated expeditiously. Id. at 131.

The critical calculation which must be performed in an alpha fetoprotein test is a calculation known as the "multiple of the median" or "MoM." A MoM is, essentially, a value which is used to describe what a "normal" alpha fetoprotein test result would be. Tr. 2/2 at 134. Test results are compared against the MoM in order to determine the extent to which they comport with or deviate from the MoM value. Id. at 135. A wide discrepancy between a test result and the MoM value signals an abnormal test result. There is no single MoM value that may be used to measure the results of all alpha fetoprotein tests. Each test method used produces a different MoM. Tr. 2/2 at 135, 138; HCFA Ex. 93 at 4, 7, 13. And, the MoM changes for each test depending on the week of gestation of the woman whose specimen is being tested. Tr. 2/2 at 135, 138.

Petitioner was manifestly incompetent in its performance of alpha fetoprotein testing. Petitioner was careless in calculating test results. It reported results incorrectly or in ways that were misleading. And, it did not report results timely. These lapses potentially put expectant mothers and their unborn fetuses at great risk for harm.

Petitioner's lapses in its alpha fetoprotein testing included the following:

- In at least four instances, Petitioner inaccurately calculated the MoM. Tr. 2/2 at 144 - 146. These miscalculations produced inaccurate test results which Petitioner communicated to physicians.

- In reporting test results, Petitioner often left out pertinent data or gave misleading information. Petitioner, on occasion, reported incorrect MoMs with test results. Tr. 2/2 at 153 - 155; HCFA Ex. 3 at 44.

- In nine instances, Petitioner did not report test results timely. Tr. 2/2 at 163 - 166; HCFA Ex. 92 at 39, 41, 61, 64; HCFA Ex. 3 at 42. In one instance involving a specimen from a woman in her 19th week of gestation, Petitioner did not perform an alpha fetoprotein test on the specimen until three days after Petitioner received the specimen. Tr. 2/2 at 163, 165 - 166; HCFA Ex. 92 at 48.

Petitioner asserts that it did not inaccurately calculate MoMs. It contends that the New Jersey Department of Health surveyors failed to consider that Petitioner was using software to calculate MoMs which incorporated special factors which take into consideration the weight, race and diabetic status of the woman whose specimen is tested. Petitioner's Posthearing Brief at 22. Petitioner argues that its MoM calculations are accurate when these special factors are taken into account.

This argument is not persuasive. The New Jersey Department of Health surveyors found originally that Petitioner had incorrectly calculated the MoM in 13 instances. The surveyors reviewed their findings after Petitioner advised them that it was using software which took into account the weight of the women whose specimens were tested. Taking weight into consideration, the surveyors found that Petitioner's calculations were inaccurate in four instances. Tr. 2/2 at 144 - 146. Petitioner has not established these four calculations to be accurate. It has not shown how the "special" factors of race and diabetic status would establish these four calculations to be accurate.

Furthermore, Petitioner has not offered credible evidence to rebut the evidence adduced by HCFA which shows that Petitioner's performance of alpha fetoprotein tests was deficient in other respects. Petitioner has not rebutted evidence that Petitioner

reported alpha fetoprotein test results late, or performed tests untimely, or supplied inaccurate or misleading information with test results.

ii. Low density lipoprotein testing

Low density lipoprotein (LDL) testing is done by a clinical laboratory to measure the quantity of a form of cholesterol in a patient's blood. LDL test results are important to physicians and their patients because they are an important indicia of the possible presence of coronary artery disease. For that reason, it is important that LDL tests be performed accurately.

At issue are direct LDL tests performed by Petitioner, where LDL is measured by testing patient blood specimens. See Tr. 2/2 at 107 - 108. Petitioner's LDL test results were unreliable for the following reasons:

> • Petitioner repeated nearly all of its LDL tests. Tr. 2/2 at 109; HCFA Ex. 88 at 15. Repetition of a test by a laboratory does not in and of itself show that the laboratory is not testing specimens accurately. In fact, repetition of a test may show that the laboratory is cautious or that it is being diligent in ferreting out suspect test results. However, Petitioner repeated virtually all of its LDL testing. I infer from the high rate with which Petitioner repeated its LDL tests that Petitioner was almost never confident that the results it was obtaining on LDL tests were accurate.
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> • Rather than provide assurance that tests were being performed accurately, Petitioner's repeat testing raised additional questions about the likely inaccuracy of its LDL tests. There was a very high bias in repeat test results - a large percentage of the repeat tests were either all lower than or higher than original test results - a degree of variation that would not reflect normal analytical variation between original results and repeat results. Tr. 2/2 at 112 - 113, 115 - 116; HCFA Ex. 39 at 1; HCFA Ex. 40 at 1; HCFA Ex. 88 at 15.

Petitioner argues that it performed repeat LDL testing because at times there were problems with centrifuging specimens which resulted in cloudy specimens. Tr. 4/4 at 292 - 295; Petitioner's Posthearing Brief at 28 - 29. This explanation makes sense only if nearly all of Petitioner's initial LDL testing was done incorrectly, given the very high rate at which Petitioner retested specimens for LDL. That hardly constitutes reassurance that Petitioner did its LDL tests consistent with prevailing quality standards.

Petitioner argues also that it passed proficiency tests for high density lipoproteins (HDL). Petitioner's Reply Brief at 8 - 9. HDL is another form of cholesterol. Petitioner reasons that, if it performed satisfactorily on proficiency tests for HDL, then its overall cholesterol testing must be satisfactory. I do not accept this argument. The fact that Petitioner may have passed a proficiency test does not derogate from the evidence gathered by the New Jersey Department of Health which shows Petitioner's overall failure to use acceptable testing techniques in its LDL testing.

iii. Indirect immunofluorescent antibody testing

Indirect immunofluorescent antibody (IFA) testing (also called immunofluorescent antibody testing) is a technique that is designed to detect the presence in a patient's blood of viral or other types of infections such as herpes, measles, or syphilis. Tr. 2/2 at 235 - 237. IFA tests are important diagnostic tools. Erroneous IFA test results pose a potential for significant harm to patients. Tr. 2/3 at 72 -73.

IFA testing seeks to find the presence of an infection by determining whether a patient's blood contains antibodies to a known disease agent. Tr. 2/2 at 235 - 236. The test is performed by adding an antigen (a specific disease agent) to a specimen of blood and then testing the blood to see if antibodies have combined with the antigen. Id. at 237 - 238. The antibody-antigen combination, assuming it is present, is made to fluoresce. Id. at 238. Test results are established by observing under a microscope the patterns and intensity of the fluorescence. Id.

The results of IFA tests may be affected by a number of variable factors. For that reason, the tests must be done with great precision and controlled carefully. For example, the volume of blood that is being tested must be measured carefully, because the amount of antibodies present, and, hence, the quantity of the disease agents, is affected by the volume of blood that is tested. Test results are affected by the temperatures at which testing materials are stored. Tr. 2/2 at 246 - 247. Test results are also affected by the amount of time that a reaction is given to take place. Tr. 2/3 at 68.

The persuasive evidence in this case is that Petitioner's IFA testing was highly unreliable because Petitioner failed to properly control its IFA test methodology. Tr. 2/3 at 71. The credible testimony of Ms. Mikita is that:

> All the indicators - all the principal steps in the procedures were not adhered to . . . [T]he incubation, the wash procedures, the initial specimen screening dilution was not correct for most of the procedures. The interpretation of these results . . . the interpretation of the slides could not be made correctly . . . [T]here were errors on the test reports.

Id. at 71 - 72. Ms. Mikita also observed that Petitioner's plan of correction for its IFA testing contained errors, which, if implemented, would continue to make Petitioner's IFA testing unreliable. Id. at 72.

Among the errors that were present in Petitioner's IFA testing procedures were the following:

- Petitioner failed to screen IFA test results for fluorescence in a darkened room. Tr. 2/2 at 239 - 240.

- Petitioner's testing records failed to grade test results for fluorescence even though the degree of fluorescence in a specimen is an important factor in reading the results of an IFA test. Tr. 2/2 at 243 - 244. Rather, Petitioner merely noted results as being positive or negative.

- Petitioner failed to store IFA testing materials in a manner that was consistent with the instructions issued by the manufacturers of these materials. Tr. 2/2 at 244 - 245. For example, Petitioner stored working IFA test kits at minus fifteen degrees despite the manufacturer's instructions that the kits be stored at two to eight degrees. Id. at 245 - 248.

- Petitioner failed to incubate slides properly. Tr. 2/2 at 250 - 252; HCFA Ex. 3 at 33; HCFA Ex. 33 at 2, 5 - 8.

- Petitioner failed to wash test slides properly. Tr. 2/2 at 254 - 255.

- Petitioner failed to maintain accurate records of its testing procedures. Tr. 2/2 at 255 - 256, 263 - 264.

• Petitioner failed to perform or to interpret properly various of its IFA tests. For example, Petitioner incorrectly diluted the specimens that it tested for thyroglobulin/microsomal antibodies. Tr. 2/2 at 258 - 260. As another example, Petitioner failed to correctly dilute specimens for the DNA IFA test. Tr. 2/3 at 47 - 48. In another instance, Petitioner failed to correctly dilute specimens for the herpes simplex types 1 and 2 IFA tests. Id. at 51 - 52. In yet another instance, Petitioner failed to properly perform the Measles IFA test. Id. at 53 - 54. And, in its plan of correction, Petitioner offered a "correction" that in fact was an additional error in the way that this test would be conducted. Id. at 55- 56.

Petitioner asserts that, to the extent that it was deficient in performing IFA testing, it corrected these deficiencies. Petitioner avers that it has established a dark room for reviewing IFA slides for fluorescence. It asserts, additionally, that it had its staff retrained in IFA testing by representatives of the companies that manufacture and distribute IFA test materials. Petitioner's Reply Brief at 13.

The fact that Petitioner has taken corrective action concerning the way it conducts its IFA testing does not vitiate my conclusion that Petitioner committed errors in its IFA testing procedures. Indeed, to some extent, Petitioner's corrective actions support my conclusion. For the most part, the evidence that HCFA offered concerning Petitioner's IFA testing procedures stands unrebutted by Petitioner.

2. Petitioner failed to comply with condition level requirements of participation in CLIA.

HCFA told Petitioner in its determination notice to Petitioner that it had found Petitioner not to be complying with nine enumerated condition level requirements of participation in CLIA. In its posthearing brief, HCFA asserts that Petitioner was in fact not complying with 10 condition level requirements. It notes that the statement of deficiencies, which had been sent to Petitioner by the New Jersey Department of Health, listed 10, and not nine, condition level deficiencies.

I have opted to consider the evidence only as it pertains to the nine conditions that were cited in HCFA's notice letter. The question of whether Petitioner was in fact deficient in complying with a tenth condition raises due process and notice considerations that are not necessary for me to decide here. The preponderance of the evidence strongly supports my conclusion that Petitioner was not complying with the nine conditions that were cited in the notice letter. That evidence justifies the imposition of the remedies that HCFA determined to impose. Indeed, the presence of just *one* condition level deficiency in Petitioner's operations justifies the imposition of the remedies that HCFA determined to impose. 42 C.F.R. § 493.1806.

I have reviewed HCFA's allegations of noncompliance in light of my Finding that Petitioner was not providing laboratory services in a manner which complied with accepted standards of quality. Finding 1. I have also reviewed HCFA's allegations in light of additional evidence that addresses some of the specific conditions that are at issue.

Petitioner makes a general argument in opposition to HCFA's assertions of noncompliance with condition level CLIA requirements that it has been certified as a clinical laboratory by the College of American Pathologists (CAP). Petitioner asserts that the evidence adduced by HCFA should be weighed against CAP's determination that

Petitioner has satisfied its requirements. Petitioner reasons that it cannot be found to be seriously deficient inasmuch as CAP did not find serious deficiencies in Petitioner's operations.

I am not persuaded that CAP's certification of Petitioner overcomes the very specific and strong evidence of noncompliance with conditions of participation that HCFA presented. I find nothing in CAP's certification that rebuts directly this evidence. Moreover, the CLIA certification process is not subordinate to, nor does it defer to, whatever accreditation or certifications may be made by private organizations.

Petitioner acknowledges that it may have failed to comply with some standards of participation. It asserts that in no instance did these admitted standard level deficiencies rise to the level of a condition level deficiency. I have considered whether Petitioner failed to comply with conditions of participation or merely failed to comply with standards of participation. I conclude that, in those instances where standard level deficiencies were identified by the New Jersey Department of Health surveyors, such deficiencies were so egregious and pervasive as to create overall condition level deficiencies in Petitioner's operations.

a. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1201.

The condition level requirement that is stated at 42 C.F.R. § 493.1201 provides, among other things, that a clinical laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method utilized by the laboratory to assure the accuracy and reliability of patient test results and reports. I find that Petitioner failed to comply with this requirement in the following respects.

• Petitioner failed to follow meaningful quality control protocols for nephelometer testing. That is evidenced by Petitioner's failure to detect replicating results and to assure that such results did not recur.

• Petitioner failed to follow meaningful quality control protocols for other types of tests. That is made manifest by the way in which Petitioner conducted alpha fetoprotein tests and other types of tests, as I have discussed above, at Finding 1.

b. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1441.

The condition level requirement that is stated at 42 C.F.R. § 493.1441 provides, among other things, that a laboratory must have a director who provides overall management in accordance with the requirements that are stated at 42 C.F.R. § 493.1445. That regulation provides that a laboratory director is responsible for the overall operation and administration of the laboratory. These responsibilities include the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately, and proficiently, and assure that applicable regulations are complied with.

It is evident from the regulation that the laboratory director assumes responsibilities for assuring that a laboratory meets CLIA requirements. A systemic failure by a laboratory to meet these requirements is evidence from which I may infer that the laboratory director is failing to discharge his or her responsibilities.

Petitioner's laboratory directors failed to discharge their obligations under 42 C.F.R. §§ 493.1441 and 493.1445. There plainly were systemic failures by Petitioner, as I discuss above, at Finding 1, to meet accepted standards of quality.

c. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1447.

The condition level requirement that is stated at 42 C.F.R. § 493.1447 states that a laboratory must have a technical supervisor who meets prescribed qualification requirements and who provides technical supervision in accordance with the requirements of 42 C.F.R. § 493.1451. This regulation, 42 C.F.R. § 493.1451, states that a technical supervisor is responsible for resolving technical problems and insuring that remedial actions are taken whenever test systems deviate from a laboratory's established performance specification. Additionally, the regulation requires that a technical supervisor assure that test results are not reported until all corrective actions have been taken and that test systems are functioning correctly.

Petitioner failed manifestly to comply with this requirement. That is made evident by Petitioner's failures, discussed at Finding 1, to: identify and address problems with nephelometer and other tests; to take remedial actions to deal with these problems; and to assure that inaccurate test results were not reported.

d. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1459.

The condition level requirement that is stated at 42 C.F.R. § 493.1459 states that a laboratory must have one or more general supervisors who meet specified qualification requirements and who provide general supervision in accordance with the requirements of 42 C.F.R. § 493.1463. This regulation, 42 C.F.R. § 493.1463, provides that a laboratory must have one or more general supervisors who provide day-to-day supervision of testing personnel and the reporting of test results. Moreover, 42 C.F.R. § 493.1461 provides that a general supervisor works under the direction of the laboratory director and the supervision of the technical supervisor.

Petitioner's wholesale failure to comply with generally accepted standards of quality is evidence from which I infer that Petitioner was failing to provide acceptable general supervision of laboratory activities. That conclusion is reinforced by the New Jersey Department of Health surveyors' findings that Petitioner's supervisors were not able to answer their questions about laboratory operations. Tr. 2/2 at 46 - 48. The answers that the supervisors gave the surveyors in response to their questions is strong evidence that the supervisors were not aware of what was going on under their ostensible authority. For the most part, the supervisors responded to the surveyors' questions by averring that the actual testing was performed at times when the supervisors were not on duty.

e. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1701.

The condition level requirement for participation that is stated at 42 C.F.R. § 493.1701 directs a laboratory that performs moderate or high complexity testing to establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the

laboratory's testing program. The requirement provides that a laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results; and assure the adequacy and competency of the laboratory's staff. The requirement directs a laboratory to, as may be necessary, revise policies and procedures based upon the results of its evaluations.

There was a wholesale failure by Petitioner to monitor, evaluate the quality of, and address deficiencies in its testing program. That is made evident by the numerous quality failures, discussed above at Finding 1, that the New Jersey Department of Health surveyors identified in Petitioner's operation. One example, Petitioner's failure to monitor and evaluate the quality of its testing program, is apparent in the numerous quality deficiencies that were present in Petitioner's IFA testing program. Finding 1.b.iii.

f. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1241.

The condition level requirement that is stated at 42 C.F.R. § 493.1241 requires that, in order to meet the condition level requirements for general immunology, a laboratory must comply with the requirements that are stated at 42 C.F.R. §§ 493.1201 - 493.1221. The referred-to regulations establish requirements for performance of immunology testing.

Petitioner failed to comply with these requirements. That is apparent from my discussion at Finding 1. For example, 42 C.F.R. § 493.1215 requires that a laboratory perform equipment maintenance and function checks that include any electronic, mechanical and operational checks necessary for the proper test performance and test result reporting of equipment, instruments and test systems, to assure accurate and reliable test results and reports. I infer from the evidence relating to Petitioner's nephelometer test results that Petitioner failed to perform equipment function checks of its nephelometer equipment. Petitioner as much as admits that when it avers that the replicating test results that were produced by its nephelometer equipment were as a consequence of a software "glitch."

As another example, 42 C.F.R. § 493.1205 requires a laboratory to utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports. Petitioner failed systematically to comply with this requirement. That is plain from the many quality failures in its conduct of IFA testing and nephelometer testing.

The requirements that are stated at 42 C.F.R. §§ 493.1201 - 493.1221 are standards of participation and not conditions. However, my conclusion that Petitioner failed to comply with these standards is not a conclusion that Petitioner failed to comply with standards only. The degree of noncompliance manifested by Petitioner was so pervasive as to comprise a failure to comply with the overall condition stated in 42 C.F.R. § 493.1241.

g. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1245.

The condition of participation governing the performance of routine chemistry testing that is stated at 42 C.F.R. § 493.1245 requires a laboratory to comply with the requirements of 42 C.F.R. §§ 493.1201 - 493.1221. The routine chemistry requirements largely duplicate the immunology requirements which I discuss above, at Finding 2.f.

Petitioner manifested the same poor quality in the area of routine chemistry testing that it manifested in the area of general immunology. That is evident, for example, from the many examples of poor quality that Petitioner demonstrated in its LDL testing.

h. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.801.

The condition of participation that is stated at 42 C.F.R. § 493.801 requires a clinical laboratory to enroll in an approved proficiency testing program. The condition establishes as standards the criteria which must be adhered to by a clinical laboratory in its performance of proficiency testing. 42 C.F.R. § 493.801(a), (b).
Petitioner failed in several respects to comply with the standards established for proficiency testing. I find these failures to be so extensive and serious as to constitute a failure by Petitioner to comply with the overall condition established by 42 C.F.R. § 493.801. Petitioner's compliance failures included the following:

- Petitioner failed to assure that the person who did proficiency testing was an employee who routinely performed testing at Petitioner as is required by 42 C.F.R. § 493.801(b)(1). The analyst-employee of Petitioner who acknowledged doing proficiency testing for IFA specimens worked during daytime hours, whereas routine IFA testing was done by Petitioner at night. Tr. 2/3 at 100 - 102; HCFA Ex. 3 at 2. This lapse by Petitioner made meaningless its IFA proficiency testing. The whole point of such testing was to have the employees who did routine IFA testing demonstrate their proficiency. It is irrelevant that someone other than those employees might be able to test IFA specimens proficiently.

- Petitioner's directors signed statements attesting that proficiency testing specimens had been tested in the same manner as routine test specimens. However, that was not the case, as is demonstrated by the way in which Petitioner's employees performed proficiency testing for IFA specimens. HCFA Ex. 3 at 2.

In the plan of correction that Petitioner submitted in response to the findings that were made by the New Jersey Department of Health surveyors, Petitioner asserted that the surveyors' findings that proficiency tests were not being conducted by the laboratory employees who performed routine tests on patients' specimens comprised "the exception and not the rule." HCFA Ex. 3 at 2. According to Petitioner, employee absences accounted for the occasional performance of a proficiency test by an employee other than the employees who performed routine tests on patient specimens. Id.; Petitioner's Posthearing Brief at 10 - 11.
I am not persuaded from this explanation that Petitioner complied with the requirements of 42 C.F.R. § 493.801 by assuring that the employees who did tests also performed proficiency tests. Petitioner has not provided affirmative proof in this case to satisfy me that proficiency tests were always performed by the employees who performed routine tests on patients' specimens.

i. Petitioner failed to comply with the condition level requirement that is stated at 42 C.F.R. § 493.1101.

The condition of participation that is stated at 42 C.F.R. § 493.1101 requires a clinical laboratory that performs moderate or high complexity tests to employ and maintain a system that provides for proper patient specimen preparation, proper specimen collection, identification, preservation, transportation, and processing; and accurate

result reporting. The standards which recite the particular requirements of the condition are stated at 42 C.F.R. §§ 493.1103 - 493.1111. Petitioner failed pervasively to comply with these standards to the extent that it failed to comply with the overall condition of participation.

Petitioner's compliance failures include the following deficiencies:

> •Petitioner failed to comply with the requirement that a laboratory perform tests only at the written or electronic request of an authorized person. 42 C.F.R. § 493.1105; Tr. 2/2 at 168 - 171; HCFA Ex. 3 at 7 - 8; HCFA Ex. 117 at 1 - 5, 11 - 12. On numerous occasions, Petitioner performed a test for the presence of Lyme disease where such test had not been requested by the patient's physician. Id.
>
> •Petitioner failed to comply with the requirement that a laboratory maintain a record system that insures that patient specimens are reliably identified as they are processed and tested to assure that accurate test results are reported. 42 C.F.R. § 493.1107. For example, some of Petitioner's work records had control results recorded on them and were signed and dated by a supervisor - to signify that work had been done properly - before tests actually were performed. Tr. 2/3 at 84 - 85; HCFA Ex. 3 at 8 - 9; HCFA Ex. 100. As another example, the work record that Petitioner generated for ANA testing on July 10, 1998, showed that tests had been performed on seven patients' specimens. In fact, on that date Petitioner had performed 11 ANA tests. HCFA Ex. 3 at 9; HCFA Ex. 101 at 1- 2.

3. HCFA is authorized to impose principal remedies against Petitioner.

The presence of one or more condition level deficiencies in Petitioner's operations authorizes HCFA to impose principal remedies against Petitioner. 42 C.F.R. § 493.1806. These remedies may include suspension of Petitioner's CLIA certificate and cancellation of Petitioner's approval to receive Medicare payments. Furthermore, as I discuss above, that suspension becomes a revocation effective with my decision that Petitioner manifested condition level deficiencies.

I do not address the question of whether the condition level deficiencies manifested by Petitioner posed immediate jeopardy to patients. As I discuss above, at Part I.B. of this decision, I have no authority to consider whether a condition level deficiency poses immediate jeopardy.

ANALYSIS

CONCLUSION

JUDGE

Steven T. Kessel
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF Diagnostic and Educational Laboratory Date: 1999 June 9 - v. - Health Care Financing Administration.
Docket No. C-98-218
Decision No. **CR600 DECISION**

For the reasons stated below, I sustain the determination of the Health Care Financing Administration (HCFA) to impose the principal sanctions of revocation of the CLIA certificate of Petitioner, Diagnostic and Educational Laboratory (Petitioner), and cancellation of its approval to receive Medicare payments under Title XVIII of the Social Security Act for its services, pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The collateral sanction prohibiting Dr. Omar Amin, the director of Petitioner, from owning or operating another laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed as well.

I. Background

A. Applicable law and regulations

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), 42 U.S.C. § 263a, were enacted by Congress to ensure that the results of tests performed in clinical laboratories, including those tests performed in physicians' office laboratories, are reliable and accurate. See H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3829. The statute provides as follows:

> [n]o person may solicit or accept materials derived from the human body for laboratory(1) examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

42 U.S.C. § 263a(b).
CLIA '88 was intended by Congress to establish one set of standards which would govern all suppliers of laboratory services, including those which supply laboratory services to Medicare beneficiaries. See 1988 U.S.C.C.A.N. at 3829, 3843.
The statute directed the Secretary of the United States Department of Health and Human Services (Secretary) to issue regulations to implement various provisions set out in CLIA '88, including standards to assure consistent performance of valid and reliable laboratory examinations by laboratories issued a certificate under the Act. 42 U.S.C. § 263a(f)(1). The Secretary's regulations implementing CLIA '88 are found in 42 C.F.R. Part 493.
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.

Moreover, 42 C.F.R. § 493.816(b) provides that upon a revisit survey if the laboratory fails to correct deficiencies at the standard level within 12 months of the initial survey, HCFA follows rules requiring (1) cancellation of payment for services and (2) notification of the lab of HCFA's intent to suspend, limit or revoke the CLIA certificate and the lab's right to a hearing.

Finally, under 42 U.S.C. § 263a(i)(3) and 42 C.F.R.§ 493.1840(a)(8), no person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation own or operate (including serve as laboratory director - see 42 C.F.R. § 493.2) a laboratory.

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in Hillman Rehabilitation Center, DAB No. 1611 (1997). Under Hillman, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that: (1) Petitioner failed to comply with participation requirements and (2) the collateral sanction against its director is warranted and lawful under the regulations and the Act. Petitioner has the burden of proving, by a preponderance of the evidence, that it complied substantially with participation requirements and the collateral sanction against its director is unwarranted and unlawful under the regulations and the Act. In determining whether HCFA has met its burden of establishing a prima facie case, I may consider rebuttal evidence offered by Petitioner that HCFA's evidence is neither credible or relevant to the issue of Petitioner's compliance with the CLIA requirements or that the weight of the evidence establishes that the regulatory deficiencies alleged by HCFA did not occur. Hillman Rehabilitation Center, DAB CR500, at 3-8 (1997). If I conclude that the preponderance of the evidence establishes that such circumstances exist, then I will find that HCFA has not met its burden of establishing a prima facie case (but rather its case is based on unsubstantiated allegations) and Petitioner will not be obligated to prove that it was substantially complying with the participation requirements.(2)

B. Procedural History

Petitioner is a laboratory located in Arizona, engaged exclusively in the performance of parasitology testing. Tr. 24-25.(3)

Petitioner received its initial CLIA certification in 1994. Tr. 22, 127-128. The survey was conducted by a surveyor from the Arizona Department of Health Services, Office of Laboratory Licensure and Certification (State agency), the purpose of which was to certify that Petitioner was in compliance with the CLIA regulations. Tr. 127.

On June 21, 1996, a State agency surveyor, accompanied by a HCFA laboratory consultant, conducted a recertification survey of Petitioner. At the time of this survey, it was determined that Petitioner had three Standard-level deficiencies. They were 42 C.F.R. §§ 493.1445(e)(12)[(4)] and 493.1445(e)(13)[(5)], both of which fall under the laboratory director condition, and 42 C.F.R. § 493.1713[(6)], concerning personnel assessment under the quality assurance condition. The deficiencies were set forth in a HCFA form 2567 - Statement of Deficiencies (Statement of Deficiencies), which was

forwarded to Petitioner by the State agency. Tr. 38; HCFA Ex. 2. The surveyors found that: 1) the laboratory director failed to ensure that documentation of the educational qualifications of personnel were available in the laboratory, and that a system was in place to document that testing personnel had received, or were receiving, the appropriate training for the type and complexity of services offered; (2) the laboratory director failed to ensure that policies and procedures were established for monitoring individuals who conducted testing and that performance evaluations were conducted on an annual basis; and 3) the laboratory failed to document that the policies which were established for ensuring staff competency were performed and completed. HCFA Ex. 2. Petitioner submitted a Plan of Correction (POC) on the Statement of Deficiencies to the State agency, accompanied by additional supporting documentation.

HCFA subsequently recertified Petitioner in November 1996. P. Ex. 14.

On December 4, 1997, surveyors from the State agency conducted another survey of Petitioner in response to complaints concerning Petitioner. Tr. 62, 218. As a result of this complaint survey, the surveyors determined that Petitioner remained out of compliance with the same three Standards identified during the previous June 1996 survey. In addition, during the survey, the surveyors identified Condition-level deficiencies as well.

By letter dated December 22, 1997, which was sent to Petitioner along with the HCFA 2567 for the December 1997 survey, HCFA informed Petitioner that, based on its failure to correct the three Standard-level deficiencies within twelve months after the June 21, 1996 survey, it would impose the principal sanctions of revocation of Petitioner's CLIA certificate, effective February 20, 1998, unless a timely hearing request was received, and cancellation of its approval to receive Medicare payments for its services performed on or after January 6, 1998. Petitioner was also informed that if revocation took place, its present owner or operator would be prohibited from owning or operating another laboratory for two years from the date of revocation, in accordance with 42 C.F.R. § 493.1840(a)(8).

By letter dated January 7, 1998, HCFA informed Petitioner that the documents it had submitted dated January 5, 1998, did not show that the three Standard-level deficiencies had been corrected within twelve months of the June 21, 1996 survey. HCFA stated, inter alia, that Petitioner's CLIA certificate would be revoked effective February 20, 1998, unless it filed an appeal, and cancellation of its approval to receive Medicare and Medicaid payments for its services would go into effect January 6, 1998.

By letter dated February 18, 1998, addressed to HCFA, Petitioner requested a hearing. On June 3, 1998, I held a telephone prehearing conference in this case.

I held a hearing in this case in Phoenix, Arizona, from August 25-27, 1998.[(7)] At the hearing, I received and admitted into evidence HCFA's exhibits (HCFA Ex(s).) 1 through 27 and Petitioner's exhibits (P. Ex(s).) 1 through 14, 20 through 40, 43 through 70, 114, 125, 127-129, 131, 143-151. P. Exs. 71-102 were rejected (Tr. 795).[(8)] The parties filed posthearing briefs and response briefs. I base my decision in this case on the governing law, the evidence I received at hearing, and on the parties' arguments as expressed in their briefs. Any arguments raised by the parties but not specifically addressed in this decision have been rejected. I use the following format for the Discussion section of my decision. The numbered paragraphs set out in bold face represent my findings of fact

and conclusions of law. The descriptive text under each numbered paragraph contains my rationale for such finding.

II. Discussion

As stated above, Petitioner is a laboratory that conducts only testing to identify parasites. Its director, Dr. Omar Amin, originally founded the laboratory in Wisconsin and then relocated it to Arizona in June 1994. Tr. 512-513. At the hearing, Dr. Amin testified that initially, his laboratory had no employees, and he did all the tasks, including clerical duties. Tr. 513. Petitioner obtains its customers through word-of-mouth, and its primary customers are homeopathic physicians and alternative health practitioners. Tr. 514. Dr. Amin testified that Petitioner receives its specimens by mail. Tr. 514-515. Ninety-six to ninety-seven percent of the specimens received by Petitioner come from out-of-state and some come from overseas. Tr. 514.

Petitioner's initial posthearing brief described the process and methodology used by Petitioner as of June 1996 to identify parasites, as testified to by Dr. Amin. HCFA did not take issue with the description, and I will briefly set it out here, as presented in Petitioner's brief and Dr. Amin's own testimony.

According to Dr. Amin, patient specimens arrive at Petitioner in an envelope. The envelope contains two vials "which had fecal samples which had been preserved in formalin; the samples had been collected by the patient on two separate days." Tr. 516. The vials are accompanied by a patient requisition form. The form includes patient data, the identity of the physician doing the referral, "the times and dates of collection of the sample, the conditions under which the samples are collected " and "other patient information, such as symptoms, history of foreign travel, history of previous infections, ..." Tr. 516-517.

A laboratory assistant opens the envelope and enters the information received into the computer, which generates a preliminary worksheet. The assistant summarizes the patient data on the computer form. Tr. 517. The computer assigns a unique number to each patient and that number is used throughout the whole process. The number is placed on the patient's vials and computer form. Tr. 518. A laboratory assistant combines the two vials of specimens into one test tube. Tr. 519.

Based on Dr. Amin's testimony,

> The samples are then filtered, homogenized and centrifuged after adding an ethyl acetate component, which is used to separate the fibers and contaminants that would obstruct the viewing of possible parasites. After the test tube has undergone centrifuging, fecal material, called a fecal plug, is concentrated at the bottom of the test tube. The remaining portion of the test tube appears as a clear liquid if the centrifuging has been properly performed.

P.'s Proposed Findings of Fact and Conclusions of Law (P.'s Brief), at 5. (Transcript cites omitted).

Dr. Amin testified that a laboratory assistant then takes the test tube from the processing area to the screening area of the laboratory, where testing personnel will make the slides for examination under the microscope. Tr. 520. Laboratory assistants are not involved in the preparation of slides. Id. To prepare a slide, the tester tilts the test tube and spreads out the contents on the slide with a wooden probe. A coverslip is placed on the specimen in such a way that it squeezes away fibers and other materials from the prospective field of vision. Tr. 521. Iodine is used to stain the slide. Id. This

method of using iodine to stain a slide is known as a wet preparation, or a wet mount. Tr. 522.[(9)] Dr. Amin testified that, as of March 1997, the laboratory began using another wet mount preparation -- the consed stain protocol. Tr. 638, 640-641.

The tester then views the slide under a microscope, looking for "possible parasites and . . . other observations which are relevant to the practitioner . . . " Tr. 521. Dr. Amin testified that the slide is usually first viewed under 100 power (100X) magnification, and the tester would "make a few runs back and forth" to see if there was anything that resembled a parasite or something unusual. Id. Then, the tester would "shift to the other higher objective lens to bring the total magnification to 400X." Tr. 522. Dr. Amin stated that 400 power is "usually the magnification by which [a tester] make[s] identification." Id. With the 400 power magnification, one is able to easily identify all the cellular components, including nuclei and other structures. Id. If a tester wished to view the specimen in greater detail, he or she could shift the lens to obtain a total magnification of 1000X. Id. Dr. Amin stated that an experienced tester would take an average of fifteen minutes to screen a slide. Tr. 523. The tester writes down the patient's identifying number and records observations next to it on a pad of paper next to the microscope. Id. The laboratory assistants transfer this information regarding identification to the computer forms which were generated when the specimens first arrived at the laboratory. Tr. 524. Parasites and other particles that were identified are logged into the computer, and the level of intensity of infection is rated on a scale of one to four. Id. The laboratory assistants fax, as well as mail out, an identical, clean computer report containing all of the information to the physician. Tr. 525.

At the time of the June 21, 1996 survey, Dr. Amin had three employees at his laboratory -- Scott Cagle, Karim Amin (Dr. Amin's son), and Cindy Cordery. Tr. 517, 529. Scott and Karim were the laboratory assistants or laboratory technicians and were involved in the preanalytical processing of the specimens. Tr. 517-518, 520, 530. Dr. Amin testified that Karim began working at the laboratory in January 1995, and Scott started working there in January 1996. Tr. 530. According to Dr. Amin's testimony, as of June 1996, Scott and Karim did administrative tasks such as receiving samples, entering data into the computer, doing the necessary paperwork, handling telephone calls, as well as processing the samples for screening. Id. Scott and Karim also entered the handwritten test results into the computer and transmitted the results to physicians. Neither of them was involved in the identification of specimens. Tr. 530-531.

Dr. Amin testified that he hired Ms. Cindy Cordery in March 1995. Tr. 534. While Ms. Cordery initially did administrative tasks and other duties in the area of preanalytical processing (Tr. 535), Dr. Amin ultimately wanted her to become involved in parasite identification. Tr. 534-535. Ms. Cordery did later test and report out results at the laboratory. Tr. 348, 350, 670, 674.

At the time of the December 4, 1997 survey, Karim Amin and Scott Cagle were still working at the laboratory in the area of specimen processing. Tr. 63. The testing personnel, besides Dr. Amin, consisted of Mr. Ronald Mann and Dr. Edwin Noboa. Tr. 63, 222-223. Dr. Amin testified that he hired Mr. Mann in October 1996, and he hired Dr. Noboa in July 1997. Tr. 571, 573. Ms. Cordery was no longer employed at Petitioner at the time of the December 1997 survey. Tr. 63-64, 348.[(10)]

ISSUES

1. A laboratory must possess written documentation to demonstrate its compliance with the regulatory requirements set forth in 42 C.F.R. § 493.1445 of the CLIA regulations.

Under 42 C.F.R. § 493.1445 of the CLIA regulations, the laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. Section 493.1445(e)(12) imposes the responsibility on the laboratory director to ensure that prior to testing of patients' specimens all personnel have 1) had the appropriate education and experience, 2) received the appropriate training for the type and complexity of the services offered, and 3) demonstrated that they can perform all testing operations reliably to provide and report accurate results. Similarly, 42 C.F.R. § 493.1445(e)(13) imposes the responsibility on the laboratory director to ensure once the personnel are trained to carry out the test procedures that they are monitored and their competency tested so that they continue over their tenure with the laboratory to report out accurate results. A fair and reasonable reading of these two CLIA standards imposes an obligation on the laboratory to have written documentation of its compliance with these regulations.[(11)]

There must be some objective way for HCFA and the public who benefit from enforcement of the CLIA regulations to ensure that the laboratory complies with the regulatory requirements. Written documentation is mandatory. Oral representations or development of documentation after the fact by the laboratory of its compliance with these regulations would lead to confusing and unnecessarily prolonged efforts to determine compliance. Such documentation must be in existence at the time laboratory personnel begin to perform their testing functions and must be maintained for a reasonable period. It is not unreasonable to place the burden of establishing compliance on the laboratories. They should possess contemporaneous substantiation to support their purported compliance with the regulations.

The CLIA regulations contemplate compliance to be determined by surveys of the laboratory operations. The regulations place the burden on the laboratory to possess at the time of the survey documentary evidence demonstrating its compliance. Such evidence should include objective documentation of the education and experience of the laboratory employees, a written description of the training procedure utilized, including a detailed description of the methodology and goals to be attained in the training and a written description of the process, including performance measurements used by the laboratory to ensure that personnel receiving the training can satisfactorily report out accurate results. Objective evidence measuring and demonstrating competency of its testing personnel likewise should be maintained by the laboratory. For competency to be maintained, the laboratory would have to establish a benchmark which would be indicative of a level of competency which would produce the reliable

and accurate test results mandated by the regulations. All persons conducting tests should be periodically examined through a process established by the laboratory to ensure that they continue to achieve the level of competency established by the laboratory for the particular testing procedures done by such personnel.

The State and HCFA surveyors who conducted the surveys in issue all testified that written documentation of compliance with the above regulatory standard is necessary. Tr. 44, 48-50, 208. This was corroborated by HCFA's consultant, Dr. Michael Saubolle. Tr. 748. Even Ms. Grace Mossman, Petitioner's own CLIA laboratory consultant, admitted that compliance with this standard would require the development and maintenance of written documentation. See Tr. 443.[(12)] Moreover, the surveyors at the initial survey in June 26, 1996 advised Dr. Amin that his laboratory would need to maintain documentation to establish compliance with these standards. Tr. 47. Consequently, as I reviewed Petitioner's alleged compliance with these regulations, I looked for contemporaneous documentation which was available to the surveyors at the time of the survey which demonstrated Petitioner's compliance with these regulatory provisions of CLIA.

June 26, 1996 recertification survey:

2. Petitioner did not ensure that, prior to testing patients' specimens, all personnel(other than Dr. Amin) had appropriate education and experience as required by 42 C.F.R.§ 493.1445(e)(12) of the CLIA regulations.

At the hearing, Ms. Rios-Jakeway, a State agency surveyor testified that in determining whether the testing and processing personnel have the appropriate education and experience, the surveyors look at, among other things, "transcripts from schools attended or copies of diplomas." Tr. 39. At the time of this survey, Dr. Amin was the only person who was identified as the person who was reading and reporting out test results. Tr. 39, 43. Since Dr. Amin's credentials had been established in the prior certification survey, the surveyor concluded there was no need to re-establish those credentials for purposes of the June 1996 survey. Tr. 40. Despite this, Dr. Amin provided documents of his own credentials. Id. However, he had no documentation of the credentials of his son, Karim, and Scott, who did the preanalytical processing of the specimens -- preparation of the specimens prior to reading and reporting of the test results. Tr. 41. Nor did Dr. Amin have any documentation of the credentials of Ms. Cindy Cordery who was identified as a person who was to begin reading and reporting out test results. Tr. 38-42. Ms. Rios-Jakeway did interview Ms. Cordery as to her education and experience. Ms. Rios-Jakeway testified that Ms. Cordery informed her that she had a non-clinical biology degree having to do with soil and plants, had taught biology at the college level, and had no prior experience working in a clinical laboratory. Tr. 42. Ms. Cordery had taken a medical parasitology course at Arizona State University (ASU). Tr. 43. No evidence of completion of the course or grade was supplied by Dr. Amin. Id. Ms. Rios-Jakeway explained to Dr. Amin that Petitioner must maintain written evidence of the training and experience of its testing personnel to be compliant with the CLIA regulations. Tr. 50.

3. Petitioner did not ensure that, prior to testing patients' specimens, all personnel(other than Dr. Amin) had received the appropriate training for the type and complexity of the services offered, and had demonstrated that they could perform all testing operations reliably to provide and report accurate results, as required by 42 C.F.R. § 493.1445(e)(12) of the CLIA regulations.

Ms Rios-Jakeway looked for evidence that testing personnel (those persons who did the preanalytic phase of the process and those persons who actually did the testing in the analytical phase of the process) had received appropriate orientation and training prior to engaging in preparation or testing of specimens. Tr. 41. Ms. Rios-Jakeway explained, "[a]ny subsequent training that is done, we look for evidence of that. What it addressed, the extent of the training and how the individual performed in the training." Tr. 39. She wanted evidence that individuals who were processing specimens understood the process for preparing the specimen and that testing individuals understood how to read and report the test results prior to their actually engaging in such testing and reporting. Ms. Rios-Jakeway testified that, during the time of the survey, she did not find any documents concerning training for any of the laboratory employees. Tr. 40. She also found no evidence of a written orientation program for either the specimen processing personnel or testing personnel. Tr. 41.

Moreover, Ms. Esther-Marie Carmichael, a HCFA laboratory consultant who accompanied Ms. Rios-Jakeway on the survey, testified that although Ms. Cordery had stated she was in training, "there was nothing in the records that indicated what that training would be, and at what point her competency would be established." Tr. 211. The record itself contains Dr. Amin's own admission that he had no records of any of his activities with respect to the training of Scott, Karim, or Ms. Cordery at the time of the June 1996 survey. Tr. 667. Specifically, with respect to Ms. Cordery, Dr. Amin conceded that, at the time of the June 1996 survey, he did not have any documentation in the laboratory regarding the training protocols and the length of time he trained Ms. Cordery. Tr. 661-662. In response to questioning, he testified,

> the general recollected impression I have from the survey of '96 was that documentation was needed and this was an area in which I did not provide documentation.

Tr. 662.

The fact that there was no such documentation is even more troubling in light of the fact that Dr. Amin testified that, as of the June 21, 1996 survey, Ms. Cordery was, at times, identifying parasites independently and was reporting some test results on her own. Tr. 670, 674. Such information was apparently withheld from Ms. Rios-Jakeway, who believed that Ms. Cordery was allegedly not doing any testing at the time of the survey but was to begin testing in the future. Tr. 42.

4. Petitioner did not ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills, as required by 42 C.F.R. § 493.1445(e)(13) of the CLIA regulations.

Ms. Rios-Jakeway indicated that this standard means that a laboratory director is required to have procedures in place to monitor the competency of testing personnel. Tr. 43, 82. She testified that Dr. Amin had no such procedures in place. Id. Ms. Rios-Jakeway pointed out that, at the time of June 1996 survey, it was the surveyors' understanding that only Dr. Amin was viewing parasitic specimens and reporting results. Since he was the laboratory director as well, Ms. Rios-Jakeway indicated that under the regulations he could not be expected to monitor himself. Tr. 43. However, because the

surveyors were under the impression that Ms. Cordery was to begin testing and reporting in the future, they explained to Dr. Amin that he needed to develop a mechanism for determining tester competency. Tr. 44. Such mechanism had to demonstrate whether the testing personnel could properly identify parasites using whatever procedures were established by the laboratory. Id.[(13)] To do this, Dr. Amin would need to establish a competency measure or level which the testers had to attain during their period of testing specimens and reporting out results at Petitioner. This could be done with the use of Petitioner's split samples or samples from an independent proficiency testing source. Dr. Amin could observe their testing and reporting or administer written examinations to determine their accuracy and to ensure they attained the minimum level of proficiency he established for laboratory testing personnel. Tr. 44-45.

Ms. Rios-Jakeway testified that before Ms. Cordery could perform any testing, Dr. Amin had to have such a system in place. Tr. 45.[(14)] Additionally, Ms. Carmichael stated that she would expect to see documentation that Ms. Cordery had been subjected to competency testing demonstrating that she was capable of reading potential parasitic specimens by the method which was established by the laboratory. Tr. 208. Ms. Carmichael (confirmed by Ms. Rios-Jakeway) explained that the laboratory could develop the methodology for the competency testing but it had to demonstrate by written record that it was carried out. Id.; see Tr. 78-79. She found no evidence that Dr. Amin had established any threshold guidelines concerning competency. Tr. 208.

The surveyors have interpreted the above regulation to mean that, because Dr. Amin was apparently the only individual in the laboratory reading and reporting out test results at the time of the June 1996 survey, he did not have to monitor himself since he was the director of the laboratory. I disagree with their interpretation where the laboratory director is the only person conducting the testing and reporting of results. It is not a question of Dr. Amin conducting self-monitoring; rather, the objective of this regulation is to ensure that he maintained the required competency for reliable testing and reporting. Proficiency testing samples could be obtained from an outside source and Dr. Amin could analyze the specimen samples and report the results. Some entity other than himself would review his work and determine his competency. But even under this scenario, Dr. Amin should be required to establish a minimum level of proficiency which he had to attain to demonstrate his proficiency and, if not achieved, to be required to undertake appropriate remedial training or continuing education. From my understanding of what Dr. Amin provided to the surveyors, he had no evidence of a process in place to measure his own proficiency in reviewing and reporting specimen results (analytical) or that of Karim Amin or Scott Cagle, who were involved in specimen processing (preanalytical), so this regulation was not met at the time of this survey. The surveyors did explain to Dr. Amin the type of documentation which would be needed to meet the requirements of this standard. Tr. 44.

5. Petitioner did not have an ongoing mechanism in place to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence, as required by 42 C.F.R. § 493.1713 of the CLIA regulations.

This standard requires that the laboratory have in existence a quality assurance policy which, when implemented, would ensure the competency of testing personnel in

performing and reporting test results. Ms. Rios-Jakeway testified that the mechanism must be put in writing. Tr. 48-49. During the June 1996 survey, it was determined that Petitioner had a quality assurance policy in place which indicated that "spot checks, observations and evaluation of [staff] performance are routinely practiced." HCFA Ex. 2, at 4. No evidence was found during the survey to support that such policy was ever implemented. Tr. 49. The record does not reflect any documents which would demonstrate that the laboratory adhered to such policy and that the testing personnel met the criteria used to support their meeting the required competency in processing, performing testing procedures, and reporting test results.

The evidence cited above relating to the lack of procedures or mechanisms to evaluate and monitor testing personnel competency demonstrates that Petitioner was not in compliance with this regulatory standard at the time of the survey.

Furthermore, Dr. Amin admitted that he had no records of any activities with respect to quality assurance at the time of the June 1996 survey. Tr. 667.

December 4, 1997 complaint survey:

6. Petitioner did not ensure that, prior to testing patients' specimens, all personnel (other than Dr. Amin) had the appropriate education and experience, and received the appropriate training for the type and complexity of the services offered, as required by 42 C.F.R. § 493.1445(e)(12) of the CLIA regulations.

At the time of the December 4, 1997 survey, the laboratory assistants were the same two individuals, Karim Amin and Scott Cagle, who had been employed at Petitioner during the time of the June 1996 survey, and, as before, they were processing and preparing the specimens (preanalytical stage) for viewing and reporting by the testing personnel. Tr. 63. Dr. Amin continued to be one of the testing personnel. In addition to him, Mr. Ronald Mann and Dr. Edwin Noboa were analyzing patient specimens and reporting out test results on a part-time basis. Id.[(15)] Dr. Amin had hired Mr. Mann in October 1996, and Dr. Noboa in July 1997. Tr. 571, 573. Ms. Cordery was no longer working at the laboratory by the time of this second survey, but there was evidence that she had reviewed specimens and reported results prior to her departure from the laboratory.[(16)] Tr. 63-64, Tr. 121-122.

Ms. Rios-Jakeway testified that, although Ms. Cordery no longer worked at Petitioner at the time of the December 1997 survey, her personnel credentials were required to be kept on file for two years following her departure, pursuant to CLIA regulations. Tr. 65, 67. Ms. Rios-Jakeway testified further that, with respect to Ms. Cordery, she was looking for "evidence that she had indeed taken that medical parasitology course and that her orientation in the testing phase had been conducted and her competency had been evaluated and that Dr. Amin had authorized her to do patient testing and under what circumstances." Tr. 64-65. Ms. Rios-Jakeway stated that she was looking for the same information regarding the two other testers, Mr. Mann and Dr. Noboa. Tr. 65.

Ms. Rios-Jakeway testified that she was unable to further evaluate Ms. Cordery's credentials because her educational credentials were no longer in the laboratory. Tr. 67. She stated that she "didn't see any information on her at all." Id. With respect to Mr. Mann and Dr. Noboa, Ms. Rios-Jakeway testified that their education credentials were on file. Id. She stated, however, that their files "didn't have any documents regarding orientation or in-house training or determination of competency." Id.

According to Ms. Rios-Jakeway, the laboratory had established an acceptable written orientation program for the processing personnel. Tr. 67-68. However, she could not find any evidence that an orientation and training program had been established for the testing personnel. Tr. 68. When asked if she had seen any evidence that Ms. Cordery had been found competent to analyze specimens, Ms. Rios-Jakeway responded, "No, I didn't see any information regarding Ms. Cordery at all other than there was evidence that she had reported out patient samples." Tr. 69-70. Moreover, in reviewing documents, Ms. Rios-Jakeway could not find anything to indicate that the testing personnel had undergone any training. Tr. 69. She found no evidence of any orientation for the analytical testing phase. Id.[(17)] The only documentation consisted of the educational credentials (see above).

It is clear from Dr. Amin's own testimony that he was not in compliance with the requirements of this standard. He conceded that, as of the December 1997 survey, he had no documentation of the training that he provided Scott and Karim. Tr. 668. Furthermore, Dr. Amin admitted that he had no documentation of any training he provided Mr. Mann or Dr. Noboa. Dr. Amin stated that he "had no reason to consider training " Mr. Mann because of Mr. Mann's prior training and experience, and his belief that Mr. Mann was "more competent than [Dr. Amin]." Tr. 702. In fact, Dr. Amin stated that Ms. Cordery trained Mr. Mann initially on his first day at work in October 1996. Tr. 703; see Tr. 350-351. This training consisted of examining ten slides under the microscope, all of which were negative for the presence of parasites. Tr. 704. Dr. Amin acknowledged, and Mr. Mann confirmed, that this session with Ms. Cordery was the only "training" that Mr. Mann received before he began reporting out test results on his own. Tr. 491, 704. Mr. Mann testified that he began reporting results on his second day at work. Tr. 491. According to Dr. Amin, subsequently, there were times when he and Mr. Mann looked at slides together under the dual microscope, but he had no documentation of these activities. Tr. 704.

With respect to Dr. Noboa, Dr. Amin stated that he trained him in the same manner as he had done with Ms. Cordery, looking at slides together under the dual-head microscope. Tr. 575. Dr. Amin stated that they first looked at the mounted specimens from his permanent collection and then at other samples from other sets from which they made wet mounts. Tr. 575-576. Dr. Noboa's training lasted "perhaps one month full time, eight hours a day going through three sets of samples, the permanent mounts." Tr. 576. In September 1997, Dr. Amin allowed Dr. Noboa to begin testing on his own. Id. Whatever training Dr. Amin may have given Dr. Noboa, the record is devoid of any contemporaneous documentation of such training. Dr. Amin admitted he had no documentation dated prior to December 1997 indicating that Dr. Noboa was trained. Tr. 705-706. He stated that the only document he had relating to Dr. Noboa's training was written after December 1997, and is a document created by Ms. Mossman, the laboratory consultant he had hired in January 1998. Id.

In examining Ms. Cordery's employment at Petitioner, it appears from the testimony of both Dr. Amin and Ms. Cordery that Dr. Amin did provide Ms. Cordery with some training so that she could become one of the testing personnel at the laboratory.[(18)] According to Dr. Amin, he began formally training Ms. Cordery in February 1996.[(19)] Tr. 654, 669; see Tr. 340. Prior to this, Ms. Cordery had taken a parasitology course at ASU in the fall of 1995. Tr. 339-340. Ms. Cordery described this course as a lecture

class, with no laboratory component.[(22)] She stated that she had no training in parasitology prior to taking this course. Tr. 339.

In trying to determine whether Ms. Cordery possessed adequate ability to read slides, Dr. Amin stated that he "needed to know if she has a good eye for parasites . . . can pick up the diagnostic features." Tr. 657. Dr. Amin testified that he did not refer to any specific written guideline or goal, but made the determination based on his own subjective judgment. Tr. 658-659. Dr. Amin testified, "There's no guideline or goal that is written as such." Tr. 658. When asked whether he had any documentation concerning the aforementioned training he gave Ms. Cordery, Dr. Amin stated that, if there arose a need for such documentation, he would have written "his perceptions and impressions" from memory. Tr. 660-661.

According to Ms. Cordery's testimony, from March 1996 to around May 1996, she began looking at reference slides under the microscope, as well as making wet mount slides using prior client specimens that had tested positive for parasites.[(23)] Tr. 341-342, 388-389, 391-392. She stated that she looked at these slides on her own when she had free time from her other work responsibilities. Dr. Amin did not look at these slides with her. Tr. 341; See Tr. 388.

Dr. Amin testified that, following their session at ASU, he provided additional training to Ms. Cordery beginning February 1996. Tr. 545. He estimated that, together, they spent about twenty-five hours jointly looking at about 100 slides from his permanent collection under the single-head microscopes and a dual-head microscope. Tr. 546, 548.

According to Dr. Amin, he and Ms. Cordery next examined slides of actual patient specimens that had been processed. Tr. 549. Dr. Amin stated that they reviewed patient samples starting in February 1996 and continued through July 1996. Tr. 550. He estimated that he and Ms. Cordery spent jointly "at least 50 hours a month" reviewing patient samples. Id.

According to Ms. Cordery, her sessions at the dual-head microscope began on or about April 18, 1996, and ended on or around May 8, 1996. Tr. 392, 411. The specimens that she and Dr. Amin examined under the microscope were not pre-labeled reference slides, but actual patient specimens most of the time. Tr. 424. According to Ms. Cordery, they did not have a regularly scheduled time for having these sessions at the dual-head microscope.[(24)] Tr. 395-396.

Ms. Cordery testified that from May 8, 1996, she was examining slide specimens on a more independent basis and, after that date, she and Dr. Amin did not have further training sessions. Tr. 422. The record indicates that on May 10, 1996, Dr. Amin made Ms. Cordery the laboratory manager. Tr. 677-678. HCFA Ex. 27.

When questioned about their sessions at the dual-head microscope, Dr. Amin testified that Ms. Cordery sat at the "passive" side of the dual-head microscope for six weeks to two months, and she viewed about forty specimens a week with him during this time. Tr. 557-558. He stated that, during June and July 1996, Ms. Cordery sat at the "active" side, and they also looked at about forty specimens a week during this time. Tr. 558-559. Further, Dr. Amin stated that looking at slides of patient specimens became Ms. Cordery's primary responsibility from June 1996 through the end of her employment in July 1997. Tr. 561-562.

Based on the collective testimonies of Dr. Amin and Ms. Cordery, it appears that Ms. Cordery was trained by Dr. Amin in some fashion. However, there is no evidence of

record to support any of these claims other than their verbal statements. Dr. Amin himself testified that as of the December 1997 survey, he had no documentation of the training that he provided Ms. Cordery. Tr. 668. Dr. Amin did not record the length of time he and Ms. Cordery spent together viewing slides under the dual-head microscope, nor did he record on what days he sat down with her at the microscope. Tr. 421. Thus, the fact remains that his self-serving account of his training of Ms. Cordery is wholly unsupported. It is evident from the record and from his own admissions that Dr. Amin had no training protocols by which to train Ms. Cordery to become one of the testing personnel. Dr. Amin's failure to document any of his alleged training sessions with Ms. Cordery further demonstrates his noncompliance with 42 C.F.R. § 493.1445(e)(12). Furthermore, I find the testimony elicited from HCFA's expert witness, Dr. Saubolle, to be instructive in providing guidance as to what appropriate training and monitoring in the area of parasitology testing would encompass.[(25)] Dr. Saubolle stressed the importance of receiving proper training since parasitology is "all visual." Tr. 164. He stated:

> . . . someone who reads them all the time and frequently is better off than someone who does them infrequently or has poor training and poor supervision.

Tr. 165.[(26)]
Dr. Saubolle commented also that, based on his experience, someone who had no prior laboratory training would require "a lot more training." Tr. 178. HCFA counsel inquired further into this area:

> Q: In your opinion would it be more difficult to train a person with no laboratory background to identify parasites using only wet mounts?
>
> A: Well, I guess the two compound each other. So, yes. . . . One, someone who doesn't have experience in a laboratory, especially parasitology, and then someone who is only going to be looking at a system that's fairly difficult to read in the first place requires more training, yes.

Tr. 178-179.
Dr. Saubolle testified that, with respect to training, especially where the wet mount technique is being used, it would be important to make sure that the trainee is knowledgeable of all the structures and organisms and knows what to look for. Tr. 165. Additionally, he stated that it would be important that the trainee know how to use reference works as well. Id.
Dr. Saubolle testified that, when training someone,"known" slides should be used, rather than "Dr. Amin's method of using just unknowns." Tr. 746. Dr. Saubolle defined "known" slides as "slides that have been validated by someone else as well, not just by yourself." Tr. 747.[(27)] With "known" slides, Dr. Saubolle testified that one can be tested against them to ensure that he or she is able to recognize common parasites. Tr. 746. In response to my questioning regarding what type of particular training would be needed if a laboratory only used the wet mount methodology for parasite identification, Dr. Saubolle testified:

> . . . give them unknowns. Make sure that they report those unknowns correctly in your estimation, and then test them at six months again to make sure they keep that, that expertise.

Tr. 174.

When asked to define "unknowns," Dr. Saubolle explained that "unknowns" would be specimens containing defined organisms which had been previously identified or preparations from the College of America Pathology Proficiency Testing. Tr. 174-175. Dr. Saubolle stated that these unknowns would be given to the technologist to read as wet mounts, and it could be determined whether the technologist came up with the correct identifications. Tr. 175. The distinction Dr. Saubolle makes is the reader of the sample does not know what the outcome should be from his or her reading of the slide, thus the slide is "unknown," but the slide has been independently read and the results verified, so it is a "known" sample in that context.

With respect to the amount of supervision needed for a trainee, Dr. Saubolle testified that he would expect someone with the requisite laboratory experience to give direct supervision for at least a month, with continuing consultation and supervision given to the trainee over the next five months. Tr. 179-180. At the end of the first six months, Dr. Saubolle stated that the trainee's performance would be evaluated. Tr. 180.

In the area of documentation, Dr. Saubolle testified:

> [Y]ou'd have to [have] documentation saying what kind of training you provide and what organisms that person is expected to be able to pass during an examination course, and that if you signed off on a person he has been -- he or she has been checked for these specific organisms and these specific preparations.

Tr. 748.

Dr. Saubolle stated further that such documentation should be maintained by the laboratory and that periodically, there should be follow-up training. Tr. 748.

In response to questioning regarding the training procedures in his own laboratory, Dr. Saubolle testified that the duration of training at his laboratory depends on the individual's background, but it is usually one to three months. Tr. 156, 760. Dr. Saubolle explained further,

> But that person needs to be tested beyond the two months at least to show his competency and then at the end of six months, we test it to show that he still has competency, and in between we do some quality assurance work in terms of we're following the patient.

Tr. 760.

In terms of documentation, Dr. Saubolle stated that there "is a procedure that says that before anyone is documented as being competent they have to undergo testing with these unknown slides, and show competency in being able to identify each one of those slides." Tr. 762. He explained further that one way in which monitoring is carried out is through proficiency testing. Tr. 765-766.

When evaluating the training of Ms. Cordery in terms of Dr. Saubolle's testimony, I note first that although Ms. Cordery was one of the testing personnel, she was not a medical technologist and did not have any prior clinical laboratory experience. In light of this, she would have required much more extensive and rigorous training than someone who already possessed a background in medical technology or had worked previously at a clinical laboratory. Moreover, based on Dr. Saubolle's testimony, Ms. Cordery would have required close supervision of her work for at least one month, if not more, followed by more months of supervision. After a period of time, possibly six months, Ms. Cordery's work performance should have been evaluated. I find that Dr. Amin's undocumented "training sessions" with Ms. Cordery did not provide her with the

necessary rigorous training required for parasite identification, and was therefore, grossly inadequate, given her background. Nor is there any evidence that Dr. Amin gave her direct supervision for a sufficient amount of time or evaluated her work through performance evaluations.

7. Petitioner did not ensure that, prior to testing patients' specimens, all personnel (other than Dr. Amin) had demonstrated that they could perform all testing operations reliably to provide and report accurate results, as required by 42 C.F.R.
§ 493.1445(e)(12) of the CLIA regulations.

At the time of the December 1997 survey, there still was no evidence that Dr. Amin had a mechanism in place for monitoring the competency of testing personnel. Moreover, Dr. Amin had not documented any criteria by which the testers' competency would be measured.

At the hearing, there was testimony from Dr. Amin that he normally monitored Ms. Cordery's work and the work of the other testing personnel by looking at ten to thirty percent of their samples. Tr. 570-571; see Tr. 577. In response to questioning, Dr. Amin stated that, during the period of June 1996 through July 1997, he monitored Ms. Cordery by "looking into the microscope . . . to check a specimen, either at Ms. Cordery's request or at his own discretion. Tr. 562.

However, despite these statements, Dr. Amin testified that he had no records to show the surveyors that he had monitored Ms. Cordery's competency. Tr. 699. Dr. Amin admitted that he had no documentation in the laboratory indicating when he determined she was able to report test results on her own. Tr. 686. Further, the record indicates from Ms. Cordery's testimony that Dr. Amin gave no hands-on training with Mr. Mann prior to Mr. Mann's reporting out test results on his own from his second day at work. At no time did Dr. Amin document that Mr. Mann had demonstrated that he could perform all testing operations reliably to provide and report accurate results. Although Dr. Amin testified that he routinely monitored Dr. Noboa by verifying his findings through the dual-head microscope (Tr. 577), he again could produce nothing in writing in support of this. The record reflects that, at the time of the December 1997 survey, Dr. Amin had not established any competency measures or levels nor had he documented that the testing personnel had attained some minimum level of proficiency in the areas of testing specimens and reporting out results.

Ms. Mossman, Petitioner's own laboratory consultant, testified about this deficiency based on her review of Petitioner's laboratory procedures.

> Q: And did you find any documentation that the laboratory had a training program for all the testing people ?
>
> A: The only documentation that I found for that was statements in the procedure manual which Dr. Amin had been putting together which addressed the types of training that people would go through.[(28)]
>
> Q: And is that with respect to all of the individuals in the laboratory at the time?
>
> A: Yes, it was.

As reflected above, Ms. Mossman confirmed the absence of documentation needed to support Petitioner's compliance with this Standard.

8. Petitioner did not ensure that policies and procedures were established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills as required by § 493.1445(e)(13) of the CLIA regulations.

I find that Petitioner continued to be out of compliance with this regulation at the time of the December 1997 survey. Although Ms. Rios-Jakeway had explained to Dr. Amin what would be needed to comply with this standard during the June 1996 survey (Tr. 44), Dr. Amin failed to have a written policy for competency evaluations in place at the laboratory. Dr. Amin conceded that, in evaluating his employees' competency, he had no documents that set forth written goals or criteria used for establishing competency, but merely measured their ability against his own subjective idea of what constituted an adequate level of performance. Tr. 668. Dr. Amin admitted that he never wrote down any scores or any results relating to competency that was demonstrated by Scott, Karim, or Ms. Cordery during the time they were employed between 1996 and 1997. Tr. 668-669. Under this standard, Dr. Amin was required to have documentation of performance evaluations of his preanalytical and analytical testing personnel. This he failed to do. Support for this conclusion, can also be found in the testimony of Ms. Mossman, Petitioner's consultant, who testified as follows:

> Q: And did you find any evidence that there was an ongoing evaluation policy to evaluate the competency of these testing individuals?
>
> A: I found no written policy but in talking with individuals in the laboratory, they did indicate that there
>
> [sic] work was reviewed and criticized by Dr. Amin. There was no documentation to support this however.
>
> Q: . . . And was there any established criteria that you found by which competency would be measured in the laboratory ?
>
> A: There was criteria at that time because that had been furnished. The general criteria had been furnished to Dr. Amin the first part of January [1999].
>
> Q: . . . did you find any evidence that that was in existence as of early December 1996?
>
> A: No, I did not.

Tr. 454-455.

Again, Ms. Mossman's testimony further supports the absence of documentation needed to support Petitioner's compliance with this Standard.

9. Petitioner did not have an ongoing mechanism in place to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence as required by 42 C.F.R. § 493.1713 of the CLIA regulations.

With respect to this regulation relating to quality assurance, Dr. Amin failed to introduce any evidence to indicate that his laboratory was in compliance with its requirements at the time of the December 1997 survey. Dr. Amin admitted that, as of the December 1997 survey, he had no documentation concerning the frequency of the monitoring and quality control. Tr. 668. He stated that he knew "what [he] did but it was not on paper." Id. Dr. Amin stated that the laboratory had a quality assurance policy statement, which had been in place at the time of the June 1996 survey. However, there was no documentation demonstrating how the policy was carried out. Dr. Amin testified that he had no records of daily or monthly quality assurance activities. Tr. 701. Based on his own testimony, it is evident that Dr. Amin's efforts at quality assurance remained unchanged from the June 1996 survey, continuing to be minimal, at best, and did not meet the requirements of 42 C.F.R. § 493.1713.

I find that Ms. Mossman's testimony further supports and confirms the fact that the deficiencies cited by the surveyors were in existence for over a year.

When questioned by Petitioner's counsel, Ms. Mossman testified that she reviewed the December 1997 Statement of Deficiencies and generally agreed with the deficiencies stated therein. Tr. 441; see Tr. 454. Moreover, in response to a question about "what policies and procedures" needed to be in place at the laboratory, Ms. Mossman responded by stating, "[a]lmost everything." Tr. 442. She stated further that--

> ". . . there were scattered documents of procedures, . . . None of these were adequate to supply the documentation trail that is required by CLIA for compliance purposes. So we pretty much had to start from the bottom up and build the entire program."

Tr. 442-443.

As reflected above, Ms. Mossman was unable to find adequate documentation to support Petitioner's compliance with any of these Standards and had to develop all of the required documentation herself.

Petitioner's Argument on the Acceptance of the Plan of Correction

10. Petitioner's argument that HCFA should not have imposed the sanction of revocation against its CLIA certificate since HCFA accepted its Plan of Correction and, subsequently, issued a Certificate of Compliance, is without merit.

Dr. Amin has contended in these proceedings that the contents of the POC which he submitted on or about July 17, 1996, can not be characterized as an actual POC and moreover, that he never intended his response to be construed as a POC. Tr. 600; HCFA Ex. 2; see Tr. 591, 592, 664.[(29)] There is no dispute that, in response to the Statement of Deficiencies which he received from the State agency following the June 1996 survey, Dr. Amin submitted a document known as a POC. Tr. 600; HCFA Ex. 2. Dr. Amin's POC consisted of statements typed in the right-hand column of the Statement of Deficiencies, and these statements can be correlated to the alleged deficiencies set forth in the left-hand column of the Statement of Deficiencies.[(30)] Although a provider is required in a POC to give dates as to when the deficiencies will be corrected, Dr. Amin gave no completion dates in his POC.

Dr. Amin testified that, when he received the Statement of Deficiencies from the State agency, he did not believe that his laboratory was engaged in any deficient practices as set forth in the document. Tr. 590. He thus characterized his statements in the right-hand column as "disagreements" with the deficiencies. Tr. 591. Indeed, rather than documenting the steps he would take to correct the alleged deficiencies, what Dr. Amin

wrote in the right-hand column was an apparent description of the laboratory activities and practices as they then currently existed. Tr. 591-592, 600-601. Petitioner argues that Dr. Amin's failure to give any expected completion dates indicated further that he did not intend his statements to be indicative of a POC. See P.'s Brief, at 40.

The record establishes that Petitioner's POC was acceptable to both the State agency surveyor and HCFA. When Dr. Amin submitted his POC to the State agency, he also submitted additional supporting documentation. Tr. 53, 75. Ms. Rios-Jakeway, the State agency surveyor who had conducted the June 1996 survey, testified that she found the POC to be adequate and accepted it. Tr. 54-55, 58, 84. Ms. Carmichael also was of the opinion that Petitioner's POC was "appropriate" and concurred with Ms. Rios-Jakeway's decision to accept it. Tr. 216.[(31)]

Ms. Rios-Jakeway testified that she had conversations with Dr. Amin in which she discussed with him the requirements of having a written orientation program for employees (Tr. 81), a written policy for competency evaluations (Tr. 82), documentation of performance evaluations (Tr. 82, 89) and other compliance issues (Tr. 79, 49-50). While Ms. Rios-Jakeway acknowledged that Dr. Amin's POC did not contain remedial measures addressing the deficiencies or contain any implementation dates as to when such measures would be in place, she stated that she "accepted the plan based on the conversations we had and the supporting documents that came along with this document." Tr. 55. Moreover, Ms. Rios-Jakeway gave testimony that she did review Dr. Amin's POC for appropriateness and completeness, as instructed by the SOM. Tr. 97. She testified that found the POC to be appropriate, and determined also that it was properly completed, based on her conversations with Dr. Amin, his statements in the POC, and the documents that were submitted with the Plan to demonstrate compliance. Id.

Ms. Rios-Jakeway stated also that, while a POC was to be submitted with ten days of receipt of the Statement of Deficiencies, she was aware that Dr. Amin could not develop all the necessary documentation within ten days. Tr. 54, 109. She testified:

> They don't have to submit completed documents or completed evidence of correction with that time frame. It wouldn't be possible. But we do expect them to have an adequate plan that they are going to implement so that the deficiencies are corrected and they don't recur.

Tr. 57-58.

Ms. Rios-Jakeway stated that, overall, she viewed the statements in Dr. Amin's POC as an indication that he did intend to implement certain procedures to attain compliance. Tr. 118; see Tr. 54.

Petitioner, however, argues that HCFA should not have accepted its POC, which, on its face, had not been properly completed. In connection with this claim, Petitioner has attempted to discredit Ms. Rios-Jakeway's evaluation of the adequacy of Petitioner's POC. Petitioner asserts that Ms. Rios-Jakeway, when questioned on cross-examination about Dr. Amin's statements in the right-hand column of the POC, acknowledged that his statements were "a description of what he was then doing" and did not address the deficiencies set forth in the left-hand column of the Statement of Deficiencies. Tr. 87-89, 106. Petitioner notes also that Ms. Rios-Jakeway testified that she and Dr. Amin had not had a discussion about an expected completion date for the correction of the deficiencies. Tr. 93, 110. There was also testimony from Ms. Rios-Jakeway on cross-

examination that the supporting documentation that accompanied Petitioner's POC did not address all the deficiencies. Tr. 100-101, 106.

Petitioner also appears to make the claim that Ms. Rios-Jakeway did not comply with the guidelines in the HCFA State Operations Manual (SOM) with respect to review of a POC. Petitioner pointed out that the SOM contains information regarding the manner that a laboratory's POC is to be reviewed, including "appropriateness, legibility, completeness, and timeliness." P. Ex. 44. Petitioner seems to assert that Ms. Rios-Jakeway did not abide by the SOM in accepting Dr. Amin's POC, which "contained no plan whatsoever and contained no completion date." P.'s Brief, at 44.

Petitioner has contended further that HCFA's consideration and acceptance of the POC submitted by Dr. Amin, notwithstanding its lack of correction measures and completion dates, and HCFA's subsequent issuance of a Certificate of Compliance, constituted "extenuating circumstances", and therefore, Petitioner should have been permitted to demonstrate compliance subsequent to December 4, 1997. Petitioner argues that based on these actions by HCFA, HCFA's determination to sanction Petitioner by revocation of its CLIA certificate is harsh and arbitrary. I find little merit in these arguments advanced by Petitioner. As I will discuss below, HCFA's acceptance of Petitioner's POC and the subsequent issuance of a Certificate of Compliance did not relieve Dr. Amin of his responsibility to correct the Standard-level deficiencies that were identified during the June 1996 survey.

Based on Ms. Rios-Jakeway's experience as a State agency surveyor and her knowledge of the CLIA regulations, I do not find her review of Petitioner's POC to be erroneous. While the POC, on its face, did not contain remedial measures addressing the deficiencies or implementation dates and thus, should probably have been rejected by HCFA, Ms. Rios-Jakeway was not prohibited under the regulations from evaluating the POC in the context of conversations she had with Dr. Amin. Ms. Rios-Jakeway's testimony indicates that she used the information Dr. Amin provided in the survey as to his future plans, along with the contents of the POC, to justify accepting the POC. See Tr. 60. She considered the POC as an indication of a plan in progress which, in conjunction with other actions to occur later, would complete the process. Additionally, Ms. Rios-Jakeway also took into consideration the fact that Dr. Amin had undergone an initial CLIA survey in 1994 and was therefore familiar with the survey process.[(32)] Tr. 52-53, 55. I conclude that Dr. Amin did submit a POC, which was evaluated and found to be adequate, resulting in HCFA's issuance of a recertification certificate.

Petitioner makes the further argument that its failure to correct the deficiencies found in the June 1996 survey should be excused since it was issued a Certificate of Compliance in November 1996. See P.'s Brief, at 45-46. In support of this position, Dr. Amin contends that HCFA's issuance of a recertification certificate was an indication to him that, based on the contents of his POC, the laboratory had been found to be in compliance with CLIA regulations. Tr. 603. According to Dr. Amin, he did not take any steps to correct the deficiencies found in the June 1996 survey following his receipt of the Certificate of Compliance because he "believed that [his] response was satisfactory . . . [he] believed that the documentation [he] provided on the right-hand side of that HCFA form was the documentation that was needed." Id.

Dr. Amin's attempt to justify his laboratory's continuing noncompliance with CLIA regulations by pointing to its receipt of a Certificate of Compliance is disingenuous. Ms.

Rios-Jakeway testified that the recertification was premised on the fact that Dr. Amin had submitted an acceptable POC following the June 1996 survey.[(33)] See Tr. 60. As discussed above, Ms. Rios-Jakeway found the POC to be adequate when examined in context with her discussions with Dr. Amin. Ms. Rios-Jakeway had no reason to doubt that Dr. Amin understood the nature of the deficiencies. Moreover, she believed, from their discussions, that Dr. Amin was, or would be, in the process of implementing measures to correct them. Because of this, Ms. Rios-Jakeway had no reason to think that Dr. Amin would not correct the deficiencies and thus recommended to HCFA that his laboratory be recertified.

It was Dr. Amin's responsibility to correct the three Standard-level deficiencies that were identified in the June 1996 survey, and this responsibility did not end when HCFA issued his laboratory the Certificate of Compliance in November 1996. The deficiencies did not "disappear" once the Certificate was issued. Dr. Amin could not have been oblivious to the fact that his laboratory remained out of compliance with CLIA regulations in November 1996. Indeed, the record is clear that, despite whatever representations Dr. Amin made to Ms. Rios-Jakeway, the deficient practices at the laboratory continued. There is no merit to Dr. Amin's contention that HCFA's issuance of a Certificate meant that he did not have to take any steps to correct the deficiencies, especially in light of his discussions with Ms. Rios-Jakeway. Based on Ms. Rios-Jakeway's testimony, it is evident that Dr. Amin was aware that, in addition to the POC and his submission of documentation with the POC, there were other actions he needed to take to ensure that his laboratory came into compliance.

Petitioner argues that receipt of the Certificate of Compliance "was not in any manner conditioned." P.'s Brief, at 45. However, what Dr. Amin fails to grasp is that HCFA issued the Certificate with the expectation that he would correct the deficiencies found during the June 1996 survey, and this expectation was founded on Dr. Amin's statements to Ms. Rios-Jakeway, the contents of his POC, and the documents attached with it.

In addition to the above analysis of Petitioner's position, it is evident that Dr. Amin ignores the fact that the regulations themselves contain the obligations which must be met so that his laboratory is in conformity with the CLIA requirements. It was found to be deficient in three Standards. The Standards reflect the level of performance which his laboratory must attain to be in conformity with law. Even assuming the State agency or HCFA's failure to reject the POC, a benefit Dr. Amin readily accepted, this would not relieve the laboratory from being in conformity with CLIA. At best, Dr. Amin's POC did not state how he was to correct the deficient Standards and by what date. The POC gave no indication to the State agency or HCFA that he would not conform to the CLIA requirements. HCFA and the State agency apparently were willing to provide Petitioner some leeway in the aftermath of the June 26th survey, especially since they believed he was the only one in the laboratory doing any testing. While this generosity in hindsight may have been misguided, it does not provide a basis to stop HCFA from enforcing sanctions based on Petitioner's non-compliance with the deficient Standards. At no time did the State agency or HCFA ever indicate to Petitioner that its deficient practices were acceptable. Issuance of the Certificate did not contain such a connotation. That Certificate merely allowed Petitioner to operate during the next certification period; it did

not indicate that it would be allowed to operate in a manner inconsistent with its CLIA obligations.

Petitioner's Other Arguments

11. Petitioner's other arguments are also without merit.

Petitioner has raised a number of other arguments in its attempt to show that HCFA's sanction of revocation of its CLIA certificate is unreasonable and unjustified under the circumstances. See, P.'s Brief. I have considered these arguments and found them to be without merit.[(34)] To a large extent, Petitioner attempts to excuse its failure to be in substantial compliance with the Standards cited in the Statements of Deficiencies for the June 1996 and December 1997 surveys based on "misunderstandings" between Dr. Amin and the surveyors. Id. This attempted "straw man" is inconsistent with the record as shown below. Lastly, Petitioner argues erroneously that HCFA's decision to revoke the laboratory's certificate was arbitrary and capricious and that a lesser sanction would be appropriate. I have addressed this argument below as well.

Petitioner asserts that a principal reason underlying HCFA's decision to revoke its CLIA certificate was HCFA's belief that, during the June 1996 survey, Petitioner had misrepresented that Ms. Cordery was not reporting out test results. Petitioner states, however, that HCFA never cited this alleged misrepresentation as a basis for revocation in any of its correspondence with Petitioner or in any prehearing filings. Petitioner claims that HCFA mentioned Petitioner's misrepresentation for the first time at the first day of the hearing.[(35)] Contrary to Petitioner's assertions, however, HCFA's December 22, 1997 Notice stated "Based on the June 21, 1996 survey, it was the practice of the laboratory to use testing personnel not trained in the subspecialty of parasitology to perform and report patient parasitology test results." There can be no dispute that, with this statement, HCFA gave Petitioner notice as to its concerns.

It is evident from the record that the surveyors' later discovery that Ms. Cordery was one of the testing personnel at the time of the June 1996 survey was one of several factors considered by HCFA in making its sanction determination. Tr. 323-324.[(39)] Moreover, the fact that Petitioner may have learned of HCFA's allegation of misrepresentation for the first time at the hearing does not mean that HCFA's decision to revoke Petitioner's CLIA certificate was unjustified. The record is clear that Ms. Cordery's status at the time of the June 1996 survey was not, in and of itself, the basis for HCFA's decision to revoke. As stated in HCFA's December 22, 1997 letter to Petitioner, it was Petitioner's ongoing failure, for over a year, to correct the three Standard-level deficiencies which had been identified at the June 21, 1996 survey, which resulted in HCFA's action to impose the revocation sanction. Furthermore, Petitioner's failure to come into compliance under these circumstances, irrespective of what the surveyors believed to be the situation with Ms. Cordery, constituted an explicit basis under 42 C.F.R. § 493.1816 authorizing HCFA to impose a principal sanction. Thus, HCFA was more than warranted to impose a revocation sanction.[(40)]

Petitioner also claims that, because 42 C.F.R. § 493.1816 gives a laboratory twelve months to correct deficiencies that are not at the Condition level, Standard-level deficiencies "could never warrant a sanction as harsh and serious as suspension or revocation." P.'s Brief, at 48. It points out that, in HCFA's December 22, 1997 Notice, both Condition-level and Standard-level deficiencies were cited as grounds for revocation, but that HCFA later withdrew the Condition-level deficiencies and cited only

the Standard-level deficiencies as grounds for revocation. Contrary to Petitioner's assertion, under the regulations, it is within HCFA's discretion to chose to revoke a laboratory's CLIA license when it has failed to correct its Standard-level deficiencies within twelve months after a survey. Such was the case with Petitioner, which failed to correct three Standard-level deficiencies within twelve months after the June 21, 1996 survey.

As another argument, Petitioner contends that an important factor considered by HCFA in deciding to impose the sanction of revocation was that Petitioner was conducting its parasite testing using a non-traditional method, and yet this factor was never cited in the December 1997 Statement of Deficiencies or in any subsequent HCFA correspondence with Petitioner. In support of this assertion, Petitioner cites to the testimony of Ms. Jew, who, when asked if there were other factors that were considered in deciding what sanction to impose against Petitioner, stated that " . . . basically one of the important factors was here was a laboratory that was doing testing using an unusual method, basically not a traditional method, for identifying parasites." Tr. 325-326.

HCFA disputes Petitioner's claim, and asserts that Petitioner's method of testing (i.e., using wet mount preparations only) was never an issue, but rather, was another reason underlying the importance for Petitioner to have properly trained and competent testing personnel.[(41)] HCFA emphasizes that the decision to revoke Petitioner's CLIA certificate was based on its failure to correct deficiencies for over twelve months, and not on "any questions as to the accuracy of his testing methods." HCFA's Posthearing Response Brief, at 17. While HCFA did take note of Petitioner's testing methods, I find that whatever consideration HCFA may have given to Petitioner's use of wet mounts was in the context of its evaluation of the cited deficiencies. In this case, because the cited deficiencies related to employee training, monitoring, and competency, some inquiry by the State surveyors and HCFA into Petitioner's testing method was valid and appropriate. However, as I have discussed above, it is clear that HCFA's decision to revoke Petitioner's CLIA certificate was based on its continuing failure, for over twelve months, to correct deficiencies. I note, moreover, that HCFA has not cited Petitioner's use of wet mounts as the basis for a deficiency. At the hearing, while there was testimony concerning the differences between using wet mounts and trichrome stains to identify parasites, I informed the parties that I would not make any findings as to the relevancy of the fact that Petitioner did not use the trichrome staining technique. Tr. 154; see Tr. 169. Furthermore, I informed the parties that whether or not one method of slide preparation is better than another method for the identification of parasites is not an issue before me. Tr. 169. Thus, I make no findings on this subject.

Petitioner also advances the argument that HCFA wrongly based its decision to seek revocation in part upon "complaints" received by it, without giving Petitioner any notice and an opportunity to respond. Petitioner contends that HCFA did not set forth the basis of these complaints in its Statement of Deficiencies following the December 1997 survey, or in any of its correspondence with Petitioner. While it was made known at the hearing that complaints had been made to HCFA regarding Petitioner, I again reiterate my earlier conclusion that HCFA, in making its revocation determination, was entitled to consider various factors germane to the choice of remedy.

Petitioner attempts to play down any significance of the cited deficiencies by arguing that "[t]here was absolutely no evidence that a single specimen had ever been

misidentified by Petitioner's laboratory." P.'s Brief, at 50. Moreover, Petitioner characterizes the deficiencies as "paperwork deficiencies." Petitioner's Response Brief (P.'s R. Brief), at 21. In making these assertions, Petitioner misses the point of the CLIA regulations. The deficiencies at issue in this case involved Petitioner's failure to have written documentation in the areas of training, competency, monitoring, and quality assurance, and the failure to have such written documentation in place for over a year. The regulation at 42 C.F.R. § 493.1804 sets forth the purposes of the CLIA enforcement mechanisms, which are the following:

> (1) [t]o protect all individuals served by laboratories against substandard testing of specimens [,]
>
> (2) [t]o safeguard the general public against health and safety hazards that might result from laboratory activities [,] and
>
> (3) [t]o motivate laboratories to comply with CLIA requirements so that they can provide accurate and reliable test results.

42 C.F.R. § 493.1804.

Congress by statute and HCFA through the CLIA regulations ensure the health and safety of recipients of laboratory testing by imposing obligations on the laboratory director to make sure that such testing meets all federal regulatory standards; this, Petitioner failed to do. Petitioner's self-serving statement that its test results have been accurate does not excuse the fact that it has flouted the CLIA regulations for over a year.[(42)] Petitioner's deficient practices go directly to CLIA's enforcement objective to ensure that individuals are protected against substandard laboratory testing of specimens.

Another of Petitioner's arguments is directed to the issue of whether HCFA has wrongly interpreted both 42 C.F.R. § 493.1816 and the CLIA statute found at 42 U.S.C. § 263(a) and thus, abused its discretion in revoking Petitioner's CLIA certificate. Petitioner contends that, under 42 C.F.R. § 493.1816, HCFA could have considered the other sanctions of limitation or suspension as alternative options, but did not. P.'s Brief, at 50-51; P.'s R. Brief, at 17. Moreover, Petitioner argues that "HCFA's interpretation of 42 C.F.R. § 493.1816 such that imposition of principal sanctions was mandatory conflicts with 42 U.S.C. § 263a and is unenforceable." P.'s R. Brief, at 12. Petitioner interprets 42 U.S.C. § 263a as giving HCFA the discretion to decide whether to impose sanctions against Petitioner and to decide what sanctions to impose. Id. at 15.

I find Petitioner's position to be unpersuasive. The regulation at 42 C.F.R. § 493.1816 states, in relevant part:

> If a laboratory has deficiencies, that are not at the condition level, the following rules apply:
>
> . . .
>
> (b) *Failure to correct deficiencies.* If, on revisit, it is found that the laboratory has not corrected the deficiencies within 12 months after the last day of inspection, the following rules apply:

(1) HCFA cancels the laboratory's approval to receive Medicare payment for its services.

(2) HCFA notifies the laboratory of its intent to suspend, limit, or revoke the laboratory's CLIA certificate and of the laboratory's right to a hearing.

42 C.F.R. § 493.1816(b).

HCFA's witnesses explained at the hearing why, of the three principal sanctions listed in 42 C.F.R. § 493.1816(b), suspension or limitation of Petitioner's CLIA certificate would not apply in this case. Ms. Carmichael testified on this point:

Q: . . . you mentioned that limitation would not apply to this laboratory. What is limitation of the license itself ?

A: Limitation is when a laboratory is limited to the scope of testing that they can perform . . . we will apply that to a laboratory who has several specialties . . . And in some laboratories they may not be performing testing at an adequate level in a certain specialty, but the rest of the testing is up to the CLIA standards. So we have the option to limit the certificate and the testing that is not up to CLIA standards, and therefore, the laboratory can still remain in operation for those specialties that they are performing at the CLIA standards.

Q: Is that option ever available in the laboratory which is only performing one type of testing --

A: No.

Tr. 263. (See also testimony of Ms. Jew, Tr. 322-323.)

Additionally, on cross-examination, Ms. Carmichael stated that "limitation was not considered because [Petitioner] only [does] one specialty so that's not even a consideration. A suspension is a consideration and with just one specialty it's not something that we would . . . it wouldn't even occur to us to even think about it." Tr. 249. Ms. Jew testified also that limitation of Petitioner's CLIA certificate was not an option because it only performed testing in one specialty. Tr. 322-323.

There is no dispute that Petitioner performed testing in only one area, the subspecialty of parasitology. Based on the testimony of HCFA's witnesses, the sanctions of limitation and suspension were not considered applicable to Petitioner because Petitioner did not do testing in any other areas. The purpose of limiting a CLIA certificate is to restrict a laboratory's testing to only those specialties or subspecialties in which it has been found to be in compliance, while prohibiting testing in the deficient area(s). Thus, by definition, the sanction of limitation cannot apply to a laboratory which tests in only one specialty or subspecialty, as is the case with Petitioner. Moreover, HCFA's interpretation of limitation of a CLIA certificate is supported by 42 C.F.R. § 493.1808(b), which states that "[w]hen HCFA limits any type of CLIA certificate, HCFA concurrently limits Medicare approval to only those specialties or subspecialties that are authorized by the laboratory's limited certificate."

Petitioner contends that HCFA wrongly refused to consider limiting its CLIA certificate in such a way that only Dr. Amin would be permitted to do testing until the laboratory

corrected the deficiencies. However, Petitioner's definition of limitation is not one that is contemplated by the CLIA regulations. Limitation of a CLIA certificate does not apply to circumscribing the duties of employees; rather, as discussed above, it is intended to bar a laboratory from testing in the area or areas in which noncompliance is found while permitting it to test in the remaining areas.

In light of the above discussion, HCFA's decision to revoke, rather than limit or suspend, Petitioner's CLIA certificate, does not seem arbitrary or an abuse of discretion. I agree with HCFA that, because Petitioner only tested in one area, the sanctions of limitation or suspension were not viable options.

With respect to 42 U.S.C. § 263a, Petitioner contends that the statutory language does not mandate HCFA to impose any sanction at all against Petitioner and instead, gives HCFA broad discretionary authority. I do not agree with this interpretation.

42 U.S.C. § 263(a)(i) provides:

> . . . [T]he certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory
>
> . . .
>
> (C) has failed to comply with the requirements of subsection (d) of this section or the standards prescribed by the Secretary under subsection (f) of this section, . . .

As support for its interpretation of this statutory section, Petitioner draws attention to the fact that it states that a laboratory's certificate "**may** be suspended, revoked, or limited" [emphasis added] for failure to comply with the requirements or standards. Petitioner argues that because HCFA interprets 42 C.F.R. § 493.1816 in such a way as to make the imposition of principal sanctions mandatory, this interpretation conflicts with 42 U.S.C. § 263a and is unenforceable.

As written, the language in 42 C.F.R. § 493.1816(b)(2) states that HCFA will "suspend, limit, or revoke" a laboratory's CLIA certificate where the laboratory has non-Condition level deficiencies that were not corrected within twelve months after the last survey. HCFA thus has the discretion to decide which of the three sanctions to impose. Contrary to Petitioner's assertion, this does not appear to be inconsistent with the plain language or meaning of 42 U.S.C. § 263a(i), which states that a laboratory's certificate "may be suspended, revoked, or limited." Both the statute and the regulation contemplate that either suspension, revocation, or limitation of a laboratory's CLIA certificate will occur should circumstances warrant it under the regulations. However, even if 42 C.F.R. § 493.1816 is arguably inconsistent with 42 U.S.C. § 263a, I have no authority to find a regulation to be ultra vires the CLIA statute. But, based on the record, I find that, in determining to revoke Petitioner's CLIA certificate, HCFA has acted in accordance with 42 C.F.R. § 493.1816. I further find that HCFA had a lawful basis for its determination of the choice of remedy and such remedy is supported by the record.

In a further attempt to demonstrate that revocation is an improper sanction, Dr. Amin pointed out that, following receipt of HCFA's December 22, 1997 Notice, he "immediately set about extensive efforts to bring the laboratory in compliance with the standards in question." P.'s Brief, at 53. To achieve this objective, Dr. Amin hired Ms.

Mossman, a private laboratory consultant, in January 1998. While I will discuss certain aspects of Ms. Mossman's testimony, Dr. Amin's efforts to correct the deficiencies and come into compliance with the CLIA regulations occurred after the second survey and thus, do not have any relevance to my analysis of this case.[(43)] I find that Ms. Mossman's testimony further supports and confirms the fact that the deficiencies cited by the surveyors were in existence for over a year.

When questioned by Petitioner's counsel, Ms. Mossman testified that she reviewed the December 1997 Statement of Deficiencies and generally agreed with the deficiencies stated therein. Tr. 441; see Tr. 454. Moreover, in response to a question about "what policies and procedures " needed to be in place at the laboratory, Ms. Mossman responded by stating, "[a]lmost everything." Tr. 442. Due to the absence of the required documentation, she was forced to create the necessary documentation required by CLIA so that Petitioner could come into compliance with CLIA. This occurred substantially after the time period that Petitioner needed to be in compliance with CLIA. Ms. Mossman testified that she completed her work on or about February 13, 1998, and at that time, she "considered the facility to be in compliance with the written requirements for CLIA." Tr. 444. She stated also that what she and Dr. Amin had put together, while it was acceptable, could not really be considered a "final program" but did meet "the bare bones of the regulations." Tr. 443-444.

I questioned Ms. Mossman on whether she would have been available to perform these duties at an earlier time:

> Q: So everything you did for Petitioner in 1998 during the period that Counsels' asked, you were available to perform back in June '96 up through 1997; is that correct?
>
> A: Yes.

Tr. 456-457.

Thus, based on Ms. Mossman's testimony, it is evident that Dr. Amin could have hired Ms. Mossman back in June 1996 and utilized her expertise to correct the deficiencies found during that month's survey. As a private laboratory consultant, Ms. Mossman has worked in the past with both DHS and the Arizona Medical Association, among other entities, in presenting a series of workshops regarding compliance with CLIA regulations. Dr. Amin could have easily made inquiries within the clinical laboratory or medical community regarding such workshops or the hiring of private consultants. As a laboratory director, Dr. Amin was responsible for ensuring that his laboratory was in compliance with the CLIA regulations. The record reflects that he made no attempts to do this whatsoever until he decided to retain the services of Ms. Mossman in January 1998, after the deficiencies at his laboratory had been in existence for over a year and he was notified by HCFA that his laboratory certificate would be revoked.

Petitioner makes a further argument that HCFA's issuance of a Certificate of Compliance, dated November 22, 1996, effectively tolled the running of the 12-month period referred to in 42 C.F.R. § 493.1816. Under this reasoning, Petitioner contends that it should thus have been allowed a period of time to submit an acceptable plan of correction and seven months from the December 1997 survey to correct the deficiencies. Petitioner's position is unpersuasive. The CLIA regulations contain no provision under which the 12-month period referred to in 42 C.F.R. § 493.1816 would be "tolled." Moreover, as I have discussed earlier in this decision, Petitioner never received

word from either the State agency nor HCFA that its deficient practices were acceptable or that it would be allowed to operate for months on end while deficiencies existed. Petitioner had the obligation to correct the deficiencies in a timely manner. This it did not do.

CONCLUSION

I sustain the determination of HCFA to impose the principal sanctions of revocation of the CLIA certificate of Petitioner, and cancellation of its approval to receive Medicare payments under Title XVIII of the Social Security Act for its services, pursuant to CLIA. The collateral sanction prohibiting Dr. Omar Amin, the director of Petitioner, from owning or operating another laboratory for two years in accordance with 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), is affirmed as well.

JUDGE

Edward D. Steinman
Administrative Law Judge

FOOTNOTES

1. CLIA defines a "laboratory" or a "clinical laboratory" as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical,
cytological, pathological, or other examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. See 42 U.S.C. § 263a(a).
2. In a recent decision, an appellate panel of the Departmental Appeals Board reiterated that the burden of persuasion set forth in Hillman applies only where the evidence proffered by both sides is "in equipoise." Oak Lawn Pavilion, Inc., DAB No. 1638, at 16-17 (1997). In such cases, the burden of persuasion would be on Petitioner.
3. I cite to the transcript of the hearing, which I held in Phoenix, Arizona, from August 25-27, 1998, as "Tr." (page number).
4. 42 C.F.R. § 493.1445(e)(12) states as follows: Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. (Emphasis added).
5. 42 C.F.R. § 493.1445(e)(13) states as follows: Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. (Emphasis added).
6. 42 C.F.R. § 493.1713 states as follows: The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

7. Subsequent to the close of the hearing, some portions of the hearing were lost due to the loss of some of the hearing tapes. I convened a telephone conference with the parties and discussed with them how they wished to proceed. At Petitioner's counsel's request, I allowed him time to submit an affidavit setting forth any rulings he believed I had made during his opening statement. I gave HCFA an opportunity to submit a response. With respect to the missing testimony, I provided counsel with that portion of the testimony which was reflected in my notes and which was not included in the transcript provided by the court reporter. The parties were advised that, after reviewing this, they could consider a stipulation or, if necessary, request that the testimony be re-created through a telephonic hearing. Additionally, in light of the delay associated with attempting to re-create the missing testimony, and at the joint request of the parties, I adjusted the briefing deadlines.
Petitioner's counsel submitted an Affidavit regarding his opening statement. HCFA's counsel did not submit anything. The parties did not stipulate to the missing portion of the transcript.
8. The portion of the transcript that was lost contained reference to receipt of P. Exs. 1-14. However, there is no dispute that P. Exs. 1-14 were received into evidence.
P. Exs. 103-105 were tentatively rejected but were subsequently withdrawn by Petitioner.
9. Another method of slide preparation involves use of a trichrome stain, which, unlike a wet mount, is a permanent or fixed staining technique. Dr. Amin testified that his laboratory had never used the trichrome staining technique. Tr. 633, 635.
According to HCFA's expert witness, Dr. Michael Saubolle, most authoritative works now suggest that both the permanent stain technique and wet mount technique be used to test for parasites in stool specimens. Tr. 144-145. Dr. Saubolle stated that if a wet mount preparation is used to identify parasites, then permanent staining should also be done to confirm the results obtained from the wet mount. Tr. 145. Dr. Saubolle testified that he was unaware of "anybody" that identified parasites using only the wet mount technique. Id. If one had to choose between using permanent staining and the wet mount, Dr. Saubolle testified that the former technique is recommended "in all cases." Id.
10. Ms. Cordery left her employment at Petitioner in July 1997. Tr. 348.
11. This rationale apples equally to compliance with 42 C.F.R.
§ 493.1713 of the CLIA regulations pertaining to policies and procedures for assuring the competence of testing personnel at the laboratory.
12. Prior to becoming a private laboratory consultant, Ms. Mossman was employed by the Arizona Department of Health Services (DHS). At DHS, among the positions she held was that of laboratory surveyor with the laboratory licensure office. Ms. Mossman estimated that she performed approximately 600-650 surveys of clinical laboratories while she was at DHS. Tr. 435-436. Ms. Mossman testified that, as a private consultant, she has presented workshops on compliance with CLIA regulations. Tr. 436. She stated that, in 1993, she was asked by DHS "to participate and assist them in presenting a series of workshops throughout the state for clinical laboratories in regard to the CLIA requirements." Tr. 437. Following that, Ms. Mossman presented a series of workshops regarding CLIA requirements for the Arizona Medical Association at its request, as well as acting as a consultant to them. Id.

13. Ms. Rios-Jakeway testified that accuracy is important when diagnosing parasitic infections. See Tr. 62.
14. As discussed above, the surveyors were unaware at the time of the June 1996 survey that Ms. Cordery had already reported out some test results.
15. Although Ms. Rios-Jakeway testified that a "Mr. Ron Miller" was testing part-time (Tr. 63), it appears that she misspoke and was referring to Mr. Ron Mann.
16. Ms. Cordery was identified as the person reporting the test results on certain of the specimens that were examined by the surveyors during the complaint survey. Tr. 64.
17. When asked what she would have been looking for in terms of an orientation process for the analytical personnel, Ms. Rios-Jakeway testified that :
. . . I was looking to see that Dr. Amin had indeed defined competency and established that criteria, and that he had challenged the testing personnel to see whether or not they met that criteria, that mechanism was in place. And that he had made a determination to the level of competency and authorized them to report out patient test results and under what conditions. Whether or not supervision was needed or he needed to evaluate the specimens before they got reported out. That's what I was looking for.
Tr. 70.
18. I note for the record that discrepancies existed between Dr. Amin's and Ms. Cordery's accounts of Ms. Cordery's training. For this reason, I have not relied solely on either of their accounts, and have used my own judgment where discrepancies arose between their testimonies. I am also mindful of the potential self-interest each of them had in presenting their testimony. Consequently, my findings here are based on my reading of the record and my evaluation of their credibility.
19. Dr. Amin recalled a "preliminary " session at ASU in December 1995 during which time he and Ms. Cordery looked at reference slides together for three to five hours using a dual-head microscope. Tr. 654-658. A dual-head microscope is a microscope at which two people can sit and examine a slide simultaneously, with each looking through a separate lens. One person sits at the "active" side, and the other person is at the "passive" side. The person at the "active" side has the ability to control and adjust the focus of the lens for both heads of the dual-head microscope. Thus, when the person at the "active" side changes the focus of the lens, this automatically adjusts the focus of the lens for the person at the "passive" side. Tr. 394-395; 418.
20. A dual-head microscope is a microscope at which two people can sit and examine a slide simultaneously, with each looking through a separate lens. One person sits at the "active" side, and the other person is at the "passive" side. The person at the "active" side has the ability to control and adjust the focus of the lens for both heads of the dual-head microscope. Thus, when the person at the "active" side changes the focus of the lens, this automatically adjusts the focus of the lens for the person at the "passive" side. Tr. 394-395; 418.
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22. Ms. Cordery stated that there was one class session during which the instructor set up microscopes and identified parasites on slides. Tr. 339.
23. When referring to "reference slides," Ms. Cordery appears to be referring to the permanently mounted slides from professional supply companies.
24. When the sessions took place depended on when Dr. Amin was in the laboratory and on Ms. Cordery's workload. Tr. 396.
25. Dr. Saubolle testified that he is familiar with the type of training given in a medical technology program with respect to reading parasite slides. Tr. 171.
26. Dr. Saubolle noted,"There's very little in terms of automated systems that helps you make the identification." Tr. 155.
27. Dr. Saubolle stated that "slides that have been validated by a trichrome stain as well as a wet mount" would be appropriate to use in training as well. Tr. 747.
28. Contrary to this statement, my review of the record fails to reflect any specific training documentation for the individuals in the laboratory.
29. Dr. Amin testified that he "had never contemplated in my mind to write [a] Plan of Correction. There's no Plan of Correction in my mind." Tr. 592.
30. The left-hand column of the Statement of Deficiencies has the heading "Summary Statement of Deficiencies (Each Deficiency Must be Preceded by Full Regulatory or LSC Identifying Information)."
31. Ms. Carmichael testified that Dr. Amin's POC with respect to the June 1996 survey "could have been better, but it was adequate." Tr. 216.
32. Deficiencies were found at this survey, and Petitioner had submitted a POC following the survey. In the plan, Dr. Amin had set forth the measures he would take to address the cited deficiencies. P. Ex. 7.
33. Ms. Rios-Jakeway testified that, where a provider submits a POC that is unacceptable, the State agency would not recommend recertification, but instead would impose a sanction. Tr. 60.
34. A number of the arguments raised are based on a misconstruction of the record or circumstances irrelevant to the issue of Petitioner's compliance with the CLIA requirements. Such arguments warrant no direct response.
35. Based upon Dr. Amin's testimony, I find that, as of the June 21, 1996 survey, Ms. Cordery was, at times, identifying parasites independently and was reporting some test results on her own by June. Tr. 670, 674. Whether or not Dr. Amin intended to mislead the surveyors regarding Ms. Cordery's status as one of the testing personnel, this information about Ms. Cordery was apparently withheld from the surveyors at the time of the June 1996 survey. According to Ms. Carmichael, at the June 1996 survey, Dr. Amin indicated that "Ms. Cordery was not testing and that she was as [sic] a lab assistant." Tr. 266. [(36)]
36. For example, Mr. Yamamoto, a HCFA laboratory consultant, testified that "because of the nature of the testing performed, the complexity of the tests being performed, the competency of the personnel performing the tests is important to the quality of the results being issued. And so the deficiencies related directly to the quality of the results issued and ultimately patient outcome." Tr. 287. [(37)]
37. For example, Mr. Yamamoto, a HCFA laboratory consultant, testified that "because of the nature of the testing performed, the complexity of the tests being performed, the competency of the personnel performing the tests is important to the quality of the

results being issued. And so the deficiencies related directly to the quality of the results issued and ultimately patient outcome." Tr. 287. (38)
38. For example, Mr. Yamamoto, a HCFA laboratory consultant, testified that "because of the nature of the testing performed, the complexity of the tests being performed, the competency of the personnel performing the tests is important to the quality of the results being issued. And so the deficiencies related directly to the quality of the results issued and ultimately patient outcome." Tr. 287.
39. Ms. Mary Jew, a CLIA team leader with HCFA, testified that, if at the time of the June 1996 survey, the surveyors had been aware that Ms. Cordery was doing parasite testing and reporting out test results on her own, there would have been Condition-level deficiencies cited rather than Standard-level deficiencies. Tr. 323. Additionally, in response to a question concerning the factors considered by HCFA in deciding to revoke or suspend a laboratory's CLIA certificate, Ms. Carmichael stated that HCFA looks at the laboratory's compliance history, any complaints, the severity of the deficiencies, patient outcome, and any misrepresentations that the laboratory has made to HCFA. Tr. 265-266.
40. Many of Petitioner's arguments go to HCFA's choice of revocation as the appropriate remedy in response to Petitioner's failure to correct the cited deficiencies for over a 12-month period from the June 1996 survey. Once the failure to correct the cited deficiencies has been established, my review of HCFA's remedy selection is quite limited. HCFA has the discretion to either limit, suspend, or revoke Petitioner's laboratory certificate. I have no authority to alter that remedy unless the basis for the remedy is lacking, which is not present in this case, or the remedy selected bears no reasonable relationship to the cited deficiencies and is consequently an arbitrary and capricious act on HCFA's part. As will be subsequently discussed, Petitioner's arguments in this regard are without merit.
41. For example, Mr. Yamamoto, a HCFA laboratory consultant, testified that "because of the nature of the testing performed, the complexity of the tests being performed, the competency of the personnel performing the tests is important to the quality of the results being issued. And so the deficiencies related directly to the quality of the results issued and ultimately patient outcome." Tr. 287.
42. There was no direct evidence relating to the accuracy of Petitioner's test results and I make no findings on this issue. Nor does the record permit me to make any findings on Dr. Amin's competency in accurately reporting parasite test results.
43. At the hearing, I ruled that "documentation of compliance with the CLIA regulations after the survey and evidence of that compliance is not relevant." Tr. 445.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Departmental Appeals Board
Civil Remedies Division

In the Case of: Allstate Medical Laboratory, Inc.,

Petitioner,
v.

Health Care Financing Administration.

Docket No. C-99-309
DATE: October 6, 1999

RULING

The purpose of this ruling is to decide whether Pantaleon de Jesus, M.D., the director of Allstate Medical Laboratory, Inc., has a right to a hearing and, if so, the scope of that hearing right.

Forr the reasons set forth below, I have determined that Dr. de Jesus has a right to a hearing, which flows from the sanctions imposed by HCFA against Allstate Medical Laboratory, Inc. (Allstate). Accordingly, I deny HCFA's Motion to Dismiss.

Backqround

In a January 8, 1999 letter (Notice), HCFA informed Dr. de Jesus and Allstate that because it had not received any response from de Jesus as to why certain proposed sanctions should not be imposed, it was imposing the following sanctions as proposed in earlier letter dated December 23, 1998 [see footnote 1 below].

(1) a directed Plan of Correction of cease testing effective December 28, 1998, and submission of a client list of all clients since February 20, 1998;

(2) a civil money penalty of $10,000 per day for December 28 through December 30, 1998 for a total of $30,000;

(3) suspension of the laboratory's CLIA certificate and cancellation of Medicare and Medicaid payments effective December 31, 1998; and

(4) revocation of the laboratory's CLIA certificate effective February 21, 1999.

HCFA informed Dr. de Jesus further that, upon revocation of the laboratory's CLIA certificate, he would be prohibited from owning, operating, or directing a laboratory for at least two years from the date of the revocation. HCFA noted that Dr. de Jesus was currently directing five other laboratories besides Allstate, which was in itself a violation of the CLIA regulations.

Dr. de Jesus filed a request for hearing dated February 11, 1999 [see footnote 2 below]. His letter did not make any reference to the January 8, 1999 Notice letter sent by HCFA to Allstate, but stated at the end that it was a "formal request for a hearing on HCFA's actions affecting Dr. de

Jesus." In his letter, Dr. de Jesus asserted, among other things, that "he [was] not responsible for the deficiencies listed in the survey report."

HCFA filed a motion to dismiss Dr. de Jesus, hearing request. In the alternative, and in accordance with numbered paragraph 2.D. of my June 18, 1999 Order, HCFA also filed its report of readiness to present evidence for adjudication of the case. Dr. de Jesus filed a response brief in which he opposed HCFA's motion.

The Parties' Positions

HCFA asserts that, under the CLIA statute and the regulations, Dr. de Jesus as an individual and in his capacity as the laboratory director is not a proper party to contest any of the sanctions imposed against the laboratory and does not otherwise have any right to a hearing to challenge the two-year prohibition against his owning or operating a laboratory. HCFA argues that only the laboratory is a proper party to challenge the sanctions imposed by HCFA. In response, Dr. de Jesus argues that he is an "affected party" under 42 C.F.R. § 498.2 and has the right to a hearing, which right flows from the sanctions imposed by HCFA against the laboratory. Dr. de Jesus relies on *Eugene R. Pocock, M.D.*, DAB CR527 (1998) to support his contention that a person who is alleged to be an "operator" of a laboratory under the regulations has a direct right to appeal the prohibition against owning or operating (or directing) a laboratory for at least two years, resulting from a CLIA revocation.

DISCUSSION

I have considered the arguments of the parties and the applicable statutory and regulatory provisions. My analysis begins with an examination of HCFA's Notice dated January 8, 1999. HCFA's Notice is addressed to "Pantaleon De Jesus, M.D., Director" and "Allstate Medical Laboratory, Inc." Thus, on its face, the Notice names Dr. de Jesus as one of the addressees, and refers to him in his capacity as the laboratory director.

The principal sanction affecting Dr. de Jesus as an individual is that he is now prohibited from owning or operating (or directing) a laboratory for at least two years from the date of Allstate's CLIA certificate revocation, which became effective February 21, 1999. Dr. de Jesus' ability to have any meaningful involvement with any other laboratory as a director is now effectively suspended for a two-year period.

In its brief, HCFA recognizes that under 42 U.S.C. § 263a(i)(1), reasonable notice and opportunity for hearing must be given to the owner or operator of the laboratory before a laboratory's certificate may be suspended, revoked, or limited. HCFA contends, however, that the statute does not give any hearing rights to laboratory owners and operators who become prohibited from owning or operating other laboratories for two years following a CLIA certificate revocation. See 42 U.S.C. 263a(i)(3). HCFA asserts that only laboratories have been afforded hearing rights under-the CLIA statute and regulations.

In light of my analysis in *Pocock*, I find that HCFA's assertion that only laboratories are the proper parties to request a hearing to challenge HCFA's sanctions is without merit. The fact that the statutory provision at 42 U.S.C. § 263a(i)(1) references the laboratory's owner or operator signifies that these individuals have standing and would be parties in interest in proceedings which affect a laboratory's CLIA certificate. Simply put, in an administrative proceeding such as

the one before me, a laboratory is merely a legal entity. For this reason, a laboratory and its owner and operator are essentially one and the same for purposes of contesting any adverse actions initiated by HCFA. A laboratory's owner and/or operator are the only individuals who could possibly represent its interests. Accordingly, I conclude that a laboratory, its owner, and its operator, all have equal standing and all possess a right to be heard on sanctions imposed by HCFA against the laboratory. I conclude further that a laboratory owner or operator has a right to a hearing to challenge the mandatory two-year prohibition against owning or operating a laboratory, as set forth in 42 U.S.C. § 263a(i)(3).

Moreover, I disagree with HCFA's argument that Dr. de Jesus is not an "affected party" within the meaning of 42 C.F.R. § 498.2. The regulation at 42 C.F.R. 498.2 defines the term "affected party" as follows:

. . . a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part . . . .

Because Dr. de Jesus is a physician, there can be no dispute that he is also a "practitioner." HCFA's determination to impose sanctions against Allstate adversely affects Dr. de Jesus' rights since, as a result, he will be prohibited for two years from owning or operating a laboratory. Thus, due to HCFA's sanctions, Dr. de Jesus can be characterized as a "practitioner that is affected by an initial determination issued under this part," and therefore falls within the definition of "affected party" under 42 C.F.R. § 498.2. Because Dr. de Jesus is an "affected party," he is entitled to a hearing under 42 C.F.R. §§ 498.40 and 498.42.

It is nonsensical to state that when the statute and the regulations refer to adverse actions taken against the "laboratory", that no individual has a right to a hearing. HCFA's attempt to "play down" the role of a laboratory's owner or operator in the context of appealing adverse actions is contrary to what is reasonable or fair. A laboratory's owner and operator play essential roles in the functioning and conduct of the laboratory. To exclude a laboratory's owner and operator from having hearing rights would cause an outcome that is unacceptable and raises questions of fairness and due process.

The regulation at 42 C.F.R. § 493.2 defines the term "operator" to include "[a] director of the laboratory if he or she meets the stated criteria." HCFA, in its Notice, has named Dr. de Jesus, indicating that he is the director of the laboratory. Were I to accept HCFA's position that Dr. de Jesus, as Allstate's director, is not a proper party and is without any right to a hearing, he would be precluded from asserting in these proceedings that he is not an "operator," as that term is defined in the regulations.

In conclusion, as I interpret 42 C.F.R. § 498.2, Dr. de Jesus has the status of an "affected party" and therefore, has a right to a hearing under 42 C.F.R. § 498.40. The scope of Dr. de Jesus's hearing right encompasses the following issues:

1) whether or not Dr. de Jesus is an "operator" as defined in the regulations;

2) whether any of the laboratory activities which are alleged to be deficiencies were in violation of federal regulatory standards for a laboratory;

- whether any of the alleged deficiencies, if proven, are

subject to sanctions; and

4) whether any of the alleged deficiencies occurred while Dr. de Jesus was an operator, assuming he is found to be an operator.

Edward D. Steinman
Administrative Law Judge

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ATTACHMENT II RULING FOOTNOTES:

(1) In its earlier letter dated December 23, 1998, HCFA informed Dr. de Jesus and Allstate that it concurred with the State agency's November 12, 1998 survey findings and its recommendations, and would be imposing sanctions against Allstate. HCFA recounted that at the November 12, 1998 survey, the State agency had found Allstate to be out of compliance with several conditions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as numerous standard-level deficiencies. Based on these findings, the State agency had determined that immediate jeopardy to patient health and safety existed and directed Allstate to take immediate action to remove the jeopardy situation. HCFA stated in this letter that "due to your failure to remove jeopardy and correct all cited deficiencies, and your failure to properly report a change in ownership within the 30 day time frame as required by 42 C.F.R. § 493.51," it would impose the sanctions of a civil money penalty, directed plan of correction, suspension and revocation of Allstate's CLIA certificate, and cancellation of Allstate's approval to receive Medicare payments. HCFA stated further that under 42 U.S.C. § 263a(i)(3) and 42 C.F.R.§ 493.1840(a)(8), the present owner or operator (including director) would be prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the CLIA certificate revocation. HCFA concluded the letter by giving ten calendar days to Allstate to submit any written evidence or other information against the imposition of the proposed sanctions.

(2). Allstate, through its owner, also filed a request for hearing dated January 14, 1999,

which contested only the imposition of the CMP. As a result, revocation of Allstate's CLIA certificate became effective February 21, 1999.

Decision No. **CR632**
Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF
SUBJECT:
US Bio-Chem Medical Laboratories, Inc.
DATE: December 7, 1999
Petitioner,
- v - The Health Care Financing Administration.
Docket No. C-99-601
DECISION

I sustain the determination of the Health Care Financing Administration to impose principal administrative remedies against Petitioner, US BIO-Chem Medical Laboratories, Inc., based on Petitioner's failure to comply with the Clinical Laboratory Improvement Amendments of 1988, section 353 of the Public Health Services Act, 42 U.S.C. § 263(a) (CLIA), and with implementing regulations published at 42 C.F.R. Part 493. The remedies which I sustain are as follows:

- Pursuant to 42 C.F.R. §§ 493.1773(d), (g) and 493.1842, cancellation of Petitioner's approval to receive Medicare payments for laboratory services effective June 14, 1999. Also, pursuant to section 1902(a)(9)(C) of the Social Security Act (Act) and 42 C.F.R. § 440.30(c), denial of payment to Petitioner under the State Medicaid programs for laboratory services performed on or after June 14, 1999.
- Pursuant to 42 C.F.R. §§ 493.1773(d), (g) and 493.1840(d)(2)(ii), suspension of Petitioner's CLIA certificate effective June 14, 1999.
- Pursuant to 42 C.F.R. §§ 493.1773(g) and 493.1840(e)(1), revocation of Petitioner's CLIA certificate.

I. Background

A. Procedural history

Petitioner is a clinical laboratory that is located in Metairie, Louisiana. On May 28, 1999, HCFA sent a notice to Petitioner. In that notice, HCFA advised Petitioner that it had determined that Petitioner no longer complied with CLIA participation requirements. HCFA advised Petitioner that it had determined to impose administrative remedies against Petitioner.

Petitioner requested a hearing. The case was assigned to me for a hearing and a decision. I held an in-person hearing in New Orleans, Louisiana on September 15, 1999. At that hearing the following witnesses testified:

- Sandy Pearson Hearing Transcript (Tr.) at 25 - 63. Ms. Person is presently employed by HCFA as a laboratory consultant. Her duties include performing CLIA surveys on behalf of HCFA. Tr. at 26 - 27. Ms. Person was present at a CLIA survey of Petitioner that was conducted on May 25, 1999. Id. at 31.
- Diane Weiss (Tr. at 64 - 75). Ms. Weiss is employed as a Medicare Part B field representative by Arkansas Blue Cross-Blue Shield. Tr. at 64. Arkansas Blue Cross-Blue Shield has a contract with HCFA to administer Medicare Part B in the

State of Louisiana. Id. Ms. Weiss accompanied Ms. Pearson to Petitioner on May 25, 1999. Id. at 65.

- Barbara M. Borel (Tr. at 75 -81; 87 - 88). Ms. Borel is Petitioner's office manager. Tr. at 76. She has been employed by Petitioner for the past seven years. She is a registered medical assistant and phlebotomist. Id. Ms. Borel was present during the visit of Ms. Pearson and Ms. Weiss on May 25, 1999 and was a witness to the events which transpired on that date.
- A. S. Lee Fernandez (Tr. at 81 - 86). Mr. Fernandez is president of Petitioner. Tr. at 82. He was present during the visit of Ms. Pearson and Ms. Weiss on May 25, 1999.

At the hearing I received into evidence HCFA Exhibits (Exs.) 1-15. I declined to receive into evidence P. Ex.1. This exhibit consists of documents which Petitioner sought to offer into evidence but which Petitioner had failed to exchange with HCFA prior to the hearing pursuant to my prehearing order. I ruled that Petitioner had not demonstrated good cause for offering its exhibit untimely and that receipt of the exhibit into evidence would prejudice HCFA.

At the close of the hearing I directed the parties to file posthearing briefs. Each party filed a posthearing brief. Petitioner attached three additional exhibits - described by Petitioner as invoices - to its posthearing brief. Petitioner did not designate these additional exhibits as exhibits. For purposes of identification, I am identifying the exhibits as P. Ex. 2 , P. Ex. 3, and P. Ex. 4. I am not receiving P. Exs. 2-4 into evidence. Petitioner has offered them untimely and has made no showing of good cause for offering them untimely. I note also that some of the invoices in P. Exs. 2-4 resemble, and may in fact duplicate, invoices that Petitioner offered as part of P. Ex. 1.

B. Governing law

CLIA requires, among other things, that the Secretary of this Department establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263(a). The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained at 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both conditions and standards for participation under CLIA. Conditions of participation are set forth as general requirements which must be met in order that a laboratory qualify under CLIA. Standards of participation are set forth as specific quality requirements that a laboratory must meet in order to meet the more general requirements of conditions of participation.

The CLIA regulations authorize HCFA or its designees to conduct complaint 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(b). The regulations confer 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" as an administrative remedy against the laboratory which include

suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against the laboratory. 42 C.F.R. § 493.1810(e). A laboratory may make an allegation of compliance once it believes it has corrected the deficiencies. HCFA will verify whether the deficiencies have been corrected if it finds the allegation of compliance to be credible and will lift alternative sanctions effective as of the correction date. Id. However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted based on self-correction of deficiencies and an allegation of compliance by the laboratory. Id.

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. The standard of proof that is employed at a hearing concerning HCFA's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. HCFA has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by HCFA. Hillman Rehabilitation Center, DAB No. 1611 (1997), aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health & Human Services, No. 98-3789, slip op. at 25 (D.N.J. May 13, 1999).

ISSUE, FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Issue

The issue in this case is whether Petitioner failed to comply with a CLIA condition of participation, thereby authorizing HCFA to impose a principal sanction as an administrative remedies against Petitioner, which includes revocation of Petitioner's CLIA certificate.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision that HCFA is authorized to impose principal sanctions against Petitioner based on Petitioner's failure to comply with a condition of participation in CLIA. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. Cooperation with HCFA in a CLIA inspection is a mandatory condition of participation in CLIA.

It is a condition of participation that a laboratory that participates in CLIA cooperate with HCFA in any CLIA inspection that is conducted of that laboratory. Failure by the laboratory to comply with this condition leads to the imposition of principal sanctions against that laboratory which include cancellation of the authority to receive payment from Medicare or State Medicaid programs for laboratory services and suspension limitation or revocation of the laboratory's CLIA certificate.

The regulations which establish condition mandating cooperation are unequivocal. The general condition of participation governing inspection requirements that is stated in 42 C.F.R. § 493.1771(a) provides that each laboratory issued a CLIA certificate must

comply with the requirements contained in, among other regulations, 42 C.F.R. § 493.1773. Pursuant to 42 C.F.R. § 493.1773(a):

> A laboratory issued a [CLIA] certificate must permit HCFA or a HCFA agent to conduct an inspection to assess the laboratory's compliance with the requirements of this part.

42 C.F.R. § 493.1773(g) provides that:

> Failure to permit HCFA or a HCFA agent to conduct an inspection or reinspection results in the suspension or cancellation of the laboratory's participation in Medicare and Medicaid for payment, and suspension or limitation of, or action to revoke the laboratory's CLIA certificate . . . .

2. On May 25, 1999, Petitioner refused to produce documents requested by inspectors who were sent to Petitioner on behalf of HCFA to conduct a CLIA complaint inspection.

On May 25, 1999, Ms. Pearson and Ms.Weiss went to Petitioner's facility. Tr. at 31, 65. Their purpose in going there was to conduct a complaint investigation. Id. at 31. The purpose of the visit was to investigate whether Petitioner was performing unauthorized tests. Id. at 32-33. The inspectors did not inform Petitioner in advance of their visit to the facility. Id. at 32. On their arrival the inspectors told Mr. Fernandez, Petitioner's president, the reason for their visit to the facility. Id. However, at the time of the visit the inspectors did not inform Mr. Fernandez of the source of the complaint that led to their visit. Id.

Initially, Mr. Fernandez permitted Ms. Pearson and Ms. Weiss to enter Petitioner's facility in order to conduct their inspection of the premises. During the course of the visit, Ms. Weiss noticed the presence of reagents that are used for blood typing. Tr. at 39, 42. Petitioner was not authorized by its certificate of waiver to perform blood typing. Id. at 38-39. Ms. Weiss asked Ms. Borel, Petitioner's office manager, whether Petitioner was performing blood typing. Id. at 39. Ms. Borel averred that Petitioner had in the past performed some blood typing pursuant to a contract with another company but that Petitioner had ceased doing such tests recently. Id.

Ms. Pearson then requested that Petitioner produce its patient log book. Tr. at 43, 66, 77. Her purpose in requesting the patient log book was to ascertain when Petitioner had done blood typing tests and what tests Petitioner had performed. Id. at 43-44. Mr. Fernandez denied Ms. Pearson's request to see the log book. Id. at 44, 66, 77. Ms. Pearson restated her request several times to no avail. Id. at 44 She then explained to Mr. Fernandez the possible ramifications of his refusal to produce the log book and Mr. Fernandez continued to refuse to produce the log book. Id. at 44, 66. At that point, Ms. Pearson and Ms. Weiss terminated their inspection of Petitioner's facility and left the premises. Id.

3. Petitioner's refusal to cooperate with the inspectors constituted a failure by Petitioner to comply with the condition of participation which requires a laboratory to cooperate with inspectors.

Petitioner's refusal to produce its log book for review by the inspectors constitutes a clear failure by Petitioner to comply with the condition of participation which requires it to cooperate with inspectors. 42 C.F.R. §§ 493.1771 and 493.1773. The inspectors determined that the log book might contain evidence which would establish whether Petitioner was operating outside of the parameters of its CLIA certification. In refusing to

produce the log book Petitioner denied the inspectors access to potentially necessary evidence and frustrated the inspectors' investigative efforts.

Petitioner's sole defense to the overwhelming evidence of its failure to cooperate was that it was justified in refusing to produce evidence by the surveyors' refusal to inform Petitioner of the source of the complaint which triggered the complaint investigation. However, that is not a valid defense to Petitioner's refusal to cooperate. The regulations which govern a laboratory's duty to cooperate do not permit a laboratory to withhold information from inspectors under any circumstance. The duty to cooperate is unconditional. 42 C.F.R. §§ 493.1771 and 493.1773.

Furthermore, Petitioner cannot assert reasonably that it was unaware of its unconditional duty to cooperate. Ms. Pearson explained to Mr. Fernandez the ramifications of his refusal to produce the log book, but Mr. Fernandez was adamant in refusing to produce the document. Petitioner knew in advance of the inspection that it was obligated to cooperate with inspectors. Petitioner knew that failure to cooperate would result in the imposition of remedies against Petitioner, including cancellation of approval to receive payment, suspension, limitation or revocation of Petitioner's CLIA certificate. On February 15, 1995, Mr. Fernandez signed an application for CLIA certification. HCFA Ex. 13. Just above the line on the application to which Mr. Fernandez signed his name is the following statement in large type:

CONSENT: THE APPLICANT HEREBY AGREES . . . TO PERMIT THE SECRETARY OR ANY FEDERAL OFFICER OR EMPLOYEE DULY DESIGNATED BY THE SECRETARY, TO INSPECT THE LABORATORY AND ITS OPERATIONS AND PERTINENT RECORDS AT ANY REASONABLE TIME.

(capitalization in original). Id. at 4. The CLIA certificates that were issued to Petitioner all contained the following statement:

> This certificate is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

HCFA Ex. 11 at 1-3.

4. Petitioner's failure to comply with a condition of participation in CLIA is a basis for the imposition of principal administrative remedies against Petitioner.

The overwhelming evidence in this case is that Petitioner failed to comply with the condition of participation that required it to cooperate with CLIA inspectors. The presence of this condition level failure by Petitioner to comply with CLIA requirements is sufficient basis for HCFA to impose principal sanctions against Petitioner that HCFA. 42 C.F.R. § 493.1806. Such sanctions may include any of the remedies that HCFA imposed in this case against Petitioner. Furthermore, those remedies are authorized specifically and additionally by Petitioner's failure to comply with the requirements of 42 C.F.R. §§ 493.1771 and 493.1773(d). See 42 C.F.R. § 493.1773(g).

5. Petitioner's possible failure to comply with additional standard-level requirements of participation has no effect on my decision in this case.

The inspectors found that, as of May 25, 1999, in addition to not complying with the condition of participation governing cooperation, Petitioner was not meeting several standards of participation in CLIA. These standards related to performance of tests pursuant to certificates of waiver. HCFA Ex. 6.

I do not make findings in this decision whether Petitioner was failing to comply with standards of participation in addition to its failing to comply with the condition governing

cooperation. My reason for not making findings as to Petitioner's compliance with standards is that Petitioner's compliance or non-compliance with these standards has no effect on my decision to sustain the imposition of principal remedies against Petitioner. That is because the authority to impose such remedies results from Petitioner's failure to comply with a condition of participation and not from any findings that Petitioner may have failed to comply with some additional standards of participation. Failure by Petitioner to comply with some standards of participation in addition to the condition that is at issue here would not enhance or strengthen HCFA's authority to impose principal remedies. And, compliance by Petitioner with those standards would not detract from HCFA's authority to impose principal remedies.

JUDGE

/S/ Steven T. Kessel
Administrative Law Judge

ATTACHMENT I:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Departmental Appeals Board
Civil Remedies Division

Docket No. C-99-797

Date: Dec 21, 1999

In the Case Of: Carlos A. Cervera, M.D.,
Director, San Fernando Diagonostic Laboratory, Inc.
Petitioner

V.

Health Care Financing Administration.

RULING DENYING HCFA'S MOTION TO DISMISS AND GRANTING EXTENSION OF TIME FOR SUBMISSION OF READINESS REPORTS

In its motion, dated December 3, 1999, HCF contends that Dr. Cervera does not have the right to an appeal in a matter involving sanctions taken by HCF under the Clinical Laboratory Improvement, Amendments of 1988 (**CLIA**), against San Fernando Diagnostic Laboratory, Inc. HCF persists in its contention even though the letter imposing sanctions against the laboratory, dated June 17, 1999, was addressed to Dr. Cervera, and even though the sanctions proposed included a two year ban on his owning or directing a laboratory.

On August 1.0, 1999, Dr. Cervera appealed the HCF determination, and asked that his letter be considered a request for a hearing. Dr. Cervera essentially argued that he never acted as Director of the laboratory in question, that to his knowledge the laboratory never opened, and that he did not have a contract with the laboratory, among other statements in his letter.

The issues raised by this motion have been fully addressed by Judge Steinman in his order in *Allstate Medical Laboratory, Inc,* Docket No. C-99-309, October 6, 1999. (Copy attached). I adopt Judge Steinman's rationale in *Allstate.* In particular, I find that Dr. Cervera is an "affected party" within the meaning of 42 C.F.R. § 498.2, and that to cite Dr. Cervera as laboratory director and prohibit him from owning or operating a laboratory for two years, while at the same time denying him the same right to a hearing that the laboratory has raises significant issues of fairness and due process.

Accordingly, HCF's motion is denied.

The parties are instructed to promptly submit the report of readiness to present evidence as per my September 30, 1999 Order in this case. Since recent correspondence has demonstrated that the parties are having some difficulties regarding communicating with each other I will extend the date of filing this report to **January 10, 2000.** L will set up a prehearing conference in this matter during the week of **January 24, 2000.**

It is so ordered.

Marc R. Hillson
Administrative Law Judge

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Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF Edison Medical Laboratories, Inc.,
Petitioner
DATE: December 23, 1999 - v. -
Decision No. **1713**
Health Care Financing Administration
Civil Remedies CR599
App. Div. Docket No. A-99-96 **DECISION**

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION
Edison Medical Laboratories, Inc., (Edison) appealed the June 9, 1999 decision of Administrative Law Judge (ALJ) Steven Kessel finding that the Health Care Financing Administration (HCFA) was authorized to impose remedies on Edison under the Clinical Laboratory Improvement Amendments of 1988, Public Law No. 100-578, *amending* ' 353 of the Public Health Service Act, *codified at* 42 U.S.C. ' 263a et seq. (CLIA), and effectively revoking Edison's CLIA certificate. *Edison Medical Laboratories, Inc.*, DAB CR599 (1999) (ALJ Decision).
Edison excepted to the ALJ Decision on several bases. Edison argued that it had not received a due process hearing because (1) the ALJ wrongly concluded he could not reach the question of whether the deficiencies charged constituted immediate jeopardy, (2) the ALJ employed the wrong burden of proof, and (3) neither HCFA nor the ALJ provided a neutral and objective review of the State inspection results. Edison asserted that the findings of the inspectors were erroneous and unfair because the State agency designated by HCFA to perform surveys in New Jersey was seeking to close down minority-owned laboratories. Edison also alleged that the ALJ misunderstood the CLIA survey and sanction process, which Edison argued had been misapplied to it in this case, because it was not given a chance to show that it had corrected any deficiencies before it was suspended. Further, Edison contended the ALJ erred in weighing the evidence in the record concerning specific deficiency findings.
We find that Edison's exceptions to the ALJ Decision are without merit for the reasons explained below. Therefore, we affirm the ALJ Decision and uphold the revocation of Edison's CLIA certificate.[1]
FINDINGS OF FACT AND CONCLUSIONS OF LAW

Legal Background
Under CLIA, any laboratory that performs clinical diagnostic tests on human specimens must meet federal certification requirements established by the Secretary of the United States Department of Health and Human Services (Secretary). 42 U.S.C. ' 263a; 42 C.F.R. Part 493. Furthermore, in order to bill for services provided under Medicaid and Medicare, Titles XVIII and XIX of the Social Security Act (Act), the laboratory must be in compliance with CLIA requirements. The requirements consist of conditions that set out general guidelines for a laboratory to qualify for certification in applicable areas of testing and standards that define specific elements under the general conditions. 42 C.F.R. Part 493. The standards are components of the conditions of laboratory certification, so that non-compliance with one or more particular standards relating to a

condition may or may not be serious enough to cause a deficiency at the level of the condition. *See* 42 C.F.R. " 493.2, 493.1812-16; 57 Fed. Reg. 7218, 7219 (Feb. 28, 1992). Each "condition" represents a major division of laboratory services to be offered by the laboratory or required safety protections, so that a failure by a laboratory to comply with even a single condition in a area of testing offered by that laboratory represents a serious breakdown in one of the major health care delivery or safety systems of the laboratory critical to ensuring the provision of acceptable health care services. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997).

CLIA empowered the Secretary to adopt a range of intermediate or alternative sanctions to deal with laboratories that fail to maintain compliance with applicable conditions of participation. *See* Act, ' 1846(a). HCFA retains broad discretion under CLIA to select a course of action to ensure that laboratories remain in or promptly return to compliance with CLIA requirements. 42 C.F.R. ' 493.1800(a)(2)(iii); *see also* 57 Fed. Reg. at 7224.. The action which HCFA will take if a survey finds that a laboratory is not in compliance with the requirements depends in part on (1) whether the deficiencies are only at the level of one or more standards or rise to the level of noncompliance with one or more conditions, and (2) whether the deficiencies pose an immediate jeopardy. *See* 42 C.F.R. " 493.1812 to 493.1816.[2]

Where none of the deficiencies are at the level of a condition requirement, the laboratory must submit a plan of correction and show on revisit that it has corrected the deficiencies. 42 C.F.R. ' 493.1816. If the deficiencies are not corrected within 12 months, HCFA will cancel the laboratory's approval to receive Medicare payments and give notice of suspension, limitation or revocation of the laboratory's CLIA certificate. *Id*. Where the deficiencies are at the condition level but do not pose immediate jeopardy, HCFA has the option of imposing a "principal sanction," i.e., canceling Medicare approval or suspending, limiting or revoking the CLIA certificate, or of imposing one or more "alternative sanctions." 42 C.F.R. ' 493.1814. If alternative sanctions are imposed, and the deficiencies are not corrected within 12 months, a further sanction, including suspension or revocation, may be imposed. *Id*. Where the deficiencies are found to pose immediate jeopardy, HCFA "requires the laboratory to take immediate action to remove the jeopardy;" HCFA may choose to put alternative sanctions into place to bring the laboratory into compliance, in which case a principal sanction will be imposed if a revisit indicates that the jeopardy has not been removed. 42 C.F.R. ' 493.1812. HCFA may impose a principal sanction in the case of immediate jeopardy with five days' notice to the laboratory. 42 C.F.R. ' 493.1844(g) and (h). In such cases, any suspension or limitation of the laboratory's CLIA certificate will take effect without delay, even if a hearing is requested. 42 C.F.R. ' 493.1844(d)(2).

The suspension of a laboratory's CLIA certificate because of noncompliance with CLIA requirements is an initial determination subject to appeal to an ALJ. 42 C.F.R. ' 493.1844(b)(1). If the laboratory appeals, the suspension generally does not take effect until after an ALJ hearing. 42 C.F.R. ' 493.1844(d)(1). However, as noted, in cases where immediate jeopardy was found, an appeal will not delay the suspension. The laboratory may still appeal the suspension but may not appeal the determination that the deficiencies constituted immediate jeopardy (and therefore justified suspension taking effect while the appeal was pending). 42 C.F.R. ' 493.1844(c)(6) and (d)(2).

However, in those circumstances, the laboratory is entitled to an expedited hearing. 42 U.S.C. ' 263a(i)(2).

Factual Background

It was not disputed that Edison is a clinical laboratory in New Jersey that performs tests subject to CLIA. It was surveyed by the New Jersey Department of Health and Senior Services (NJDHSS) to determine if it was in compliance with the applicable conditions of participation. The inspection was triggered by a complaint and resulted in findings that Edison was out of compliance with nine condition-level requirements.[3] Multiple survey visits took place between April and July of 1998; in addition, there were later reviews by the inspectors of documents requested from Edison.

The dates of visits were April 28-30, May 1 and 6, June 4, 5, 11, 16, and 24, and July 8-10. The parties disputed the reasons that the survey was conducted over this extended period. The inspector testified that the initial focus was on possible billing problems but that the conditions which were observed raised serious concerns about quality which led to a more in-depth survey. Transcript of Hearing on February 2, 1999 (Tr. 2/2) at 38, 99 (Duffy). (We note that since the hearing continued over three days and transcripts were not numbered consecutively we have included a date in each transcript citation.) HCFA further explained that a time-consuming review of raw data records was required to determine the authenticity of reported results and that the surveyors encountered difficulty in obtaining requested records and in getting cooperation from Edison's staff. HCFA Br. at 3-4, citing Tr. 2/2, at 40-47, 194, 199 and HCFA Ex. 3, at 14-18. Edison, on the other hand, attributed the length of the survey to the inspectors' bias against minority laboratories, and their resultant unreasonable demands and threats, and further complained that the visits disrupted operations. *See*, *e.g.*, Edison Br. at 52-53, 87, 91-93. We discuss the charges of bias in the section on Edison's legal arguments. Ultimately, however, the issue before us is whether substantial evidence supports the ALJ's findings that Edison violated one or more conditions, not whether the survey which generated the findings appealed to the ALJ was well-conducted or inconvenient. The case must rest on what the evidence in the record demonstrates as to Edison's compliance. We discuss the evidence in the section on Edison's factual arguments.

NJDHSS notified Edison of its findings in a letter dated September 30, 1998 which read, in part, as follows:

> The complaint survey and the subsequent in-office examination of the collected information revealed the occurrence of numerous and extraordinarily serious deficiencies. These deficiencies included the deliberate fabrication of test data and the on-going reporting, through gross carelessness, of erroneous test results and, therefore, the laboratory's client physicians were being given false information to be used in the diagnoses of their patients' medical conditions. . . . The documented deficiencies reflect non-compliance with crucial conditions for participation in the CLIA program and they are of so serious a nature as **to constitute immediate jeopardy to patient health and safety**.

HCFA Ex. 1, at 1 (emphasis in original). Attached with this notification was a lengthy statement of the deficiencies found. HCFA Ex. 2. The NJDHSS letter informed Edison that it had ten days in which to provide a "credible allegation of compliance," consisting of either evidence that the deficiencies did not exist or were already corrected or a satisfactory plan for their correction in an acceptable amount of time. *Id.* at 2. Should a

credible allegation be provided within the specified time, NJDHSS indicated that it would promptly conduct a follow-up survey. *Id*.

Edison responded with a letter dated October 9, 1998 in which it denied that any serious deficiencies existed and asserted that the College of American Pathologists had recertified its accreditation after a re-examination conducted during the same time frame. HCFA Ex. 4, at 1. Edison asserted that the inspectors' findings were false or erroneous because the inspectors failed to ask Edison's staff for information that would have documented compliance, while at the same time making unreasonable and disruptive demands for voluminous records. *Id.* at 2. Edison denied that it fabricated test data or deliberately reported erroneous results. *Id*. Further, Edison complained that it was not informed of the allegation of conditions constituting immediate jeopardy until it received the report long after the close of the survey. *Id*. Edison enclosed a copy of the statement of deficiencies annotated with its responses to each finding which allegedly showed credible documentation of compliance and requested a follow-up visit by different inspectors. HCFA Ex. 4, at 3; HCFA Ex. 3.

NJDHSS rejected Edison's response as inadequate to demonstrate either that the inspection findings were wrong or a credible plan for correcting them was instituted. HCFA Ex. 5, at 1. Consequently, NJDHSS did not perform a follow-up survey and instead recommended that HCFA impose sanctions, including the immediate suspension of Edison's CLIA certificate. HCFA agreed and notified Edison, in a letter dated November 20, 1998, that its CLIA certificate would be suspended and all Medicare payments to it canceled as of November 27, 1998. HCFA Ex. 7. HCFA noted that Edison had been found out of compliance with nine CLIA conditions set out in the following regulations: 42 C.F.R. " 493.801, 493.1101, 493.1201, 493.1241, 493.1245, 493.1441, 493.1447, 493.1459, and 493.1701. *Id.* at 1. Based on reviewing those specific deficiencies, HCFA stated that it had determined that they posed an immediate jeopardy and, in particular, expressed concern about three major areas: (1) fabrication of results from a particular apparatus for clinical testing known as a nephelometer; (2) numerous errors in performing a variety of immunofluorescent tests leading to reporting incorrect clinical results; and (3) incorrect calculations with the result that false positive hepatitis results were routinely reported and incorrect interpretations were made in reporting Rheumatoid factor tests. *Id.* at 2.

Edison requested and received an expedited hearing before the ALJ. *See* Edison Hearing Request at 1 (Nov. 21, 1998); Edison letter to Civil Remedies Division (Dec. 7, 1998); Order and Notice of Hearing (Dec. 22, 1998). The ALJ found that Edison "failed to provide laboratory services in a manner that complied with accepted standards for quality." ALJ Decision at 6. The ALJ found that Edison's derelictions included reporting to physicians test results on the nephelometer that were "not technically possible" and that therefore were the product of either intentional falsification or gross incompetence. *Id*. The ALJ also found that Edison's staff conducted other clinical tests incompetently, including alpha fetoprotein tests, low density lipoprotein (LDL) tests, and indirect immunofluorescent antibody (IFA) tests. *Id*. The ALJ concluded that the deficiencies demonstrated in Edison's clinical testing were "so egregious and pervasive" as to rise to the level of violating conditions of participation, rather than failing to meet individual standards, in regard to all nine conditions listed above. *Id.* at 15-20. Based on his findings and conclusions, the ALJ upheld HCFA's imposition of principal remedies,

including the suspension which automatically converted to a revocation of Edison's CLIA certificate upon issuance of the ALJ Decision. *Id.* at 20.

Standard of Review

Our standard for review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard for review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole.

ANALYSIS

In our discussion, we have grouped Edison's arguments in order to address first those that attack the legal foundation of the ALJ Decision and then those that attack the factual findings underlying that decision. In its briefing, Edison intermingled these contentions, but since the standard of review differs, we address them separately here.[4]

Legal Arguments

Duplicative and untimely documents submitted by Edison on appeal are inadmissible.

As a preliminary matter, we note that Edison attached six documents to its reply brief that were styled as DAB Rebuttal Attachments A through G. Attachment D appears to be the same as Edison's Exhibit 36 before the ALJ and is therefore merely duplicative. As for the remaining attachments, Edison offered no explanation justifying its proffer of this evidence at the end of the appeal process. Nothing on the face of the documents suggests any basis to believe that these documents could not have been made available for submission earlier in the proceedings before the ALJ. The documents consisted of: (A) a 15-page list of HCFA exhibits with unattributed commentaries; (B) a letter dated April 19, 1999 from an apparent supplier of antisera which states that it was sent in response to a request by Dr. Patel of Edison on April 16, 1999 (i.e., Edison did not even ask for this letter until months after the ALJ hearing was completed); (C) a letter to Edison dated May 27, 1998 from the Medicare Fraud Investigations Unit requesting cooperation in a review of fiscal and other records; (D) a letter dated April 8, 1998 to Edison from HCFA reporting adverse findings of a complaint survey of Edison conducted by the American Society for Cytotechnology; (E) a five-page list, from no identifiable source, of clinical laboratories in New Jersey assertedly closed and the purported racial profiles of their owners; (F) a letter dated June 9, 1998 signed by the President of Network Solutions apparently relating to a computer system crash at Edison on June 5, 1998; and (G) four pages of materials purporting to be selected pages from a Benetech Reference Manual on alpha fetoprotein with a attached memorandum dated October 6, 1998.[5]

The appeal regulations provide that the Board "may admit evidence into the record in addition to the evidence introduced at the ALJ hearing . . . if the Board considers that the additional evidence is relevant and material to an issue before it." 42 C.F.R. ' 498.86(a). The Board, thus, has discretion to admit evidence in appropriate cases where the proponent shows that it is relevant and material. We decline to admit the exhibits proffered by Edison because their unexplained untimely submission makes their reliability and authenticity questionable, and hence undercuts their relevance and materiality. Further, to permit evidence to be received under these circumstance would undermine the purposes of holding evidentiary hearing in the first instance.

The purpose of requiring parties to present evidentiary materials in a timely fashion is to allow the opposing party a fair opportunity to test their reliability, authenticity and relevance at the hearing and to present conflicting evidence to bear on the proper weight to be given to the conflicting evidence. Edison had ample notice of the proper times for submission of exhibits and did not assert any difficulty in meeting those deadlines. *See*, *e.g.*, Order and Notice of Hearing at 2 (December 22, 1998). Admitting these attachments as evidence at this late date would merely serve to permit Edison to evade the adversarial system and to undermine the hearing process. The documents are therefore excluded.

***The ALJ properly reviewed the underlying deficiencies and properly declined to review finding of whether the deficiencies constituted immediate jeopardy*.**

The ALJ held that Edison could appeal the findings of condition-level deficiencies on which the imposition of remedies against it was based, but not the determination that those deficiencies posed an immediate jeopardy to patients. ALJ Decision at 5, 20. The ALJ then considered the issue of whether Edison was in fact out of compliance with one or more conditions of participation, which would authorize HCFA to suspend its CLIA certificate and cancel its approval to receive Medicare payments, or whether, as Edison contended, any problems in its operations were minor and were corrected. *Id.* at 6. Based on a detailed review of each of the nine conditions with which HCFA alleged that Edison was out of compliance, the ALJ reached the overall conclusion that the "evidence plainly establishes that [Edison] was grossly incompetent in the way it conducted laboratory tests to the extent that patients were at risk from [Edison's] performance of those tests." *Id.* at 7.

Edison contended that the ALJ erred in failing to address whether the deficiencies posed immediate jeopardy. Edison Br. at 2. Edison further argued that, since the suspension was based on deficiencies which pose immediate jeopardy, the ALJ could not uphold the suspension based on such deficiencies when he declined to reach the question of whether the deficiencies constituted immediate jeopardy. *Id.* at 2-3. Instead, Edison contended, the ALJ had waived his authority to review the deficiencies and therefore, "technically as a matter of law," Edison's CLIA certificate could not be revoked. *Id.* at 82-83. In addition, Edison argued that it was prejudiced by HCFA's determination of immediate jeopardy, as distinct from the issue of the validity of the deficiency findings themselves, in that Edison was not given an opportunity to present a revised plan of correction and demonstrate renewed compliance but rather was suspended before a hearing based on the claim of immediate jeopardy could be held. *Id.* at 72. Edison argued that this action was inconsistent with CLIA's purpose of inducing laboratories to come into compliance during the review process, rather than suspending laboratories. *Id*.

While one aim of the CLIA enforcement scheme is indeed to motivate laboratories to correct noncompliance and improve quality, the preamble to the enforcement regulations points out that the central purpose of CLIA "is to strengthen the Federal oversight of laboratories in order to ensure that test results are accurate and reliable." 57 Fed. Reg. 7,218 (Feb. 28, 1992). Consequently, the goal of improving laboratory performance is made subject in the regulations to the need to protect "all individuals served by laboratories against substandard testing of specimens" and to safeguard the public "against health and safety hazards that might result from laboratory activities." 42

C.F.R. ' 493.1804(a). Edison's complaint about the regulatory bar on appeal of a finding of immediate jeopardy must thus be considered in light of the overriding and important considerations of patient protection.

The ALJ's decision not to address the determination that the deficiencies constituted immediate jeopardy, while nevertheless reaching the factual challenges posed to the underpinnings of those deficiency findings is clearly mandated by the regulations on the scope of appeal. 42 C.F.R. '493.1844(c)(6); ALJ Decision at 5. Edison is mistaken in its argument that, by not reaching the question of immediate jeopardy, the ALJ must perforce have declined to evaluate the deficiencies on which the immediate jeopardy finding was based. The issues of whether condition-level deficiencies did in fact exist and whether those deficiencies posed immediate jeopardy are analytically distinct.

Edison also contended that the charge of immediate jeopardy must have been unfounded because it was not lodged until the NJDHSS notification letter quoted in the background section which was sent September 30, 1998, while the survey concluded July 10, 1998.[6] Edison argued that HCFA's manual for state survey agencies required a warning letter to the laboratory no later than three working days after a survey where immediate jeopardy findings were made. Edison Br. at 5; HCFA State Operations Manual (SOM) at SOP 6282 (erroneously cited as 6340 in Edison's briefing). The time line spelled out in the manual provides for at least five calendar days' notice before any sanction will be imposed and for a ten-day period in which a laboratory may make corrections and demonstrate compliance. The manual states that the enforcement action will be completed within 23 calendar days of the survey and it follows that the short time frame for the state agency to report the immediate jeopardy is necessary to provide the required notice and correction opportunities to the laboratory.

In the present case, NJDHSS did not provide notice within the contemplated time frame that it had found immediate jeopardy, at least in part because its conclusion was based on later in-office review of the extensive documents and data set retrieved from Edison. *See* HCFA Br. at 2-4, and record citations therein. However, Edison failed to demonstrate any prejudice from the extra time which it had after the close of the survey before NJDHSS determined that its deficiencies posed an immediate jeopardy and initiated enforcement action. Edison eventually received the full notice period to which it was entitled prior to the imposition of sanctions, and an opportunity to submit a credible allegation of compliance as called for by the manual.

Even though Edison repeatedly asserted that it had no idea until it received the statement of deficiencies that the inspectors thought that it had serious quality problems, Edison admitted that the inspectors asked during the inspection itself that the laboratory voluntarily suspend alpha-fetoprotein testing because of the many problems the inspectors said they had seen with those tests. *See* Edison Reply Br. at 65; Tr. 2/2, at 133-34. Edison refused to do so. Tr. 2/2, at 134. Despite this warning, and despite the additional time resulting from the delay in issuance of the statement of deficiencies in which Edison could have been improving its operations, Edison still submitted an unacceptable response to the statement of deficiencies. HCFA Ex. 3.

The ALJ correctly assigned the burden of proof.

The ALJ stated that HCFA had the burden of coming forward with sufficient evidence to prove a prima facie case of non-compliance with one or more CLIA conditions. ALJ Decision at 5. Edison then had the ultimate burden of showing by a preponderance of

the evidence that it was not out of compliance with the conditions placed at issue by HCFA in its prima facie case. *Id*. The ALJ relied on a Board decision which addressed the allocation of the burden of proof in the analogous area of nursing home participation in the Medicare and Medicaid programs. *Hillman Rehabilitation Center*, DAB No. 1611, at 8-25 (1997) (Hillman I), *aff=d in Hillman Rehabilitation Center v. U.S. Dep't of Health and Human Services*, No. 98-3789, at 21-38 (D.N.J. May 13, 1999); *see also Cross Creek Health Care Center*, DAB No. 1665, at 13, n.10. (1998); *Warren N. Barr Pavilion of Illinois Masonic Medical Center*, DAB No. 1705 (1999).

The basic reasoning behind the allocation of the burden in nursing homes cases applies as well to the CLIA enforcement scheme. Just as payment to a nursing home is permissible only when it demonstrates that it is in substantial compliance with the requirements for participation (and not merely because it has a provider agreement), payment of Medicaid funds to a laboratory for services is permitted by section 1902(a)(9)(C) of the Act only if the laboratory meets CLIA requirements (and not merely because it holds a CLIA certificate).[7] *See also* Act, " 1861(e)(9) and 1861(s)(16) and (17). Just as the nursing home participation requirements are intended to protect the health and safety of the residents who are the beneficiaries of the program, the CLIA standards and conditions are intended to protect the health and safety of patients who depend on the services of the certified laboratories. *Id.*; House Rep. No. 899, 100th Cong., 2d Sess. at 8-19 (Oct. 6, 1988) (House Report). Suspension or revocation of a laboratory's certification for failure to maintain compliance is also analogous to nursing home termination in that it does not necessarily derive from reasons bearing on the integrity or reputation of the provider, unlike exclusions based on wrongdoing or fraud. Instead, laboratory sanctions, like terminations of nursing homes or Head Start grantees, raise the central issue of whether conditions for receipt of federal funds have been met. In such cases, this Board has held that the federal agency must make a prima facie case that there exists sufficient evidence to satisfy the regulatory standards for adverse action, but that the provider or grantee has the ultimate burden of persuasion. *Hillman I* at 8; *Richmond Community Action Program, Inc.*, DAB No. 1571, at 6-7 (1996); *see also Rural Day Care Ass'n of N.E. North Carolina*, DAB No. 1489, at 8 (1994), *aff'd* Civ. No. 2:94-CV-40-BO (E.D.N.C., Dec. 19, 1995) (unpublished).

We thus find that the ALJ's reliance on *Hillman I* in articulating the distribution of the burden of proof in this case was appropriate. As is clear in our discussion below, the witnesses and documentation presented by HCFA unquestionably established a prima facie case that Edison was not in compliance with CLIA conditions. The allegations against Edison in the statement of deficiencies and in the case presented by HCFA were clear, specific, and detailed. Edison's response consisted largely of personal attacks on the veracity and competence of the inspectors, self-serving denials of wrongdoing by Edison's principals, and proffers of large amounts of disorganized documentation lacking any useful explanation through expert testimony as to how particular documents might support any of Edison's defenses. Even in the few instances where some expert testimony was offered, it often failed to support the arguments made by Edison. Edison thus failed to carry its burden of proof to show by a preponderance of the evidence as a whole that it was in compliance with CLIA conditions.

We also note that, in light of the factual record of egregious and dangerous conditions prevailing at Edison as discussed below, the distribution of the burden of proof was

largely irrelevant, since HCFA clearly proved by at least a preponderance of the evidence that Edison was out of compliance with at least one condition requirement. Thus, even under Edison's proposed reversal of the burden of proof, the evidence would have sufficed to sustain the imposition of principal sanctions on Edison.

***Edison's remaining due process claims are meritless*.**

Edison also alleged generally that it had not received due process to which it was entitled, although it was not entirely clear in which respect Edison claimed that the procedural protections accorded it were lacking. *See*, *e.g.*, Edison Reply Br. at 84-86, 90-94. For the most part, Edison's arguments under this heading related to matters discussed elsewhere, such as its attack on the ALJ's refusal to evaluate the existence of immediate jeopardy, its dispute of the factual basis for the ALJ's findings of condition-level deficiencies, its claims that inspectors and/or the ALJ were hostile or biased against it, and its argument that alternative rather than principal sanctions could or should have been applied. To the extent that Edison was also making a more general complaint about whether it received all due process, however, we find no basis for its contention.

Edison received more than five days' notice before its suspension, as required, and was furnished ample information about the reasons for the action taken against it in the form of the statement of deficiencies and correspondence with NJDHSS and HCFA discussed in the background section. Edison was provided on request with a full formal hearing before the ALJ, and has now received a second impartial review by virtue of its appeal to this Board. It is true that Edison was suspended prior to the ALJ hearing, and for that reason the hearing was provided on an expedited basis. However, CLIA expressly provides authority for the pre-hearing imposition of suspension or limitation of a laboratory's CLIA certificate in cases of immediate jeopardy determinations. 42 U.S.C. ' 263a (i)(2)(A). The rationale for this provision was explained as follows in the legislative history:

> The Committee included this prehearing exclusion to allow the Secretary the opportunity to respond promptly to situations in which a laboratory's failure to comply may sacrifice the integrity of test results. Where this occurs or where a laboratory's interference with the Secretary's ability to make a determination about laboratory quality occurs, it is imperative that the Secretary have the authority either to force prompt compliance or to move quickly to protect the public health. The Committee has been informed that, under current law, lengthy court proceedings and appeals may interfere with the Secretary's ability to stop a laboratory from operating irrespective of the seriousness of the violations.
>
> The bill's requirement of a prompt opportunity for a hearing is designed to limit the potential adverse effects on a laboratory of such a pre-hearing determination by the Secretary and to allow a timely airing of the issues.

House Report at 35. As the Board noted in Hillman I, courts have held in the past that a Medicare or Medicaid provider has no due process right to a pretermination hearing. *See Hillman I* at 20-22 and cases cited therein. HCFA has simply implemented the provision for suspension of a laboratory's CLIA certificate before a hearing in cases of immediate jeopardy. *See* 42 C.F.R. " 493.1840(d)(2)(i), 493.1844(d)(2)(ii); SOM at SOP 6282.

We conclude that Edison received the procedural protections contemplated under CLIA.

Edison provided no support for its allegations of bias against it on the part of the NJDHSS inspectors or the ALJ.

Edison charged that it was unfairly targeted by the NJDHSS inspectors because of an animosity based on the race or ethnicity of its owner. No credible evidence was presented at the hearing to support this allegation of racial bias. Among the exhibits belatedly proffered with Edison's reply brief on appeal was a document purporting to be a list of clinical laboratories closed under the supervision of one of the NJDHSS inspectors (Ms. Duffy). Edison offered no justification or explanation for its failure to produce this material before the ALJ. Given the absence of any showing of good cause for the late submission, as discussed above, we declined to accept this exhibit as evidence.

Further, this document vividly illustrates how problematic submission of evidence for the first time on appeal can be. The provenance of this list is entirely unexplained; and its accuracy, reliability and statistical validity are completely untested. On its face, it raises far more questions than it appears to answer. Those unanswered questions include (1) what time period is covered and how comprehensive is this list; (2) what is the racial or ethnic makeup of the owners, operators, or employees of the laboratories inspected during the same period but not closed or of those not selected for inspection; (3) what is meant by a laboratory having been "closed under the supervision of Ms. Duffy;" (4) what deficiencies or violations were found at these laboratories; (5) how was the owner's "race" ascertained (and what is the meaning of a racial identification of Italian, Polish, Hebrew or Pakistani); and (6) what evidence is there that anyone at NJDHSS had knowledge of the ethnic background of the laboratory owners. Edison thus failed to produce any cognizable evidence whatsoever to substantiate its charge of racial animus against its owner.

Even more importantly, Edison failed to explain how any claimed selective enforcement by the inspectors could constitute a valid defense to suspension of a laboratory where the evidence in the record demonstrated that it was not complying with applicable requirements. *See Rural Day Care Ass=n*, DAB No. 1489, at 94-115 (1994) (analogous arguments rejected in a Head Start termination case). Regardless of the motives of the inspectors in their survey, the evidence produced before the ALJ, as discussed below, that Edison was grossly incompetent in the way it conducted laboratory tests to the extent that patients were at risk from" Edison performing the tests more than suffices to establish the existence of condition-level deficiencies and therefore the authority of HCFA to take the actions at issue. ALJ Decision at 7.

Edison offered no other basis on which we could conclude that its treatment by HCFA was arbitrary or capricious. Clearly, HCFA had a strong interest in protecting patients from risks of the kind found at Edison once it was confronted with the evidence. In the face of such compelling evidence, tenuous and unsupported assertions about the motivations of state inspectors in collecting the evidence are neither credible nor relevant.

Edison also asserted that the ALJ was "observed in continuous informal conversation and laughter with the State Agency Inspectors" and "did not communicate informally or laugh" with Edison representatives. Edison Br. at 12. Apart from this bald assertion of improper familiarity, Edison offered no evidence of any ex parte communications or of any basis to find bias on the part of the ALJ. If such observations were made at the time

of the hearing, Edison or its counsel should have placed them on the record then. Edison makes no claim that it tried to do so and was denied the opportunity. A thorough review of the transcripts of the hearing in this case demonstrates that the ALJ's on-the-record dealings with both parties and witnesses were even-handed and professional. Tr. 2/2, 2/3, and 2/4 *passim*. In any case, the weight of the objective evidence presented here is so overwhelmingly opposed to Edison's position that it is difficult to imagine any substantive impact that such alleged familiarity could have had on the outcome of the case.

HCFA had the discretion to apply principal rather than alternative sanctions where condition-level deficiencies were found.

Edison further contended that A[t]he enforcement authority might have used the alternative sanction route@ and that therefore Edison should be reinstated as if it had already met the requirements that might have been imposed under such alternative sanctions. Edison Br. at 37-38; Edison Reply Br. at 86-87. This argument is far-fetched and speculative.

Edison complained that HCFA arbitrarily failed to consider all the evidence submitted by Edison before accepting the State agency's recommendation, so that HCFA must not have given Edison fair consideration in imposing the sanction at issue. Edison Br. at 11, 73. There is no basis for Edison's conclusion that, simply because HCFA accepted the sanction recommended by NJDHSS, HCFA did not take "an objective look" at Edison's responses to the deficiency findings and the documentation Edison submitted. Since even the more extensive arguments and evidence which Edison proffered by the time of the ALJ hearing was unpersuasive, it is more likely that HCFA considered and rejected Edison's positions.

In addition, it does not follow that, because HCFA might have chosen, under its discretionary authority, to use another route to enforce CLIA requirements, HCFA was somehow obliged to select the course preferred by Edison or to eschew legally-available enforcement options, including those imposed on Edison here. The Act expressly states that the alternative sanctions developed under CLIA are "in addition to sanctions otherwise available under State or Federal law." Act, ' 1846(b)(2)(B).[8] Nor is there any assurance that Edison would have made necessary corrections and achieved compliance under any set of alternative sanctions, given Edison's failure even to submit an acceptable plan of correction.

Finally, Edison pointed to no legal authority that would permit it to be reinstated on the grounds that it should be "deemed" to have met requirements, as it suggested, without any actual showing that it did meet all conditions for participation. The ALJ was empowered to determine whether the remedy imposed by HCFA was authorized because of Edison's noncompliance with one or more CLIA conditions. 42 C.F.R. ' 493.1844(b)(1). However, HCFA, not the ALJ, had the discretion to make the determination of which remedy to impose. 42 C.F.R. " 493.1806 and 493.1807.

Edison was properly subject to inspection by NJDHSS.

In its briefing on appeal, Edison attacked the legitimacy of the inspection by NJDHSS which found the deficiencies at issue here. Edison asserted that it applied in 1995 for accreditation by the College of American Pathologists (CAP) Clinical Laboratory Accreditation program, which Edison asserted had "deemed status" from HCFA, and that Edison had received a favorable inspection and recommendation from CAP. Edison

Br. at 8; *see generally* 60 Fed. Reg. 7,774 (Feb. 9, 1995) (approval of CAP as accrediting organization for CLIA). Further, Edison asserted that NJDHSS did not have deemed status, apparently implying that somehow the survey by NJDHSS was improper or irrelevant. Edison Br. at 8.

Edison's argument in this regard misunderstands the effect of provisions allowing HCFA to deem a laboratory to meet all CLIA standards when accredited by an organization or State licensure program with requirements that are at least as stringent as those under CLIA and have been approved by HCFA. 42 C.F.R. ' 493, Subpart E. A laboratory with accreditation is not immune from inspection by a State agency acting on behalf of HCFA, where, as here, it has been the subject of a complaint, even though the accrediting organization handles routine inspections. In fact, the notice approving CAP stated that HCFA or any State agency could still conduct validation or complaint investigation surveys. 60 Fed. Reg. 7,774, 7,776. Furthermore, HCFA is not obligated to ignore the results of an inspection finding serious deficiencies at a certified laboratory simply because an organization had earlier accredited the laboratory. In addition, the record evidence in this case shows that CAP also found Edison to be incompetent in its laboratory operation, although it did not find conditions so egregious as to constitute immediate jeopardy during its October 30, 1998 inspection visit. *See* HCFA Ex. 9, at 1.

CLIA provides authority for inspection of any certified laboratory:

> The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it be submitted to the Secretary.

42 U.S.C. ' 263a(g). The Secretary implemented this inspection authority in regulations with which all CLIA-certified laboratories must comply. 42 C.F.R. " 493.1771, 493.1773, and 493.1780. Among those provisions are requirements to permit HCFA or its agent to conduct inspections to follow up on complaints, to validate the performance of the accrediting body, and to reinspect "at any time to evaluate the ability of the laboratory to provide accurate and reliable test results." 42 C.F.R. ' 493.1773(a) and (e).

The inspection by NJDHSS resulted from a complaint. HCFA Ex. 1, at 1. There is thus no question that NJDHSS was authorized, as agent of HCFA, to follow up with an inspection. Edison complained at length of the disruptiveness and scale of the survey efforts. *See*, *e.g.*, Edison Br. at 7; Edison Ex. 21, at 62. However, the conduct of the survey was not properly at issue in this case.[9] The issue before the ALJ was whether HCFA had a basis to impose principal sanctions because of Edison's failure to meet required conditions. It would be inappropriate for alleged procedural flaws in the survey process to be made the issue in a CLIA decertification case, just as we have previously held in the provider termination context. *Hillman I* at 46; *Hillman II* at 20. If a laboratory could seek to force HCFA to maintain its certification despite deficiencies on the grounds of alleged procedural improprieties in the survey, the goal of CLIA to assure that only qualified laboratories participate in federal programs would be defeated.

Factual Arguments

The core of the case against Edison was the finding by the ALJ that Edison failed wholesale to provide laboratory services of acceptable quality, thus failing to comply with nine specific CLIA conditions. ALJ Decision at 6. The laboratory tests at issue included nephelometer testing of prealbumin, LDL tests, alpha fetoprotein testing, and IFA testing. Edison contended that the ALJ erred in each area in finding that its testing was deficient and conducted incompetently. *See*, *e.g.*, Edison Br. at 15, 18, 20, 23, 29. We address the evidence relating to these areas of testing below. Edison argued broadly, however, that HCFA failed to meet its burden of proof because its prima facie case was based on mere allegations and false statements by HCFA witnesses, rebutted by testimony from Edison's witnesses. *See*, *e.g.*, Edison Br. at 52-53, 57; Edison Reply Br. at 51, 53-54. We therefore address first the broad attack on the HCFA witnesses, particularly the NJDHSS inspectors.

The ALJ's assessment of the credibility of witnesses appearing before him was fully explained by him and adequately supported.

Edison argued that the ALJ erred in crediting the testimony of witnesses that testified against Edison and not relying on the witnesses presented by Edison. In general, we defer to the assessment of witness credibility by an ALJ who has the opportunity to observe their demeanor in testifying. Moreover, here, the ALJ stated his rationale for finding the testimony of HCFA's witnesses more persuasive and plausible.

Edison attacked the overall credibility of the inspectors' testimony. Edison's attack on appeal was based mostly on unsupported after-the-fact allegations. For example, Edison asserted that one inspector was "summarily fired by NJ State Department of Health and HCFA agency effective May 7, 1999 at 2:30 PM," and that this action should be taken to substantiate Edison's claims that the inspector made "false allegations" and was herself "the problem" rather than the problem resulting from the laboratory's own practices. Edison Br. at 71. Edison offered no evidence whatsoever to support this charge. HCFA responded that the inspector in question "retired voluntarily after 28 years of distinguished service and received a letter of appreciation from HCFA." HCFA Br. at 35. In its reply, Edison did not respond to this information except by repeating the charge without substantiation. *See* Edison Reply Br. at 94. We find no basis to rely on these unsupported claims to undermine the testimony presented by HCFA.

Edison also asserted in its reply brief that two clinical chemists presented as experts by HCFA were a "farce," because they had limited experience with nephelometers and because the witnesses might have been intimidated by the possibility of an intrusive inspection by the same surveyors. Edison Reply Br. at 34-35. The witnesses were both employed as clinical chemists in hospital laboratories in New Jersey for more than 15 years. Tr. 2/3, at 6 and 31. While one expert (Dr. Kampa) stated that his laboratory rarely did prealbumin tests, he also testified that he was familiar with them. *Id.* at 13-14. He further testified that his conclusion that Edison's nephelometer looked bogus and should have triggered review within the laboratory was based on the conclusion that obtaining multiple repetitions of results identical to two decimal points within a run of less than one hundred samples was "pretty much impossible." *Id.* at 17; *see also id.* at 14-19, 26-27. Edison did not prove that it was necessary for an expert chemist to run frequent nephelometer tests in order to know how the device operated and to be able to interpret the statistical significance of such results. Furthermore, the second expert (Dr. Warkentin) testified that he had been responsible for a nephelometer from the same

manufacturer for more than ten years, until the preceding six months. *Id.* at 36. He too testified that his laboratory would perform trouble-shooting rather than release such results if, like Edison's, they did not fit any normal distribution of laboratory results. *Id.* at 34-35. He stated that the patient results which Edison had reported to physicians looked "specious" or "false" to him on their face because he had "never seen data like this in [his] 25 years of being a clinical biochemist." *Id.* at 39. Finally, Edison did not lay any foundation to suggest that either witness was intimidated or improperly influenced in any way.

In any case, both witnesses were offered for the limited purpose of corroborating the inspector's testimony concerning the inexplicable nature of Edison's nephelometer results. Ultimately, however, the responsibility for explaining how the results could have been obtained in a manner assuring their authenticity was Edison=s. Edison did not meet that responsibility on this record.

In many areas, Edison's testimony and evidence was simply obfuscatory, and did not rebut the central points made by HCFA. For example, in regard to LDL testing, Edison did not dispute that it repeated nearly all its LDL tests, and generated results on the repeat tests that themselves raised questions of unaccountable bias.[10] *See* ALJ Decision at 11; Tr. 2/2, at 112-118; HCFA Exs. 39, at 1, 40, at 1, and 88, at 15. The ALJ inferred that such high repeat rates and unexplained bias in repeat results suggested not careful review to eliminate problem results but rather lack of confidence in any of the initial results. ALJ Decision at 11. Dr. Patel, Edison's owner and supervisor, testified as to possible reasons for repeating LDL tests at the discretion of technician, such as cloudy specimens resulting from cetrifuging problems. Tr. 2/4, at 290-97. But, as the ALJ noted, such explanations only reinforce the fact that Edison's LDL testing results were problematic and unreliable, at best. ALJ Decision at 11-12.

In every instance where the testimony presented by Edison did conflict with that of HCFA's witnesses, the ALJ explained fully why he found Edison's witnesses to be uncorroborated and unpersuasive. For example, Dr. Patel offered a possible explanation for the implausible nephelometer readings (discussed below) that was speculative, was not raised prior to the hearing, was not corroborated by the manufacturer's representative who testified for Edison, and was contradicted by other test runs. *See* ALJ Decision at 9; Tr. 2/4, at 200-09, 284-85. The ALJ thus had ample reason to decline to credit Dr. Patel's explanation.

We find that Edison has failed to provide any evidence to undermine the ALJ's assessments of the witnesses' credibility.

***Substantial evidence in the record supported the ALJ's finding that Edison failed to provide laboratory services at an acceptable level of quality*.**

Edison failed to prove that nephelometer results reported by it were authentic or accurate.

One of the devices used by Edison in performed testing was a nephelometer which used scattered light for automated analysis of blood samples to produce a computerized printout of results. ALJ Decision at 7; Tr. 2/2, at 52-54. This device was employed in performing a variety of tests, such as those for prealbumin in the blood, a nutritional status marker. ALJ Decision at 7; Tr. 2/2, at 55. HCFA presented expert testimony that a pattern of replicating results for different specimens found in Edison's data, results that were identical out to two decimal places, were "bogus" and could not represent

actual test results. ALJ Decision at 7; Tr. 2/2, at 65-66; Tr. 2/3, at 8, 39; HCFA Exs. 75-83.

Much of Edison's evidence and argument in relation to the nephelometer results was directed at refuting the charge that the challenged results were falsified, mostly by arguing that human intervention could not have intentionally created these results because the testing system was automated. *See*, *e.g.*, Edison Br. at 43. The ALJ found that neither HCFA nor Edison was able to demonstrate convincingly how the unusual replicating results might have been obtained. ALJ Decision at 8. Edison offered the possibility that the replication was caused by software in the nephelometer "binning" close results and reporting them as the same precise number.[11] The record evidence supported the ALJ's finding that this argument was "fanciful" and based on unsupported speculation. ALJ Decision at 9. The theory conflicted with testimony from representatives of the equipment manufacturer, including one offered by Edison itself, which suggested that the results that Edison obtained would raise suspicions that "there might be something wrong" and that the software used by Edison did not "bin" data in clusters of this kind. Tr. 2/3, at 208-09 (Grey). Further, the idea that such data could occur through some non-aberrant operation of the equipment was contradicted by Edison's own testing which did not show the alleged clustering effect. ALJ Decision at 9; HCFA Ex. 49, at 11. Edison's arguments in this regard were self-contradictory. On the one hand, Edison claimed that the replicating nephelometer readings were the normal functioning of the software; on the other hand, it argued that the replication was "non-recurrent" and that it was monitoring all nephelometer results for replication. Edison Br. at 18. As the ALJ pointed out, Edison's own exhibits showed that its staff had noticed and questioned the pattern of replicating results on at least one occasion. ALJ Decision at 8; Edison Ex. 23, at 279, 282, 286.

Edison offered considerable evidence that the nephelometer automated the readings in such a way that human intervention to directly produce a desired result would not have been possible. *See*, *e.g.*, Edison Br. at 17; Tr. 2/2, at 186-214. However, Edison failed to prove that the pattern of repeating results was likely to have been an authentic outcome from properly handled samples. Moreover, Edison did not show that it took any steps either to determine the cause of the errors or to prevent their reporting to physicians who would rely on them in the treatment of patients. The deficiency finding here did not depend on proof of intentional wrong-doing. Rather, it sufficed that HCFA presented prima facie evidence that results reported by Edison were questionable on their face and Edison did not present persuasive evidence that it took any appropriate action to investigate the problem or prevent patients from being harmed by erroneous results. The ALJ correctly applied criteria for weighing Edison's conduct that were rooted not in proving fraud or intentional misconduct but rather in evaluating failure to meet requirements of competence and compliance with the conditions set for laboratory testing. Based on those criteria, Edison failed to offer any plausible explanation for the nephelometer results that would justify its having had sufficient confidence in them to report them to physicians as authentic and accurate results.

Edison pointed to nephelometer results from two other laboratories that were submitted by HCFA as comparisons and argued that they showed similar replications. Edison Reply Br. at 15.[12] However, a comparison of the exhibits shows that the occasional repetition of one or two results in the other laboratories' data contrasts dramatically with

the large clusters of identical results (as many as six to ten results) for different patients found in the data from Edison. *Compare* HCFA Exs. 73, at 8, and 74, at 11-12, *with*, *e.g.*, HCFA Exs. 77, at 11-12, 78, at 13-14, and 83, at 10-11. Edison simply failed to offer any persuasive rebuttal to the evidence that its nephelometer results were inauthentic, whether or not they were deliberately fabricated.

Edison failed to prove that it competently performed the other testing at issue.

The other tests which HCFA alleged were incompetently performed by Edison staff included alpha fetoprotein tests, LDL tests, and IFA tests. The ALJ's findings in regard to each of these were also supported by substantial evidence based on the whole record.

In regard to alpha fetoprotein testing, Edison's main argument was that the inspectors did not use the correct methodology to evaluate the accuracy of the test result calculations. The test is mainly used to identify fetal abnormalities. The calculations used a multiple of median (MoM) to define an abnormal result for a particular patient based on her gestational week. Edison contended that the apparent errors in its calculation actually reflected its use of software that adjusted the MoM for such additional factors as weight, race, menstrual cycle, number of pregnancies, and diabetic status. Edison Br. at 23-26, 46-47. The ALJ did not credit this claim. ALJ Decision at 10-11. Originally, the inspectors found that thirteen of sixteen MoMs reviewed were incorrectly calculated, based on the product insert instructions for those calculations provided to them by Edison. Tr. 2/2, at 143-44; HCFA Ex. 2, at 41. In its plan of correction, Edison indicated that it had used a weight correction factor which it alleged then demonstrated the calculations were accurate. HCFA Ex. 3, at 41. The inspectors found that four of the calculations were inaccurate even using the weight correction factor suggested by Edison. Tr. 2/2, at 144-48. At the hearing, Dr. Patel asserted that the remaining errors could be eliminated by considering the "right, most important critical" factor, which he said was the mother's race. Tr. 2/4, at 303. The ALJ found that Edison failed to demonstrate how the shifting variety of "special" or "critical" factors would establish the accuracy of the remaining four apparent errors. ALJ Decision at 11. We agree. Edison should have been able to explain correctly the basis for its calculations at the time of the survey, yet even long after the hearing, Edison was continuing to search for additional factors to explain these discrepancies.

Furthermore, the ALJ found that Edison offered no credible evidence to rebut HCFA's evidence of late performance or reporting of alpha fetoprotein tests or of misleading information supplied with the results. ALJ Decision at 10-11. Timeliness is particularly important in reporting these results since decisions about a pregnancy may be based on them. *Id.* at 9; Tr. 2/2, at 131, 163-66. Edison claimed that the evidence of untimeliness credited by the ALJ was erroneous because the dates on the reports were actually reprinting dates rather than reporting dates, and that this was evident on the face of the reports. Edison Br. at 27-28, 47. A review of the reports cited does not support Edison's claims. Some of the laboratory reports do have accompanying interpretative reports that show reprinting dates. *See* HCFA Ex. 92, at 39-41. However, this evidence does not establish that timely reports were actually made to the affected physicians or patients at some earlier date. Edison produced no evidence of those original reporting dates even though it asserted that the actual reporting dates were always obtainable on their computer screens. *Cf.* Edison Reply Br. at 71. It was Edison's, not HCFA's, burden to

demonstrate timely and accurate reporting of these time-sensitive results. Therefore, it does not suffice to support Edison's defense to show that these reports were reprints without showing when original reports were printed and provided to physicians.

We discussed above in relation to credibility the repetition of nearly all LDL cholesterol tests. We find reasonable and well-supported the inference drawn by the ALJ that these tests had not been shown to be accurate and reliable. ALJ Decision at 11-12. In its brief on appeal, Edison alleged that it repeated a much smaller percentage of tests than found by the ALJ. *Compare* Edison Br. at 22 *with* ALJ Decision at 11. Yet in its plan of correction, Edison did not dispute the very high frequency of retesting but only claimed that this observation confirmed its own active monitoring process. HCFA Ex. 3, at 28. Edison argued that the quality of its LDL testing was established by its success in proficiency tests for cholesterol, but the ALJ rejected this argument because the proficiency tests cited were for HDL (high density lipoproteins) not LDL and because such success would not in any case necessarily contradict the NJDHSS observations about Edison's unacceptable techniques. ALJ Decision at 12. On appeal, Edison cited to various documents which it asserted showed excellent calibration, instrument maintenance and function checks, and quality control and validation. Edison Br. at 22, citing Edison Exs. 21, at 65 and 22, at 319-49. Edison asserted that LDL results "were never altered, fabricated, or falsified." Edison Br. at 22. Even if these documents were what they purport to be and even if they covered the relevant time frame, they would not explain the need for constant repetition of LDL tests if Edison were generating adequate and reliable results.

Furthermore, the inspectors found that Edison was using reagents that it produced in the laboratory, rather than standardized commercial reagents, but had neither proper controls nor validation for them. HCFA Ex. 2, at 27-29. Edison did not deny in its plan of correction that it had not had a control methodology in place for this testing for more than a year. HCFA Ex. 3, at 28. Edison also claimed that its failure to produce adequate validation studies for its in-house reagents was not significant because it followed the same chemical formula in producing them as in manufacturer's literature. The ALJ reasonably accepted HCFA's evidence that the absence of controls and of careful validation of reagents contributed to "highly unreliable" results. ALJ Decision at 12.

In the case of IFA testing, the inspectors found widespread errors and problems in performing and reporting test results in the evaluation of such infectious conditions as herpes, measles, and syphilis. *See generally* ALJ Decision at 12-14; Tr. 2/2, at 235-264; Tr. 2/3, at 47-56, 68-72; HCFA Ex. 2, at 31-41. In the majority of these areas, Edison did not contest the existence of the problems but alleged that it had taken corrective action that would have been verified if its allegation of compliance had been accepted and another survey performed. *See* Edison Br. at 29-34. However, as the ALJ noted, the plan of correction that Edison submitted as its credible allegation of compliance, while claiming some corrections, introduced additional sources of error into IFA testing if it was implemented as written. ALJ Decision at 13; Tr. 2/3, at 55-56, 72; HCFA Ex. 3, at 32. The claimed corrections amount to concessions that testing was not properly performed in the past. For example, the inspectors found that Edison staff had been attempting to read fluorescent results without having a dark room as required. *See* ALJ Decision at 13; Tr. 2/2, at 239-40. Edison responded that "[s]ince the inspector [sic], IFA test procedures are performed in a dark room with the fluorescent microscope." Edison

Br. at 29. This statement simply corroborates that proper practices were not followed before the inspectors' visits. Similarly, the inspectors found that Edison staff failed to perform proper dilutions and controls for various tests, including anti-DNA screening, and Edison responded that it had "clearly corrected" the deficiency as of November 1998. *Compare* ALJ Decision at 13; Tr. 2/3, at 47-48 *with* Edison Br. at 31. But this contradicts Edison's claim that its allegation of compliance submitted in October 1998 should have been accepted as credible.

Edison fired the technician who, it said, had been diluting samples improperly. Edison Br. at 44; *see* Tr. 2/2, at 254, 258-60. This action amounts to an acknowledgment of poor technique and certainly does not contradict the inspection findings. HCFA Ex. 2, at 35-37. Not only were the dilutions used wrong, but the results reported were found by the inspectors to be impossible with the dilutions used and the controls recorded did not exist. *Id.* at 35. Edison's plan of correction merely promised to research these allegations. HCFA Ex. 3, at 35. Edison claimed that it now posted charts with the correct dilution methods, but did not explain the apparent inauthenticity of the earlier reports. *See* Edison Br. at 43-44.

Besides claiming that it had corrected many of the conceded problems, in this area as with many others, Edison simply insisted that the findings and testimony of the inspectors should have been disregarded and the testimony of its owner and employees accepted. For example, Edison argued that the ALJ was wrong to accept testimony that IFA test materials were improperly stored because Edison claimed that its staff had shown the inspector that kits stored at improper temperatures contained only slides and not the sensitive test materials. Edison Br. at 30; Edison Reply Br. at 75; ALJ Decision at 13; *see also* HCFA Ex. 3, at 32. As discussed above, we defer to the ALJ's clearly-explained and reasonable assessment of the relative credibility of the witnesses.

Conclusion regarding Edison's failure to meet accepted standards of quality in laboratory services.

We conclude that the ALJ's primary finding that Edison "failed to provide laboratory services in a manner that complied with accepted standards for quality" is amply supported by the evidence in the record. We therefore uphold this finding. Given that a single condition-level deficiency would suffice to establish HCFA's authority to impose a principal sanction, this finding alone would be enough to sustain the revocation. As discussed below, however, we find that the additional deficiency findings made by the ALJ were also supported by the record.

Substantial evidence in the record supported the ALJ's findings that Edison failed to comply with eight other conditions.

Much of the evidence discussed above and analyzed in more detail in the ALJ Decision is also sufficient to establish the lack of compliance with other conditions that were necessarily deficient to permit the wholesale failures of laboratory operations to have occurred on the scale found. None of the evidence put forward by Edison successfully rebutted the inferences to this effect drawn by the ALJ. ALJ Decision at 15-20.

Thus, the evidence of egregious performance failures in regard to the nephelometer results and other testing discussed above, in itself, sufficed to establish that Edison could not have been following adequate, written quality control procedures as required by 42 C.F.R. ' 493.1201. ALJ Decision at 15. In addition, that evidence also supported finding noncompliance with the condition-level requirement that a qualified laboratory

director provide overall management meeting applicable standards. ALJ Decision at 15-16; 42 C.F.R. " 493.1441 and 493.1445. Among the standards for which the laboratory director is responsible are the employment of competent staff, ensuring that the test methodologies and performance are as required to provide timely, accurate and reliable results, and maintaining quality control. The ALJ correctly found that the evidence of systemic failures by Edison to meet quality requirements was sufficient for him to infer that the laboratory directors could not have been adequately discharging their responsibilities. Similarly, given what the ALJ properly described as Edison's "wholesale failure" to "monitor, evaluate the quality of, and address deficiencies in its testing program," it follows that no technical supervisor could have been taking the necessary steps to resolve technical problems and ensure that no patient test results are reported absent correction thereof. *See* ALJ Decision at 16; 42 C.F.R. " 493.1447, 493.1449 and 493.1451.

Edison's briefing on these conditions was essentially peripheral. For example, Edison argued that it should not have been found out of compliance with the requirement for a qualified laboratory director. Generally, its argument was that it rebutted the evidence that the deficiencies were serious enough to violate conditions rather than standards. Edison Br. at 48. Having concluded above that ample evidence supported the ALJ's findings as to the many testing deficiencies, we do not find that this defense gives any independent reason to believe that the laboratory was adequately directed.

Edison also argued that it should not have been found deficient with this condition on the additional basis that the laboratory director did not adequately oversee proficiency testing. *Id.* at 49. Edison admitted that a day-shift supervisor was found to have tested proficiency samples for IFA testing (which are supposed to be run in the same way as normal laboratory specimens in order to test laboratory performance) even though a night-shift technician normally did IFA testing. *Id.* at 49. However, Edison contended that the same staff member ran all the samples that day because of staffing problems. *Id.* at 49-50. Even if accurate,[13] the response that both normal and proficiency testing samples were run the same way that day answers only the concern that proficiency tests might have been "singled out for special treatment". *Cf. id.* at 50. However, the failure to have adequate staffing to handle samples in the routine manner by the staff member whose skills are normally depended on is itself simply more evidence of the widespread dysfunctions in the systems for which the director and supervisors are responsible. Similarly, Edison's attempt to address the charges of inadequate supervision in the reading of cytology slides by testimony that a cytologist reviewed both all abnormal and a sample of normal slides falls far short of addressing the failure of supervision in the laboratory to adequately supervise operations to guarantee quality tests and competent staff. *Cf. id.* at 51-52; Tr. 2/4, at 244-51. The failures of quality control in the cytology area alone covered eight pages in the statement of deficiencies. HCFA Ex. 2, at 61-69. The cytologist testified that he did not think there was "very much there" in the deficiency findings since the subsequent CAP inspections did not find "anything significant" in this area. Tr. 2/4, at 254. However, many of the findings in this area were either acknowledged as "oversights" or as requiring changes in procedures or practices to correct. HCFA Ex. 3, at 63-64, 67-69.

The ALJ further found that the condition-level requirement for qualified general supervisors in fields where testing is performed to provide day-to-day supervision of

tests and personnel could not have been met given the breakdowns in laboratory operations. ALJ Decision at 16-17; 42 C.F.R. " 493.1459, 493.1461, and 493.1463. The ALJ also found that the inability of Edison's supervisors to answer inspectors' questions about laboratory operations was "strong evidence" of their lack of awareness of testing practices under their "ostensible authority." ALJ Decision at 17. One of the inspectors testified as follows:

> So there were two supervisors [Gopimath Mallya and Ranjit Jani] there all of the time with us. He, too, [Jani] whenever we asked him questions, would say, no, he wasn't the right person to ask the question. Yet these are the people who are responsible for the operation of the laboratory. So how could they not know how the testing was done or how the testing was controlled or what and where the records were?

Tr. 2/2, at 47. Edison responded that the problem lay with the inspectors requesting too many records and expecting day-shift supervisors to respond to questions about how a specific sample was tested at night. Edison Br. at 52-55. Instead, Edison suggested that the inspectors should have inquired in writing about such tests so that night-shift technicians could respond. *Id.* at 55. The ALJ reasonably credited the inspector's testimony that the supervisors' inability to answer appropriate questions or to produce records for review was highly unusual and suspect. ALJ Decision at 17; Tr. 2/2, at 47-48.

The ALJ found that Edison also failed to comply with requirements to establish and follow a comprehensive quality assurance program, including monitoring quality, identifying problems, and making corrections. ALJ Decision at 17; 42 C.F.R. ' 493.1701. Edison denied that it had deficiencies in this area serious enough to reach the level of non-compliance with a condition, since the later CAP re-inspection did not find them. Edison Br. at 56-58. We discuss this claim below in light of the more general weight Edison attributed to the CAP inspection findings. However, we note that results on other inspections do not invalidate the substantiated findings of the inspection at issue here. Edison also argued that the deficiencies found by NJDHSS inspectors were corrected immediately or were the fault of the inspectors who "either read the wrong instructions used for a particular test or questioned the wrong people," so that "the HCFA Statement of Deficiencies was not a true measure of the laboratory's capabilities." *Id.* at 58. This response is not persuasive in light of the "wholesale failure" found by the ALJ in monitoring, evaluating and correcting problems with testing programs, such as the numerous flaws in the various IFA tests.

The ALJ further found Edison out of compliance with conditions governing the performance of general immunology and routine chemistry tests. ALJ Decision at 17-18; 42 C.F.R. " 493.1241 and 493.1245. The ALJ found that the standards adopted for each of these areas of testing were so pervasively violated as to constitute non-compliance with the overall conditions. *Id.*; 42 C.F.R. " 493.1205 - 493.1221. Edison offered little in defense of its performance of the tests in this area beyond "explanation" of its errors and claims of correction after the NJDHSS inspection. Edison Br. at 59-61. For example, in regard to the false positive results in hepatitis testing about which HCFA expressed particular concern, Edison claimed that a re-analysis showed that "only" 2.8% of its hepatitis results were reported incorrectly. *Id.* at 60; *see* HCFA Ex. 7, at 2.

The ALJ also found that Edison failed to comply with a condition-level requirement for participation in a proficiency testing program. ALJ Decision at 18-19; 42 C.F.R. ' 801. The ALJ rejected Edison's explanation that the performance of IFA tests by a supervisor who was not an employee "who routinely perform[s] the testing in the laboratory, using the laboratory's routine methods," was excusable as an exceptional event resulting from employee absences. ALJ Decision at 19; 42 C.F.R. ' 801(b)(1). We agree with the ALJ that (1) such a practice defeats the entire purpose of proficiency testing since the supervisor's proficiency says nothing about the competence of the laboratory employees to routinely perform these tests, (2) the attestations of Edison's directors that these samples were tested in the same manner as routine test specimens were not correct, and (3) Edison failed to carry its burden to affirmatively establish that employees doing routine testing performed proficiency testing. ALJ Decision at 19.
Finally, the ALJ found Edison out of compliance with the condition for a patient test management system. ALJ Decision at 19-20; 42 C.F.R. '' 1101 - 493.1111. Among the problems that the ALJ noted in this area were Edison's performance of Lyme testing without required requests from physicians for that test and problems with Edison's record system for identification of patient specimens. Edison disputed the factual bases of these findings, but the ALJ credited the inspector's testimony and documentation. Edison Br. at 66-70. We see no basis to disturb the ALJ's conclusion.
Edison failed to prove that it violated only standard-level, rather than condition-level, requirements.
Edison acknowledged that there were deficiencies in its laboratory's operations during the inspection but argued that its deficiencies were not serious enough to rise to the level of failing to comply with conditions of participation, but rather constituted simple noncompliance with subsidiary standards. Edison Br. at 35-36.
While Edison claimed that 80% of the deficiencies were the result of errors or miscommunication by the inspectors, it did not dispute the accuracy of many of the specific factual findings on which the ALJ relied in finding condition-level violations. In other cases, Edison's evidence was simply not persuasive in rebutting the overwhelming evidence presented by HCFA of careless and incompetent operations.
It is true, as Edison stated, that CAP returned after the NJDHSS's inspection to re-survey and determine why the NJDHSS found such serious deficiencies relatively close in time to a CAP inspection on July 28, 1998 that had not made similar findings of condition-level deficiencies or immediate jeopardy. Edison Br. at 39, 56. Edison argued that its history of accreditation by CAP and the fact that CAP would have been willing to continue Edison's accreditation if it took corrective actions must mean that NJDHSS was wrong in finding condition-level deficiencies. *Id.* at 57.
A closer look at the history of CAP inspection reports, however, is hardly reassuring. In March 1998, CAP did recommend re-accreditation and described the laboratory operators as well-qualified, but it also commented that the "specific problems that plagued them in the past have been more than adequately solved" and expressed confidence that Edison would "correct the deficiencies cited." Edison Ex. 23, at 7-8. CAP inspected again in July 1998 and in September 1998 extended Edison's accreditation. Tr. 2/3, at 164-67; Edison Ex. 21, at 45-47.
In October 1998, the CAP inspectors returned, looking specifically at the discrepancies between the earlier CAP inspections and the NJDHSS report. They found "a number of .

. . deficiencies indicating a partial or complete lack of compliance with either CAP Standards or CLIA >88 requirements." Edison Ex. 21, at 26 (same as HCFA Ex. 8). Overall, the CAP team wrote that the "fundamental problem in this laboratory is a lack of cognitive ability to understand sound principles of laboratory medicine and documentation requirements." *Id.* at 27 (same as HCFA Ex. 9, at 1). While the CAP inspectors disagreed with some of the specific NJDHSS findings, their report noted that they visited only during the day "when very little analytic activity occurs" and only for one day. *Id*. at 27. Edison claimed that none of the deficiencies found by CAP would have required more than 30 days to address, but that assertion overlooks the fact that the CAP inspection took place almost 30 days after Edison had received notice of the immediate jeopardy findings and several months after many of the problems had been pointed out to them by state inspectors. *See* Edison Br. at 57. Clearly, this supports the evaluation by HCFA and NJDHSS that Edison's allegation of compliance as of October 9, 1998 was not credible. *See* HCFA Ex. 3; HCFA Ex. 7, at 2; Edison Ex. 21, at 39-40. Furthermore, much of the CAP report substantiates charges by the NJDHSS inspectors and undercuts testimony by Edison staff. Edison Ex. 21, 27-32. For example, the report stated Edison had switched to commercial reagents rather than the in-house preparations criticized by the NJDHSS, but clearly Edison did not understand the importance of the changes. The report noted that the CAP inspectors told the laboratory that

> it was impossible for the in-house preparations to be "exact chemical formulations as the commercial manufacturer" who had FDA 510(k) clearance for similar reagents. Their naive response was "how would we go about obtaining 510(k) approval?" The laboratory did not perform any validation procedures on the new reagents except for linearity studies, which were completed 10 days after patient testing began. Currently, there are no specific, detailed procedures for these new reagents. The laboratory is utilizing the procedures from the old reagents and doesn't understand why this is a problem. They appear to simply "accept" all manufacturers' information and data with little in the way of internal validation . . .

Edison Ex. 21, at 30. This finding undercuts Edison's claim in the plan of correction submitted as an allegation of compliance that the citation for improper use of inadequately validated in-house reagents was "inspector error," because there were --

> no "in-house methods" in use to perform routine chemistry profile testing[,] reagents were prepared in the lab for established procedures using the exact chemical formulations of commercial (BMC) reagent manufacturer's [sic] as listed on the reagent literature references . . . The literature references were shown to the inspector on-site. We showed validation studies to the inspector because there were no "in-house methods" we were not required to validate sensitivity, specificity, interfering substances, reportable range, etc.

HCFA Ex. 3, at 47; *see also* HCFA Ex. 3, at 28; Edison Br. at 44-45; Edison Ex. 21, at 37.

CONCLUSION

Conclusion regarding other condition-level deficiencies.

We find that substantial evidence supported the ALJ's conclusions about the eight other condition-level deficiencies.

Based on the foregoing analysis, we sustain the ALJ decision in its entirety and uphold the revocation of Edison's CLIA certificate and cancellation of Edison's approval to receive Medicare payments.

JUDGE

Cecilia Sparks Ford

Donald F. Garrett

M. Terry Johnson
Presiding Board Member **FOOTNOTES**

[1] Because the ALJ upheld a suspension imposed based on immediate jeopardy, upon issuance of his decision, the suspension automatically converted to a revocation under the regulations. ALJ Decision at 5, 20; 42 C.F. R. 493.1844(d)(4)(ii).

[2] The "condition-level requirements" are defined as those set out as conditions in 42 C.F.R. Part 493, Subparts G through Q. 42 C.F.R. ' 493.2. "Immediate jeopardy" is defined as --

> a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public.

42 C.F.R. ' 493.2.

[3] HCFA alleged that Edison was out of compliance with a tenth condition, but that condition was not cited in HCFA's notice letter and the ALJ declined to consider it. ALJ Decision at 14. HCFA did not appeal that ALJ ruling and therefore we do not discuss that condition in this decision. *See* HCFA Br. at 2, n.1.

[4] In reviewing this case, we have considered each and every argument presented by the parties. Although particular issues may not be discussed in detail in this decision, we have nevertheless considered all of the points in the parties' briefs in reaching the conclusions set forth here.

[5] We note that Edison previously attempted to submit additional exhibits without permission and without a showing of good cause to the ALJ after the close of the evidentiary hearing. ALJ Decision at 2. The ALJ did not admit those exhibits. The attachments to Edison's reply brief on appeal do not appear to fit the description given by the ALJ of the previously-rejected exhibits.

[6] Edison repeatedly characterized this as a 90-day delay, but the time frame speaks for itself. *See*, *e.g.*, HCFA Ex. 4, at 2 (Edison letter to NJDHSS).

[7] HCFA is permitted, but not required, under the Act to continue Medicare payments to a non-compliant laboratory for up to one year while employing alternative sanctions in lieu of canceling its approval for Medicare payment. Act, ' 1846.

[8] HCFA is permitted, but not required, under the Act to continue Medicare payments to a non-compliant laboratory for up to one year while employing alternative sanctions in lieu of canceling its approval for Medicare payment. Act, ' 1846.

[9] We note that the regulations provide a limited list of initial determinations which may be appealed under CLIA and specifically provide that any actions not listed as initial

determinations are not subject to appeal. 42 C.F.R. ' 493.1844(b) and (c). The scope or conduct of an inspection is not among the appealable initial determinations. *Id*.

[10] In the statistical sense used here, bias means that the percentage of repeat results that were consistently either higher or lower than the original test results in a run was far greater than should have resulted from normal analytical variation. ALJ Decision at 11.

[11]" Binning" was used at the hearing to mean reporting results that were actually spread over a range but clustered in the same vicinity as if they were all at precisely the same number (presumably near the center of the range). ALJ Decision at 9.

[12] Actually, Edison made several somewhat inconsistent assertion with respect to the nephelometer data from the two other laboratories. Edison stated that the ALJ pointed to one replication of results at the hearing but those data were from Quest Laboratories, not Edison. Edison Br. at 19. The transcript shows that the exhibit in question was clearly identified at the hearing as coming from one of the other laboratories and the ALJ merely noted that HCFA's witness overlooked that one value was repeated one time in the results in that exhibit. Tr. 2/2, at 81-82; HCFA Ex. 73. This point did not undercut the witness's testimony that the major clusters of identical results shown in multiple exhibits of Edison's data were inexplicable and unlike anything in the examples from the other laboratories. *See* Tr. 2/2, at 57-84. Edison also argued that the other laboratories's results were not comparable because they used different software, reagents, or equipment, and that the other laboratories showed evidence of worse quality problems than Edison. Edison Br. at 19-20; Edison Reply Br. at 15-17. If the results are not comparable to Edison's because of the asserted differences in technique, than the occasional repetition of a result in those data is even less relevant to explaining the striking multiple replications in Edison's data. It is not relevant to this proceeding to determine whether other laboratories had quality problems or not. In any case, their data in no way substantiate that replications of the kind seen in Edison's data could occur in properly handled nephelometer tests.

[13] We discuss the credibility of this response further below in relation to the proficiency testing participation deficiency

Decision No. **CR642**
Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF
SUBJECT: Kaulson Laboratories, Inc.,

Petitioner, DATE: January 21, 2000
- v - The Health Care Financing Administration. Docket No. C-98-178 **DECISION**

I decide that Kaulson Laboratories, Inc. (Petitioner) failed to comply with one or more laboratory conditions of participation under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The suspension and revocation of Petitioner's CLIA certificate by the Health Care Financing Administration (HCFA) become effective based on my decision that Petitioner manifested condition-level deficiencies. Petitioner's approval to receive Medicare payment for its services was canceled effective January 23, 1998.

Applicable Law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both conditions and standards for participation under CLIA. Conditions of participation are set forth as general requirements which must be met in order for a laboratory to qualify under CLIA. For example, under 42 C.F.R. § 493.1201 (general quality control for tests of moderate or high complexity), the condition of participation is stated to include the requirement that a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each testing method to assure the accuracy and reliability of patient test results and reports.

Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. For example, under 42 C.F.R. § 493.1202 (standards for moderate or high complexity testing or both), specific requirements are set forth which govern the way such moderate or high complexity tests must be performed by a laboratory.

The regulations confer enforcement authority on HCFA in order to ensure 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 the laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). HCFA may also impose alternative sanctions against a noncompliant laboratory in lieu of, or in addition to,

principal sanctions. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against the laboratory. 42 C.F.R. § 493.1810(e). A laboratory may make an allegation of compliance once it believes it has corrected the deficiencies. HCFA will verify whether the deficiencies have been corrected if it finds the allegation of compliance to be credible and will lift alternative sanctions effective as of the correction date. Id. However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted based on self-correction of deficiencies and an allegation of compliance by the laboratory. Nor is HCFA obligated to accept as credible a laboratory's allegation of compliance. The determination to accept or not to accept a noncompliant laboratory's allegation of compliance is a matter of discretion for HCFA to exercise.

A laboratory that is dissatisfied with a determination by HCFA to impose sanctions against it may request a hearing before an administrative law judge (ALJ) to contest HCFA's determination. 42 C.F.R. § 493.1844. As a general rule, a determination to suspend, limit, or revoke a CLIA certificate is not effective until after a decision by an ALJ that upholds HCFA's determination to impose such a remedy. 42 C.F.R. § 493.1844(d)(2)(i). Hearings before an ALJ do not necessarily require in-person testimony, but can instead, as here, be hearings on a written record. The parties submit documentary evidence accompanied by briefs, thereby providing the basis for the hearing decision. The preponderance of the evidence standard is applied to resolve disputed issues of fact. HCFA bears the burden of coming forward with evidence sufficient to prove a prima facie case that the laboratory was not complying with one or more CLIA conditions. Once HCFA has established a prima facie case, the laboratory has the ultimate burden of persuasion: to prevail, the laboratory must prove by a preponderance of the evidence that it was in substantial compliance with each condition at issue. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), aff'd., *Hillman Rehabilitation Center v. United States Department of Health and Human Services, Health Care Financing Administration,* No. 98-3789 (GEV), slip op. at 25 (D.N.J. May 13, 1999).

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Background

Petitioner is a clinical laboratory specializing in blood testing for lead poisoning and is located in West Caldwell, New Jersey. By letter dated December 8, 1997, Petitioner received notification from HCFA that HCFA was suspending Petitioner's CLIA certificate due to condition-level noncompliance with CLIA requirements, canceling its approval to receive Medicare payments, and revoking its CLIA certificate as of February 22, 1998, if, by that date, Petitioner had not corrected the conditions which were out of compliance. Specifically, HCFA stated that the New Jersey Department of Health and

Senior Services (NJDHSS) had found Petitioner to be deficient in meeting four conditions of participation under CLIA, following a survey conducted on March 21, 1997. The survey cited the following four conditions of participation to be deficient: (1) Patient test management for moderate or high complexity testing (42 C.F.R. § 493.1101); (2) General quality control for tests of moderate or high complexity testing (42 C.F.R. § 493.1201); (3) Laboratories performing high complexity testing; laboratory director (42 C.F.R. § 493.1441); and (4) Quality assurance for moderate or high complexity testing (42 C.F.R. § 493.1701). The NJDHSS conducted revisit surveys on December 23 and December 29, 1997, the results of which confirmed the deficiencies found during the March 21, 1997 survey.

By letter dated January 22, 1998, HCFA informed Petitioner that, as a consequence of these findings, Petitioner's CLIA certificate would be suspended and its approval to receive Medicare payments for laboratory services would be canceled. Petitioner was advised that it had a right to a hearing before an ALJ to contest HCFA's determinations. Petitioner filed a timely request for a hearing.

This case was transferred to me on December 11, 1998, from Judge Riotto's docket. By order dated January 12, 1999, I established a schedule for the filing of documentary evidence and briefs. Regrettably, however, during the January 12, 1999 telephone prehearing conference that led to my order, HCFA mischaracterized the issue (a mischaracterization to which Petitioner acquiesced), suggesting that the controversy in this case centered on Petitioner's employment of a filter paper method test to determine blood lead levels, rather than Petitioner's alleged failure in its performance of the filter paper test to follow proper quality control standards and conditions as mandated by CLIA. Thus, my January 12, 1999 order mischaracterized the issue, indicating that the issue concerned the employment of the filter paper method, as opposed to the manner in which testing was performed. Neither party pointed out this mistake prior to submitting evidence and briefs. HCFA's opening brief focused on Petitioner's alleged failure to comply substantially with CLIA requirements. Petitioner's response brief, in contrast, contained an extensive defense of the filter paper test in general, leaving unaddressed HCFA's allegations that Petitioner had not properly performed its testing. In its reply brief, HCFA highlighted Petitioner's failure to address in its brief HCFA's specific allegations of deficiencies regarding Petitioner's performance of filter paper testing. In fact, only in Petitioner's reply brief did it begin to address the findings of the NJDHSS surveys, and then only in a cursory manner.

At my direction, the Civil Remedies Division staff attorney assigned to work with me on this case conducted another prehearing conference with the parties on September 9, 1999. The staff attorney expressed my concern that Petitioner may have relied on the "Issue" paragraph from my January 12, 1999 order when it prepared its briefs, rather than addressing the actual findings of the NJDHSS surveys and HCFA. During the conference call, the parties were given the opportunity to clarify their positions and supplement the record, either by requesting an in-person hearing or by additional written submissions and/or documentary evidence. Both parties declined the opportunity.

Since both parties waived their opportunity to supplement the record with either an in-person hearing or additional written submissions and/or documentary evidence, I have decided this case based on the documentary evidence and other written submissions of

record. I admit into evidence Petitioner's Exhibits (P. Exs.) 1-26, which accompanied Petitioner's brief filed in June 1999, and P. Exs. 1A-C, 2A, 3A, 4A, 5A-B, 6A, 7A, and 8A, which accompanied Petitioner's brief filed in August 1999; and HCFA's Exhibits (HCFA Exs.) 1-34, which accompanied its brief filed in May 1999. Deciding this case, given the complexity of the issues and the meagerness of the material that comprises the record, was challenging. In many instances, Petitioner's briefs did not touch on the allegations put forth by HCFA. Relying on the exhibits and the two sets of briefs that each party submitted (HCFA's briefs were filed in May and July 1999, and Petitioner's briefs were filed in June and August 1999), I also scoured the record for evidence to support each party's position, even where the parties have left their positions essentially unsupported or unaddressed.

Issue

The issue is whether Petitioner failed to comply with one or more conditions of participation under CLIA, thereby giving HCFA the authority to suspend and revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare payments.

Findings of Fact and Conclusions of Law

Each finding of fact and conclusion of law, set forth as a separate heading, is discussed below in detail.

1. Petitioner failed to comply with the condition of participation set forth at 42 C.F.R. § 493.1101.

The condition of participation that is stated at 42 C.F.R. § 493.1101 requires a clinical laboratory that performs moderate or high complexity testing to employ and maintain a system that provides for proper patient specimen preparation, proper specimen collection, identification, preservation, transportation and processing, and accurate result reporting. The standards which recite the particular requirements of this condition are stated at 42 C.F.R. §§ 493.1103-493.1111. I find that Petitioner has not met the requirements of three of these standards, as explained in detail below. Based on the pervasiveness of Petitioner's deficiencies under these standards, I further find that Petitioner failed to comply with this condition of participation.

1.a. Petitioner failed to comply with the standard-level requirement that is stated at 42 C.F.R. § 493.1105(f).

The standard level requirement that is stated at 42 C.F.R. § 493.1105(f) provides, among other things, that a clinical laboratory must include any additional information on the requisition or test authorization form necessary to a specific test to assure accurate and timely testing and reporting of results. HCFA contends that, contrary to Petitioner's statements in its August 22, 1997 plan of correction, the type of specimen received was not always marked by the laboratory when a physician had not entered this information on the request form. According to HCFA, the NJDHSS surveyors reviewed 100 requisition and test authorization forms and found eight that lacked specimen type information. *See* HCFA Ex. 32 at 2-3. One example of this oversight was submitted to me as evidence. *See* HCFA Ex. 27.

I find Petitioner to be deficient under this standard. Information pertaining to the type of specimen is "relevant and necessary to a specific test to assure accurate and timely testing and reporting of results." 42 C.F.R. § 493.1105(f). Petitioner does not contest this premise in either of its briefs or in either of its plans of correction. Rather, Petitioner states that this information is known to Petitioner from other sources and because each

physician submits only one type of specimen. *See* HCFA Ex. 32 at 2. However, the regulation specifically provides that such "relevant and necessary" information is to be included on "the requisition or test authorization." 42 C.F.R. § 493.1105(f). Accordingly, Petitioner's repeated failure to ensure that this information is included on the requisition or test authorization form is a deficiency under this standard.

1.b. Petitioner failed to comply with the standard-level requirement that is stated at 42 C.F.R. § 493.1107(a).

Under this standard, a "laboratory must maintain a record system to ensure reliable identification of patient specimens *as they are processed and tested* to assure that accurate test results are reported." 42 C.F.R. § 493.1107 (emphasis added). Accurate identification of a particular specimen at all stages of testing is critical to the integrity of the test performed. *See generally*, 42 C.F.R. § 493.1101. The standard requires that the record system include "[t]he patient identification number, accession number, or other unique identification of the specimen." 42 C.F.R. § 493.1107(a).

I conclude that Petitioner did not comply with the requirements of this standard. HCFA, relying on the NJDHSS March 21, 1997 survey, raises serious systemic concerns regarding Petitioner's ability to accurately cross-reference patient specimens on the worksheets to the sample cup numbers on the corresponding analyzer printout of the test results. The deficiency is evidenced by the following factors:

- Petitioner identified patient specimen #96-15427 as being in cup position #3 with a result of 29 ug/dl, although the printout showed two other analytical results of 3.9 and 25.1 ug/dl that were also listed in the cup #3 position. HCFA Ex. 4 at 3-4; HCFA Ex. 17 at 2-3; HCFA Ex. 18 at 3, 6, 8.

- Petitioner listed on the repeat worksheet that patient specimen #96-15446 was in cup position #4 with a result of 25 ug/dl, while the printout for that day shows a result of 2.4 ug/dl. HCFA Ex. 18 at 3, 8.

Neither Petitioner's briefs nor its reponses in its plans of correction contain any argument to refute this evidence or otherwise explain or defend its position specific to the cited deficiency under 42 C.F.R. § 493.1107(a). HCFA Ex. 17 at 2-3; HCFA Ex. 32 at 3.

1.c. Petitioner failed to comply with the standard-level requirement that is stated at 42 C.F.R. § 493.1109(a).

The standard level requirement governing test reporting is stated at 42 C.F.R. § 493.1109(a). Under this section, a CLIA-certified laboratory is required to maintain records of blood and blood product testing. 42 C.F.R. § 493.1109. The laboratory must "have adequate systems in place to report results in a timely, accurate, reliable and confidential manner . . . ." 42 C.F.R. § 493.1109(a). HCFA asserts that systemic problems exist in Petitioner's record-keeping and reporting practices and cites numerous instances as evidence to support its position.

While some of the examples of deficient conduct provided by HCFA were not sufficiently established or are not applicable to this subsection of the CLIA regulations, I find Petitioner to be deficient under this standard. Petitioner failed to maintain complete and accurate records of blood testing and its current system is inadequate to ensure the reporting of results in an accurate and reliable manner. This finding is supported by the following factors:

- During the March 1997 survey, nine of 17 retested samples were found to have produced inexplicably large discrepancies in the results. HCFA Ex. 4 at 8; HCFA Ex. 15 at 4; HCFA Ex. 32 at 8. Of the nine retested samples which produced discrepant results, the repeat values were reported on seven occasions without indicating that the initial analytical results were abnormally high.*Id*. Furthermore, in five of the nine cases of inexplicably large differences between test results, there were no work records to substantiate the repeat analysis and reported test values.*Id*.

- During the December 1997 revisit, the surveyors found six of 16 repeat testing results were not entered into the initial and repeat testing log despite Petitioner's October 10, 1997 plan of correction stating that such a log was being maintained. HCFA Ex. 4 at 5; HCFA Ex. 5; HCFA Ex. 14 at 2; HCFA Ex. 32 at 15.

- In seven of nine specimens, the date of reporting preceded the date of repeat testing. HCFA Ex. 4 at 6; HCFA Ex. 6; HCFA Ex. 21; HCFA Ex. 32 at 6.

- On December 19, 1997, Petitioner submitted a clarification which stated that venous specimens with initial lead values above 30 micrograms per deciliter are retested regardless of the erythrocyte protoporpyrin (ep) value. HCFA Ex. 4 at 4; HCFA Ex. 28 at 2; HCFA Ex. 32 at 4-5. Yet, the surveyors could not find six specimens that tested above 30 micrograms per deciliter on the retesting log. HCFA Ex. 4 at 4; HCFA Ex. 23 at 3, 5, 11; HCFA Ex. 32 at 4-5.

Again, Petitioner has provided little or no evidence to rebut HCFA's allegations. In fact, Petitioner's briefs fail to address adequately, if at all, the specific factual issues raised by HCFA. In most instances, Petitioner's plans of correction are the only documents in the record that provide Petitioner with any sort of defense against HCFA's assertions. HCFA Ex. 17; HCFA Ex. 32. For the most part, however, the statements contained in the plans of correction do not address the scope of the allegations or challenge the evidence submitted by HCFA.

2. Petitioner failed to comply with the condition of participation set forth at 42 C.F.R. § 493.1201.

The condition-level requirement that is stated at 42 C.F.R. § 493.1201 provides, among other things, that a clinical laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method utilized by the laboratory to assure the accuracy and reliability of patient test results and reports. The standards which recite the particular requirements of the condition are stated at 42 C.F.R. §§ 493.1202-493.1221. Petitioner has not complied with several of the standards under this condition. I find the deficiencies under these standards amount to a failure to meet this condition of participation.

2.a. HCFA has not sufficiently established that a deficiency exists under the standard that is set forth at 42 C.F.R. § 493.1205.

The standard governing test methods is stated at 42 C.F.R. § 493.1205. A laboratory is required, among other things, to utilize test methods, equipment, and materials that provide accurate and reliable test results. 42 C.F.R. § 493.1205. HCFA alleges that Petitioner's deficiencies under this standard are particularly egregious. *See* HCFA Brief

of May 19, 1999 (HCFA Br.) at 19. More specifically, HCFA claims that Petitioner could not demonstrate on a continuing basis that it was calculating its filter paper lead results correctly.*Id*. For example, HCFA contends that Petitioner failed to demonstrate that it was using 17 microliters of blood in each filter paper disc produced by the punch used by the laboratory where the laboratory director claimed that 17 were to be on each disc. According to HCFA, "Kaulson [also] failed to dilute the patient specimens to the same extent as the calibrator, thus further compromising the accuracy of the filter paper calculations." *Id*. at 20.

Despite stressing the seriousness of these claims, HCFA relies almost exclusively on the NJDHSS survey report as evidence of these charges, and for this deficiency I do not find that the survey report is sufficient to establish a prima facie case. *See* HCFA Br. at 19-22, *citing* HCFA Ex. 4 at 12-14. HCFA provided little information to explain the shortcomings of Petitioner's test methodologies and provided no evidence or authority to support its explanation as to how Petitioner should have conducted its testing. HCFA also provided no evidence or authority to demonstrate that Petitioner's methodologies, as explained in its plans of correction, were improper. Based on the record, I find that HCFA has not established a prima facie case here, because insufficient evidence exists to support HCFA's claim that Petitioner was deficient under this standard.

2.b. Petitioner failed to comply with the standard-level requirement that is stated at 42 C.F.R. § 493.1211(a).

The standard stated at 42 C.F.R. § 493.1211(a) requires that "a written procedural manual for the performance of all analytical methods used by the laboratory must be readily available and followed by laboratory personnel." 42 C.F.R. § 493.1211(a). I find that Petitioner has failed to follow its own written procedures. Petitioner's written instructions for the Perkin-Elmer ZL4100 whole blood procedure specified that, for all values over 50 ug/dl, the sample must be diluted and re-analyzed, or if not repeated, then reported as greater than or equal to 50 ug/dl. *See* HCFA Ex. 19 at 14. However, contrary to its own procedures, a review of Petitioner's work records and final reports for the period of December 13, 1996 through February 27, 1997, revealed that of the 14 results that had values over 50 ug/dl or greater, only two specimens were diluted and retested, and no specimens were reported as greater than or equal to 50 ug/dl. HCFA Ex. 4 at 16-17. *See*, *e.g.*, HCFA Ex. 27.

In addition, this standard requires a laboratory to include in its procedural manual a description of the laboratory's system for reporting patient results. 42 C.F.R. § 493.1211(b)(14). This system, once described in the procedural manual, must be followed by laboratory personnel. *See* 42 C.F.R. § 493.1211(a). The inconsistent manner in which Petitioner reported repeat testing results further evidences a deficiency under this standard. Petitioner's log book of venous specimen testing shows that the reported value is predominantly an average of the initial and repeat test values. *See* HCFA Ex. 4 at 15; HCFA Ex. 7; HCFA Ex. 23 at 2-3, 9. However, in several instances, Petitioner reported only the lower repeat value.*Id*.

Petitioner does not directly address these allegations or the evidence in its briefs. In fact, Petitioner's only rebuttal to this evidence can be found in its plan of correction. *See* HCFA Ex. 32 at 14-15. Yet, the arguments that Petitioner has made in its plan of correction are incomplete, unsupported by evidence, or did not focus on the requirements of this standard.

2.c. Petitioner failed to comply with the standard-level requirement that is stated at 42 C.F.R. § 493.1217(a).

Under this standard, a laboratory must perform calibration procedures in accordance with criteria established by the laboratory, including the number, type and concentration of calibration materials, acceptable limits for calibration, and the frequency of calibration. 42 C.F.R. § 493.1217(b). According to HCFA, Petitioner failed to establish written criteria for its acceptable limits for calibrating both analyzers used by the laboratory. HCFA Br. at 25. HCFA's brief summarizes the NJDHSS survey report which is cited as support for these allegations.*Id*. However, Petitioner, in both of its plans of correction, states that it has described this procedure in its manual. *See* HCFA Ex. 17 at 10-11; HCFA Ex. 32 at 18-19. Yet, Petitioner apparently has not submitted this manual, nor has it identified where this information can be found. As previously stated, once HCFA has met the initial burden of establishing a prima facie case, it is Petitioner's responsibility to rebut that case. Although it may have been within its power to do so, Petitioner has not provided the evidence it asserts it has to rebut HCFA's case.

2.d. Petitioner failed to comply with the standard-level requirement that is stated at 42 C.F.R. § 493.1218(b).

Control procedures should be routinely conducted to monitor the stability of the method or test system. 42 C.F.R. § 493.1218. "A laboratory must evaluate instrument and reagent stability and operation variance in determining the number, type and frequency of testing calibration or control materials and establish criteria for acceptability used to monitor test performance during a run of patient specimens." 42 C.F.R. § 493.1218(b). HCFA alleges that Petitioner has improperly utilized controls in all stages of testing. In support of its contention, HCFA has asserted numerous examples of Petitioner's mishandling of the control tests. *See* HCFA Br. at 13-18. However, while citing particular acts of Petitioner as improper, HCFA often did not sufficiently demonstrate how such allegedly improper tests violated a standard under CLIA. Moreover, HCFA often failed to include a citation to a particular standard, leaving me to guess which standard is applicable. For example, HCFA made the following unsupported claim, "[A] specific batch of controls used by a lab must always be identified in advance of the testing process." HCFA Br. at 14. HCFA proceeds to discuss the impropriety of using different batches of homemade controls on different days with different yet overlapping results.*Id*. Yet, HCFA provides no evidence or authority to substantiate its allegation other than the NJDHSS survey report to establish that Petitioner has violated a standard. In this instance, I have not found that the NJDHSS survey report is sufficient to establish a prima facie case of noncompliance under this standard. HCFA did not even cite which standard this action violated, and the NJDHSS survey report provided little guidance. *See* HCFA Ex. 32 at 9-11.

Nevertheless, HCFA has established a deficiency under 42 C.F.R. § 493.1218. In its plan of correction, Petitioner stated that a high level control of 30 units would be performed in each test run. *See* HCFA Ex. 17 at 12. According to the NJDHSS surveyors, however, the highest control Petitioner used was only 27 units. *See*, *e.g.*, HCFA Ex. 21 at 29, 34, 37, 39, 42, and 44. Petitioner has largely left HCFA's allegation unchallenged, providing only a scant and unsupported statement in its second plan of correction that a high level control at or near 30 ug/dl is sufficient. *See* HCFA Ex. 32 at 20. I find this argument unpersuasive. The standard requires that a laboratory establish

and follow its procedures for administering controls. *See* 42 C.F.R. § 493.1218. By failing to perform a high level control of 30 ug/dl, Petitioner did not follow its control procedures and, thus, is deficient under this standard.

3. Petitioner was out of compliance with the condition of participation set forth at 42 C.F.R. § 493.1441.

The condition-level requirement that is stated at 42 C.F.R. § 493.1441 requires, among other things, a laboratory to employ a director who provides overall management and direction in accordance with the standards set forth at 42 C.F.R. § 493.1445. The standard holds a laboratory director responsible for the overall operation and administration of the laboratory. These responsibilities include the employment of personnel who are competent to perform test procedures, to record and report test results promptly, accurately and proficiently, and to assure compliance with applicable regulations.

It is evident from the regulations that a laboratory director is responsible for assuring that a laboratory meets CLIA requirements. A systemic failure by a laboratory to meet these requirements is evidence from which I may infer that the laboratory director is failing to discharge his or her duties.

I find that Petitioner's laboratory director failed to discharge his obligations under the standard at 42 C.F.R. § 493.1445, to such an extent that it amounts to Petitioner's failure to comply with this condition of participation. Petitioner's systematic failures are evidenced by its inability to meet the conditions of participation as described above at Findings 1 and 2.

4. Petitioner was out of compliance with the condition of participation set forth at 42 C.F.R. § 493.1701.

The condition-level requirement for participation that is stated at 42 C.F.R. § 493.1701 directs a laboratory that performs moderate or high complexity testing to establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the laboratory's total testing process. The requirement provides that a laboratory's quality assurance program must evaluate the effectiveness of its policies and procedures, identify and correct problems, assure the accurate, reliable and prompt reporting of test results, and assure the adequacy and competency of the laboratory's staff. The requirement directs a laboratory to, as may be necessary, revise policies and procedures based upon the results of its evaluations.

I find that Petitioner has failed to meet this condition of participation. Based upon the deficiencies as discussed at Findings 1 and 2 above, I find that Petitioner failed to monitor properly and evaluate its quality assurance systems and to take corrective actions when problems were discovered. This failure is apparent from the numerous quality deficiencies that were present in Petitioner's testing program. *See*, *e.g.*, Findings 1 and 2, *supra*.

CONCLUSION

Petitioner appears to recognize that deficiencies exist in its processing of patient specimens and attempts to minimize this by suggesting that such errors are inevitable and should be acted upon if they appear deliberate or due to carelessness. *See* Petitioner's June 18, 1999 Brief at 10-11; P. Ex. 9 at 2-3; P. Ex. 10 at 2. These

deficiencies, however, are not trivial and go to the integrity of the laboratory's testing process. Clerical and reporting omissions are important under CLIA.
Petitioner failed to comply with four laboratory conditions of participation under CLIA. The presence of one or more condition-level deficiencies in Petitioner's operations authorizes HCFA to impose the remedies of suspension and revocation of Petitioner's CLIA certificate, which become effective based on this decision.

JUDGE

Jill S. Clifton
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Southfield Medical Clinic,

Petitioner,
DATE: May 9, 2000
- v -

Health Care Financing Administration
Docket No.C-00-071
Decision No. **CR667 DECISION**

I enter summary disposition in favor of the Health Care Financing Administration (HCFA) sustaining HCFA's determination to impose remedies against Petitioner, Southfield Medical Clinic. The remedies which I sustain include: (1) cancellation of Petitioner's approval to receive Medicare payment for its services from September 20, 1999 until the date of this decision; and (2) revocation of Petitioner's certificate to provide laboratory services pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA); and (3) modification of the determination to revoke Petitioner's CLIA certificate from two years to a period without a minimum term.

I. Background

A. Background facts

Petitioner is a clinical laboratory that is located in Southfield, Michigan. On August 31, 1999, HCFA notified Petitioner that it had been found to be deficient in complying with CLIA conditions of participation and other federal requirements governing clinical laboratories. HCFA advised Petitioner that it had determined to impose remedies against Petitioner. These included cancellation of Petitioner's approval to receive Medicare payment for its services and revocation of Petitioner's CLIA certificate. HCFA informed Petitioner that it had based its determination on the results of a complaint investigation survey that was conducted at Petitioner's premises on July 1, 1999 by the Michigan Department of Consumer and Industry Services (MDCIS) and HCFA. HCFA advised Petitioner that it had a right to a hearing before an administrative law judge at which it could contest HCFA's determinations.

Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. HCFA then moved for summary disposition. Petitioner opposed HCFA's motion. HCFA offered 22 exhibits in support of its motion (HCFA Ex. 1 - HCFA Ex. 22). Petitioner offered three exhibits in opposition to HCFA's motion (P. Ex. 1 - P. Ex. 3). I am receiving into evidence HCFA Ex. 1 - HCFA Ex. 22 and P. Ex. 1 - P. Ex. 3.

B. Governing law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as broadly stated general requirements which must be met in order that a laboratory qualify under CLIA. Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. Standards are subparts of the more broadly stated conditions. A failure by a laboratory to comply with one or more standards may be so serious as to constitute failure to comply with the condition of which the standards are subparts.

The CLIA regulations authorize HCFA or its designee (such as MDCIS) 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 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 as remedies *principal* sanctions against the laboratory which may include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). HCFA may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against that laboratory. 42 C.F.R. §493.1810(e). However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted.

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. The standard of proof that is employed at a hearing concerning HCFA's determination that a laboratory is not in compliance with CLIA conditions is a preponderance of the evidence. HCFA has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by HCFA. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

II. Issue, findings of fact and conclusions of law

A. Issue

The issue in this case is whether Petitioner failed to comply with one or more conditions of participation in CLIA thereby giving HCFA the authority to impose remedies against Petitioner including canceling Petitioner's approval to receive Medicare payments and revoking Petitioner's CLIA certificate.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. Summary disposition is appropriate in this case.

A threshold question in this case is whether summary disposition is appropriate. I conclude that in this case it is.

Generally, summary disposition is appropriate in a case where there are no disputed issues of material fact and where the only issues involve either questions of law or of application of the law to the undisputed material facts. Summary disposition is appropriate in the circumstance where the parties agree as to the material facts. It may also be appropriate where there is disagreement as to the facts but where the moving party prevails as a matter of law when all disputed facts are resolved in favor of the party against whom the motion for summary disposition is made. However, summary disposition should not be issued where there is a genuine dispute as to material facts and where the outcome of the case may depend on how that dispute is resolved. In that circumstance further proceedings will be necessary in order to resolve factual disputes. I have carefully considered the parties' respective fact assertions and arguments in this case and I conclude that there are no genuinely disputed issues of material fact here. I am relying on Petitioner's rendition of the facts in any instance where there may be a disparity in the parties' respective recitations of the facts.

2. Petitioner did not contest HCFA's determination that Petitioner failed to comply with CLIA conditions of participation that are stated at 42 C.F.R. §§ 498.801 and 498.839.

In *Family Home Health Services*, DAB CR615 (1999), *aff'd,* DAB No. 1716 (2000), I held that summary disposition is appropriate in a case where a potentially outcome determinative allegation is made by a party that is not denied by the opposing party. DAB CR615 at 4. That principle is applicable here concerning the allegations that Petitioner failed to comply with the CLIA conditions that are stated at 42 C.F.R. §§ 493.801 and 493.839. I enter summary disposition in HCFA's favor on the question of whether Petitioner failed to comply with these two conditions.

Petitioner has effectively conceded the findings in the July 1, 1999 survey report and in the August 31, 1999 notice letter that Petitioner did not comply with CLIA conditions stated at 42 C.F.R. §§ 493.801 and 493.839. There is nothing in Petitioner's reply to HCFA's motion which I can construe as a response to the specific allegations that Petitioner did not comply with the requirements of 42 C.F.R. §§ 493.801 and 493.839. The report of the July 1, 1999 survey of Petitioner alleged two condition-level deficiencies in Petitioner's operations. These are the conditions that are stated at 42

C.F.R. §§ 493.801 and 493.839. In its August 31, 1999 notice letter to Petitioner, HCFA concurred with these findings. HCFA also advised Petitioner on August 31, 1999 that it had found that Petitioner failed to comply with a third condition of participation. This is the condition that is stated at 42 C.F.R. § 493.803.

The condition of participation that is stated in 42 C.F.R. § 493.801 requires that a laboratory must enroll in a proficiency testing program that meets defined criteria and which is approved by the United States Department of Health and Human Services. It provides that the laboratory must test proficiency testing samples in the same manner as it tests patients' laboratory specimens. Petitioner was found not to have complied with this condition because it tested proficiency testing samples differently than it tested patients' laboratory specimens. (HCFA Ex. 7 at 1 - 2). Specifically, Petitioner was found to run patient samples only once and to report them out whereas Petitioner ran proficiency testing samples for glucose, cholesterol, and triglycerides in duplicate. Additionally, it was found that the results of proficiency tests run at Petitioner's laboratory were added to the results of proficiency tests that were run at another laboratory and an average of the test scores was obtained in order to produce a single averaged result that was reported out as a proficiency test result for both Petitioner's laboratory and for the other laboratory. HCFA Ex. 7 at 2.

The condition of participation that is stated at 42 C.F.R. § 493.839 establishes criteria for the purposes of proficiency testing in the subspecialties of routine chemistry, endocrinology, and toxicology. The criteria are provided as separate standards. The allegation in the survey report is that Petitioner's failure to comply with several of these standards was so serious as to comprise a failure to comply with the overall condition. (HCFA Ex. 7 at 6 - 8). The report alleges that Petitioner failed to: 1) attain satisfactory proficiency test scores as is required by 42 C.F.R. § 493.841(b); and 2) properly train its staff as is required by 42 C.F.R. § 493.841(e)(1) to address failures to attain satisfactory proficiency test scores; and 3) take and document remedial action to address unsatisfactory proficiency test scores as is required by 42 C.F.R. § 493.841(e)(2).

The CLIA condition of participation that is stated at 42 C.F.R. § 493.803(a), requires that a laboratory performing tests of moderate and/or high complexity must successfully participate in a proficiency testing program. HCFA based its determination that Petitioner had failed to comply with the condition stated in 42 C.F.R. § 493.803 on the surveyors' findings that Petitioner had contravened several standards governing proficiency testing. HCFA essentially alleges that, when Petitioner's failure to comply with these standards is considered in its totality, it establishes that Petitioner's deficiencies are so severe as to establish an overall failure by HCFA to comply with the condition.

HCFA determined that Petitioner had not routinely integrated proficiency testing samples into its regular workload as is required by 42 C.F.R. § 493.801(b)(1). Additionally, HCFA concluded that Petitioner had violated 42 C.F.R. § 493.801(b)(4) in that it allegedly referred proficiency testing samples to another laboratory. Further, HCFA concluded also that Petitioner had collaborated with another laboratory in the administration of proficiency testing samples for the first and second testing events of 1998 and for the first testing event of 1999 in violation of the requirements of 42 C.F.R. § 493.801(b)(3). Finally, HCFA determined that Petitioner's laboratory director and one of its employees had signed attestation statements affirming that proficiency tests had

been done in the same manner as patient tests when, in fact, proficiency tests had not been performed in the same manner as patient tests. According to HCFA, this was a violation of 42 C.F.R. § 493.801(b)(5).

Petitioner has, to some extent, contested HCFA's determination that Petitioner failed to comply with the condition stated in 42 C.F.R. § 493.803. However, it has not addressed any of the findings that were made concerning the conditions stated in 42 C.F.R. §§ 493.801 and 493.839. This is evident, both from Petitioner's hearing request and from Petitioner's reply to HCFA's motion for summary disposition.

> Petitioner's hearing request focuses on the allegations that it referred proficiency test samples to another laboratory and collaborated in the performance of proficiency tests. Petitioner avers that:
>
> 1. There was no "intentional referral of . . . [proficiency test] samples to another laboratory for analysis;
>
> 2. There was no improper referral within the meaning of the Statute;
>
> 3. There was no improper collaboration within the meaning of the Statute;
>
> 4. There were no other deficient test practices regarding . . . [proficiency test]
>
> samples; . . . .

Petitioner's hearing request at 1. Additionally, Petitioner asserts that the "statute, regulations and case law do not support a finding that a laboratory technician acting alone can create the intent element of the statute." *Id.* at 2.

Petitioner's reply to HCFA's motion also focuses on the allegations of referral and collaboration. Petitioner argues that the impetus for HCFA's determination to impose remedies against Petitioner was an allegation that Petitioner had engaged in improper referral of proficiency tests or improper collaboration concerning test results. Petitioner's reply at 2. But, Petitioner makes no argument addressing the allegations that it failed to comply with the conditions stated at 42 C.F.R. §§ 493.801 and 493.839. Indeed, Petitioner essentially concedes that it was not in compliance with these conditions. It characterizes the findings of deficiency that are not related to allegations of referral or collaboration as being "other minor PT [proficiency test]-related deficiencies" which Petitioner allegedly largely addressed in a corrective action plan dated September 13, 1999. *Id.* Petitioner asserts that HCFA is criticizing it inappropriately for:

> making the informed and strategic decision to have the other cited minor deficiencies, which Petitioner immediately corrected in good faith, appropriately resolved with the Secretary through a more flexible intermediate sanction, such as a directed plan of corrected action and monitoring.

Id.

Petitioner has offered no affirmative evidence to respond to the allegations that Petitioner did not comply with the conditions stated at 42 C.F.R. §§ 493.801 and 493.839. None of the exhibits that Petitioner offered with its reply to HCFA's motion address these allegations. *See* P. Ex. 1 - P. Ex. 3. Petitioner's only assertion of fact in

its reply is to deny that it improperly referred proficiency tests or engaged in improper collaboration about the results of proficiency tests.

I have considered whether Petitioner's denial of referrals of proficiency test samples and of collaboration, assuming them to be true, might constitute a defense to HCFA's determination that Petitioner failed to comply with the conditions that are stated in 42 C.F.R. §§ 493.801 and 493.839. Although Petitioner's denials are relevant to HCFA's determination that Petitioner did not comply with the condition that is stated in 42 C.F.R. § 493.803, they do not provide a defense to the determination that Petitioner failed to comply with the conditions that are stated in 42 C.F.R. §§ 493.801 and 493.839. The allegations of noncompliance in the survey report concerning these two conditions do not rest on improper referral of proficiency test samples nor do they rest on improper collaboration.

The allegations concerning Petitioner's failure to comply with the requirements of 42 C.F.R. § 483.801 are that Petitioner used incorrect or improper techniques in processing proficiency tests. At bottom, the allegations rest on the assertion that Petitioner did not process proficiency tests *in the same manner* that it processed patient specimens. For example, Petitioner is alleged to have run proficiency tests twice whereas it ran patient specimen tests only once. And, Petitioner is alleged to have averaged proficiency test results. Petitioner has offered nothing to challenge these specific allegations of noncompliance.

Indirectly, the allegations that were made with respect to Petitioner's noncompliance with the requirements of 42 C.F.R. § 493.801 touch on allegations of collaboration with another laboratory in the performance of proficiency testing. Petitioner is alleged to have averaged the results of proficiency tests performed at its laboratory with results of tests performed at another laboratory. Implicit in this allegation is a charge that Petitioner collaborated with another laboratory in the performance of proficiency testing. Petitioner has denied collaborating with another laboratory. However, as I discuss below at Finding 3, Petitioner's denial is, in fact, a denial that its management authorized or approved collaboration with another laboratory. Petitioner does not deny that an employee combined and averaged proficiency testing results from Petitioner with proficiency testing results from another laboratory. Indeed, Petitioner concedes that this occurred. Thus, Petitioner admits to the allegation made with respect to 42 C.F.R. § 493.801 that it averaged test results obtained from its laboratory with those that were obtained from another laboratory. And, Petitioner does not deny that this represented a departure from its standard testing procedure.

Nor has Petitioner offered affirmative evidence which refutes the allegation that it failed to comply with the condition that is stated in 42 C.F.R. § 493.839. The allegation of noncompliance under this condition is that Petitioner failed to establish proficiency test scores that demonstrated its competence and failed to take remedial action to improve its performance. Petitioner has offered nothing which responds to this allegation.

Petitioner characterizes its deficiencies in complying with the requirements of 42 C.F.R. §§ 493.801 and 493.839 as being only "minor." Petitioner's argument appears to be that the seriousness of Petitioner's noncompliance with the requirements of 42 C.F.R. §§ 493.801 and 493.839 is not so great as to constitute condition-level deficiencies. However, Petitioner has offered no affirmative facts which would show that its noncompliance was merely minor. It has elected to rest on its characterization of the

deficiencies without offering any supporting evidence. Thus, it has not rebutted the prima facie evidence of noncompliance, including evidence that Petitioner's noncompliance was of a condition level, which HCFA presented to support its motion. On their face, the allegations of noncompliance that are stated in the report of the July 1, 1999 survey make out a prima facie case of noncompliance by Petitioner with the conditions that are stated at 42 C.F.R. §§ 493.801 and 493.839. Petitioner has an obligation to show why the deficiencies that are asserted in the survey report are only "minor" deficiencies. However, Petitioner has offered no affirmative proof which would establish a genuine dispute as to the facts. Its naked characterization of the deficiencies as "minor" is, in the absence of some evidence to support that characterization, merely a conclusion without substance.

3. The undisputed material facts establish that Petitioner failed to comply with the requirements of the condition that is stated in 42 C.F.R. § 493.803.

The undisputed material facts of this case establish the elements of a failure to comply with the condition that is stated in 42 C.F.R. § 493.803. I am satisfied from these undisputed material facts that Petitioner failed to engage successfully in a proficiency testing program. Petitioner does not deny that it failed to integrate proficiency testing samples into its regular laboratory operations. It collaborated with another laboratory in the performance of proficiency testing. And, its director signed attestation statements which were incorrect.

As I describe above at Finding 2, HCFA premised its determination that Petitioner had not complied with the requirements of 42 C.F.R. § 493.803 on findings that Petitioner had contravened several standards governing the performance of proficiency testing. HCFA's findings included determinations that Petitioner had referred proficiency testing samples to another laboratory and that Petitioner had collaborated with another laboratory in performing proficiency testing. Those were not the sole allegations that form the basis that Petitioner did not comply with 42 C.F.R. § 493.803. HCFA alleged additionally that Petitioner failed to integrate proficiency testing into its normal sample testing procedures. And, it found that Petitioner's director and staff had not complied with the requirements of 42 C.F.R. § 493.801(b)(5) in signing attestations of testing performance.

Petitioner has challenged only the findings of referrals and collaboration. I have examined closely the evidence offered by HCFA and by Petitioner as to these issues. I conclude that the evidence does not establish that Petitioner referred proficiency testing samples to another laboratory for testing. However, the undisputed material facts plainly establish collaboration between Petitioner and another laboratory in the performance of proficiency testing.

I conclude that the undisputed material facts establish that Petitioner failed to comply with the condition that is stated at 42 C.F.R. § 493.803. I enter summary disposition in favor of HCFA as to the question of whether Petitioner complied with that condition. The failures by Petitioner to comply with standards governing proficiency testing are so severe as to establish that Petitioner did not comply with the overall condition governing proficiency testing. I find that to be the case even though the undisputed material facts do not show that Petitioner referred proficiency testing samples to another laboratory for testing.

HCFA premises its assertions of referral and collaboration on facts which relate to certain proficiency testing events. A proficiency testing "event" is an instance in which a laboratory is sent proficiency testing samples from the American Association of Bioanalysts (AAB) for testing. The laboratory tests the samples and returns the results to the AAB for scoring. The laboratory's score for a proficiency testing event is one basis for determining whether that laboratory has met minimum testing requirements.

In the four proficiency testing events, which occurred during the period beginning March 1998 through March 1999, Petitioner and another laboratory, Family Care Medical Center (Family Care), obtained identical scores on seven different analytes. HCFA Ex. 4; HCFA Ex. 16 at 1. These identical scores were submitted even where the test results were incorrect. HCFA Ex. 16 at 1. The two laboratories submitted identical scores on 32 of 35 individual tests in March 1998. HCFA Ex. 8 at 1; HCFA Ex. 21 at 1. They submitted identical scores on 36 of 40 individual tests in March, 1999. HCFA Ex. 13 at 6; HCFA Ex. 21 at 6. During this period, the same individual, Dorothy Lott, was employed by both Petitioner and Family Care and did proficiency testing for both laboratories. HCFA Ex. 8 at 2, 4; HCFA Ex. 21 at 4.

HCFA argues that the reasonable inference that may be drawn from the aforesaid facts is that Petitioner referred proficiency testing samples to another laboratory for testing. HCFA further argues that these facts also show collaboration between Petitioner and Family Care in conducting proficiency testing.

Petitioner responds by arguing that it cannot be reasonably inferred that Petitioner referred proficiency testing samples to Family Care. Petitioner asserts that other reasonable explanations exist to account for the test scores. Petitioner also denies the allegations of collaboration. Petitioner does not deny that Ms. Lott engaged in improprieties in the way she performed and reported proficiency testing results. But, Petitioner asserts that it did not authorize these improprieties and was not aware of them when they occurred. Petitioner argues that, as a matter of law, it cannot be held responsible for the acts or omissions of an employee when it neither authorized them nor was aware of them.

I agree with Petitioner that the evidence adduced by HCFA in support of its motion does not establish referral of testing samples. It is unclear from this evidence how Ms. Lott obtained identical test results for the two laboratories. And, there are several equally possible explanations for the results. Ms. Lott could have tested all of the samples at either Petitioner or at Family Care. She could have tested samples at the respective laboratories but altered the testing results in order to obtain identical scores at both laboratories. She could have tested only one set of samples at one of the laboratories and simply duplicated the test results for the other laboratory.

HCFA argues that it is not necessary to establish actual referral of testing samples to prove that samples are referred from a laboratory to another laboratory. HCFA asserts that an unlawful "referral" occurs where two laboratories collaborate to produce a shared result. As support for this argument, HCFA cites to the administrative law judge's decision in *Blanding Urgent Care Center Laboratory*, DAB CR438 (1996). I disagree with that decision to the extent that it supports the proposition that an unlawful "referral" of a testing sample to another laboratory may occur without an actual physical transport of the sample from one laboratory to another laboratory. The regulation which prohibits referrals of proficiency testing samples and collaboration between laboratories

concerning proficiency testing plainly defines an unlawful referral to be the act of sending proficiency testing samples to another laboratory for analysis. 42 C.F.R. § 493.803(b)(4). And, that regulation clearly distinguishes between unlawful referrals (42 C.F.R. § 493.803(b)(4)) and unlawful collaboration (42 C.F.R. § 493.803(b)(3)). However, although the undisputed material facts of this case do not establish an unlawful referral of proficiency testing samples from Petitioner to another laboratory, those same facts establish that there was collaboration between Petitioner and Family Care in the performance of proficiency testing. The only reasonable inference that I can draw from the near identical testing scores produced by the two laboratories over a 12-month period and from the fact that the employee who did proficiency testing, Ms. Lott, was employed by both laboratories during this time frame, is that Ms. Lott manipulated proficiency testing results at the two laboratories to produce identical scores for both of them. That plainly is collaboration within the meaning of 42 C.F.R. § 493.803(b)(3). Petitioner does not deny any of the facts adduced by HCFA which establish that Ms. Lott manipulated proficiency testing scores at Petitioner and Family Care. Petitioner asserts that Ms. Lott was only an employee of Petitioner and was not in a position to make decisions on Petitioner's behalf. It argues that any collaboration engaged in by Ms. Lott was unauthorized and was, furthermore, unknown to Petitioner's management. Petitioner asserts that it should not be held legally responsible for the unauthorized acts of its employee.

Petitioner argues equitable considerations as support for its argument that it should not be responsible for the actions of its employee. The thrust of Petitioner's argument is that a laboratory should not be held liable for CLIA deficiencies where the laboratory's management has acted in good faith and where the actions of its employee run counter to the expressed wishes of management.

For purposes of deciding this question, I am assuming to be true Petitioner's representations that its management neither knew about nor authorized Ms. Lott's actions. However, I conclude that, even assuming the truth of Petitioner's representations, it remains responsible for the actions of Ms. Lott. The requirements of CLIA, of the regulations which implement CLIA, and of 42 C.F.R. § 493.803 in particular, are not limited to laboratory behavior which is the product of knowing acts by the laboratory's management. Both CLIA and its implementing regulations impose compliance requirements on a "laboratory" and not just on its management. Under CLIA, a laboratory is liable for the acts of its employees whether or not those acts are authorized or even known about by the laboratory's management. *Melvin C. Murphy, M.D., P.C.*, DAB CR590 (1999).

A purpose of CLIA is to assure that laboratory testing of patients' specimens is done in a manner which assures that testing be of acceptable quality. For that reason, CLIA and the regulations which implement CLIA establish strict compliance standards. The statutory purpose of attaining satisfactory laboratory performance would be frustrated if a laboratory were liable only for deficiencies that were the consequence of willful decisions by its management.

4. HCFA is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions.

As I discuss above at Part I.B. of this decision, HCFA is authorized to impose principal sanctions including revocation of a laboratory's CLIA certificate as remedies for that

laboratory's failure to comply with one or more CLIA conditions. 42 C.F.R. § 493.1806(a), (b). HCFA may impose the additional remedy of cancellation of a laboratory's approval to receive Medicare payment for its services where the laboratory has not complied with one or more CLIA conditions. 42 C.F.R. § 493.1807.

HCFA is authorized to impose principal sanctions against Petitioner. In this case, the undisputed material facts establish that Petitioner failed to comply with three CLIA conditions of participation. HCFA would be authorized to impose principal sanctions against Petitioner even if the evidence were to show that Petitioner failed to comply with only one CLIA condition of participation.

Petitioner argues that any failures by it to comply with CLIA requirements was not so severe as to necessitate the imposition of the remedies of revocation of Petitioner's CLIA certificate and cancellation of Petitioner's authority to receive payment from Medicare for its services. Petitioner repeatedly characterizes its deficiencies as being "minor" and asserts that HCFA should have accepted a plan of correction from Petitioner wherein Petitioner pledged to correct deficiencies.

However, HCFA's determination to impose principal sanctions against Petitioner is an act of discretion that is authorized by Petitioner's failure to comply with CLIA conditions of participation. Petitioner has no right to offer a plan of correction to address condition-level deficiencies. As I discuss above, at Part I.B. of this decision, a laboratory is afforded the opportunity to offer a plan of correction only where HCFA imposes alternative sanctions for deficiencies that are at less than a condition level of severity. 42 C.F.R. § 493.1810(e). I have no authority to direct HCFA to accept a plan of correction from Petitioner in lieu of imposing principal sanctions against Petitioner given that there exist condition-level deficiencies.

HCFA has elected to impose the principal sanction of revocation of Petitioner's CLIA certificate. Additionally, HCFA has determined to impose against Petitioner cancellation of Petitioner's authority to receive Medicare payments for its services. HCFA is authorized to impose both of these remedies.

In its August 31, 1999 notice to Petitioner, HCFA stated that it was imposing a two-year term of revocation against Petitioner. I conclude that this determination is based on an incorrect reading by HCFA of CLIA and its implementing regulations. HCFA cited as authority for its determination to impose a two-year revocation 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8). However, these authorities do not state or suggest that a term of revocation of a CLIA certificate be for two years in any instance. Rather, they permit revocation of a laboratory's CLIA certificate where that laboratory has been acquired by the owner or operator of a laboratory whose CLIA certificate has been revoked within the past two years. These provisions of CLIA are aimed at preventing an owner or operator of a laboratory whose CLIA certificate has been revoked from resuming business under another name within two years.

I am modifying the determination to revoke Petitioner's CLIA certificate in view of HCFA's misreading of the law. I modify the revocation so that it becomes a revocation without a minimum term. The effect of my modification is to allow HCFA to exercise its discretion to reinstate Petitioner's CLIA certificate, if it chooses to do so, in less than two years. I make no finding here as to when Petitioner's CLIA certificate should be reinstated.

In making this modification I note that the only situation in which CLIA mandates a minimum period of revocation of a CLIA certificate is where a laboratory has been found to refer proficiency testing samples to another laboratory. In that circumstance both CLIA and its regulations mandate a minimum revocation period of one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.1840(b). In this case, I have concluded that there is no persuasive evidence that unlawful referrals of proficiency testing were made. My decision to modify the term of revocation so that there is no minimum term is, therefore, consistent not only with my reading of 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), but also with my conclusion that no intentional referrals of proficiency tests were established here.

JUDGE

Steven T. Kessel
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT:
US Bio-Chem Medical Laboratories, Inc.,

Petitioner,
DATE: June 21, 2000
- v -

Health Care Financing Administration
Civil Remedies CR632
Docket No.A-2000-37
Decision No. **1731**
DECISION

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

US Bio-Chem Medical Laboratories, Inc. (Bio-Chem), appealed a December 7, 1999 decision by Administrative Law Judge (ALJ) Steven T. Kessel. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. CR632 (1999) (ALJ Decision). The ALJ found that Bio-Chem had failed to comply with the Clinical Laboratory Improvement Amendments (CLIA), 42 U.S.C. § 263a, and with implementing regulations set forth at 42 C.F.R. Part 493. Specifically, the ALJ found that Bio-Chem had failed to comply with a condition for CLIA certification requiring Bio-Chem to cooperate, pursuant to 42 C.F.R. § 493.1773(a), in a CLIA inspection of its facilities. The ALJ found that Bio-Chem had refused to produce documents requested by inspectors conducting a CLIA complaint investigation. The ALJ Decision accordingly sustained the determination by the Health Care Financing Administration (HCFA) to impose the following three remedies: 1) cancellation of Bio-Chem's approval to receive Medicare payments for laboratory services, effective June 14, 1999, pursuant to 42 C.F.R. §§ 493.1773(d),(g) and 493.1842, and denial of payment to Bio-Chem under State Medicaid programs for laboratory services performed on or after June 14, 1999, pursuant to section 1902(a)(9)(C) of the Social Security Act and 42 C.F.R. § 440.30(c); 2) suspension of Bio-Chem's CLIA certificate effective June 14, 1999, pursuant to 42 C.F.R. §§ 493.1773(d),(g) and 493.1840(d)(2)(ii); and 3) revocation of Bio-Chem's CLIA certificate, pursuant to 42 C.F.R. §§ 493.1773(g) and 493.1840(e)(1).

For the reasons stated below, we affirm the ALJ Decision. That decision is based on substantial evidence in the whole record and correctly applies the law. Bio-Chem's arguments are collateral attacks on the decision that have no merit.

Factual Background

The following facts are undisputed.[(1)] Bio-Chem held a certificate of waiver under CLIA, meaning that Bio-Chem was authorized to perform only those laboratory tests listed at 42 C.F.R. § 493.15(c). On May 25, 1999, HCFA inspectors arrived at Bio-Chem to

investigate a complaint that Bio-Chem was performing unauthorized tests. During the course of the visit, one of the inspectors noticed the presence of reagents that are used for blood typing. Bio-Chem was not authorized to perform blood typing. The inspectors requested that a Bio-Chem employee produce its patient log book to ascertain when Bio-Chem had done blood typing tests and what other tests Bio-Chem had performed. The President of Bio-Chem then interrupted the inspection, requesting to know the identity of the complainant. Hearing Transcript (Tr.) at 84; HCFA Exhibit 5, at 3. The inspectors informed the President that HCFA could not divulge the name of the complainant. HCFA Exhibit 5, at 3. The President of Bio-Chem then refused to hand over the patient log book. The inspectors repeated the request for the log book and explained to the President the possible ramifications for a refusal to produce the log book. When Bio-Chem's President continued to refuse the log book, the inspectors terminated the inspection of Bio-Chem and left the premises. HCFA later disclosed the identity of the complainant to Bio-Chem.

Discussion

In an appeal of an ALJ decision, our standard of review on a disputed issue of law is whether the decision is erroneous; for a disputed issue of fact, the standard is whether the ALJ decision is supported by substantial evidence in the whole record. CLIA Guidelines ¶ 4(b).

Bio-Chem did not take specific exception to any of the ALJ's findings of fact or conclusions of law (FFCLs). Substantial evidence in the whole record supports the ALJ's findings, and his conclusions correctly state the applicable law authorizing the actions that HCFA took. Bio-Chem clearly had notice that CLIA regulations provided an unconditional right to inspect Bio-Chem's laboratory, and had notice of what the possible consequences could be of obstructing such an inspection. Yet, Bio-Chem admitted that it had refused to produce its log book. None of Bio-Chem's arguments specifically call into question the facts found by the ALJ or his analysis of the applicable law.[(2)]

Instead, Bio-Chem raised a number of arguments that challenge HCFA's authority to act against Bio-Chem, that assert Bio-Chem's right to know who complained against it and why, or that charge that Bio-Chem has been discriminated against. As HCFA pointed out, there is a question about whether some of these arguments, and the underlying factual assertions, were timely raised. In any event, we conclude that the arguments do not provide a basis for reversing the ALJ Decision.

Bio-Chem challenged HCFA's authority to act against Bio-Chem, asserting that Bio-Chem has never participated in the Medicare program.[(3)] Bio-Chem's position is based on a misunderstanding of the scope of CLIA and HCFA's role in establishing and certifying compliance with CLIA requirements. While HCFA has jurisdiction over the Medicare program, it has numerous other responsibilities, including the implementation of CLIA. *See* 42 C.F.R. Part 493. Moreover, the CLIA regulations at Part 493 clearly apply to a broader set of laboratories than those participating in Medicare. *See* 42 U.S.C. § 263a(a); 42 C.F.R. §§ 493.1 and 493.3.

Many of Bio-Chem's arguments were based on its asserted right under the United States Constitution to know who complained against it. Bio-Chem also implied that the fact that HCFA ultimately disclosed the complainant means that HCFA should have disclosed it earlier. The key problem with these arguments is that they assume that the

right to know the complainant, if established, would also establish that Bio-Chem had the right to refuse to produce the log book and that HCFA's remedies were unauthorized.[(4)] As the ALJ concluded, however, the right to inspect is unconditional and Bio-Chem could not reasonably refuse to produce the log book based on the inspectors' failure to disclose the complainant at that time. Moreover, Bio-Chem was informed of the nature of the complaint and did not assert that it needed to know who complained in order to understand the scope of the authorized inspection. We also note that, while Bio-Chem attributed its refusal to the inspectors' failure to disclose, the record suggests a different reason since the refusal occurred under circumstances where the inspectors had reason to question whether Bio-Chem was engaging in testing outside the scope of its CLIA certificate of waiver.

Bio-Chem also alleged violation of its civil rights, asserting that it had suffered discrimination both because it did not have a pathologist on staff and because of its minority-owned status. Bio-Chem attempted to show a pattern of such discrimination, but did not provide any evidence to establish a connection between such alleged discrimination and the attempted inspection here. Moreover, we know of no special protection accorded to laboratories merely because they do not have a pathologist on staff.

Bio-Chem further argued that it had provided evidence that it was referring out non-waiver tests, which the ALJ ignored in his decision. What tests were referred to other laboratories is irrelevant, however, to the basis for the ALJ Decision -- Bio-Chem's refusal to permit an inspection of its records. The ALJ specifically found that this basis was sufficient and that he need not reach other compliance issues raised before him. ALJ Decision at 7-8. Furthermore, while Bio-Chem may have submitted some evidence regarding the referral of tests, that evidence is contradicted by Bio-Chem's own admissions that some non-waiver tests were conducted on its premises, as HCFA pointed out. Tr. at 80 and 86.

The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R.Rep. No. 899, 100th Cong. 2d Sess. 8 (1988). To accomplish this purpose, HCFA reasonably determined it must have the ability to conduct unannounced inspections. Clearly, the position advanced here by Bio-Chem would undercut the Congressional intent in CLIA by permitting a laboratory to refuse an inspection and then to evade the consequences by mounting collateral attacks on HCFA. While Bio-Chem offered to permit an inspection now that it knows who the complainant is, such an inspection would not provide the same assurance as if Bio-Chem had permitted the log book to be examined immediately upon the inspectors' request.

Conclusion

For the reasons discussed above, we uphold the ALJ Decision. We affirm and adopt each of the FFCLs from that decision and incorporate the ALJ's analysis here.

JUDGE

Donald F. Garrett

Marc R. Hillson
Judith A. Ballard
Presiding Board Member

FOOTNOTES

1. This summary of the undisputed facts is intended to provide a general framework for understanding this decision. The reader should consult the ALJ Decision for a detailed statement of the relevant facts.
2. Bio-Chem's arguments imply that Bio-Chem was not informed at the time of the inspection of the nature of the complaint against it. The ALJ found, however, that the inspectors had informed Bio-Chem's President of the reason for the visit, which was to investigate whether Bio-Chem was performing unauthorized tests. ALJ Decision at 5-6. This finding was based on testimony by one of the inspectors. Bio-Chem did not allege that it had provided any evidence to the contrary, which the ALJ had failed to consider.
3. In several letters to the Board, Bio-Chem similarly questioned whether the procedures set forth at 42 C.F.R. Part 498 apply to an entity not participating in Medicare. While Part 498 was originally published to govern appeals of determinations that affect participation in the Medicare program, the types of determinations subject to Part 498 procedures have been expanded over time to include CLIA determinations. 61 Fed. Reg. 32,350 (1996). This is reflected in § 498.3 on "Scope and Applicability." Specifically, § 498.3(a)(2) provides in pertinent part:

> The determinations listed in this section affect participation in the Medicare program. Many of the procedures of this part also apply to other determinations that do not affect participation in Medicare. Some examples follow:
>
> * * *
>
> (iii) HCFA's determination under the Clinical Laboratory Improvement Act (CLIA), to impose alternative sanctions or to suspend, limit, or revoke the certificate of a laboratory even though it does not participate in Medicare.

The CLIA regulations at Part 493 incorporate by reference the hearing procedures in subpart D of Part 498 and the request for review provisions in subpart E of Part 498.
4. Bio-Chem specifically invoked the Sixth and Tenth Amendments to the Constitution (misciting them as Articles VI and X). Bio-Chem Appeal Brief at 2 and 9. The Sixth Amendment provides, "In all criminal prosecutions, the accused shall enjoy the right . . . to be informed of the nature and cause of the accusation; [and] to be confronted with the witness against him . . . ." Bio-Chem did not explain how this Amendment applies in this administrative context, nor how it justified Bio-Chem's refusal to produce the log book. The Tenth Amendment provides, "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." Bio-Chem appeared to argue that it had reserved to itself the power to know the complainant since HCFA had not been specifically delegated the authority to withhold the complainant's name. This is a strained reading of the Tenth Amendment, however, which is directed at State sovereignty, not individual rights.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Sentinel Medical Laboratories, Inc.,

Petitioner,
DATE: June 27, 2000
- v -

Health Care Financing Administration
Docket No.C-98-277
Decision No. **CR679 DECISION**

For the reasons stated below, I sustain the determination of the Health Care Financing Administration (HCFA) to apply the collateral sanction prohibiting Dr. Sol Teitelbaum (Petitioner), the former director of Sentinel Medical Laboratories, Inc (SMLI), from owning or operating another laboratory for two years in accordance with 42 U.S.C. § 263a(l)(3) and 42 C.F.R. § 493.1840(a)(8).

I. Background

A. Applicable law and regulations

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, were enacted by Congress to ensure that the results of tests performed in clinical laboratories, including those tests performed in physicians' office laboratories, are reliable and accurate. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N., 3828, 3829. The statute provides as follows:

> [n]o person may solicit or accept materials derived from the human body for laboratory[(1)] examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

42 U.S.C. § 263a(b).

CLIA was intended by Congress to establish one set of standards which would govern all suppliers of laboratory services, including those which supply laboratory services to Medicare beneficiaries. *See* 1988 U.S.C.C.A.N., at 3829, 3843.

The statute directed the Secretary of the United States Department of Health and Human Services (Secretary) to issue regulations to implement various provisions set out in CLIA, including standards to assure consistent performance of valid and reliable laboratory examinations by laboratories issued a certificate under the Act. 42 U.S.C. § 263a(f)(1). The Secretary's regulations implementing CLIA are found in 42 C.F.R. Part 493.

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 of participation, 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 of participation. 42 C.F.R. § 493.1807.

Finally, under 42 U.S.C. § 263a(I)(3) and 42 C.F.R. § 493.1840(a)(8), no person who has owned or operated a laboratory which has had its CLIA certificate revoked may, within two years of the revocation own or operate (including serve as laboratory director - *see* 42 C.F.R. § 493.2) a laboratory.

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in *Hillman Rehabilitation Center*, DAB No. 1611 (1997). Under *Hillman*, HCFA bears the burden of coming forward with evidence sufficient to establish a prima facie case that: 1) SMLI failed to comply with participation requirements; and 2) the collateral sanction against Petitioner is warranted and lawful under the statute and regulations. Petitioner has the burden of proving, by a preponderance of the evidence, that: 1) SMLI complied substantially with participation requirements; and 2) the collateral sanction against him is unwarranted and unlawful under the statute and regulations. In determining whether HCFA has met its burden of establishing a prima facie case, I may consider rebuttal evidence offered by Petitioner that HCFA's evidence is neither credible or relevant to the issue of Petitioner's compliance with the CLIA requirements or that the weight of the evidence establishes that the regulatory deficiencies alleged by HCFA did not occur. *Hillman Rehabilitation Center*, DAB CR500, at 3-8 (1997). If I conclude that the preponderance of the evidence establishes that such circumstances exist, then I will find that HCFA has not met its burden of establishing a prima facie case (but rather its case is based on unsubstantiated allegations) and Petitioner will not be obligated to prove that it was substantially complying with the CLIA requirements.[(2)]

B. Procedural History

A complaint survey of SMLI was conducted in August 1997. Tr. 67. The survey was conducted by two laboratory field examiners from the State of California, Department of Health Services, Laboratory Field Services (LFS), who were acting as agents for HCFA, for the purpose of determining SMLI's compliance with the CLIA requirements in 42 C.F.R. Part 493. Tr. 60-61, 64. SMLI had the capability to perform tests in several sub-specialties, such as hematology, chemistry, endocrinology and urology. Tr. 65. A request for documentation was made of SMLI so that a determination could be made as to its compliance with the applicable CLIA regulations. Although the examiners made repeated attempts over several months to acquire the needed documentation from SMLI, none was forthcoming. Tr. 68. Consequently, the survey was terminated on December 4, 1997. Tr. 67. The data collected at that time supported the conclusion that SMLI had failed to comply with seven conditions set forth in the CLIA regulations.

By a 24-page letter dated December 26, 1997, addressed to Petitioner, the survey team leader, Tommy Barr, gave SMLI an additional opportunity to submit the requested documents. HCFA Ex. 31. Petitioner was informed in this letter that failure to supply the

requested information by December 29, 1997, would result in an action to suspend or revoke SMLI's CLIA certificate and to cancel its approval to receive Medicare and Medicaid Payments. *Id.* Based on the absence of any response to this letter, the examiners set forth the deficiencies developed from their survey of SMLI in a Form HCFA-2567 (Statement of Deficiencies/HCFA Form 2567). HCFA Ex. 1. By letter dated January 21, 1998, LFS informed Petitioner that, based on the seriousness of the identified deficiencies, which were determined to pose immediate jeopardy to the health and safety of patients of SMLI, it was forwarding the matter to the HCFA regional office with a recommendation that principal sanctions, including suspension and/or revocation of SMLI's CLIA certificate be imposed. P. Ex. 8. In a letter dated February 3, 1998, to Petitioner, in his capacity as the laboratory director of SMLI, HCFA informed Petitioner that SMLI was out of compliance with the following seven conditions: Successful participation (proficiency testing) (42 C.F.R. § 493.803); Patient test management (42 C.F.R. § 493.1101); General quality control (42 C.F.R. § 493.1201(a) and (b)); Laboratory director, moderate complexity testing (42 C.F.R. § 493.1403); Testing personnel, moderate complexity testing (42 C.F.R. § 493.1421); Quality assurance (42 C.F.R. § 493.1701); and Inspection of laboratories requesting or issued a certificate of compliance (42 C.F.R. § 493.1777(a)). HCFA Ex. 2. In this letter, HCFA further advised Petitioner that it was taking the following actions against SMLI: revocation of its CLIA certificate (42 C.F.R. §§ 493.1806(a)-(b), 493.1840(a)(3)-(5) and 493.1840(e)); suspension of its CLIA certificate (42 C.F.R. §§ 493.1806(b) and 493.1840(d)(2)(I)-(iii)); cancellation of its approval to receive Medicare payments (42 C.F.R. §§ 493.1807(a), 493.1808(a) and 493.1842(a)); imposition of a civil money penalty (42 C.F.R. §§ 493.1806(c)(3), 493.1834, 493.1810(d) and 493.1812(a));[(3)] and a directed plan of correction requiring it to immediately cease all testing until compliance could be verified and to provide to HCFA within 10 days a list of the names and addresses of all providers and clients who were involved with it after January 4, 1996 (42 C.F.R. §§ 493.1832(b) and 493.1844(g)(1)). *Id.* Petitioner was also notified that if SMLI's certificate was revoked, he would not be permitted to own or operate (including being a laboratory director, *see* 42 C.F.R. § 493.2) a laboratory for a two-year period from the date of revocation of SMLI's certificate. *Id.* Petitioner was afforded 10 days to give reasons why the sanctions should not be imposed. *Id.*

In a letter dated February 7, 1998, to LFS, Petitioner advised that SMLI voluntarily ceased operations on December 29, 1998.[(4)] Petitioner also made written submissions dated February 9, 10, and 13, 1998, responding to HCFA's notice dated February 3rd.[(5)] Upon review of such submissions, HCFA, by letter dated February 24, 1998, indicated that there was no evidence of corrective action to remove the immediate jeopardy and correct the condition level deficiencies found in the survey of SMLI.[(6)] HCFA Ex. 4. HCFA decided to impose the sanctions outlined in the February 3rd letter, including revocation of SMLI's CLIA certificate, effective April 14, 1998, and the collateral sanction imposed against Petitioner. *Id.*

SMLI, through its owner, Nida Madamba, and Petitioner filed separate requests for hearing.[(7)] Prior to the hearing, SMLI and Nida Madamba withdrew their request for hearing and their appeal was dismissed. As a consequence, revocation of SMLI's CLIA certificate was effectuated on November 30, 1998. Despite this, Petitioner pursues his appeal of the collateral two-year sanction against him owning or operating a clinical

laboratory. HCFA has argued that a laboratory director has no separate standing from that of the laboratory to oppose HCFA sanctions imposed against the laboratory, including revocation of its CLIA certificate and the collateral sanction directed against the laboratory owner(s) and director. If I agreed with HCFA's position, then Petitioner would have no standing and his request for hearing would be dismissed. Such an outcome would deprive Petitioner of his due process rights -- his right to present evidence and make legal arguments why the collateral sanction should not be imposed against him. I concluded, in similar circumstances to the instant case, that the laboratory director has standing to request a hearing independent of the laboratory. *See Eugene R. Pocock, M.D.*, DAB CR527 (1998) at 5. In light of my ruling in *Pocock*, HCFA did not formally renew its objection by written motion but did so at the hearing. I reiterated my prior ruling and overruled the objection. Tr. 17-18.

A hearing was held in this matter from November 30 through December 3, 1998, in Los Angeles, California. At the hearing, I received and admitted into evidence HCFA's exhibits (HCFA Exs.) 1 through 37 (HCFA Exs. 1-37) and Petitioner's exhibits (P. Exs.) 1, 2, 4-6, 8-12, and 14-17. P. Exs. 3 and 7 were rejected; P. Ex. 13 was withdrawn. The parties have filed posthearing briefs and response briefs. In addition to posthearing briefs on the merits, the parties also submitted briefs on the issue of when HCFA would be entitled to enforce the two-year ban against Petitioner, in the event my decision were adverse to him. *See* Letter to parties dated April 22, 1999. The parties also submitted briefs addressing whether there was a need to reopen the record to receive additional evidence. *See* Letter to parties dated June 24, 1999. By letter dated September 10, 1999, Petitioner notified me that he had filed a suit in Federal District Court in which he requested that the District Court assume jurisdiction over this matter. In a letter sent at my direction, dated October 1, 1999, the parties were informed of my determination that Petitioner had failed to show good cause for reopening the evidentiary record. The parties were further informed that, absent an order from a court of competent jurisdiction, I would proceed to issue my decision in this case. At no time have I received any direction from any court to relinquish my jurisdiction over this case. Accordingly, I am issuing this decision.

I base my decision in this case on the governing law, the evidence in the record, and on the parties' arguments. Any argument raised by the parties but not specifically addressed in this decision has been rejected. I use the following format for the Analysis section of my decision. The main headings and subheadings, set out in bold face type, represent my findings of fact and conclusions of law. The descriptive text under each heading or subheading is my rationale for such finding.

III. Conclusion

I sustain the determination of HCFA to impose the collateral sanction against Petitioner, the former director of SMLI, from owning or operating another laboratory for two years in accordance with 42 U.S.C. § 263(I)(3) and 42 C.F.R. § 493.1840(a)(8).

ANALYSIS

II. Analysis

A. Petitioner was the laboratory director of SMLI at all relevant times when the identified deficiencies set forth in HCFA Form 2567 took place, and was responsible for the overall operation and administration of SMLI.

Petitioner admits, in his posthearing brief at 1, that he was hired as the laboratory director of SMLI in October 1995, and continued in such position until SMLI ceased operations on December 31, 1997.[(8)] The CLIA regulations place the primary responsibility for the operation and management of the laboratory upon its director. This individual is responsible for the "overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate [sic], and proficiently and for *assuring compliance with the applicable regulations*." 42 C.F.R. § 493.1407 (emphasis added). The director is the principal person (other than the owner) at the laboratory who is responsible to ensure that CLIA requirements are met. He or she is accountable if the laboratory performs in a manner inconsistent with the regulatory requirements of CLIA. Moreover, HCFA can suspend, limit or revoke the CLIA certificate of a laboratory if it finds that its director was formerly a director or owner of a laboratory that had its CLIA certificate revoked within the preceding two years. This is one of the enforcement mechanisms that ensures that laboratories meet the CLIA requirements and patients of such laboratories receive accurate test results. To do otherwise, would place the health and safety of such patients at risk.

Petitioner attempts to obscure his responsibility under the CLIA regulations by stating he was an employee of SMLI and did not have an ownership interest in the laboratory. P. Posthearing Br. at 9; P. Posthearing Response Br. at 11-12. He argues that he was without authority to take corrective actions in the laboratory, and that other personnel at the laboratory hid information from him and limited his access to the laboratory. P. Posthearing Br. at 9-14. As counsel for HCFA points out in her reply brief, however, Petititioner had full access to the laboratory for a period of time and could have made the same determinations concerning the laboratory practices that were made by the survey examiners.[(9)] HCFA Reply Br. at 14. Moreover, Petitioner admitted that he was aware generally of the findings of the examiners and that the cited deficiencies were "real and sound[ed] very bad." Tr. 857. I asked Petitioner a series of questions at the hearing regarding the findings of the examiners and why he had not known of the deficient practices or taken action to prevent them. Tr. 856-63. In response for the most part, Petitioner blamed his failure to act on others hiding information from him or lying to him. *Id.* His excuses and explanations for his failure to carry out his responsibilities as the laboratory director of SMLI lack credibility and are clearly self-serving. Consequently, I find Petitioner's arguments to be unpersuasive, without merit, and they are rejected.

The CLIA obligations on a laboratory director are clear and explicit. Moreover, CLIA defines "operator" as the person or persons who "oversee all facets of the operation of a laboratory and who bear *primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory.*" 42 C.F.R. § 493.2 (*emphasis added)*. The term "operator" may include the director of the laboratory. *Id.* "Owner" is defined as any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded. *Id.* While both the owner and the director of the laboratory are held accountable by statute and regulation when

the laboratory fails to comply with CLIA, the director, rather than the owner, is responsible for operating the laboratory.[(10)]

Petitioner was a laboratory director of three laboratories at the same time he was director of SMLI.[(11)] Tr. 822, 842-43. He has had extensive experience with the CLIA regulations and either knew or should have known what his obligations were. Tr. 845-47, 853. In fact, under the CLIA regulations, it is mandatory that the laboratory have a director who meets the qualifications for such position and carries out the responsibilities of such position. He was employed for that specific purpose and received whatever compensation that was provided to him for carrying out those responsibilities. If he became aware that he was not able to meet his responsibility under the CLIA regulations as laboratory director, then his choice of action was simple -- resign as laboratory director. In fact, Petitioner admitted that he could have resigned when he was made aware that the laboratory was receiving questionable specimens from individuals (called marketers, who received a kickback from the laboratory) for the purpose of allowing the laboratory to bill either Medicare or Medicaid for testing such specimens. Tr. 835. Rather than resign, Petitioner's self serving testimony was that he hoped to change the practice of the laboratory and that he felt he had an obligation to the patients of the laboratory. Tr. 835.[(12)]

There is no requirement under CLIA that the laboratory director remain under circumstances where he or she cannot meet the CLIA obligations. Petitioner had multiple options to correct the problems in the laboratory. The laboratory could not operate under CLIA without a director; so, any threatened departure on his part would have likely led to a change in his ability to perform his responsibilities under CLIA or have resulted in the closure of the laboratory or the employment of a new director. In addition, he could have filed a complaint either with the State of California or HCFA regarding the deficient practices he believed were occurring at the laboratory. If Petitioner was truly concerned about the patients whose specimens were tested at the laboratory, he would have exercised one or more of these options. To the contrary, he did not exercise any of these options and stayed with SMLI until its closure.

B. Application of the CLIA regulations to Petitioner does not violate his constitutional rights.

As discussed above, Petitioner admitted at the hearing that he had the option to resign from SMLI. Nevertheless, in his posthearing brief, Petitioner ignores this option, instead implying that he had no choice but to remain at SMLI, powerless to change any improper practices that might have been occurring there. Based on the premise that, as a mere employee, it would have been impossible to carry out the duties of a laboratory director under CLIA, Petitioner argues that any attempt to enforce those regulations would violate his constitutional right to due process. He argues that, as applied to him, the regulations are unconstitutional because they are vague or indefinite, shocking and oppressive, and apply unequally to him. As I explained in the previous section, I have concluded that Petitioner's status as an employee-laboratory director, as opposed to an owner-laboratory director, is irrelevant to determining what the CLIA statute and regulations require of him. Similarly, the employee/owner distinction has no bearing on Petitioner's constitutional claims. Therefore, Petitioner's constitutional arguments are without merit and I reject them.[(13)]

Petitioner argues that the CLIA regulations are unconstitutional because they lack definiteness. P. Posthearing Br. at 5. Petitioner cites several cases for the proposition that a statute must not be impossible to satisfy. *Id.* Petitioner's argument appears to be that a statute that is impossible to satisfy is insufficiently definite. His position is that, as an employee-laboratory director, he was not in a position to dictate policy to the owners and/or corporate officers of SMLI. Thus, according to him, the CLIA requirements are impossible to satisfy. As I have discussed in the previous section, I strongly disagree with the premise of Petitioner's argument. On the contrary, I firmly believe Petitioner had both the opportunity and the duty to bring any operating problems to the attention of the owners of SMLI or, if necessary, to the appropriate State or federal authorities. For this reason, I conclude that 42 C.F.R. § 493.1407 is not subject to challenge as being impossible to fulfill.

Petitioner argues that the regulations are void for vagueness, apparently because, in his view, they do not specify how an employee-laboratory director is to gain the cooperation of a laboratory's owners if the director uncovers improper or fraudulent practices. P. Posthearing Br. at 6. There is no constitutional or other requirement that HCFA's regulations must specify the precise steps a laboratory director is to take to carry out his or her responsibilities under CLIA. Common sense dictates the conclusion that no set of regulations could prescribe a course of action for every situation in which a laboratory director might find him or herself. The CLIA regulations are not invalid for their failure to do so.

Petitioner argues additionally that if a laboratory director discovers wrongdoing at his or her laboratory and is unable to correct it, he or she could not be required to report the wrongdoing to HCFA or the State agency, because to do so would violate the laboratory director's constitutional right against self-incrimination. *Id.* Petitioner argues that, in such a situation, the laboratory director will subject him or herself to the statutory two-year ban on operating another laboratory. *Id.* The statutory ban to which Petitioner points is part of a remedial, civil scheme to protect the beneficiaries of federal health care programs. It is not a criminal punishment. As such, the Fifth Amendment right against self-incrimination is inapplicable. *See*, *e.g.*, *Helvering v. Mitchell*, 303 U.S. 391, 402 (1938). Moreover, Petitioner's argument assumes facts not in the record. No HCFA witness testified as to whether it is HCFA policy to apply the two-year ban to a laboratory director who has acted in the role of a whistle-blower. Further, it is not clear whether a laboratory director who resigns his or her position and then turns whistle-blower would even be regarded as the director of the offending laboratory. Thus, even if Petitioner's constitutional right against self-incrimination were at issue, it would be purely speculative for me to conclude that the CLIA regulations would be applied in a manner that would violate a laboratory director's right against self-incrimination. I decline to enter into such speculation.

Petitioner argues that the CLIA regulations violate the due process clause because they are shocking and oppressive. P. Posthearing Br. at 6. Petitioner contends that to apply the two-year ban on operating a laboratory to an employee-laboratory director is so unfair that it shocks the conscience. *Id.* at 6-7. I disagree. Instead, I conclude that it would lead to an absurd result if a laboratory director could avoid his or her responsibilities to ensure that a laboratory operates in accordance with CLIA requirements on the grounds that he or she was only an employee, and then avoid the

consequences of such failure. Every laboratory director who was not an owner would make such an argument to avoid the consequences of the statue and regulations. Such a result would clearly be to the disadvantage of the patients of the laboratory, whom the CLIA regulations were designed to protect.

Petitioner argues finally that the regulations are invalid because they do not apply equally to laboratory directors and other laboratory employees. *Id.* at 7-8. It is true that the statute and regulations provide for a sanction of laboratory directors that is not applicable to other employees. However, the regulations also assign special responsibilities to the laboratory director. It is the laboratory director, not other employees, who is responsible for the overall operation of the laboratory. Thus, if there are problems at the laboratory, it is reasonable to hold the laboratory director, and not the other employees, responsible. If the laboratory director is not comfortable with assuming these responsibilities, then the laboratory director is free to seek some other type of employment. Indeed, the untenable underlying assumption in all of Petitioner's so-called constitutional arguments is that he is entitled to continue to collect the compensation of a laboratory director--i.e. that he should not be forced to resign his position to avoid CLIA sanctions--without discharging the accompanying responsibilities. I do not find it unfair in the least to hold a laboratory director responsible for failures at the laboratory in a situation like the present case, where Petitioner took little action to discharge his duties, but continued to collect his paycheck, even as evidence of problems at SMLI continued to mount. As I discuss in the next section of this decision, the evidence presented by HCFA indicates that deficiencies at SMLI were so widespread that it is difficult to imagine that Petitioner was exercising any of his CLIA responsibilities.

C. Petitioner failed to rebut HCFA's prima facie showing that SMLI was out of compliance with CLIA conditions of participation.

In testimony at the hearing, as well as in documentary evidence offered as exhibits, HCFA offered extensive evidence demonstrating that SMLI failed to comply with CLIA conditions of participation. HCFA's evidence shows a pattern of noncompliance that was pervasive in scope and presented potential risks to patient health and safety. At the hearing and in post-hearing briefs, Petitioner has wholly failed to rebut HCFA's evidence of noncompliance. In fact, Petitioner's own consultant acknowledged that the deficiencies cited by HCFA were justified. Tr. 644. In essence, it appears that Petitioner made a tactical decision not to contest HCFA's factual findings of noncompliance, but instead to rely on his legal challenges to the procedures HCFA followed in moving to invoke the two-year ban on owning or operating a laboratory against Petitioner.[(14)] Based on the record before me, I must conclude that HCFA proved the existence of numerous deficiencies at SMLI.[(15)]

1. SMLI was out of compliance with the condition governing successful participation in proficiency testing.

Section 493.803(a) of the regulations requires that a laboratory performing tests of moderate complexity or high complexity must successfully participate in a proficiency testing program approved by HCFA for each specialty, subspecialty, and analyte or test in which the laboratory is performing tests. Proficiency testing consists of an external monitoring program that measures how accurately a laboratory is testing patient

samples. Tr. 74. A laboratory enrolls with a proficiency testing organization, which will send the laboratory three challenges each year. *Id.* Each challenge will usually consist of five different unknown samples for each analyte which the laboratory tests. *Id.* The laboratory is to test the proficiency test samples along with their patient samples, record the results, and return the results to the proficiency testing organization, which will grade the laboratory's results by comparing them with the results achieved by other laboratories enrolled in the program. *Id.* at 74-75. Successful participation in proficiency testing requires that a laboratory must pass with a score of at least 80 percent. *Id.* at 75. Mr. Barr testified that, based on his examination of the scoring documentation returned to SMLI by the proficiency testing organization, he concluded that SMLI failed to perform at the required 80 percent level for a large number of analytes in several subspecialties of testing. Mr. Barr testified that, in the subspecialties of bacteriology, general immunology, routine chemistry, and endocrinology, SMLI failed in one or more testing events to achieve a score of 80 percent or better. Tr. 76-79; *see also* HCFA Ex. 1, at 5-9. Petitioner offered no evidence to rebut Mr. Barr's conclusions. Accordingly, I conclude that HCFA proved that SMLI failed to participate successfully in proficiency testing, as required by 42 C.F.R. § 493.803(a).

Moreover, as particularly relevant to Petitioner's responsibilities as laboratory director, Mr. Barr testified that, during the survey, SMLI was unable to produce any documentation showing that any remedial action was taken to identify and address the reasons for the unsuccessful proficiency testing results. Tr. 81-82. The laboratory directory is responsible for undertaking such corrective action. *Id.* at 82; *see also* 42 C.F.R. § 493.1407(e)(4).

Finally, SMLI's failure to achieve acceptable results in proficiency testing casts serious doubt on the reliability of its patient test results. *See* Tr. 76. For this reason, I conclude that the deficiencies proved by HCFA are of such a character as to substantially limit SMLI's capacity to furnish adequate care. Accordingly, I find that SMLI was out of compliance with the condition of participation for successful participation in proficiency testing.

2. SMLI was out of compliance with the condition of participation for patient test management.

Section 493.1101 of the regulations sets forth the condition of participation for patient test management. The condition requires that each laboratory performing moderate or high complexity testing, or both, employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. The laboratory's system must assure optimum patient specimen integrity and positive identification throughout the preanalytic (pre-testing), analytic (testing), and postanalytic (post-testing) processes and must meet the standards of the subpart as they apply to the testing performed. HCFA presented evidence of extensive problems at SMLI relating to patient test management.

To ensure specimen integrity and identification during the pre-testing process, the standard at 42 C.F.R. § 493.1103 requires that a laboratory have and follow written policies and procedures for patient preparation, specimen collection, specimen labeling, specimen preservation, etc. Mr. Barr testified that, in spite of numerous requests from the surveyors, personnel at SMLI were unable to produce copies of written policies and

procedures for specimen collection, labeling, and identification. Tr. 90-91. The surveyors were never shown such written policies, either for laboratory clients or for in-house use. *Id.* Mr. Barr testified that it is the laboratory director's responsibility to ensure that written policies and procedures are in place and that such policies are appropriate, as attested by the laboratory director's signature. *Id.* at 92.

Mr. Barr found further evidence that SMLI did not provide such policies or procedures to its clients, i.e., the physicians or clinics that referred tests to SMLI. Mr. Barr concluded, from his examination of SMLI's records for the period April through September 1997, that 92 percent of the patients' records indicated that the laboratory had received an insufficient quantity of a patient's specimen to perform the requested tests.[(16)] *Id.* at 94. Normally, laboratories provide a client book to referring physicians to educate them as to how specimens must be collected. *Id.* at 95. Given that SMLI personnel could not produce any such documentation, and given the high rate of untestable specimens submitted, I infer, as did Mr. Barr, that SMLI did not have or follow such procedures and that no procedures were transmitted to referring physicians. I therefore conclude that SMLI was out of compliance with the standard governing procedures for specimen submission and handling.

HCFA also presented evidence that SMLI was out of compliance with the standard governing test requisition. Section 42 C.F.R. § 493.1105 requires that a laboratory perform tests only at the written or electronic request of an authorized person. An authorized person is usually a physician. Tr. 97. Mr. Barr testified that, in 39 out of 44 records which he examined, SMLI had performed additional tests which were not requested by the physician.[(17)] *Id.* Additionally, in 42 of the 44 records, the test requisition failed to include either the name of the authorized person requesting the test or a contact person to enable the reporting of imminently life threatening laboratory results, as is required by 42 C.F.R. § 498.1105(b). *Id.* at 137-38. Finally, on every one of the 44 test requisitions, the date of specimen collection was questionable. *Id.* at 141. Section 498.1105(d) of the regulations requires that the requisition include the date the specimen was collected.

Mr. Barr's testimony demonstrated that similar documentation problems persisted into SMLI's testing operations. Just as the test requisitions failed to note the date of specimen collection, SMLI's testing records failed to include the date on which the specimen was received in the lab and also, in 32 of 44 records, failed to show the date or dates on which testing was performed. The failure to record these dates constitutes a violation of 42 C.F.R. § 493.1107(b) and (d). Moreover, when dates could be identified, there were discrepancies which called into question the reliability of SMLI's test results. For example, for certain patients, SMLI's records indicated that test results were not reported until up to four months after the date that a specimen was supposedly received in the lab. *See*, *e.g.*, Tr. 165-67. In other instances, the report date precedes the supposed collection date. *See, e.g.*, Tr. 199-200.

In the post-testing phase, Mr. Barr testified that SMLI failed to keep records of instrument printouts and test results for two years, also in violation of 42 C.F.R. §§ 493.1107 and 1109. Tr. 155-56, 186. Moreover, SMLI could not document that it had sent test reports only to authorized persons (Tr. 185), nor that it had notified the authorized person in instances where test results were critical or "panic" values (Tr. 202-03).[(18)]

The widespread lack of documentation, as well as the discrepancies that were found in the documents that did exist, led the surveyors to conclude that SMLI lacked an adequate system to ensure that test results were reported in a timely, accurate, and reliable manner, as required by 42 C.F.R. § 493.1109(a). Tr. 190-91. I agree with the surveyors' conclusion that Petitioner, as SMLI's director, bears significant responsibility for this systematic failure. *See* Tr. 191.

The apparent system-wide failure of SMLI to maintain documentation of its testing processes calls into question the reliability of all its test results. For this reason, SMLI's deficiencies are of such a character as to substantially limit SMLI's capacity to furnish adequate care. Accordingly, I find that SMLI was out of compliance with the condition of participation for patient test management.

3. Petitioner was out of compliance with the condition of participation for general quality control.

Section 493.1201 of the regulations requires that a laboratory establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient test results and reports. Quality control in a laboratory is performed by analyzing control samples along with patient samples for each type of test the laboratory performs. *See* Tr. 221-22. Control samples are produced by commercial manufacturers, who supply the samples in kits with a guide that specifies the range of acceptable results for the control samples, depending upon the test equipment and methodology the laboratory is using. Tr. 223. In most subspecialties of testing, a laboratory is required to include at least two levels of control for each day (24 hours) of testing. Tr. 221. *See also* 42 C.F.R. § 493.1218(b). For hematology, a laboratory is required to include at least two levels of control for each eight hours of testing. Tr. 222. *See also* 42 C.F.R. § 493.1253. In the event that the laboratory's result for a given control is not within an acceptable range, the laboratory would be expected to take some remedial action to identify and correct the problem with its equipment or methodology. Tr. 224-25, 227-28.

Mr. Barr testified that, as was the case with the condition of participation for patient test management, SMLI's documentation of its quality control activities was seriously deficient. First of all, SMLI could not produce any written procedures or protocols for quality control. Tr. 217. Second, SMLI failed to produce documentation that quality control samples were run on each day of testing. Tr. 218-19, 228-29, 257. Third, in the few instances where quality control was documented, SMLI could not document that any remedial action was taken when the controls were not within acceptable ranges. Tr. 232-33. Moreover, no documentation was provided that SMLI personnel re-evaluated patient test results in those instances where the control results were outside the acceptable ranges. Tr. 233-36. Mr. Barr testified that the creation and implementation of quality control procedures, including remedial actions, are items ultimately within the responsibility of the laboratory director. Tr. 233-35. The regulations confirm that quality control is among the laboratory director's responsibilities. *See* 42 C.F.R. § 493.1407(e)(5).

I conclude that HCFA proved that SMLI lacked documentation of its quality control policies and practices. This lack of documentation in and of itself represents a deficiency. The lack of documentation also raises serious questions as to whether SMLI

performed the required quality control in any systematic way. I find that the lack of quality control documentation at SMLI creates significant uncertainty about the reliability of SMLI's patient test results. *See* Tr. 258. For this reason, I conclude that the deficiencies established by HCFA are of such a character as to substantially limit SMLI's capacity to furnish adequate care. Accordingly, I find that SMLI was out of compliance with the condition of participation for general quality control.

4. SMLI was out of compliance with the condition of participation for quality assurance.

Section 493.1701 of the regulations requires that a laboratory establish and follow written policies and procedures for a comprehensive quality assurance program to monitor and evaluate the ongoing and overall quality of the total testing process at the laboratory. The quality assurance program must evaluate the effectiveness of the laboratory's policies and procedures; identify and correct problems; assure the accurate, reliable, and prompt reporting of test results; and assure the adequacy and competency of staff. 42 C.F.R. § 493.1701.

Again, as was the case with other participation requirements, Mr. Barr found that SMLI lacked documentation that quality assurance was being carried out. According to Mr. Barr, SMLI was unable to produce any written policies and procedures for quality assurance, nor did the laboratory have any documentation that quality assurance activities were being carried out. Tr. 281-82. Mr. Barr opined that it was the lack of a quality assurance program which resulted in the widespread breakdowns in SMLI's systems, including proficiency testing, patient test management, and quality control, as outlined above. Tr. 283-84. I agree with HCFA's contention that, had any quality assurance measures been taken, SMLI personnel might have been able to detect these problems and prevent them from recurring.

The regulations specify that quality assurance is a key responsibility of the laboratory director. *See* 42 C.F.R. § 493.1407(e)(5). The preamble to the regulations reinforces that the director is expected to assume responsibility for quality assurance:

> Although all laboratory personnel must be involved in quality assurance activities, the laboratory director, regardless of the laboratory's level of testing, is ultimately responsible for the overall management of the laboratory QA program.

57 Fed. Reg. 7100 (Feb. 28, 1992). Thus, I agree with HCFA that Petitioner bears responsibility for SMLI's failure to document and implement an adequate quality assurance program.

Based on the lack of documentation found by the surveyors, I find that SMLI had no quality assurance program in place. This conclusion is reinforced by the laboratory's breakdowns in proficiency testing, patient test management, and quality control. As I have previously concluded, each of these breakdowns substantially limited SMLI's ability to provide adequate care. Because an adequate quality assurance program might have rectified these breakdowns, I conclude that the lack of such a program itself likewise substantially limited SMLI's ability to provide adequate care. Accordingly, I conclude that SMLI was out of compliance with the condition of participation for quality assurance.

5. SMLI was out of compliance with the condition of participation for laboratory director.

As I have discussed in my analysis of each of the previous conditions of participation, Petitioner, as laboratory director of SMLI, bears direct or indirect responsibility for many of the deficiencies that led to my concluding that SMLI failed to comply with the conditions of participation. Section 493.1403 of the regulations requires the laboratory director to provide overall management and direction for the laboratory.[(19)] The widespread and serious failures at SMLI are convincing evidence that Petitioner failed to provide the required management and direction at SMLI.

The standard at 42 C.F.R. § 493.1407 lists the specific areas over which a laboratory director is expected to exercise responsibility. That section also provides that, if the laboratory director delegates any of his or her duties to others, the director "remains responsible for ensuring that all duties are properly performed." 42 C.F.R. § 493.1407(b). Thus, the laboratory director retains responsibility for any deficiencies that occur as a result of a laboratory's employees' failure to carry out their duties properly.

In the present case, my earlier discussion reflects the fact that SMLI was out of compliance with the conditions of participation for proficiency testing, patient test management, quality control, and quality assurance. I agree with HCFA's argument that these failures, in and of themselves, demonstrate that the corresponding elements of the standard for Laboratory Director Responsibilities were out of compliance. Thus, for the reasons discussed above, I conclude that SMLI was out of compliance with 42 C.F.R. § 493.1407(e)(3)(iii)(test performance), 42 C.F.R. § 493.1407(e)(4)(proficiency testing), and 42 C.F.R. § 493.1407(e)(5)(quality control and quality assurance).

HCFA also presented evidence that SMLI was out of compliance with the standard at 42 C.F.R. § 493.1407(e)(1), due to Petitioner's failure to ensure that the testing systems employed by the laboratory deliver quality laboratory services. Mr. Barr testified that for all the laboratory equipment cited at page 217 of HCFA Ex. 1, SMLI staff were unable to produce any preventive maintenance protocols or documentation that preventive maintenance was done. Tr. 263. Without any assurance that preventive maintenance was being performed on SMLI's equipment, Petitioner could not be certain that the equipment was capable of producing accurate results. I find this evidence persuasive of the fact that Petitioner failed to exercise his oversight responsibilities to ensure that SMLI's maintenance activities were documented. The lack of documentation also gives rise to an inference that the required maintenance may not have been done at all. For these reasons, I conclude that SMLI was out of compliance with 42 C.F.R. § 493.1407(e)(1).

The number and seriousness of the deficiencies found by the surveyors are convincing evidence that Petitioner was not adequately carrying out his duties as laboratory director. I conclude that Petitioner's failings in carrying out his duties were likely to substantially impair SMLI's ability to provide adequate care. Accordingly, I find that SMLI was out of compliance with the condition of participation governing the laboratory director.

For all the reasons discussed above, I conclude that HCFA proved, and Petitioner failed to rebut, that SMLI was out of compliance with the conditions governing participation in the Medicare program. Therefore, HCFA proved that it had a factual basis on which to revoke SMLI's CLIA certificate and to invoke against Petitioner the two-year ban against owning or operating a laboratory.

Petitioner has raised a number of additional legal challenges in an attempt to prevent the application of these remedies. In the following sections of this decision, I discuss why I conclude that these arguments are essentially attempts to avoid the consequences of the serious deficiencies at SMLI by relying on legalistic technicalities.

D. I reject Petitioner's argument that the survey of SMLI was fatally defective because of the surveyors' alleged failure to follow survey procedures.

Petitioner argues that I should reject the extensive findings of deficiencies by the state surveyors because, according to Petitioner, the surveyors failed to follow the appropriate survey procedures as established in HCFA guidelines. Specifically, Petitioner contends that Mr. Barr ended the survey of SMLI without conducting an exit conference. According to Petitioner, HCFA guidelines require that an exit conference be conducted.

There is no provision in the regulations governing laboratories which compels HCFA or its designee to conduct an exit conference with a laboratory at the completion of a survey of that laboratory. *Ban Laboratories*, DAB CR576 (1999); *see* 42 C.F.R. § 493.1773. According to Petitioner, however, HCFA guidelines require that an exit conference be conducted. Petitioner attached to his brief a copy of a document entitled, "Appendix C Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services" (P. Attach. 1). Petitioner describes the source of this document as the HCFA Web site. The document appears to be an excerpt from one of HCFA's procedure manuals, though it is not possible to tell which manual. Regardless of the source, however, it is clear that the plain language of the guidelines does not support Petitioner's argument that an exit conference is required. On the contrary, the sections on which Petitioner relies are consistent with the regulations, contemplating that there will be occasions on which exit conferences will not be conducted.

The first provision of the guideline cited by Petitioner contains the following statement: "explain that the laboratory can schedule an Exit Conference to discuss survey findings." P. Attach. 1 at C-9. This statement encourages surveyors to offer facilities an opportunity for an exit conference; it does not state that an exit conference must be conducted. Similarly, the guideline specifically addressing the exit conference states:

> *When* an Exit Conference is held, it is to inform the facility's staff of your observations and findings and to solicit additional information from the facility.

Id. at C-18 (emphasis added). The use of the word "when" in the guideline makes explicit that there will be some occasions when an exit conference is *not* held. Thus, my reading of the HCFA guidelines produced by Petitioner is that the guidelines do not require that an exit conference be conducted at the end of every survey.

However, even if I had concluded that the guidelines required an exit conference at every survey, I would still not find that the failure to conduct such a conference would invalidate the survey findings. Appellate panels of the Departmental Appeals Board have frequently held that a procedural defect in a survey is not a sufficient basis for overturning a finding of noncompliance during that survey. *Hillman Rehabilitation Center*, DAB No. 1663 (1998); *see also Indiana Department of Public Welfare*, DAB No. 781 (1986). An appellate panel of the Board has stated that:

> [T]he substance of the compliance findings . . . must take precedence under the statute, not whether a particular process or protocol was followed in compiling evidence regarding compliance.

Golden State Manor Rehabilitation Center, DAB No. 1597 (1996). While that case involved a long-term care facility, rather than a clinical laboratory, the panel's observations about the intent of the statute, which is to protect the health and safety of program beneficiaries are equally applicable to the CLIA provisions. For these reasons, I conclude that even if an exit conference were required under the regulations or guidelines, the failure to provide the exit conference would not necessarily invalidate otherwise credible findings of noncompliance.

Notwithstanding, I would be concerned if Petitioner had shown that it was deprived of notice by HCFA or by the California Department of Health of the findings of deficiencies or the basis for those findings. Petitioner argues that he has been deprived of due process by the failure to grant an exit conference and by other defects, such as the alleged failure to serve the proper party with the Statement of Deficiencies and the notice of imposition of remedies. However, for the reasons explained in the following section, I conclude that Petitioner has not pointed to anything which would establish that he was deprived of adequate notice of these findings.

E. Petitioner received adequate notice of HCFA's findings of noncompliance and was afforded adequate due process throughout these proceedings.

Petitioner argues that the present proceedings are fatally defective because HCFA failed to serve the proper party with the Statement of Deficiencies. P. Posthearing Br. at 27. According to Petitioner, under California law, HCFA was required to serve the Statement of Deficiencies on the individual registered with the California Department of Corporations to accept service on behalf of SMLI. *Id.* That individual, according to Petitioner, was Rolando Alcayde, a co-owner of SMLI. *Id.* However, as Petitioner's own witness testified, Mr. Alcayde had fled the country. *See* Tr. 601. Thus, it is apparently Petitioner's contention that HCFA would be precluded from imposing sanctions on SMLI unless HCFA could somehow manage to obtain service on Mr. Alcayde in the Phillippines. This is an absurd suggestion.

First of all, enforcement proceedings under the CLIA statute and regulations are governed by federal, not State law. The federal regulations governing notice of CLIA proceedings do not require that HCFA obtain personal service, whether on corporations or other individuals. Instead, the regulations require only written notice and an opportunity to respond. *See* 42 C.F.R. § 493.1810. In the present case, notice of these proceedings was mailed to Ms. Madamba, who appeared to be a co-owner of SMLI, and to Petitioner, SMLI's laboratory director. That both of these individuals received actual notice of HCFA's determination to impose sanctions against SMLI is demonstrated by the fact that each of them timely filed a request for a hearing to contest HCFA's determination.

Moreover, Petitioner has had the opportunity, in the course of these proceedings, to appear at an in-person hearing to give testimony, to call witnesses on his behalf, and to cross-examine the witnesses called by HCFA. Petitioner has also had the opportunity to submit extensive briefs setting forth his legal arguments. There is simply no basis to contend that Petitioner has, in any way, been deprived of due process.

F. I reject as inconsistent with the purposes of the CLIA regulations Petitioner's arguments that SMLI's CLIA certificate cannot be revoked by HCFA because, prior to the HCFA's notice of the proposed revocation on February 3, 1998: 1) the CLIA certificate had expired on January 31, 1998; and 2) SMLI had ceased operations on December 29, 1997.

Petitioner raises two separate but related procedural arguments against imposition by HCFA of the revocation of SMLI's CLIA certificate. First, Petitioner argues that since SMLI voluntarily ceased operations on December 31, 1997,[(20)] there was no "immediate jeopardy" in existence when HCFA sent its Statement of Deficiencies to Petitioner on January 21, 1998. P. Posthearing Br. at 31. Petitioner appears to be arguing that, absent a continuing showing of "immediate jeopardy", HCFA has no regulatory basis to revoke the CLIA certification of SMLI. In a related second argument, Petitioner contends that since SMLI's compliance certificate had expired on January 31, 1998,[(21)] there is no procedure in 42 C.F.R. § 493 for the revocation of an expired CLIA certificate. P. Posthearing Response Br. at 19. I will address each of these arguments below.

On January 21, 1998, LFS sent to SMLI the Statement of Deficiencies, HCFA Form 2567, from its survey of the laboratory to determine whether it met the CLIA requirements. P. Ex. 8. A number of deficiencies were identified, which were determined to pose immediate jeopardy to patients of the laboratory. *Id.* SMLI was further advised that due to the seriousness of the deficiencies and its failure to meet the CLIA requirements for testing that LFS had recommended to HCFA a certification of non-compliance with the following sanctions: suspension and/or revocation of the CLIA certificate; cancellation of all Medicare and Medicaid payments and civil money penalties. *Id.* Petitioner, by letter dated February 7, 1998 to LFS, indicated he received the January 21 letter on January 26, 1998, and that he was no longer the laboratory director of SMLI, which ceased operations and testing on December 29, 1997.[(22)] P. Ex. 9. In this letter, Petitioner also denied the allegations in the HCFA 2567 pertaining to him as laboratory director and indicated that corrective action was not necessary in light of the closure of the laboratory. *Id.* HCFA, upon review of the submission of LFS on February 3, 1998, informed Petitioner, as laboratory director of SMLI, that: 1) it had amended the HCFA 2567 to reflect a new condition that was not met; 2) it had not received any response to the notice of immediate jeopardy; and 3) it had decided to impose various sanctions against the laboratory's CLIA certificate, including revocation of SMLI's CLIA certificate. HCFA Ex. 2. In response to communications from Petitioner, and from one of SMLI's owners, HCFA, on February 24, 1998, concluded that there was "no evidence that corrective actions have been taken to remove jeopardy and correct all Condition-level deficiencies . . ." and, consequently, HCFA decided to impose the sanctions set forth in the February 3, 1998 letter. HCFA Ex. 4.

I find no merit in Petitioner's argument that HCFA is precluded from initiating action to revoke SMLI's certificate of compliance because the laboratory ceased operations and testing on December 29, 1998. In essence, Petitioner is arguing that no public interest is being served by revoking the CLIA certificate of a non operating laboratory and any immediate jeopardy arising from its prior deficiencies of the CLIA requirements ends with its cessation of operations. I will concede that cessation of operations and testing of patient specimens ensured that physicians and patients who relied on the quality and accuracy of SMLI's test results in making health care decisions would not have to be

concerned about future operations once the laboratory ceased operations. However, the harm resulting from potentially inaccurate arising from SMLI's past practices documented in the HCFA Form 2567 still exits despite SMLI's cessation of operations. HCFA requires the laboratory owner/operator to engage in actions under a directed plan of correction that will lead to the notification of persons or entities that relied on test results emanating from the laboratory at the time the deficient practices were shown to exist. *See* HCFA Ex. 2 at 3 [42 C.F.R. §§ 493.1832(b) and 493.1844(g)(1)].

In addition to notification of users of the laboratory services, HCFA imposes accountability on the owners and operators of SMLI to ensure that the individuals who were in a position to prevent the deficient practices recited in the HCFA Form 2567 are not in a position to continue those practices in other CLIA laboratories. To ensure that such circumstances do not occur, CLIA regulations provide, as has been stated previously, that the present owners and operators (including the laboratory director) are prohibited from owning or operating another laboratory for at least two years from the date of revocation of the CLIA certificate of the sanctioned laboratory.

Cessation of the laboratory's operations while subject to a CLIA survey, or after receipt of the survey findings in the HCFA Form 2567, does not excuse the laboratory operators or owners from the two-year sanction against owning or operating a CLIA laboratory once a CLIA certificate is revoked. Section 6256(c) of HCFA's Special Procedures for Laboratories instructs HCFA's regional offices how to proceed when a CLIA laboratory ceases operations during the pendency of an action leading to the revocation of a CLIA certificate. HCFA Ex. 33.[(23)] In such circumstances, the regional offices are instructed to proceed with the revocation despite the laboratory's withdrawal from CLIA where the HCFA regional office decides that a laboratory owner or operator should be subject to the two-year prohibition against owning or operating a laboratory, which sanction is triggered by the revocation of the laboratory's CLIA certificate. *Id.* Ms. Mary Jew, HCFA's CLIA Team Leader, provided the following testimony relating to the rationale behind HCFA's pursuit of a two-year prohibition against Petitioner:

> [SMLI] had serious deficiencies. It was immediate jeopardy. And just the fact that the laboratory closed doesn't mean that the deficiencies have been corrected, nor can a laboratory say that they withdraw from the CLIA program or close the laboratory just to avoid sanctions.
>
> . . . [T]he intent of the [CLIA] regulations was that if a laboratory has been operating and putting out poor quality results, or not operating as they should, then the people who are held responsible, specifically the owner and operator, which includes the director, are responsible.
>
> . . . [The purpose of the regulation was to prevent] irresponsible people [from] being able to then go and open another laboratory. It's sort of like, . . . a small measure, but some measure, of preventing a continuation of bad practices.

Tr. 504-505.

The issue of closure of the laboratory has been addressed previously in *California Medical Associates Laboratory*, DAB CR76 (1997). The administrative law judge, in circumstances similar to those present in this case, held that:

> [n]othing 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.

Id. at 7.

As HCFA counsel points out in her posthearing brief at page 65, the public interest in terms of the health and safety of the patients who rely to their potential detriment on the accuracy of specimen test results of CLIA laboratories warrants an action by HCFA against the laboratory director and/or owner under whose directorship the deficiencies cited in the HCFA Form 2567 occurred. I agree. SMLI's voluntary closure of its operations in December 1997 provides no basis to alter HCFA's application of the two-year sanction against Petitioner's owning or operating a CLIA laboratory in the future. The CLIA regulations contemplate circumstances where the compliance certificate of the laboratory expires during the pendency of a HCFA sanction action arising from failure of the laboratory to meet the regulatory standards. 42 C.F.R. § 493.49 of the CLIA regulations sets forth the requirements for a certificate of compliance. As indicated above, SMLI's certificate of compliance was effective on February 1, 1996, and expired on January 31, 1998, for failure to pay the renewal fees. In circumstances of noncompliance with the CLIA regulations where HCFA initiates an enforcement action, section 493.49(e) of the regulations provides that the subject laboratory retains its certificate of compliance or a reissued certificate of compliance until a decision is made by an administrative law judge. While it appears from Ms. Jew's testimony (Tr. 514) that HCFA was aware that the compliance certificate had expired when it issued its notification letters to SMLI and Petitioner, HCFA never reissued the compliance certificate as contemplated in the above-cited regulation for purposes of the an eventual hearing before an administrative law judge.[(24)] Despite this regulatory requirement, HCFA notice letters, dated February 3, 1998 and February 24, 1998, sent to Petitioner and the attorney of one of the owners of SMLI, failed to reference either the closure of the laboratory on December 29, 1997, or the expiration of the compliance certificate on January 31, 1998. *See* HCFA Exs. 2-4. Nor do such letters indicate that HCFA ever reissued the compliance certificate after it expired for purposes of this proceeding. *Id.* Petitioner argues that HCFA's failure to adhere to this procedural requirement presents a fatal flaw -- there is no compliance certificate in existence which can be revoked as a consequence of the cited deficiencies in the HCFA Form 2567 and, consequently, the two-year sanction against owning and operating a laboratory cannot be applied against Petitioner.

I do not agree that failure to reissue the compliance certificate is a fatal flaw or insulates Petitioner from the regulatory sanctions arising from his laboratory directorship at SMLI. Petitioner was advised by LFS on January 21, 1998, prior to expiration of the CLIA compliance certificate, that revocation of such certificate was contemplated based on the survey results of SMLI contained in the Statement of Deficiencies and that the two-year prohibition against owning or operating a laboratory would result, based on the revocation of the certificate. *See* P. Ex. 8. At this point in time, LFS was acting as HCFA's agent in the first step of the process leading to implementation of the principal

and alternative sanctions arising from SMLI's cited deficiencies of the CLIA regulatory standards. Such notification by LFS in essence placed a constructive hold on SMLI's compliance certificate pending the outcome of the enforcement proceeding. The subsequent expiration of the compliance certificate on January 31, 1998 for failure to pay renewal fees, as explained by Ms. Jew at the hearing, did not remove the certificate from the CLIA database, and it could be reissued once the fees were repaid. Tr. 515-518. The only way to remove the certificate from the database, in the circumstances of a pending enforcement action, would be revocation of the certificate. *Id.*

Section 493.49(e)(2) of the CLIA regulations provides that when there is an appeal of a proposed revocation of a compliance certificate, the laboratory retains such certificate until a decision is made by the administrative law judge. This is a technical requirement only, and failure to reissue the certificate earlier in the sanction process has no import on the legitimacy of the sanction process. The due process rights of the Petitioner have not been abridged by HCFA's failure to reissue the certificate earlier in the sanction process. The compliance certificate has to be technically reissued prior to effectuation of my decision so that a basis exists for such revocation, as it pertains to Petitioner, the laboratory director of SMLI. That is an effectuation issue that HCFA must address, and occurs after my decision is issued providing a basis for revocation of the compliance certificate.[(25)]

G. Under the CLIA regulations, the sanctions against Petitioner are effective with my decision.

Petitioner argues that the sanction HCFA proposes to enforce against him, namely the two-year ban on owning or operating a CLIA laboratory, should be stayed pending his exhaustion of his administrative remedies, and throughout the period of judicial review. *See* P. Posthearing Br. Regarding HCFA Actions After ALJ Decision. HCFA argues that the statute and regulations clearly intend that CLIA sanctions be enforced once they have been upheld by an administrative law judge. *See* HCFA Reply to Petitioner's Posthearing Brief Regarding HCFA Actions After ALJ Decision. I am convinced that enforcing sanctions upon my decision coincides more closely with the purposes of the CLIA statute and regulations than staying such sanctions throughout the appeals process.

First of all, the plain language of the regulation states that the principal sanctions of suspension, limitation, or revocation of a laboratory's CLIA certificate are "not effective until *after a hearing decision by an ALJ is issued*." 42 C.F.R. § 493.1844(d)(2)(emphasis added).[(26)] Although this language is phrased in the negative, the implication is clear that such sanctions are effective when the ALJ decision is issued. This interpretation of the regulation is also consistent with the intent expressed by the Secretary in the preamble to the regulations.

In a response to a comment suggesting that imposition of CLIA alternative sanctions should be stayed pending further appeal, the Secretary responded:

> In those cases in which judicial review is authorized by law, it is available only after an [administrative law judge] hearing. It cannot and should not delay imposition of sanctions. To permit a noncomplying laboratory to continue to operate until all appeals were exhausted would be dangerous to the health and safety of the individuals served by the laboratory. It would also be inconsistent with section 1846(b) of the Act, which

> requires the Secretary to minimize the time between the identification of violations and the imposition of sanctions.

52 Fed. Reg. 7002, 7233 (Feb. 28, 1992). The Secretary's reasoning, although specifically applicable to noncomplying laboratories, rather than to laboratory directors, is equally applicable in the present case. Where an administrative law judge has found that HCFA is authorized to revoke a laboratory's CLIA certificate, the CLIA statute presumes that the director of that laboratory, when he or she acts as an operator, poses a risk to patient health and safety. The statute therefore imposes a two-year ban on such directors owning or operating another CLIA laboratory. To delay imposition of the two-year ban pending completion of all possible appeals and judicial review would pose the same dangers and would create the same discrepancy with the statute discussed in the preamble.

Therefore, based on the language of the regulations and the regulatory intent as described in the preamble, I conclude that, upon my issuing this decision, HCFA is authorized to impose the two-year ban against Petitioner owning or operating any CLIA laboratory.

JUDGE

Edward D. Steinman
Administrative Law Judge

FOOTNOTES

1. CLIA defines a "laboratory" or a "clinical laboratory" as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. *See* 42 U.S.C. § 263a(a).

2. An appellate panel of the Departmental Appeals Board has emphasized that the burden of persuasion set forth in *Hillman* applies only where the evidence proffered by both sides is "in equipoise." *Oak Lawn Pavilion, Inc.*, DAB No. 1638, at 16-17 (1997). In such cases, the burden of persuasion would be on Petitioner.

3. The civil money penalty was imposed against the laboratory owners, and is not an issue in this case.

4. As will be subsequently discussed, Petitioner argues that based on SMLI's cessation of operations and the lapsing of SMLI's CLIA certificate on December 31, 1997, due to failure to pay CLIA fees, the collateral sanction should not be imposed against him. For the reasons cited in my decision, I find these arguments unpersuasive. *See infra* at 28-30.

5. One of the owners of SMLI, Nida Madamba, engaged counsel, Clinton T. Bailey, who also responded to HCFA's notice of proposed sanctions. The other owner, Rolando Alcayde, was never located by HCFA, other than service at an address in Santa Ana, California. There was some testimony suggesting that Mr. Alcayde had left the U.S. for the Phillippines. Tr. 601.

6. Petitioner's February 9, 10, and 13, 1998 submissions are referenced in HCFA's February 24 letter, but are not otherwise in the record.

7. The matters were initially separately docketed. For purposes of administrative efficiency, I consolidated the cases into a single docket number.
8. Petitioner stresses that as the laboratory director he was an employee of SMLI and never had any ownership interest in the laboratory. P. Posthearing Br. at 9.
9. Petitioner testified that he initially visited SMLI five or more times per month in the first two months of its operation in 1996. Tr. 826. For the next year and half, he averaged two to three times per month. Tr. 827. After the change in ownership in March 1997, and when he noticed an increase in the volume of the specimens and some questionable practices, and until the laboratory closed in December 1997, he averaged five to six times per month, and then, in the latter part of 1997, up to ten times per month at SMLI. Tr. 826-832. He also relied on his consultant Edd Epstein and his nephew Ron Lieberworth to deal with the problems at the laboratory. Tr. 828.
10. For moderate complexity testing, as was done by SMLI, the CLIA regulations prescribe the qualifications that a director must possess in order to manage and direct laboratory personnel and the performance of moderate complexity tests. 42 C.F.R. § 493.1405. There is no dispute that Petitioner possesses the necessary qualifications to be a director as that term is defined in the regulations. *See* Tr. 261-62.
11. In addition to SMLI, Petitioner was the director of the following laboratories: Medical Diagnostic Laboratory; Santa Monica Clinical Laboratory; and American Healthnet Laboratories. P. Ex. 17. Petitioner also testified he was director of "Park Slope." Tr. 843. By CLIA regulation, the director cannot direct more than five laboratories at one time. 42 C.F.R. § 493.1407(d).
12. Despite this alleged commitment to patient care, Petitioner admitted that he had resigned as laboratory director of Park Slope because "[t]hey would say that they would pay me, but I think that would not be the truth, and I don't want to work for nothing." Tr. 844.
13. As an administrative law judge, I adjudicate cases under a delegation of authority from the Secretary. In this capacity, I am required to follow all substantive rules and regulations duly promulgated by the Secretary. *Country Club Manor II*, DAB CR433 (1996); *see also Dyer v. Secretary of Health and Human Services*, 889 F.2d 682, 685 (6th Cir. 1989). Accordingly, I lack the authority to declare any of the CLIA regulations unconstitutional. In the present case, my authority is not at issue, because Petitioner's constitutional arguments are unfounded almost to the point of being frivolous.
14. Though not necessary to my decision in this case, I would reach an even broader conclusion. Based on my observation of Petitioner's demeanor during his testimony at the hearing, I am convinced that it is more likely than not that Petitioner has no knowledge or documentation that would tend to disprove the facts as to which HCFA has established a prima facie case.
15. In this section of my decision, I discuss in detail the failure of SMLI to comply with five conditions of participation. HCFA asserted that SMLI had failed to comply with two additional conditions: Laboratories performing moderate complexity testing, testing personnel (42 C.F.R. § 493.1421); and Inspection of laboratories requesting or issued a certificate of compliance (42 C.F.R. § 493.1777). *See* HCFA Posthearing Br. at 55-57, 62. In suport of its contention that SMLI failed to comply with these conditions, HCFA relied on essentially the same evidence that I discuss in analyzing the five conditions

below. While I conclude that this evidence supports HCFA's findings of noncompliance as to the additional conditions, I do not discuss them in detail.
16. The testimony was that the abbreviation "QNS," which stands for "quantity not sufficient" is a laboratory shorthand for a specimen that is unacceptable for testing. Tr. 94.
17. In addition to instances where SMLI performed tests not requested by a physician, there were instances where SMLI failed to perform requested tests. Tr. 265-66.
18. In fact, in some instances, it appears that it would have been impossible to notify any authorized person, as some of the test requisitions came from fictitious addresses. Tr. 237-39.
19. The regulation also requires that a laboratory director meet specified qualification requirements. HCFA does not allege that Petitioner failed to meet the qualifications required for laboratory directors. Tr. 261-62.
20. In correspondence to LFS dated February 7, 1998, Petitioner indicated that SMLI "ceased operations and testing 29 December 1997." P. Ex. 9.
21. SMLI had been issued a certificate of compliance (which is valid for two years) for moderate complexity testing which was to expire on January 31, 1998. HCFA Ex. 37. Since SMLI had failed to pay the fees required for renewal, the certificate of compliance was not renewed and expired on January 31, 1998. Tr. 514. By regulation (42 C.F.R. § 493.49(a)(2)), no compliance certificate will be issued until the laboratory remits the certificate fee.
22. Petitioner also sent a letter to HCFA on January 30, 1998, responding to the Statement of Deficiencies, in which he indicated the laboratory was closed and that the closure was the "only corrective measure that appears available at this time." P. Ex. 15.
23. The record is unclear whether the source of HCFA Ex. 33 is the State Operations Manual (SOM) or a Regional Office Manual (ROM). Apparently, the two manuals were consolidated in about March of 1998. HCFA's witness, Ms. Jew, testified that the SOM provision applicable to the States is consistent with the ROM direction regarding cessation of laboratory operations. The provisions pertaining to withdrawal from CLIA are the same. *See* Tr. 505-508.
24. The instructions provided to the regional offices by HCFA indicate that the notice letter should reflect any changed circumstance involving the subject laboratory, such as its closure prior to issuance of the notice letter. *See* HCFA Ex. 33.
25. HCFA counsel pointed out in her posthearing brief at page 7 that SMLI's CLIA certificate was revoked effective November 30, 1998, following a settlement with Nida Madamba, a co-owner of SMLI, who, like Petitioner, had filed a request for hearing. I am unaware whether, for purposes of such revocation, HCFA reissued the compliance certificate.
26. I agree with HCFA that it is appropriate to look to the regulations governing principal sanctions of the laboratory for guidance in situations where it is the laboratory director, and not the laboratory itself, that has appealed HCFA's imposition of sanctions. The two-year ban on owning or operating a laboratory is imposed as a matter of law when a laboratory's CLIA certificate has been revoked. Thus, the regulations governing revocation proceedings ought to govern.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Oakland Medical Group, P.C.,

Petitioner,
DATE: July 18, 2000
- v -

Health Care Financing Administration
Docket No.C-99-731
Decision No. **CR688 DECISION**

I enter summary judgement in favor of the Health Care Financing Administration (HCFA) sustaining HCFA's determination to impose remedies against Petitioner, Oakland Medical Group, P.C., under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). HCFA properly revoked Petitioner's CLIA certificate for a period of one year. HCFA properly canceled Petitioner's approval to receive Medicare payment for its services, effective October 1, 1999.

I. Applicable Law and Regulations

CLIA was designed to promote accurate medical tests by clinical laboratories. Congress' goal was to establish a single set of standards applicable to all laboratory services, including those which provide services to Medicare beneficiaries. *See*, H.R. Rep. 899, 100th Cong., 2nd Sess. 8 (1988), *reprinted in* 1998 U.S.C.C.A.N. 3828. 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. The Act 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). The Act 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).

The standards for operation of clinical laboratories promulgated by the Secretary pursuant to the enabling legislation are found at 42 C.F.R. Part 493. Regulations governing the performance of proficiency tests by clinical laboratories are found at 42 C.F.R. § 493.801. A clinical laboratory must enroll in an approved proficiency testing (PT) program . It must notify the Department of Health and Human Services of each program or programs in which it chooses to participate to meet PT standards. HCFA approves certain companies to administer proficiency tests under CLIA. These approved testing companies send out, three times each year at approximately equal intervals, proficiency test samples to be analyzed by each laboratory for routine chemistry and endocrinology. A minimum set of five samples are sent for each testing event. The participating laboratories then perform the tests and submit their results on forms provided by the testing services. The testing services grade the results and report

them to HCFA. To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 % of 10 or more referee laboratories or 90 % or more of all participating laboratories.[(1)] A laboratory is required to examine or test each PT sample that it receives in the same manner that it tests patient specimens. 42 C.F.R. § 493.801(b). A laboratory must not engage in any inter-laboratory communications pertaining to the results of PT until after the date by which the laboratory must report PT results to the testing company. 42 C.F.R. § 493.803(b)(3). The regulations emphatically prohibits sending PT samples to another laboratory for analysis which it is certified to perform itself. 42 C.F.R. § 493.801(b)(4). The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 C.F.R. § 493.801(b)(5).

Any laboratory that the Secretary determines intentionally refers its PT samples to another laboratory for analysis shall have its certificate revoked for at least one year. 42 U.S.C. § 263a(i)(4), 42 C.F.R.§ 493.801(b)(4). The regulations further provide that when HCFA revokes a laboratory's CLIA certificate, it will also cancel that laboratory's approval to receive Medicare reimbursement for services rendered. 42 C.F.R. § 493.1842(a).

Additionally, a participating laboratory is required to test PT samples in the same manner as patient specimens, 42 C.F.R. §§ 493.61(b)(1) and 493.801(b), and have a director who provides overall management and direction in accordance with 42 C.F.R. §§ 493.801, 493.1441 and 493.1445. A technical supervisor must conform to 42 C.F.R. §§ 493.1449 and 493.1451. A laboratory that does not treat PT testing samples in the same manner as patient samples may have its certificate of accreditation revoked. 42 C.F.R. §§ 493.61(b)(1), 493.61(c)(3), and 493.801(b).

Furthermore, the regulations authorize HCFA or its agent to conduct, on a representative sample basis or in response to substantial allegations of non-compliance, surveys of an accredited laboratory as a means of validating the laboratory's performance

II. Background

Petitioner is a physician office laboratory located in Warren, Michigan that holds a CLIA certificate of accreditation. HCFA Ex. 8, at 1. The laboratory engages in high complexity testing for routine chemistry and endocrinology. *Id.*, at 3. Robert I. Moretsky, D.O., is Petitioner's director, clinical consultant, technical supervisor, and general supervisor. HCFA Exs. 8, at 1; 14, at 1. Rene Wheatley was part of Oakland's testing personnel, as well as part of the personnel working at other laboratories in the general vicinity. HCFA Ex. 14. She performed high complexity routine chemistry and endocrinology testing, as well as PT for Petitioner. *Id.*, at 1.

Some of the laboratories in the Detroit Metro area participating in a PT program operated by the American Association of Bioanalysts (AAB) are Oakland Medical Group (also known as Moretsky/Trager/Flor), John Dunn, M. D., Mark Hertzberg, M. D., Rochester Rd. Clinic, Nazar Sarafa, M.D. (also known as Garden City Medical Clinic), Liptawat Family, P.C., Lakeland Medical, Ecorse Med Center, and Stanley Boykansky, M.D. HCFA Ex. 7. As participants in the PT program, the AAB would mail to each laboratory the same group of five specimens three times a year. The laboratories were

required to test these specimens for analytes for which they did patient testing, and mail their results to the AAB by a date certain; approximately 10 days after receiving the samples. Petitioner was required to test the specimens for cholesterol, HDL cholesterol, triglycerides, glucose, thyroid stimulating hormone (TSH), total thyroxine (T4), triiodothyronine (T3), and free thyroxine (FT4).

By letter dated January 4, 1999, Dennis W. Jay, Ph.D., Technical Director of the Proficiency Testing Service of the AAB, sent the Michigan Department of Consumer and Industry Services (MDCIS) some PT results for a group of Detroit area laboratories that he deemed to be suspect. HCFA Ex. 10. Specifically, the cover letter suggested that the same PT results were being submitted by several laboratories. The following five facilities submitted identical PT results during the third testing event of 1998 for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens: Oakland Medical Group, John Dunn, M.D., Mark Hertzberg, Rochester Road Clinic, and Nazar Sarafa, M.D. *Id.*

On January14, 1999, the AAB notified the MDCIS that they had discovered another four facilities reporting duplicate results and included their 1998 third quarter summaries and attestation sheets. These four facilities were: Liptawat Family, P.C., Lakeland Medical, Ecorse Med Center, and Stanley Boykansky, M.D. HCFA Ex. 7, at 1.

In response to the above information, on February 25, 1999, Richard J. Benson, Chief, Laboratory Improvement Section, Bureau of Health Systems, MDCIS, attempted an unannounced complaint investigation of Oakland Medical Group. HCFA Ex. 11, at 3. He sought evidence regarding Petitioner's PT for all three events of 1998. He was particularly interested in reviewing testing records for endocrinology and chemistry performed in 1998, including patient, quality control and PT results. The staff present was unable to produce any testing records, nor was there anyone available who might know their location. The director was not there that day, and Ms. Wheatley was not scheduled to come in at that time. He went away empty handed. *Id.*

On March 2, 1999, Ms. Lucy Estes, Laboratory Evaluation Specialist, MDCIS, attempted to perform a complaint survey of Petitioner's facilities. HCFA Ex. 15, at 2. Her first attempt failed. During the second attempt on the same day, the attending physician gave her copies of Petitioner's records in response to a request to review quality control records, temperature records, graphs, patient testing records and PT records for 1998. *Id.* Based on her review of the testing records she received from Petitioner, and information from the AAB concerning the similarity of PT results between Petitioner and others in the Detroit area, Ms. Estes found that Petitioner was not in compliance with the CLIA requirements under 42 C.F.R. § 493.801(b)(1), Testing of Proficiency Samples, and 42 C.F.R. § 493.1451(b)(4), Technical Supervisor Responsibilities. She completed and submitted HCFA Form 2567 to her supervisor, Richard J. Benson, along with the aforementioned documents. *See* HCFA Ex. 15, Attachment A.

By letter dated July 15, 1999, HCFA served notice of cancellation, suspension, and revocation of the CLIA certificate of accreditation on Petitioner pursuant to the MDCIS' referral of its case for imposition of enforcement action. Specifically, it was found that Petitioner was not in compliance with the following CLIA statutory and regulatory requirements:

- The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4).
- Requirement for Certificate: The laboratory agrees to treat PT samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business. 42 U.S.C. § 263a(d)(E); 42 C.F.R. § 493.61(b)(1); 42 C.F.R. § 493.801(b)(1) - (3).
- The Secretary may on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section . . . 42 U.S.C. § 263a(g)(1), (2); 42 C.F.R. § 493.1780(b), (c).

HCFA Ex. 1.

Because of the improper referral of PT samples to another laboratory for analysis, the failure to treat PT samples in the same manner as patient samples, and the refusal to permit MDCIS to perform a survey of its facilities, HCFA imposed the principal sanctions of suspension of Petitioner's CLIA certificate of accreditation, cancellation of Petitioner's approval to receive Medicare payment for its laboratory services, and proposal to revoke Petitioner's CLIA certificate of accreditation. HCFA Ex. 1.

Based on MDCIS' recommendation, by letter dated August 4, 1999, HCFA informed Petitioner that although Petitioner did not provide inspection personnel immediate access to their facilities on February 25 and March 2, 1999 to which the inspection personnel were entitled to under the governing regulations, HCFA was withdrawing the determination that Petitioner refused a request to inspect the laboratory and its records. HCFA Ex. 2.

A final and more complete notice of adverse action was served on Petitioner by letter dated October 1, 1999, absent a confirmation that improper proficiency referral did not occur. HCFA Ex. 3.[(2)] The October 1, 1999 letter addressed to Petitioner's director, Dr. Robert I. Moretsky, in pertinent part, states as follows:

> As set forth on the HCFA Form 2567 that was enclosed with our letter to you of July 15, 1999, the surveyors determined that with respect to the first three events of 1998, your laboratory's proficiency testing (PT) was not performed with the laboratory's regular workload using the laboratory's routine methods, in violation of the standard at 42 CFR § 493.801(b)(1). In our July 15, 1999, letter, we also stated that the evidence revealed that your laboratory referred certain PT samples to another laboratory for analysis in violation of the standard at 42 CFR § 493.801(b)(4). The evidence strongly suggests that the results of proficiency testing reported by your laboratory during the first, second, and third events of 1998 were obtained by improper referral and/or collaboration. Inter-laboratory communications pertaining to the results of proficiency testing samples, prior to the testing event reporting due date, are prohibited by the standard at 42 CFR § 493.801(b)(3) . . .
>
> In addition, the standard at 42 CFR § 493.801(b)(5) requires that a laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples . . .

However, based on a review of the 1998 proficiency tests records and the patient sheets during the survey, it was determined that the PT samples were not examined or tested with the laboratory's regular patient work load. Since the survey findings show that integration did not occur, this violates the standard at 42 CFR § 493.801(b)(5).

The findings from the survey also reveal that you, as laboratory director, have not fulfilled your responsibility to assure that PT samples are tested as required under 42 CFR § 493, subpart H. You, as technical supervisor, failed to assure that the manufacturer's quality control expected range inserts were available for each procedure performed in your laboratory. Therefore, normal and abnormal control material ranges were not available to determine whether quality control results were within the expected range of the manufacturer. The presence of the deficiencies cited in this letter and on the HCFA-2567 demonstrates that you have failed to take responsibility for the overall operation and administration of your laboratory. Therefore, the laboratory is out of compliance with the condition level requirement for a laboratory director at 42 CFR § 493.1441. Because your laboratory did not treat PT samples in the same manner as patient samples, it is in violation of the CLIA requirements at 42 CFR § 493.61 and 42 U.S.C. § 263a(d)(1)(E) and does not meet the requirements for a certificate of accreditation . . .

Because of your laboratory's failure to meet the conditions of Proficiency Testing and Laboratory Director, and because of your intentional referral of your laboratory's PT samples for the third testing event of 1998 to another laboratory for analysis, as set forth in our letter of July 15, 1998, we have imposed the following principal sanctions against your laboratory:

- 42 CFR § 493.1808(a) and 42 CFR § 493.1842(a)(1) - Principal Sanction: Cancellation of your laboratory's approval to receive Medicare payment for its services. This sanction will become effective on October 1, 1999, and will remain in effect until a hearing decision is rendered, or the end of the revocation period . . .

- 42 U.S.C. § 263(a)(i)(4), 42 CFR §§ 493.1814(a) and 493.1840(1) - Principal Sanction: Revocation of your laboratory's CLIA certificate.

HCFA Ex. 3.

By letter dated July 30, 1999, Petitioner requested a hearing. This case was assigned to me for hearing and decision. On December 23, 1999, HCFA filed a motion and memorandum of law in support of summary judgment accompanied by 16 exhibits (HCFA Exs. 1 - 16) contending that indisputable documentary evidence established a basis for the sanctions. Subsequently, HCFA submitted additional briefs including a sur-reply accompanied by an attachment, which I have numbered as HCFA Ex. 17. On May 31, 2000, HCFA filed an unopposed motion to supplement its exhibits with the transcript of sworn testimony by Debra Sabo, taken on April 12, 2000, in the case of *Stanley Boykansky, M.D. v. HCFA* , Docket No. C-99-715. The pertinent portion of that transcript, at pages 40-43, purports to show the professional relationship between Rene Wheatley and Debra Sabo. I have admitted the transcript in the *Boykansky* parallel matter for the limited purpose previously mentioned, and I have marked it as HCFA Ex. 18. Petitioner countered with an opposing memorandum and supporting documentation

on January 24, 2000. Additionally, Petitioner argued that an evidentiary hearing was essential to explore certain factual issues in dispute. Petitioner submitted an amended brief dated February 15, 2000 accompanied by two exhibits (P. Exs. 1 - 2) and sur-replies filed February 22, March 31 and May 30, 2000. Petitioner had marked IRS Form 1099, attached to its sur-reply of February 22, 2000, as exhibit one, but I have renumbered it as Petitioner's exhibit three (P. Ex. 3) so as not to confuse it with exhibit number one filed with its reply brief dated February 15, 2000. I admit into evidence HCFA Exs. 1 - 18 and P. Exs. 1 - 3.

For the reasons set forth below, I find that summary judgment is appropriate. There are no material issues of fact in dispute that require an evidentiary hearing. Based on the documentary evidence, written declarations, arguments of the parties, and applicable law and regulations, I find that there are no genuine issues of fact in dispute, and HCFA is entitled to judgment as a matter of law. I further find that Petitioner failed to meet the CLIA conditions of PT under 42 C.F.R. §§ 493.801, 493.61, and 493.801(b)(4), and condition for laboratory director under 42 C.F.R. § 493.1441. Petitioner also failed to satisfy the standard for technical supervisor under 42 C.F.R. § 493.1451. Thus, I order the revocation of Petitioner's certification under the CLIA, 42 U.S.C. § 263a, for a period of one year as proposed by HCFA. I also direct cancellation of approval to receive Medicare payment for services, effective October 1, 1999.

Summary judgment is appropriate when there is no genuine issue as to any material fact and the proponent is entitled to judgement as a matter of law. Fed. R. Civ. P. 56. If the moving party meets this burden, the onus shifts to the opposing party to establish that a genuine issue does exist. The opposing party will have shown that genuine issues of fact are present "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 249 (1986). To accomplish this, the opposing party must go beyond mere allegations, and come forward with factual evidence that creates a genuine issue of material fact. All reasonable inferences are to be drawn in the opposing party's favor. *Pollock v. American Tel. & Tel. Long Lines*, 794 F.2d. 860, 864 (3rd Cir., 1986). I have considered all the evidence set forth in the papers submitted, and conclude that all inferences drawn from such evidence, casts no doubt as to the propriety of granting HCFA's motion for summary judgment, inasmuch as there is no issue of material fact to be tried. HCFA's motion is properly supported by affidavits and documentary evidence. Petitioner has relied on mere allegations and denials, thus falling short of showing that there is a genuine issue for hearing. A decision may be made on the basis of statements and evidence presented for the record without a hearing if there is no dispute as to the facts of the case, and one party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56.

III. HCFA's contentions

HCFA contends that the documentary evidence from Petitioner's own records and the PT results submitted to the AAB for the three testing events in 1998 leave no doubt that Oakland's PT results were obtained either in collaboration with, or referral to, other Michigan laboratories in violation of 42 U.S.C. § 263a(i)(4) and 42 C.F.R. §§ 493.801(b), 493.801(b)(4). HCFA also argues that Petitioner failed to test the PT samples with the regular patient workload, and that it was in violation of the condition for laboratory director and standard for technical supervisor. Further, HCFA argues that summary judgment is appropriate as a matter of law given the absence of a genuine or material

issue of fact and that the overwhelming evidence is that Petitioner did not meet the requirements of the statute, particularly the CLIA condition for PT. Accordingly, HCFA asks that I sustain the revocation of Petitioner's CLIA certificate for one year and the withdrawal of approval to receive Medicare payment for laboratory services.

IV. Petitioner's contentions

In opposition to HCFA's motion for summary judgment, Petitioner advances the following arguments: the laboratory technician performing PT was not an employee of Oakland Medical Group; the sanctions imposed and proposed are not appropriate according to the enforcement procedures section of CLIA regulations; the declarations of Dennis W. Jay and Richard Benson do not support HCFA's allegations; an intentional referral of PT samples has not been shown by HCFA; results received by the AAB represent small standard deviations and thus there is a high probability that multiple laboratories produced the same figures; occasional human error in rounding a few numbers does not warrant revocation of a laboratory's CLIA certificate; a plan of correction is the most appropriate sanction given the severity of the alleged standard deficiency; that the Commission on Office Laboratory Accreditation (COLA), as HCFA's agent, reported no deficiencies; and that the sanction appropriate for an alleged violation of 42 C.F.R. § 493.1451(b)(4) is a plan of correction.

V. Issue, Findings of Fact and Conclusions of Law

A. *Issue*

The issue in this case is whether Petitioner failed to comply with one or more conditions of participation under CLIA, thereby giving HCFA the authority to impose remedies against Petitioner including revoking Petitioner's CLIA certificate and canceling Petitioner's approval to receive Medicare reimbursements, effective October 1, 1999.

B. *Findings of Fact and Conclusions of Law*

I hereby make the following findings of fact and conclusions of law:

1. Petitioner is a physician office laboratory located in Warren, Michigan, engaging in high complexity testing for routine chemistry and endocrinology, and operating by virtue of a certificate of accreditation under CLIA. HCFA Ex. 8, at 1.
2. Robert I. Moretsky, D.O., is Petitioner's director, clinical consultant, technical supervisor, and general supervisor. HCFA Ex. 8 at 1; HCFA Ex. 14 at 1.
3. Rene Wheatley performed high complexity routine chemistry and endocrinology and PT for Petitioner and for other laboratories in the Detroit, Michigan, Metro area. HCFA Ex. 14.
4. Oakland Medical Group, P.C. (also known as Moretsky/Trager/Flor), John Dunn, M.D., Mark Hertzberg, M.D., Rochester Rd. Clinic, Nazar Sarafa, M.D. (also known as Garden City Medical Group), Liptawat Family P.C., Lakeland Medical, Ecorse Med. Center, and Stanley Boykansky, M.D. are some of the laboratories in the Detroit Metro area participating in a PT program operated by the AAB. HCFA Ex. 7.
5. Ms. Deborah Sabo performed PT for Stanley Boykansky, M. D., John Dunn, M..D., Garden City Medical Clinic, and Mark Hertzberg, M.D. Ms. Sabo and Ms. Wheatley had a prior professional acquaintance as co-workers at Oakland General Hospital. HCFA Exs. 14 and 18.
6. Petitioner represented that Ms. Rene Wheatley was an employee of Oakland whose duty it was to conduct high complexity testing for routine chemistry and endocrinology.

Whether Ms. Wheatley was an independent contractor or not is irrelevant, inasmuch as Petitioner is responsible for the actions of all individuals it authorizes to perform chemistry testing at its facility on its behalf.
7. The AAB would mail each laboratory participating in the PT program the same group of five specimens three time per year. The laboratories were required to test these specimens for analytes for which they did patient testing, and mail their results to the AAB
8. Testing samples for Petitioner included cholesterol, HDL cholesterol, triglycerides, glucose, TSH, T4, T3, and FT4.
9. The affidavits and documentary evidence submitted by HCFA in support of its motion to dismiss show that Petitioner reported PT results to the AAB in 1998 that were identical to the results of eight other Detroit area laboratories for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens.
10. From the multitude of identical results, I draw the inference that Petitioner intentionally referred proficiency tests to another laboratory and/or engaged in inter-laboratory communications (collaboration) and then reported the results obtained to the AAB as Petitioner's own results. Additionally, although Petitioner reported PT results to the AAB for the second testing event in June 1998, it lacked records to substantiate the basis for the reported results.
11. Petitioner's PT samples, particularly for the second testing event in June 1998, were not examined with the laboratory's regular patient workload in violation of the condition level requirement set forth at 42 C.F.R. § 493.801 and 42 C.F.R. § 493.61.
12. Petitioner did not arrive at PT results identical to that of eight other laboratories through human error or coincidence, but by intentional referral, collaboration, and manipulation of those results.
13. Dr. Robert I. Moretsky, as laboratory director and technical supervisor was responsible for Petitioner's overall operation and administration. His responsibilities included the employment of competent personnel to perform test procedures, the recording and the reporting of test results promptly, accurately and proficiently, and assuring compliance with applicable regulations. 42 C.F.R. §§ 493.1441 and 493.1445.
14. Petitioner, through Dr. Robert I. Morestsky, was in violation of the condition for laboratory director in failing to provide proper overall management and direction to the facility and by not establishing and carrying out required quality control measures. 42 C.F.R. §§ 493.1441 and 493.1445.
15. Petitioner, through Dr. Robert I. Morestsky, was in violation of the standard for technical supervisor in failing to establish a quality control program with parameters for acceptable levels of analytic performance, and ensuring that such levels are maintained throughout the entire testing process. 42 C.F.R. §§ 493.1449 and 493.1451.
16. Pursuant to 42 U.S.C. § 263a(f), the Secretary is directed to ensure that certified clinical laboratories perform tests that are valid and reliable.
17. A laboratory issued a certificate of accreditation under CLIA must enroll in a PT program and comply with the requirements of 42 C.F.R. § 493.801.
18. Petitioner's PT results for the three testing events of 1998 were obtained through referral and/or inter-laboratory communications (collaboration) with other laboratories which constitutes a violation of 42 C.F.R. § 493.801.

19. By failing to examine or test proficiency samples in the same manner as routine patient specimens, Petitioner violated the terms of 42 C.F.R. §§ 493.801, 493.801(b), and 493.61.
20. The revocation of Petitioner's CLIA certificate for a period of one year is not unreasonable in light of the failure to satisfy the condition level requirements mentioned above.
21. HCFA properly canceled Petitioner's approval to receive Medicare payment for its services, effective October 1, 1999.
22. Petitioner has submitted no affidavits or other documentary evidence that, if taken as true, would create a genuine issue of material fact that would require a hearing. Fed. R. Civ. P. 56.
23. The facts on which I base this decision are either not in dispute or uncontroverted. Thus, summary judgment is appropriate as a matter of law.

VI. Discussion

The discussion of the issues will track Petitioner's points of contention as outlined above.

A. *Petitioner's PT results for the three testing events in 1998 were obtained through referral and/or collaboration with other laboratories.*

1. *That the laboratory technician performing PT was not an employee of Oakland Medical Group does not bar HCFA from suspending, limiting or revoking Petitioner's CLIA certificate based upon the laboratory technician's alleged violations.*

Petitioner argues that HCFA cannot take action regarding its CLIA certificate based on violations by a laboratory technician, Ms. Rene Wheatley, who was not an employee. Petitioner argues that Ms. Wheatley was an independent contractor. As such, her actions cannot compromise Petitioner. In furtherance of this position, Petitioner relies on a dubious interpretation of 42 C.F.R. § 493.1840(a) and (b).[(3)] It suggests that a laboratory is only able to act through individuals, and these are specifically mentioned in paragraph (a) of 42 C.F.R. § 493.1840. Thus, Petitioner goes on to argue, at 42 C.F.R. § 493.1840(b), where the regulation speaks of adverse action based on improper referral of PT samples by a laboratory, it is implied that such referral must be carried out by an owner or operator or one of its employees. I note, however, that Petitioner listed Ms. Rene Wheatley as an employee on its Laboratory Personnel Report. HCFA Ex. 14. In addition, Ms. Wheatley is listed as an employee at the other laboratories at which she worked. HCFA Ex. 14. Ms. Debbie Sabo is also listed as an employee at the laboratories at which she worked. HCFA Ex. 14. There was no annotation on the Laboratory Personnel Reports to indicate that Ms. Wheatley's relationship to Petitioner was other than as an employee.[(4)]

Additionally, Petitioner's narrow interpretation of the regulation overlooks the requirement that an operator bear primary responsibility for the safety and reliability of the results of all specimen testing performed in a laboratory. 42 C.F.R. § 493.2. The term operator encompasses that of owner as well as director. Section 42 C.F.R. § 493.1445 establishes that the director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly,

accurately and proficiently, and for assuring compliance with the applicable regulations. 42 C.F.R. § 493.1445(b) goes on to say that if the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. It is evident that Petitioner seeks to distance itself from the testing technician in vain. It is an absurd proposition that, under CLIA, a laboratory could obtain a certificate of accreditation and then be permitted the freedom to do as it pleases regarding participation requirements as long as it hires only contract help.

Finally, I do not see that 42 C.F.R. § 493.1840(b) places such a strained limitation on the term "laboratory" so as to exclude from its sphere of import persons hired by a facility who are not salaried employees. The "offender" in this portion of the regulation is the laboratory acting through its owners, operators, directors, employees, independent contractors, agents or representatives, etc. The owners or operators cannot shirk their responsibilities under the law or regulations nor hide behind labels.

> 2. *The sanctions imposed and proposed are in accordance with the enforcement procedures*.

Petitioner contends that the sanctions imposed and proposed are not appropriate according to the enforcement procedures set forth in the CLIA regulations. It points out that the deficiencies alleged on the HCFA 2567 Statement of Deficiencies are not condition level. Consequently, Petitioner argues that revocation of Petitioner's CLIA certificate is not the proper remedy. Instead, Petitioner argues that it should be required to submit a plan of correction acceptable to HCFA within 12 months.

The implication that HCFA's notice of sanctions was deficient because the HCFA 2567 did not mention a condition level deficiency is unpersuasive. The record is clear that Petitioner had ample notice that it had failed to meet requirements that were a basis for revocation of its CLIA certificate. HCFA's notice dated July 15, 1999, states:

> Specifically, your laboratory is not in compliance with the following CLIA statutory and regulatory requirements:
>
> The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which is certified to perform in its own laboratory.

42 C.F.R. 493.801(b)(4).

HCFA Ex. 1, at 2.

Petitioner's violations were further clarified in HCFA's supplemental letter of October 1, 1999:

> As set forth on the HCFA Form 2567 that was enclosed with our letter to you of July 15, 1999, the surveyors determined that with respect to the first three events of 1998, you laboratory's proficiency testing (PT) was not performed with the laboratory's regular workload using the laboratory's routine method, in violation of the standard at 42 CFR § 493.801(b)(1). In our July 15, 1999, letter we also stated that the evidence revealed that your laboratory referred certain PT samples to another laboratory for analysis, in violation of the standard at 42CFR § 493.801(b)(4)[(5)]. The evidence strongly suggests that the results of proficiency testing reported by your laboratory during the first, second, and third events of 1998 were obtained by improper referral and/or collaboration. Inter-laboratory communication pertaining to the results of proficiency testing samples, prior to

> the testing event reporting due date, are prohibited by the standard at 42 CFR § 493.801(b)(3).

HCFA Ex. 3, at 1-2.

As an additional reason for revocation of its CLIA certificate, HCFA notified Petitioner that it was in violation of the laboratory director condition:

> The findings from the survey also reveal that you, as laboratory director, have not fulfilled your responsibility to assure that PT samples are tested as required under 42 CFR § 493, subpart H. You as technical supervisor, failed to assure that the manufacturer's quality control expected range inserts were available for each procedure performed in your laboratory. Therefore, normal and abnormal control material ranges were not available to determine whether quality control results were within the expected range of the manufacturer. The presence of the deficiencies cited in this letter and on the HCFA-2567 demonstrates that you have failed to take responsibility for the overall operation and administration of your laboratory. Therefore, the laboratory is out of compliance with the condition level requirement for a laboratory director at 42 CFR § 493.1441.

HCFA Ex. 3, at 2-3.

In view of the foregoing, I find that the notice of sanctions clearly informed Petitioner that the alleged intentional referral of proficiency samples, the improper inter-laboratory collaboration and/or communications, the failure to treat PT samples in the same manner as patient samples; and the alleged violation of the laboratory director condition were sufficient reasons for revocation of its CLIA certificate.

> 3. *The declarations of Dennis W. Jay, Ph. D. and Richard Benson, CLS, MT supports HCFA's allegations*.

As will be more particularly discussed in Part VI(A)(4) below, the declarations of Dr. Dennis W. Jay, Technical Director, Proficiency Testing Service, AAB, and Mr. Richard Benson, Chief, Laboratory Improvement Section, MDCIS, offer ample support for HCFA's allegations. Their declarations (HCFA Exs. 11 and 16) are based not only on their expertise, but also on their personal examination and analysis of the data obtained from the AAB as well as Petitioner's records. Although some of their findings are laced with statistical implications, the thrust of their declarations is more associated with the manner in which certain chemical properties will behave given specific testing conditions. For example, based on their knowledge of the poor reproducibility of testing results for triglycerides and cholesterol, with an expected variation in results on the order of 10 % to 20 %, they are competent to voice an opinion as to the improbable likelihood that Petitioner's PT results for eight analytes, from each of the five specimens would be identical to the results reported by eight other laboratories in the same geographic area.

Petitioner has produced no evidence, either by way of affidavit or other means, to contradict the affidavits of Dr. Jay or Mr. Benson. It rests upon mere allegations and denials that fall short of setting forth specific facts that point to the existence of a genuine issue for trial. In essence, Petitioner has not come forward with evidence that I would have to accept as true, and from which I could draw inferences in its favor.

It should be noted that conclusory or speculative testimony is insufficient to raise a genuine issue of fact to defeat summary judgment. *Falls Riverway Realty, Inc. v.*

Niagara Falls, 754 F.2d 49 (2d. Cir. 1985). In the case at hand, Petitioner does not go beyond self serving assertions. Ironically, Petitioner stated, "While Petitioner agrees that this is highly improbable to have identical values, it is not impossible." Petitioner's October 28, 1999 Report of Readiness, at 5.

I find that the declarations of Dr. Jay and Mr. Benson constitute appropriate evidence in support of HCFA's allegations. The positions they hold, as well as the description of their professional backgrounds in the curriculum vitae attached to each of their affidavits, attest to their expert qualifications.

HCFA Exs. 11 and 16.

> 4. *Petitioner incurred condition level deficiencies that justify revocation of its CLIA certificate of accreditation.*

42 C.F.R. § 493.801 unequivocally establishes that a laboratory must not intentionally send PT samples or portions of samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. This section includes a prohibition against engaging in any inter-laboratory communications pertaining to the results of PT samples until after the date by which the laboratory must report PT results to the program for the testing event in which the samples were sent. 42 C.F.R. § 493.801(b)(3). Intentional here means not inadvertent or not through mere oversight.

When PT results are not obtained through independent testing of samples in the same manner as patient samples are tested, the integrity of the entire proficiency program is undermined. This is so because PT is graded on a curve. As Dr. Dennis W. Jay states in his affadavit:

> To determine what constitutes a 'passing grade' for a particular analyte, results from laboratories using the same methodology and equipment are grouped together. The average value reported determines the range of 'correct' responses. Because any collaboration among laboratories necessarily skews the calculation of the average, collaboration or referral corrupts the grading range against which all laboratories in the given group are evaluated. Consequently, referral and/or collaboration not only helps insure that those who engage in this improper activity obtain a passing grade, regardless of the quality of their proficiency testing; but also it may so disrupt the average values against which all other similarly situated laboratories are rated as to make other laboratories appear to have performed poorly when, in fact, they may be reporting results well within tolerable limits of accuracy.

HCFA Ex. 16, at 3-4.

The legislative history of CLIA not only reflects the significance attached by the legislators to the accuracy and reliability of laboratory testing, but also their concern that laboratories would seek questionable ways to undercut the intent of Congress.

As stated by an administrative law judge in *Long Medical Laboratory*, DAB CR334 (1994):

> It is apparent, both from the Act itself and its legislative history, that Congress considers proficiency testing conducted pursuant to standards developed by the Secretary to be an important factor in assuring that clinical laboratories conduct tests accurately and reliably. The Act directs the Secretary to develop standards for proficiency testing. 42 U.S.C. § 263a(f)(3). The House of Representatives committee report which supported the Act provides that:

> To maintain its certification under the bill, a laboratory would have to participate successfully in a proficiency testing program that met standards established by the Secretary. The Committee believes that proficiency testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes.

1988 U.S.C.C.A.N. 3849.

Long Medical Laboratory, DAB CR344 (1998), at 4.

As indicated earlier, the identity of PT results reported to the AAB by Petitioner and eight other laboratories in the Detroit Metro area in 1998 led to closer scrutiny. According to Mr. Richard J. Benson, "the chances of nine laboratories arriving at the same values by happenstance for all five specimens of [one] analyte are remote (especially for an analyte result obtained by manual test method), and the chances of nine laboratories arriving at the same values for specimens of two or more analytes are close to nil." HCFA Ex. 11, at 5-6. Close analysis shows that this opinion is more than a statistical theory. In December 1999, Mr. Benson reviewed the work sheets produced by Petitioner. Using the values reported on those work sheets, Mr. Benson performed the calculations that Ms. Rene Wheatley would have had to perform in 1998, in order to report PT results. This exercise allowed him to determine the extent to which Petitioner's work sheets documented that the AAB samples were tested on site and the recorded values were reported. HCFA Ex. 11, at 6.

To lay the foundation for drawing a comparison between the information reported to the AAB and that which was reflected in Petitioner's records, Mr. Benson first determined the methodology employed by the laboratory. He found that the technique used by Petitioner in 1998 to test for glucose, cholesterol, triglycerides and HDL cholesterol, involved comparing the optical characteristics of a known concentration (standard concentration or (sc)) of the substance to be measured to the optical characteristics of the unknown patient sample (control or PT sample or (pc)). The known concentration is a benchmark which is also referred to as the "standard sample." From this known concentration is derived the known optical or absorption characteristics of the analyte in the standard sample (sa). The patient or PT sample is also analyzed to determine its absorption characteristics (pa). Once the (sc), (sa) and (pa) are known, the concentration of the analyte in the PT sample can be calculated by means of simple algebraic equation: [(sc) ÷ (sa)] x (pa) = (pc). The values reported to the AAB for glucose, cholesterol, triglycerides, and HDL cholesterol are the (pc) for each sample, that is, the concentration of the analyte in each of the PT samples. HCFA Ex. 11, at 6-7. These are manual techniques that yield a broad range of acceptable, or correct PT results for each sample. Consequently, variations in results on the order of 10% to 20% are expected. This broad acceptable range is determined by averaging the results reported by all participating laboratories using similar equipment and technology. HCFA Ex. 16, at 3. The procedures employed by Petitioner for arriving at the optical characteristics of the analytes in unknown patient or proficiency samples require manual dilution, timing incubation periods, and performing calculations. HCFA Ex. 11, at 3-4. This expected poor reproducibility, especially for triglycerides and total cholesterol, is what caught Dr. Dennis W. Jay's attention. HCFA Ex. 16, at 3. Not only was the lack of variability suspect, but the identity in PT results in so many samples among nine different laboratories was absurd.

Mr. Benson's comparison began with the PT results for the first event on March 11, 1998 (98-1). These are recorded at attachment C (HCFA Ex. 11, at 37) and are marked "AAB" followed by a number (AAB1, AAB2, AAB3, AAB4, AAB5). Of the 20 results reported by Petitioner to the AAB for the first event of PT in 1998, 11 are inconsistent with the calculations that the methodology explained above would yield, given the data shown on Petitioner's own work sheets. The following are only some examples of the discrepancies noted when comparing the results yielded by Petitioner's work sheets and the results reported to the AAB:

Table No. 1 (First Testing Event of 1998)

PT sample	*Results yielded by Petitioner's data*	*Results reported to the AAB*
1. Cholesterol sample #1	1. 209	1. 208
2. Cholesterol sample #2	2. 172	2. 142
3. Cholesterol sample #3	3. 153	3. 152
4. HDL sample #5	4. 40	4. 39
5. Glucose Sample #1	5. 240	5. 239
6. Glucose sample #3	6. 242	6. 240

HCFA Ex. 13, at 2.

In some instances, the discrepancy between their own underlying data and the results reported to the AAB by Petitioner was due to an inexplicable departure from their standard practice of rounding to the next higher number fractions greater than or equal to one half. In other instances, such as cholesterol sample #2, above, a difference of 30 cannot be accounted for by simply deviating from the standard rounding practice. HCFA Ex. 11, at 9 and 10.

It should be noted that Mr. Benson worked the formula for calculating the patient or proficiency concentration backwards in order to arrive at the constant standard sample (sc). He learned, from a review of Petitioner's worksheets, that testing personnel were in the habit of writing the patient absorption (pa) found through observation immediately above the resulting patient concentration (pc). For example, at page 36 of HCFA Ex. 11, for March 21, 1998, the line labeled "C1" (for control), in the glucose column, the first number, which is 28, is the (pa) and the number below it, which is 93, is the (pc), or the result of the first or "normal control" sample. Similarly, for the second control labeled "C2", or abnormal control sample, the (pa) is 88.5 and the (pc), or resulting value is 295. Immediately above that, in the line labeled "std", for standard, is the number 30. This is the (sa) that was used to obtain the result. Thus, using Petitioner's master worksheet figures for the normal control, Mr. Benson performed the following calculation: (93 ÷ 28) x 30 = 99.6 or 100 (rounded). He used this formula: [(pc) ÷ (pa)] x (sa) = (sc). With this information, I am able to determine, for example, that glucose sample #3, above, should have yielded 242. The formula would be applied like this: [100(sc) ÷ 30(sa)] x 72.5(pa) =242(pc) (rounded). Nevertheless, Petitioner reported 240 for this analyte. HCFA Ex. 11, at 37. This is not a matter of simply rounding to the next lower whole number. It is more consistent with a deliberate duplication of results submitted by other laboratories in the area. It is undeniable that the PT technician had at her disposal two sets of results. One of these can be traced to the data in Petitioner's records, and the other is

traceable to the results submitted to the AAB by other laboratories in the area. Several other facilities sent identical results of 240 for triglycerides specimen #3 for the first testing event in 1998. HCFA Ex. 7, at 6. Coincidentally, as will be discussed in greater detail below, the same technicians who did PT testing for Petitioner, also performed the same testing for some of the other laboratories whose reported results were identical to Petitioner's. HCFA Ex. 13 contains the constant figures for the standard sample and the standard absorption characteristics of each set of specimens tested for triglycerides, cholesterol, HDL cholesterol, and glucose during the three testing events of 1998.

A review of Petitioner's Master Work Sheets for the second testing event of June 20, 1998 (98-2) revealed that the laboratory did not record any PT testing for this date for any of the analytes with any of the patient testing. HCFA Ex. 11, at 10, 44. Despite the absence of underlying data, Petitioner reported PT results for the second testing event for 1998 to the AAB. HCFA Ex. 11, at 10, 24-27. Petitioner claims to have complied with the proper testing and recording requirements, yet it has failed to make any documentary evidence available for my consideration that shows the existence of any underlying data for the second testing event of June 29, 1998.

The PT results for the third testing event of October 24, 1998 (98-3) are recorded at HCFA Ex. 11, at 61-64. Eight of the 20 reported results are inconsistent with the underlying data in Petitioner's own work sheets. For purposes of this discussion it is not necessary to list all the noted discrepancies. The following are only some of the discrepancies noted when comparing the results yielded by Petitioner's work sheets and the results reported to the AAB:

Table No. 2 (Third Testing Event of 1998)

PT sample	*Results yielded by Petitioner's data (rounded)*	*Results reported to the AAB*
1. Triglyceride sample #3	1. 95	1. 96
2. Cholesterol sample #3	2. 141	2. 142
3. Cholesterol sample #4	3. 197	3. 198
4. HDL sample #5	4. 25	4. 26
5. Glucose sample #4	5. 168	5. 169
6. Glucose sample #3	6. 279	6. 280

HCFA Ex. 13, at 2; HCFA Ex. 11, at 11.

The discrepancy between the results yielded by the raw data and the values reported to the AAB cannot be dismissed as mere coincidence or occasional human error in rounding as suggested by Petitioner. The manipulation of the results to bring them into conformity with the results of other laboratories in the area is obvious. The instances of identical values are too many to list here, but can be gleaned from reviewing pages 5-7 of HCFA Ex. 3. Pertinent to this are two noteworthy findings. First, Ms. Rene Wheatley, who was assigned the PT at Petitioner's facility, also was in charge of this same task at several other laboratories. These other laboratories were: Lakeland Medical, Rochester Road Clinic, and Liptawat Family, P.C. Ms. Sabo also happened to be the proficiency tester at three other facilities, John Dunn, M.D., Garden City Medical Clinic, and Mark Hertzberg. HCFA Ex. 14. All of these are included in the group submitting identical proficiency results for the three testing events in 1998 in the Detroit Metro area. As was

stated earlier, there was a prior professional relationship between Ms. Wheatley and Ms. Sabo. HCFA Ex. 18. The second item of interest is that Petitioner has no supporting PT data for the second testing event in 1998, yet they reported PT results to the AAB.
In its most recent brief filed on May 30, 2000, Petitioner argued that in the case of *Southfield Medical Clinic v. HCFA*, DAB CR667 (May 9, 2000), Judge Kessel found that an unlawful referral necessarily involves the actual physical transport of the sample from one laboratory to another. Petitioner contends that in this case there is no evidence of physical referral. Thus, there is no basis for the revocation of its certificate pursuant to 42 C.F.R. § 493.801(b)(4). Petitioner's argument is misplaced on two counts. First of all, Judge Kessel's decision does not stand for the proposition that there must be direct evidence of physical referral of PT samples from one laboratory to another. Petitioner overlooks the fact that referral could be established, as in this case, through circumstantial evidence.[(6)]
I infer from the multitude of identical results is that Petitioner referred proficiency tests to another laboratory and then reported these to the AAB as its own. Furthermore, Petitioner's inability to document the proficiency tests which it allegedly performed in the second testing event for June 20, 1998, is additional corroboration that Petitioner referred PT samples to another laboratory. This is consistent with the fact that Petitioner's laboratory records included a chart of the temperatures for each day any testing was performed at its facility during 1998. HCFA Ex. 11, at 78. Yet, no temperature entries were recorded for March 21 and June 20, 1998, suggesting that no patient or PT was performed at Petitioner's laboratory on those days. However, Ms. Wheatley attested that PT was done on those days. HCFA Ex. 11, at 5, 19, 25. The lack of temperature entries not only confirms the absence of documentation for the June 20, 1998 PT results, but also casts aspersion on the data entered in the work sheets for March 21, 1998. *See*, HCFA Ex. 11, at 36, 37. I am not persuaded that this is a result of human error. It is more reasonable to conclude that Petitioner referred samples to another facility.
The second reason for my finding that Petitioner's contention is faulty is that the record clearly shows that there are other condition level deficiencies present in this case. I find that Petitioner failed to meet the condition requirement for testing of samples set forth at 42 C.F.R. § 493.801. It is evident from the preceding discussion that the PT samples for the second testing event in 1998 were not examined with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the facility's routine methods in violation of the standard at 42 C.F.R. §§ 493.801(b)(1) and 493.801(b)(2). Further, I find that Petitioner engaged in inter-laboratory communications pertaining to the results of proficiency testing samples. Without such communications, the multitude of identical results between Petitioner and other eight laboratories in the Detroit Metro area would not have been possible. Petitioner has offered no evidence that detracts from my conclusion that it engaged in widespread collaboration and manipulation of PT results. 42 C.F.R. § 493.801(b)(3). The severity of these deficiencies are sufficient to support a condition level violation under 42 C.F.R. § 493.801. The violation pursuant to this section alone would justify revocation of Petitioner's license. However, there is more. As will be discussed in greater detail below, Petitioner was also in violation of the condition for laboratory director, by failing to provide acceptable direction and management to the laboratory staff regarding the handling, preparation,

processing, and examination of PT samples. Thus, even if it were found that Petitioner did not refer samples to another laboratory, there is ample evidence to conclude that other condition level deficiencies existed that justify revocation of its license for one year.

> *5. The results reported to the AAB and the standard deviations do not show absence of referral or collaboration among Petitioner and other laboratories in the Detroit Metro area.*

It has been shown that Petitioner manipulated its PT results to coincide with those reported by other laboratories in the area, and that two technicians with a prior working relationship did the PT testing for the Detroit Metro area facilities reporting identical results. It is also true that Petitioner submitted PT results to the AAB identical to other laboratories without any supporting data in its worksheets to justify the reported figures. Therefore, Petitioner's dissertation on standard deviations sheds no additional light as to the reason behind the identity of its PT results with that of eight other Michigan laboratories.

Even if I were to consider the charts submitted by Petitioner in P. Ex. 2, I note that there is much volatility in the standard deviations for the groups of laboratories reported. The example given by Petitioner at page 14 of its amended brief showing a standard deviation range for 26 laboratories from 3.5 to 8.5 for five triglyceride specimens, is far from being an indication of low volatility. This is especially true, in light of all the collaboration that was going on. I am not unmindful that Dr. Jay stated in his declaration that collaboration among laboratories skews the calculation of the average and corrupts the grading range against which all laboratories in the given group are evaluated. It also corrupts the standard deviation by giving a false measure of the volatility of the random variables.

To further illustrate the absurdity of Petitioner's position, I will refer to P. Ex. 2, at 3, where it mentions the PT results for triglycerides in the third testing event for 1998. In sample number one, the lowest reported result was 140 and highest was 233, with a standard deviation of 4.8. In sample number two, the range was 125-208, with a standard deviation of 8.5; in sample number three, the range was 69-115, with standard deviation of 6.2; in sample number four, the range was 96-160, with a standard deviation of 3.5; and in sample number five the range was 69-115, with a standard deviation of 8.1. Given these variables, one would expect some scatter in PT results reported to the AAB for this group. However, these are the results submitted to the AAB by Petitioner and eight other laboratories:

	Trig.3-1	Trig.3-2	Trig.3-3	Trig.3-4	Trig.3-5
Moretsky (Petitioner)	190	172	96	127	99
John Dunn, MD	190	172	96	127	99
Mark Hertzberg, MD	190	172	96	127	99
Rochester Rd. Clinic	190	172	96	127	99
Nazar Sarafa, MD	190	172	96	127	99
Liptawat Family PC	190	172	96	127	99

Lakeland Medical	190	172	96	127	99
Ecorse Med Center	190	172	96	127	99
Stanley Boykansky	190	172	96	127	99

HCFA Ex. 3, at 7.

To attribute the identity of these results to human error, transposition of numbers or pure coincidence, defies belief.

6. *The revocation of Petitioner's CLIA certificate is not premised on human error or transposition of a few numbers.*

Revocation of Petitioner's CLIA certificate is sustainable, primarily, due to its intentional referral of PT samples to other laboratories and/or collaboration with other laboratories regarding PT results, as has been amply demonstrated. The thorough discussion of this issue in the preceding section makes further elaboration here unnecessary.

7. *A plan of correction is not the most appropriate sanction in this case.*

In view of the condition level violations incurred by Petitioner, HCFA is authorized to impose principal sanctions including revocation of its CLIA certificate of accreditation. Petitioner can exercise no option regarding the type of sanction HCFA will impose under these circumstances. It is within HCFA's discretion to impose any type of sanction it deems appropriate within the regulations.

8. *The absence of reported deficiencies by COLA, does not bar HCFA from finding Petitioner out of compliance with CLIA requirements.*

Petitioner's argument that cancellation of its CLIA certificate by HCFA is not appropriate because its laboratory was inspected by COLA for the time period at issue, and no deficiencies related to PT were determined is baseless. A laboratory with accreditation is not immune from inspection by a State Agency acting on behalf of HCFA, where as here, it acted in response to a complaint. HCFA is not bound to ignore non-compliance by a laboratory solely because that facility has been accredited by an appropriately recognized accrediting organization.

9. *A plan of correction is not the appropriate sanction in this case.*

This issue has been discussed in Part VI(A)(7), above.

B. *Petitioner's lack of compliance with laboratory director and technical supervisor responsibilities.*

A participating laboratory must have a director who provides overall direction and proper management for a laboratory pursuant to 42 C.F.R. §§ 493.1441 and 493.1445. I find a violation of the condition at 42 C.F.R. §§ 493.1441 and 493.1445 because Petitioner's laboratory director, Dr. Moretsky, failed to provide overall direction and proper management.

Petitioner's laboratory records confirm that proficiency samples were not examined with the laboratory's regular workload; testing procedures were not documented; and prohibited collaboration with other laboratories occurred. Ms. Lucy Estes, the MDCIS surveyor, found that the normal and abnormal control ranges were not available for the purpose of determining if quality control results for tests were within the manufacturer's expected ranges. HCFA Ex. 15, at 7. She also found that the laboratory could not verify

quality control values for testing because the lot numbers, the expiration dates and the expected ranges were missing. *Id.*; HCFA Ex.1, at 9.

Petitioner asserts that all of the worksheets and other information related to its laboratory were provided to the CLIA representatives. Presumably, that would include quality control documentation. Petitioner does not say who those CLIA representatives are. Certainly, it did not provide such documentation to the MDCIS surveyor, Ms. Lucy Estes. In addition, Petitioner did not provide any documentation showing that there was any underlying data to support the PT results that were submitted to the AAB for the second event of 1998. Copies of the original documents which it is duty bound to maintain, were not submitted as evidence for my consideration.

Dr. Moretsky was also Petitioner's technical supervisor. Inasmuch as it is the responsibility of the technical supervisor to establish a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results, I also find a violation of the standard at 42 C.F.R. § 494.1451(b)(4).

VII. Conclusion

Petitioner failed to meet condition level requirements regarding PT for testing events in 1998 and also failed to meet the condition requirement for laboratory director. Further, Petitioner violated the standard for technical supervisor. Accordingly, HCFA had a basis to revoke Petitioner's CLIA certificate for a period of one year and to cancel Petitioner's approval to receive Medicare payments for laboratory services.

JUDGE

Jose A. Anglada
Administrative Law Judge

FOOTNOTES

1. The score for a sample in routine chemistry is either the score determined under paragraph (c)(2) or (c)(3) of section 493.931 of 42 C.F.R. The score for endocrinology is determined under paragraph (c)(2) or (c)(3) of section 493.933 of 42 C.F.R.

2. Pages 2 and 3 of this Exhibit have been submitted by HCFA in inverted order.

3. 42 C.F.R. § 493.1840 states, in pertinent part:

> (a) *Adverse action based on actions of the laboratory's owner, operator or employees.* HCFA may initiate adverse action to suspend, limit, or revoke any CLIA certificate if HCFA finds that a laboratory's owner or operator or one of its employees has . . .
>
> (b) *Adverse action based on improper referrals in proficiency testing.* If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may impose a civil money penalty.

4. It appears from HCFA Ex. 14 that Ms. Rene Wheatley and Ms. Debbie Sabo overlapped testing duties at the Boykansky clinical laboratory. HCFA's Ex. 18, however,

indicates through Ms. Sabo's testimony, that Ms. Wheatley did not work at the Boykansky clinical laboratory in 1998. I conclude, nonetheless, that a finding of inter-laboratory communications in this case is not dependent necessarily on their common employment at the Boykansky clinical laboratory.

5. Violation under this paragraph carries a mandatory one year revocation of the facility's certification.

6. I am not unmindful of the holding in *Blanding Urgent Care Center*, DAB CR 438 (1996). However, in view of my conclusion that referral in this case can be established by way of circumstantial evidence, and since there are other condition level deficiencies that support revocation in this case, I need not opt for one view or the other.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Stanley Boykansky, M.D.,

Petitioner,
DATE: July 28, 2000
- v -

Health Care Financing Administration
Docket No.C-99-715
Decision No. **CR690 DECISION**

I sustain the determination of the Health Care Financing Administration (HCFA) to impose remedies against Petitioner, a physician-owned laboratory known as Stanley Boykansky, M.D., pursuant to the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a *et seq.* (CLIA). The remedies which I sustain include: (1) cancellation of Petitioner's approval to receive Medicare payment for its services beginning 60 days from Petitioner's receipt of HCFA's May 13, 1999 remedy determination notice and continuing until the date of this decision; and (2) revocation of Petitioner's CLIA certificate effective the date of this decision.

I. Background

A. Background facts

Petitioner is a clinical laboratory that is located in Farmington Hills, Michigan. Petitioner is owned and operated by Stanley Boykansky, M.D. Dr. Boykansky serves as Petitioner's laboratory director. On February 25, 1999, surveyors employed by the Michigan Department of Consumer and Industry Services (Michigan State survey agency) conducted a complaint investigation of Petitioner to determine whether Petitioner was complying with CLIA requirements. The surveyors made findings which were referred to HCFA. On May 13, 1999, HCFA notified Petitioner that it had been found to be deficient in complying with CLIA requirements. HCFA advised Petitioner that it had determined to impose remedies against Petitioner which included cancellation of Petitioner's approval to receive Medicare payment for its services and revocation of Petitioner's CLIA certificate.

HCFA followed its May 13, 1999 notice with a second notice that is dated June 23, 1999. In this second notice, HCFA advised Petitioner that it had based its determination to impose remedies on its finding that Petitioner had referred proficiency test samples to another laboratory for testing or had improperly collaborated with another laboratory in the testing of proficiency test samples.

Petitioner requested a hearing on July 15, 1999, and the case was assigned to me for a hearing and a decision. Attached to Petitioner's hearing request were several evidentiary documents. I am marking Petitioner's hearing request and accompanying

documents as P. Ex. 1. After Petitioner had requested a hearing, HCFA sent a third notice to Petitioner, dated August 27, 1999. In this notice HCFA reiterated and amplified its findings that Petitioner either had referred proficiency test samples to another laboratory for testing or had collaborated with another laboratory in the testing of proficiency test samples. In the August 27, 1999 notice HCFA identified two specific CLIA conditions with which it asserted Petitioner had not complied. These conditions are stated at 42 §§ 493.801 (proficiency testing) and 493.1441 (laboratory director).
HCFA moved for summary disposition. HCFA's motion was accompanied by 15 exhibits marked as HCFA Ex. 1 - HCFA Ex. 15. Petitioner simultaneously filed a brief and a request for an in-person hearing. Attached to Petitioner's brief were five documents labeled Exhibit A - Exhibit E. I identify these documents as P. Ex. 2 - P. Ex. 6. Petitioner also submitted five exhibits numbered 1 through 5. I identify these documents as P. Ex. 7 - P. Ex. 11. The parties also simultaneously submitted response briefs. Attached to Petitioner's response brief was a document labeled as Exhibit A. I identify this as P. Ex. 12. Petitioner asserted that it possessed relevant evidence which it needed to present at an in-person hearing. I decided that there existed disputed issues of material fact and I scheduled an in-person hearing in order that Petitioner could present evidence.
On April 12, 2000, I held an in-person hearing in Detroit, Michigan. At this hearing, I heard the testimony of Ms. Deborah Joy Sabo, whom Petitioner called to testify. I also admitted into evidence the 15 exhibits that HCFA had submitted in connection with its motion for summary disposition (HCFA Ex. 1 - HCFA Ex. 15). I reserved judgment on whether I would receive into evidence exhibits that Petitioner had submitted in connection with its prehearing submissions.
I gave the parties leave to file post-hearing briefs. Each party filed a brief. Petitioner filed seven additional proposed exhibits with its brief labeled as P. Ex. 1 - P. Ex. 7. I identify these as P. Ex. 13 - P. Ex. 19. I note that several of these exhibits duplicate other exhibits that are in evidence or are excerpts from the transcript of the April 12, 2000 hearing.
HCFA also filed a supplemental submission in which it submitted two additional documents. I identify these as HCFA Ex. 16 - HCFA Ex. 17. Petitioner objected to including these documents into the record. By letter dated June 5, 2000, I informed the parties that I overruled Petitioner's objection. I receive into evidence HCFA Ex. 16 - 17. In addition, I receive into evidence P. Ex. 1 - P. Ex. 19. In receiving these exhibits into evidence, I overrule any objection HCFA has made to making them part of the record. Additionally, I am receiving into evidence P. Ex. 1 - P. Ex.19 even though, as I note above, some of these exhibits duplicate aspects of the record that already are in evidence.

B. Governing law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals

procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as broadly stated general requirements which must be met in order for a laboratory to qualify under CLIA. Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. Standards are subparts of the more broadly stated conditions. A failure by a laboratory to comply with one or more standards may be so serious as to constitute failure to comply with the condition of which the standards are subparts.

The CLIA regulations authorize HCFA or its designee (such as the Michigan State survey agency) 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 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 as remedies *principal* sanctions against the laboratory which may include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). HCFA may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative sanctions that have been imposed against that laboratory. 42 C.F.R. §493.1810(e). However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted.

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. The standard of proof that is employed at a hearing concerning HCFA's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. HCFA has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by HCFA. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

II. Issue, findings of fact and conclusions of law

A. Issue

The issue in this case is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving HCFA the authority to impose remedies against Petitioner, including canceling Petitioner's approval to receive Medicare payments and revoking Petitioner's CLIA certificate.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. HCFA gave Petitioner adequate notice of the basis for its determination to impose remedies.

Petitioner asserts that HCFA failed to give it adequate notice of the basis for its determination to impose remedies. Petitioner asserts that HCFA notified Petitioner only of standard level deficiencies and not of any condition level deficiencies. Petitioner argues that, consequently, HCFA is without authority to impose principal sanctions against Petitioner.

I am not persuaded that HCFA failed to give Petitioner adequate notice of its determinations. By or shortly after August 27, 1999, Petitioner was on notice that HCFA had determined that Petitioner had failed to comply with two specific CLIA conditions of participation. And, Petitioner also knew that the principal basis for these determinations was HCFA's conclusion that Petitioner had either referred proficiency test samples to another laboratory for testing or had collaborated with another laboratory in the performance of proficiency testing.

It is true, as Petitioner contends, that the report of the February 25, 1999 survey identifies only standard level deficiencies in Petitioner's operations. HCFA Ex. 4 at 6 - 15. The notice letters which HCFA sent to Petitioner after February 25, 1999, contain somewhat shifting rationales for HCFA's determination to impose principal sanctions against Petitioner. HCFA Ex. 4; HCFA Ex. 5; HCFA Ex. 6. However, it is evident from the notices that, by August 27, 1999, HCFA had settled on a determination that Petitioner had failed to comply with two CLIA conditions of participation. HCFA plainly and clearly communicated this determination to Petitioner.

The three notice letters that HCFA sent to Petitioner all state that HCFA concluded that Petitioner had failed to comply with CLIA requirements, either by referring proficiency test samples to another laboratory for testing or by collaborating with another laboratory in the performance of proficiency testing. The notice letter of May 13, 1999 does not explicitly state that Petitioner's alleged referrals or collaboration were the basis for a determination of condition level deficiencies. HCFA Ex. 4. However, the notice letter of August 27, 1999 explicitly advises Petitioner that HCFA had determined that Petitioner failed to comply with CLIA conditions of participation that are stated at 42 C.F.R. §§ 493.801 (proficiency testing) and 493.1441 (laboratory director). HCFA Ex. 6. This letter makes it plain that HCFA premised these findings of condition level deficiencies on Petitioner's asserted referral of test samples to another laboratory or collaboration in the performance of proficiency testing.

I have considered whether HCFA's August 27, 1999 notice is an improper amendment of HCFA's May 13, 1999 notice. I conclude that it was not made improperly. In particular, I conclude that Petitioner suffered no prejudice from HCFA's amendment to its notice.

The regulations which govern a hearing in a case involving an alleged failure by a clinical laboratory to comply with CLIA requirements do not prohibit HCFA from amending or superseding a notice of an initial determination. The regulations which govern CLIA enforcement are silent as to the question of whether a notice may be amended or superseded. *See* 42 C.F.R. Part 493, Subpart R. A case involving an

alleged failure to comply with CLIA requirements is heard and decided pursuant to the regulations contained in 42 C.F.R. Part 498, Subpart D. 42 C.F.R. § 493.1844(a)(2). These regulations also are silent as to the question of whether a notice may be amended or superseded.

Parties in cases involving HCFA have been permitted to amend notices and hearing requests. Traditional due process considerations govern the circumstances under which amendment is permitted. Particularly important is the issue of whether an amendment - either to a notice or a hearing request - may be made without prejudice to the opposing party.

Petitioner has not been prejudiced by HCFA's August 27, 1999 notice. HCFA issued its August 27, 1999 notice very early in the case. Petitioner submitted its hearing request on July 15, 1999. HCFA issued its August 27, 1999 notice only slightly more than one month after Petitioner submitted its hearing request and before any substantive development of the record had occurred in this case. Petitioner has not alleged or shown that it experienced any prejudice as a consequence of HCFA's amended notice. Indeed, Petitioner did not even raise a question as to whether HCFA's August 27, 1999 notice was proper until it submitted its final brief in the case on May 15, 2000.

2. HCFA is authorized to make independent determinations about the nature and severity of Petitioner's alleged noncompliance with CLIA requirements.

Petitioner seems to be arguing that HCFA lacks the authority to make findings which differ from those which its agents make in conducting CLIA compliance surveys by asserting that HCFA's determination that Petitioner manifested condition level deficiencies in its operations exceeded the findings that were made at the February 25, 1999 survey. From this, Petitioner appears to argue that HCFA's determinations in this case are invalid inasmuch as they differ from the findings of noncompliance that were made by the Michigan State survey agency surveyors.

The fact that HCFA chose to make findings which are different than those stated in the report of the February 25, 1999 compliance survey provides no basis to disqualify those findings. It is evident from the notices that HCFA sent to Petitioner that HCFA evaluated independently the evidence that the surveyors obtained and reached independently its own conclusions as to what that evidence meant. That is entirely appropriate and consistent with the regulations which govern enforcement under CLIA.

The regulations which establish enforcement procedures under CLIA vest in HCFA the authority to determine independently whether noncompliance with CLIA exists and the extent of that noncompliance. The regulations make it clear that HCFA is not bound by the findings that are made by a State survey agency's surveyors. HCFA is free to accept or reject those findings and to modify them as it determines to be appropriate.

That is made clear by 42 C.F.R. § 493.1804(b)(1), which states:

> *HCFA's decision* to impose sanctions is based on one or more of the following:
>
> (i) Deficiencies found *by HCFA* or its agents in the conduct of inspections to certify or validate compliance with Federal requirements . . .
>
> (ii) Unsuccessful participation in proficiency testing...

(emphasis added). The plain meaning of this section is that HCFA has the final say on determining whether or not to impose sanctions against a laboratory. It is HCFA's

decision and not that of the State survey agency which controls. Moreover, the language of the regulation is equally plain in stating that HCFA may determine independently whether a laboratory is not complying with CLIA requirements and the extent of that noncompliance. Under the regulation, HCFA finds the presence of deficiencies based on the results of inspections.

3. During 1998, Petitioner colluded with other clinical laboratories in the performance of proficiency testing.

Petitioner colluded with other laboratories during 1998 in the performance of proficiency testing. The evidence in this case provides overwhelming support for this conclusion. Petitioner did not rebut the evidence of collusion, either with its exhibits, or with the testimony of Ms. Sabo.

The condition of participation that is stated at 42 C.F.R. § 493.801 requires that a clinical laboratory must enroll in a proficiency testing program that meets defined criteria and which is approved by the United States Department of Health and Human Services. Petitioner enrolled in an approved proficiency testing program that is operated by the American Association of Bioanalysts (AAB) Proficiency Testing Service. *See* HCFA Ex. 1 at 1. Petitioner received a group of proficiency testing samples from the AAB at regular intervals each year. *See Id.* Other clinical laboratories who were enrolled in the AAB proficiency testing program received the same samples at the same time as did Petitioner. I take notice of the fact that the AAB refers to each mailing of samples to laboratories for proficiency testing as an "event."

The object of the proficiency testing exercise is for each participating laboratory to test its samples independently as if they are patient specimens and to report the results of its tests to the AAB Proficiency Testing Service. The AAB scores the results for the tests that are performed for each event and rates each laboratory's testing competency for that event based on the scores that the laboratory obtains.

There was no such thing as a single "correct" score on many of the proficiency tests that Petitioner and other laboratories were asked to perform in 1998. HCFA Ex. 14 at 4. The AAB accepts as "correct" for many tests scores that fall within a range of possible scores because of the wide range of variables that are involved in the testing process. *Id.* Indeed, it is highly unlikely that two laboratories performing proficiency tests would obtain identical test results on multiple samples, given the wide range of variables that are involved in the testing process. *Id.* at 3.

For example, the third testing event of 1998 included testing of triglyceride samples. HCFA Ex. 14 at 4, 13. For the first sample of that event, a laboratory would receive a passing score if it identified a triglyceride level which fell anywhere in a range of values of between 140 to 223. *Id.* For the fourth sample, acceptable values ranged between 96 to 160. *Id.*

During 1998, Petitioner and eight other laboratories located in the Detroit, Michigan area submitted proficiency test results that were virtually identical. HCFA Ex. 2. Indeed, on numerous tests, Petitioner and the other eight laboratories submitted scores that were precisely identical. *Id.* The inescapable inference that arises from Petitioner and eight other laboratories submitting virtually identical proficiency testing results for numerous samples in three testing events during a single year - especially given the variable factors that were at play - is that Petitioner and the other laboratories colluded with each other to produce those results. There is no reasonable likelihood that nine laboratories

independently would produce nearly identical results on numerous proficiency tests for three events in a single year. HCFA Ex. 13 at 3; HCFA Ex. 14 at 4, 6; HCFA Ex. 15 at 4 - 5.

The likelihood of more than one laboratory arriving at the same value for a proficiency test result is low due to the variables that are involved in the testing process. For example, testing results for triglycerides and total cholesterol normally would vary from 10 to 20 percent from one laboratory to another. HCFA Ex. 13 at 3. Yet, in 1998, Petitioner and eight other laboratories reported the exact same values for triglyceride and total cholesterol proficiency tests. *Id.*

The evidence which supports my conclusion that Petitioner and eight other laboratories colluded with each other to produce nearly identical proficiency testing results in 1998 includes the opinions of three experts whose declarations were supplied as evidence by HCFA. HCFA Ex. 13; HCFA Ex. 14; HCFA Ex. 15. These experts include Dennis W. Jay, Ph.D., DABCC, Technical Director of the AAB Proficiency Testing Service. HCFA Ex. 13. They include also Elizabeth Clay, a certified medical technologist who is employed by HCFA. HCFA Ex. 14. And, they include Richard J. Benson, CLS, MT, who is employed as Chief, Laboratory Improvement Section, Bureau of Health Systems, of the Michigan State survey agency. HCFA Ex. 15. I find these experts to be well-qualified and their opinions to be persuasive.

Petitioner challenges these experts' opinions on the ground that none of these experts have demonstrated any background or training in statistics sufficient to enable them to opine as to the probability of different laboratories attaining identical proficiency testing results. I do not find Petitioner's argument to be persuasive. None of these experts performed statistical analyses to obtain their conclusions. Rather, their conclusions were based on their training in their respective fields, their experience in those fields, and on the evidence which pertained to the specific proficiency tests that are at issue in this case. Thus, for example, Dr. Jay concluded that the nine laboratories, including Petitioner, could not have independently reached identical results for cholesterol and triglyceride proficiency testing, because of the poor reproducibility of such tests. HCFA Ex. 13 at 2 - 3. Dr. Jay plainly based that conclusion on his training and expertise and not on a statistical analysis of test results.

I find reinforcement for my conclusion that there existed no reasonable probability that the nine laboratories would independently arrive at identical proficiency testing results on multiple occasions by the existence of differences in testing conditions among the laboratories which would have affected the test results produced by each laboratory. Although some of the laboratories had the same model spectrometer - a device that was used to perform proficiency testing - others had different models. Tr. at 77. All of the spectrometers were calibrated separately. *Id.* at 77 - 78. Each of the nine laboratories had its own supply of controls and reagents. *Id.* at 76 - 77. Room temperature varied from laboratory to laboratory. *Id.* at 78.

The evidence which I have discussed so far, in and of itself, is sufficient to support the conclusion that Petitioner and the other eight laboratories colluded in 1998 to produce nearly identical proficiency testing results. However, there exists additional evidence which supports this conclusion.

That additional evidence consists in part of evidence showing that the proficiency testing results that Petitioner submitted were not consistent with Petitioner's own

records of its proficiency tests. Such evidence strongly supports a conclusion that Petitioner manipulated its proficiency testing results in order to submit results that conformed to those which were submitted by the other eight laboratories. The evidence shows that Petitioner rounded proficiency testing values in a manner that is inconsistent with accepted practice in order to produce results that conformed with the results obtained by the other eight laboratories. HCFA Ex. 15 at 5 - 8. Thus, for example, Petitioner rounded a value for a triglyceride proficiency test down from 129.8 to 129, thereby submitting a result that is consistent with that which was submitted for other laboratories, even though accepted practice would have been to round the test value up to 130. *Id.* at 8. On another occasion, Petitioner rounded a value for an HDL cholesterol proficiency test up from 51.4 to 52 when accepted practice would have been to round the test value down to 51. *Id.*

Moreover, on another occasion, Petitioner reported a proficiency test value which was not supported by Petitioner's testing data but which was identical to the value that other laboratories submitted for the same test. For the third AAB specimen for triglycerides that Petitioner tested on October 21, 1998, the value that Petitioner should have reported based on its testing data was 196. HCFA Ex. 15 at 9. However, Petitioner reported a value of 96 for the test, which was the identical value that the eight other laboratories reported for the same test. *Id.*

Finally, the evidence establishes that the opportunity for collusion existed. All nine of the laboratories submitting identical proficiency testing results employed as testing personnel one of two individuals, Ms. Sabo and Ms. Rene Wheatley. Tr. at 78; *see* HCFA Ex. 1 at 1 - 2. During 1998, Petitioner employed Ms. Sabo. Tr. at 40 - 41. Ms. Sabo and Ms. Wheatley are well-acquainted. *Id.* at 42.

Ms. Sabo denied colluding with other laboratories or individuals. Tr. at 21. She asserted that she performed each proficiency test for Petitioner in the same manner that she performed tests on patients' specimens and that she integrated her proficiency testing into her routine specimen testing. *Id.* at 18 - 19, 20. Ms Sabo averred that discrepancies between proficiency testing data and the results that she reported for proficiency testing could be explained as simple errors on her part. *Id.* at 30 - 39.

I find that Ms. Sabo's denials of complicity in collusion are not credible. If anything, Ms. Sabo's testimony confirms my conclusion that collusion is the *only reasonable* explanation for the nearly identical proficiency test results that were produced by the nine laboratories. Ms. Sabo's testimony consisted, essentially, of unsupported denials of wrongdoing. Moreover, it failed to explain the overwhelming evidence that collusion occurred. Ms. Sabo was unable to provide any credible explanation how nine laboratories could produce identical proficiency testing results on many tests over a lengthy period of time.

Ms. Sabo acknowledged that the testing she performed was subject to a large number of variables that would be likely to produce different results at different laboratories assuming that samples were tested individually at these laboratories. Tr. at 74 - 80. She admitted that, given these variable factors, it would be surprising if identical test results were produced at different laboratories. *Id.* She offered no explanation for the virtually identical proficiency testing scores produced by the nine laboratories given the acknowledged variables in the testing process. *See Id.* at 76 - 80.

4. During 1998, Petitioner did not test proficiency test samples in the same manner as it tested patients' specimens. Also during 1998, Petitioner engaged in inter-laboratory communications pertaining to the results of proficiency tests.

A primary requirement of the CLIA condition of participation that is stated at 42 C.F.R. § 493.801 is that a clinical laboratory must test proficiency test samples in the same manner as it tests patients' specimens. An additional requirement of this condition is that a clinical laboratory not engage in inter-laboratory communications pertaining to the results of proficiency testing. 42 C.F.R. § 493.801(b)(3).

Petitioner did not comply with these principal requirements during 1998. The manner in which Petitioner performed proficiency testing - by colluding with other laboratories to obtain a collectively determined result - clearly was a departure from standard procedures for testing patients' specimens. Finding 3. Moreover, as I have found above, Petitioner communicated with other laboratories about proficiency testing in order to report scores for proficiency tests that were identical with those that were reported by the other laboratories. This also was a departure from standard testing procedures.

5. Petitioner failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

I conclude that, during 1998, Petitioner did not comply with the condition of participation that is stated at 42 C.F.R. § 493.801. Petitioner's collusion in the performance of proficiency testing was a deliberate effort to frustrate the purpose of proficiency testing, which is, to assure that a clinical laboratory establishes its competence through an impartial proficiency testing process. Petitioner's participation in proficiency testing was pointless, given its collusion. Petitioner's collusion made its enrollment in a proficiency testing program meaningless. Furthermore, as I discuss above, at Findings 3 and 4, such collusion by Petitioner meant that Petitioner was not performing its proficiency tests in the manner that it normally tested patients' specimens and it was not integrating its proficiency testing with the testing of patients' specimens.

HCFA argues that Petitioner explicitly violated the prohibitions in 42 U.S.C. § 263a(i)(4) against referring proficiency test samples to another laboratory for testing. According to HCFA, collusion in the performance of proficiency testing is at law functionally equivalent to referral of test samples to another laboratory. As support for its argument, HCFA cites to an administrative law judge's decision in *Balding Urgent Care Center Laboratory*, DAB CR438 (1996).

I disagree with HCFA's assertion and I disagree with the *Balding* decision to the extent that it supports the proposition that an unlawful "referral" of a testing sample to another laboratory may occur without an actual physical transport of the sample from one laboratory to another. As I explained in *Southfield Medical Clinic*, DAB CR667 at 11 (2000), collusion and referral of testing samples are not the same thing. The law distinguishes between the physical transport of proficiency testing samples from one laboratory to another for testing and collusion between two laboratories. *See* 42 C.F.R. §§ 493.801(b)(3) and (4).

In some instances, it may be important to distinguish between collusion and referral. The distinction is not academic in some cases because, under CLIA and implementing regulations, revocation of a laboratory's CLIA certificate is mandatory where that laboratory deliberately refers proficiency testing samples to another laboratory for

testing. By contrast, collusion in the performance of proficiency testing, absent referral of test samples, does not require revocation of a CLIA certificate. Arguably, there may be instances where collaboration is so minimal as not to warrant the imposition of a principal sanction.

However, that distinction is not important here. Petitioner's collusion was so egregious as to constitute a failure to comply with the CLIA condition that is stated at 42 C.F.R. § 493.801. And, as I explain below at Finding 7, Petitioner's failure to comply with the condition gives HCFA the authority to impose principal sanctions against Petitioner which include revocation of Petitioner's CLIA certificate. Moreover, in this case, the *effect* of Petitioner's collusion on the performance of its proficiency testing was indistinguishable from the effect resulting from other forms of cheating on proficiency testing, including referral of samples to another laboratory for testing. The effect here was to invalidate completely Petitioner's proficiency testing. That consequence of Petitioner's collusion is indistinguishable from what would have been the consequence of unlawful referrals by Petitioner of testing samples.

HCFA asserts that, in addition to colluding with other laboratories in the performance of proficiency testing, Petitioner failed to comply with standards of participation that are stated at 42 C.F.R. § 493.801. The alleged standard level noncompliance by Petitioner includes engaging in inter-laboratory communications about proficiency testing in violation of the standard that is stated at 42 C.F.R. § 493.801(b)(3). It includes failing to perform proficiency testing as part of Petitioner's regular workload using Petitioner's routine testing methods in violation of the standard that is contained at 42 C.F.R. § 493.801(b)(1). And, it includes a failure by Petitioner's owner and laboratory director to sign required attestation statements that were submitted as part of the first three proficiency testing events in 1998 in violation of the standard that is stated at 42 C.F.R. § 493.801(b)(5). That standard requires that a clinical laboratory's laboratory director must sign proficiency testing attestations. HCFA asserts that Ms. Sabo, who was employed by Petitioner as its testing personnel and not as Petitioner's laboratory director, signed the statements.

Petitioner did not comply with these standards. Petitioner's collusion with other laboratories in the performance of proficiency testing meant that Petitioner was not performing its proficiency tests as part of its regular workload using its normal testing procedures. It plainly engaged in prohibited inter-laboratory communications about proficiency testing. Petitioner did not rebut the allegation that its laboratory director failed to sign proficiency testing attestation statements.

At the in-person hearing, Petitioner's counsel asked Ms. Sabo if she had served as Petitioner's "technical supervisor." Tr. at 26. Apparently, counsel was trying to elicit testimony from Ms. Sabo to the effect that she served as the functional equivalent of Petitioner's laboratory director. However, counsel's question did not address the issue of who was Petitioner's laboratory director. Petitioner laid no foundation to show that a "technical supervisor" at Petitioner's laboratory performed the functions of a laboratory director. I note that regulations which define the role of laboratory director state that a laboratory director may function as a laboratory's technical supervisor as part of his or her broader responsibilities. 42 C.F.R. § 493.1445(a). But, this regulation does not suggest that a laboratory director and a technical supervisor have interchangeable roles. To the contrary, the regulation suggests that a technical supervisor's duties are, at

most, a component of a laboratory director's responsibilities. Furthermore, Ms. Sabo answered the question equivocally, by asserting first that she was the "testing personnel" for the laboratory and then, by saying that she might have at times been referred to as "technical supervisor" because of her degree. Tr. at 26.

Standing by themselves, Petitioner's noncompliance with various standards under 42 C.F.R. § 493.801 might arguably not be a basis for concluding that Petitioner failed to comply with the broader condition of participation. However, if standard level deficiencies are sufficiently egregious, they can constitute a failure by a laboratory to comply with the overall condition of which the standards are subparts. That is certainly the case here. Petitioner's violation of the standards of 42 C.F.R. § 493.801 are elements of Petitioner's collusion in the performance of proficiency testing. And, as I discuss above, Petitioner's collusion was so egregious as to make its participation in proficiency testing meaningless.

6. Petitioner failed to comply with the condition of participation that is stated at 42 C.F.R. § 493.1441.

HCFA alleges that Petitioner failed to have a laboratory director who provided overall management and direction of Petitioner as is required by the CLIA condition of participation that is stated at 42 C.F.R. § 493.1441 (which incorporates by reference 42 C.F.R. § 493.1445). HCFA made a number of assertions about the alleged failures of Dr. Boykansky to provide the direction that is required under 42 C.F.R. § 493.1445. Foremost among these allegations is that Dr. Boykansky failed to assure that Petitioner tested proficiency test samples in accordance with the requirements of CLIA.

The evidence in this case sustains HCFA's allegations. The evidence shows that, in 1998, Dr. Boykansky abdicated the supervisory authority that he had as Petitioner's laboratory director. This abdication of authority was so serious as to comprise a failure to comply with the laboratory director condition of participation under CLIA. The failure to supervise Ms. Sabo enabled her to collaborate with other laboratories in the performance of proficiency testing. Had Dr. Boykansky been more vigilant in supervising Ms. Sabo, the collusion that transpired between Petitioner and other laboratories might not have happened.

I do not find that Dr. Boykansky was involved personally in the collusion between Petitioner and other laboratories concerning proficiency testing that was performed in 1998. There is no evidence to establish that Dr. Boykansky was aware of the collusion. But, there is ample evidence to show that he was remiss in supervising Ms. Sabo and that this lax supervision facilitated collusion between Petitioner and other laboratories. The collusion between Petitioner and other laboratories transpired over a period of approximately one year. During this period Ms. Sabo manipulated the proficiency testing data generated by nine different clinical laboratories so as to assure that these nine laboratories produced virtually identical proficiency testing results. During this entire period there is no evidence that Dr. Boykansky, acting as laboratory director of Petitioner and Ms. Sabo's supervisor, exercised any supervision of Ms. Sabo that would have exposed her actions. The inference I draw from his failure to intervene was that Dr. Boykansky was not providing required oversight of Ms. Sabo's work. My conclusion that Dr. Boykansky was not supervising Ms. Sabo is buttressed by Dr. Boykansky's failure to sign proficiency testing attestation statements. Rather, he permitted Ms. Sabo to sign these statements.

7. HCFA is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions of participation.

As I discuss above at Part I.B. of this decision, HCFA is authorized to impose principal sanctions including revocation of a laboratory's CLIA certificate as remedies for that laboratory's failure to comply with one or more CLIA conditions. 42 C.F.R. § 493.1806(a), (b). HCFA may impose the additional remedy of cancellation of a laboratory's approval to receive Medicare payment for its services where the laboratory has not complied with one or more CLIA conditions. 42 C.F.R. § 493.1807.

HCFA is authorized to impose principal sanctions against Petitioner along with cancellation of Petitioner's approval to receive Medicare payment for its services. The sanctions HCFA may impose include revocation of Petitioner's CLIA certificate. Additionally, HCFA may cancel Petitioner's approval to receive Medicare payment for its services. The evidence in this case establishes that Petitioner failed to comply with two CLIA conditions of participation. HCFA would be authorized to impose principal sanctions and cancellation of Petitioner's approval to receive Medicare payment for its services if Petitioner had failed to comply with only one CLIA condition of participation.

Petitioner argues that, even if some deficiencies may have existed in its operation, it filed a plan of correction on May 28, 1999, which addressed these deficiencies. According to Petitioner, all of its deficiencies - which it characterizes as being standard level deficiencies - have long since been corrected by Petitioner. Petitioner asserts that HCFA lacks authority to impose principal sanctions against it inasmuch as there exist no outstanding failures by Petitioner to comply with CLIA participation requirements.

I do not agree with Petitioner's argument. As I have discussed at length in this decision, Petitioner's deficiencies were not merely standard level failures by Petitioner to comply with CLIA participation requirements. It is true that the report of the February 25, 1999 survey of Petitioner characterized Petitioner's noncompliance as failures to comply with CLIA standards. But it is also true that, as of August 27, 1999, HCFA had made it plain to Petitioner that HCFA had determined that Petitioner's noncompliance with CLIA requirements was at a condition level of seriousness. As I discuss above, at Part I.B., HCFA is under no obligation to accept a plan of correction from a laboratory where that laboratory has failed to comply with CLIA conditions of participation. *See* 42 C.F.R. § 493.1810(e).

JUDGE

Steven T. Kessel
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Garden City Medical Clinic,

Petitioner,
DATE: September 11, 2000
- v -
Health Care Financing Administration
Docket No.C-99-766
Decision No. **CR698 DECISION**

I enter summary judgment in favor of the Health Care Financing Administration (HCFA) sustaining its determination to impose remedies against Petitioner, Garden City Medical Clinic, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). HCFA properly revoked Petitioner's CLIA certificate for a period of one year. HCFA also properly canceled Petitioner's approval to receive Medicare/Medicaid payment for its services, effective September 11, 1999.

I. Applicable Law and Regulations

CLIA was designed to promote accurate medical tests by clinical laboratories. Congress' goal was to establish a single set of standards applicable to all laboratory services, including those provided to Medicare beneficiaries. *See* H.R. Rep. No. 899, 100th Cong., 2nd Sess. 8 (1988), *reprinted in* 1998 U.S.C.C.A.N. 3828.

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. The Social Security Act (Act) 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). The Act 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)(1).

The standards for the operation of clinical laboratories promulgated by the Secretary pursuant to the enabling legislation are found at 42 C.F.R. Part 493. 42 C.F.R. § 493.801 sets forth requirements for performance of proficiency tests. A clinical laboratory must enroll in an approved (PT) program. It must notify the Department of Health and Human Services (DHHS) of each program or programs in which it chooses to participate to meet proficiency testing standards. HCFA approves certain companies to administer proficiency tests under CLIA. Sections 931 and 933 of Title 42 of the Code of Federal Regulations require that for routine chemistry and endocrinology, three times each year at approximately equal intervals, these approved testing companies send out proficiency test samples to be analyzed by each laboratory. A minimum set of five samples are sent for each testing event. The participating laboratories then perform the

tests and submit their results on forms provided by the testing services. The testing services grade the results and report them to HCFA. To determine the accuracy of a laboratory's response for qualitative and quantitative chemistry tests or analytes, the program must compare the laboratory's response for each analyte with the response that reflects agreement of either 90 per cent of 10 or more referee laboratories or 90 per cent or more of all participating laboratories.[(1)] A laboratory is required to examine or test each PT sample that it receives in the same manner that it tests patient specimens. 42 C.F.R. § 493.801(b).

Any laboratory that the Secretary determines intentionally refers its PT samples to another laboratory for analysis shall have its certificate revoked for at least one year. 42 U.S.C. 263a(I)(4), 42 C.F.R. § 493.801(b)(4). Additionally, the regulations provide that when HCFA revokes a laboratory's CLIA certificate, it will also cancel that laboratory's approval to receive Medicare reimbursement for services rendered. 42 C.F.R. § 493.1842(a).

A participating laboratory is required to test PT samples in the same manner as patient specimens, as well as appoint a director who provides overall management and direction in accordance with 42 C.F.R. §§ 493.801, 493.1441, and 493.1445. A laboratory that does not treat PT samples in the same manner as patient samples or whose director fails to provide overall management and direction may have its certificate of accreditation revoked. 42 C.F.R. §§ 493.61(b)(1) and 493.61(c)(3).

It is also a violation of the regulations to engage in any inter-laboratory communications pertaining to the results of proficiency testing samples until after the date by which the facility must report PT results to the proficiency testing service. 42 C.F.R. § 493.801(b)(3).

The CLIA condition of participation at 42 C.F.R. § 493.803(a), requires that a laboratory performing tests of moderate and/or high complexity must successfully participate in a proficiency testing program.

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must be prepared, stored, and handled in a manner to ensure that they are not used beyond their expiration date, have not deteriorated, nor are of substandard quality. 42 C.F.R. § 493.1205(e)(1).

42 C.F.R. Part 493, Subpart E, requires HCFA or its agent to conduct, on a representative sample basis or in response to substantial allegations of non-compliance, surveys of an accredited laboratory as a means of validating its performance.

The regulations set forth "conditions" as well as "standards" for participation under CLIA. While conditions are expressed as broad, general requirements, standards are set forth as more specific requirements of participation. A participating laboratory's failure to comply with one or more standards may be so egregious as to constitute a failure to comply with a condition of participation. If HCFA determines that a facility has not complied with a condition of participation, it may impose principal sanctions which include revocation and/or suspension of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). In lieu of, or in addition to, principal sanctions HCFA may impose alternative sanctions. HCFA may allow a non-compliant laboratory the opportunity to remove alternative sanctions, but the regulations do not provide a laboratory the same opportunity for removing principal sanctions.

A laboratory that is not satisfied with the imposition of remedies by HCFA may request a hearing before an administrative law judge. 42 C.F.R. § 493.1844.

II. Background

HCFA filed a motion and memorandum of law accompanied by documentation and written declarations in support of its motion for summary judgment on January 12, 2000. Petitioner countered with an opposing memorandum on February 21, 2000. It offered no supporting affidavits or other documentation. HCFA submitted a reply brief on March 9, 2000. I admit into evidence HCFA's Exhibits 1-18 (HCFA Exs. 1-18) which accompanied its brief dated January 12, 2000. On June 27, 2000, Petitioner filed a supplemental brief and four proposed exhibits. These have been admitted into evidence as Petitioner's Exhibits 1-4 (P. Exs. 1-4).

Petitioner is a physician office laboratory located in Garden City, Michigan, that holds a CLIA certificate of accreditation. (Identification Number 23D0367601.) HCFA Ex. 6. The laboratory engages in high-complexity testing for routine chemistry. HCFA Ex. 7. Nazar Sarafa, M.D. is Petitioner's laboratory director. HCFA Ex. 7. Deborah Sabo was part of the testing personnel of Garden City's laboratory as well as other laboratories in the Detroit Metro area. HCFA Ex. 7. She performed high complexity routine chemistry testing for Petitioner as well as proficiency testing. HCFA Exs. 7-10.

Garden City Medical Clinic (Nazar Sarafa, M.D.); Oakland (also known as Moretsky/Trager/Flor); John Dunn, M.D.; Mark Hertzberg, M.D.; Rochester Rd. Clinic; Liptawat Family PC; Lakeland Medical; Ecorse Med Center; and Stanley Boykansky, M.D. are some of the laboratories in the Detroit Metro area participating in a PT program operated by the American Association of Bioanalysts (AAB). HCFA Ex. 2. As participants in this program, AAB would mail each laboratory for PT the same group of five specimens three times a year. The laboratories were required to test these specimens for analytes for which they did patient testing and mail their results to AAB by a date certain, approximately 10 days after receiving the samples. Testing samples for Garden City, among others, included cholesterol, HDL cholesterol, triglycerides, glucose, thyroid-stimulating hormone (TSH), total thyroxine (T4), triiodothyronine (T3), and free thyroxine (FT4).

By letter dated January 4, 1999, Dennis W. Jay, Ph.D., Technical Director of the Proficiency Testing Service of the AAB sent the Michigan Department of Consumer and Industry Services (MDCIS) some proficiency testing results for a group of Detroit area laboratories that he deemed to be suspect. HCFA Ex. 1 at 3-8. Specifically, the cover letter suggested that the same PT results were being submitted by several laboratories. There where five facilities that submitted identical PT results for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens.[(2)] The five facilities were: (1) Oakland Medical Group (ID 23D036505); 2) John Dunn, M.D. (23D0367266); 3) Mark Hertzberg (23D0671668); 4) Rochester Road Clinic (23D0363051); and 5) Nazar Sarafa, M.D. (23D0367601).

On January14, 1999, AAB notified MDCIS that they had discovered another four facilities reporting duplicate results and included their 1998 third quarter summaries and attestation sheets.[(3)] These four facilities were: (1) Liptawat Family, P.C. (23D0363230); 2) Lakeland Medical (23D0371925); 3) Ecorse Med Center (23D06733353); and 4) Stanley Boykansky, M.D. (23D0372207).

On March 2, 1999, Ms. Lucy Estes, Laboratory Evaluation Specialist, MDCIS, performed a complaint survey of Petitioner's facilities. Based on her review of the testing records she received from Petitioner, and information from AAB concerning the similarity of PT results between Petitioner and others in the Detroit area, Ms. Estes found that Petitioner was not in compliance with the CLIA requirements under 42 C.F.R. § 493.801(b)(1), Testing Proficiency Samples; 42 C.F.R. § 493.1205(e)(1), and 42 C. F. R. § 493.1451(b)(4), Technical Supervisor Responsibilities. She completed and submitted HCFA Form 2567 to her supervisor, Richard J. Benson, along with the aforementioned documents. *See* HCFA Ex 3 at 6-10.

By letter dated July 9, 1999, HCFA served notice of cancellation, suspension, and revocation of CLIA certificate of accreditation to Petitioner, pursuant to MDCIS referral of its case for imposition of enforcement action. Specifically, it was found that Petitioner was not in compliance with the following CLIA statutory and regulatory requirements: (1) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4). (2) The laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures. 42 U.S.C. § 263a(d)(E); 42 C.F.R. § 493.61(b)(1); 42 C.F.R. § 493.801.(b)(1), (2), (3).

Because of the improper referral of laboratory and PT samples to another laboratory for analysis and other serious deficient test practices found during the survey, HCFA imposed the principal sanctions of cancellation of Petitioner's approval to receive Medicare payment for its laboratory services and revocation of Petitioner's CLIA certificate of accreditation. HCFA Ex. 3.

A final and more complete notice of adverse action was served on Petitioner by letter dated October 15, 1999. HCFA Ex. 3. The letter addressed to Petitioner's director, Dr. Nazar N. Sarafa, where pertinent here, states as follows:

> [a]s set forth on the HCFA Form 2567 that was enclosed with our letter to you of July 9, 1999, the surveyors determined that with respect to the first three events of 1998, your laboratory's proficiency testing (PT) was not performed with the laboratory's regular workload using the laboratory's routine methods, in violation of the standard at 42 C.F.R. § 493.801(b)(1). We also stated that the evidence revealed that your laboratory referred certain PT samples to another laboratory for analysis in violation of the standard at 42 C.F.R. § 493.801(b)(4). The evidence strongly suggests that the results of proficiency testing reported by your laboratory during the first, second, and third events of 1998 were obtained by improper referral and/or collaboration. Inter-laboratory communications pertaining to the results of proficiency testing samples, prior to the testing event reporting due date, are prohibited by the standard at 42 C.F.R. § 493.801(b)(3).
>
> The evidence on which we based these determinations, in addition to the survey findings, is abstracted in the enclosed chart. The chart compares proficiency testing results reported to AAB by your laboratory and eight other laboratories in Michigan. We believe that the identity of the results reported by these nine laboratories, especially in the third quarter of 1998, is strong evidence of improper referral, or collaboration, or both.

In addition, the standard at 42 C.F.R. § 493.801(b)(5) requires that a laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples . . .

. . . based on a review of the 1998 proficiency test records and patient sheets during the survey, it was determined that PT samples were not examined or tested with the laboratory's regular patient workload. Since the survey findings reveal that integration did not occur, this violates the standard at 42 C.F.R. § 493.801(b)(5).

The findings from the survey also reveal that you, as laboratory director, have not fulfilled your responsibility to assure that PT samples are tested as required under 42 CFR Part 493, Subpart H. It was determined that the laboratory's personnel were not testing and reporting proficiency test results using the laboratory's routine methods; that you failed to assure that reagents and control materials were not stored beyond their expiration dates; determine whether quality control results were within the expected range of the manufacturer. The presence of the deficiencies cited in this letter and on the HCFA-2567 demonstrates that you have failed to take responsibility for the overall operation and administration of your laboratory. Therefore, the laboratory is out of compliance with the condition level requirement for a laboratory director at 42 C.F.R. § 493.1441. Because your laboratory did not treat PT samples in the same manner as patient samples, it is in violation of the CLIA requirements at 42 C.F.R. § 493.61 and 42 U.S.C. § 263a(d)(1)(E) and does not meet the requirements for a certificate of accreditation . . .

Because of your laboratory's failure to meet the conditions of Proficiency Testing and Laboratory Director, and because of your intentional referral of your laboratory's PT samples for the 3rd. Testing event of 1998 to another laboratory for analysis, as set forth in our letter of July 9, 1998, we have imposed the following principal sanctions against your laboratory:

> 42 C.F.R. § 493.1808(a) and 42 C.F.R. § 493.1842(a)(1) - Principal Sanction: Cancellation of your laboratory's approval to receive Medicare payment for its services. This sanction will become effective on October 1, 1999, and will remain in effect until a hearing decision is rendered, or the end of the revocation period . . .
>
> 42 C.F.R. § 493.263a(I)(4), 42 C.F.R. §§ 493.1814(a) and 493.1840(b) - Principal sanction: Revocation of your laboratory's CLIA certificate . . .

By letter dated August 18, 1999, Petitioner requested a hearing before an administrative law judge. The case was assigned to me for hearing and decision.

Petitioner argues that an evidentiary hearing is essential to explore certain factual issues in dispute. I disagree. For the reasons set forth below, I find that summary judgment is appropriate. There are no material issues of fact in dispute that require an evidentiary hearing. Based on the documentary evidence, written declarations, arguments of the parties, and applicable law and regulations, I find that there are no

genuine issues of fact in dispute, and HCFA is entitled to judgment as a matter of law. I further find that Petitioner failed to meet the CLIA conditions of PT under 42 C.F.R. Part 493, Subpart H, generally. Specifically, Petitioner did not satisfy the conditions for testing of samples pursuant to 42 C.F.R. §§ 493.801 and 493.803 and for laboratory director under 42 C.F.R. § 493.1441. Petitioner also failed to satisfy the standard for test methods under 42 C.F.R. § 493.1205(e)(1). Pursuant to 42 C.F.R. § 493.61, Petitioner failed to satisfy the requirements for a certificate of accreditation. Thus, I order the revocation of Petitioner's certification under the Clinical Laboratory Improvement Act of 1988, 42 U.S.C. § 263a, for a period of one year as proposed by HCFA. I also direct cancellation of approval to receive Medicare payment for services.

Summary judgment is appropriate when there is no genuine issue as to any material fact and the proponent is entitled to judgement as a matter of law. If the moving party meets this burden, the onus shifts to the opposing party to establish that a genuine issue does exist. The opposing party will have shown that genuine issues of fact are present "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 249 (1986). To accomplish this, the opposing party must go beyond mere allegations, and come forward with actual evidence that creates a genuine issue of material fact. All reasonable inferences are to be drawn in the opposing party's favor. *Pollock v. American Telephone & Telegraph Long Lines*, 794 F.2d 860, 864 (3rd Cir. 1986). I have considered all the evidence set forth in the papers submitted and conclude that all inferences drawn from such evidence, casts no doubt as to the propriety of granting HCFA's motion for summary judgment inasmuch as there is no issue of material fact to be tried. HCFA's motion is properly supported by affidavits and documentary evidence. Petitioner has relied on mere allegations and denials, thus falling short of showing that there is a genuine issue for hearing. More significantly, the facts upon which summary judgment rests are facts conceded or not disputed by Petitioner.

III. HCFA's Contentions

HCFA contends that the documentary evidence from Petitioner's own records and the PT results submitted to AAB for the three testing events in 1998 leave no doubt that Oakland's PT results were obtained either in collaboration with, or referral to, other Michigan laboratories in violation of 42 U.S.C. § 263a(i)(4), 42 C.F.R. § 493.61 and 42 C.F.R. Part 493, Subpart H. HCFA also argues that Petitioner failed to test PT samples with patient regular workload and that it was in violation of the condition for laboratory director and standard for test methods. HCFA further argues that summary judgment is appropriate as a matter of law given the absence of a genuine or material issue of fact and the overwhelming evidence that Petitioner did not meet the requirements of the statute, particularly the CLIA conditions for PT and the laboratory director. Accordingly, HCFA asks that I sustain the revocation of Petitioner's CLIA certificate for one year and withdrawal of approval to receive Medicare payment for laboratory services.

IV. Petitioner's Contentions

In opposition to HCFA's motion for summary judgment, Petitioner advances the following arguments: (1) there was no intentional referral of proficiency samples; (2) the laboratory acted in good faith by terminating the employee who created the problem; (3) the Government has not shown that the proficiency testing was not performed in the

ordinary course of business; and (4) the statistical analysis offered by HCFA is not statistically significant.

V. Issues

1. Whether Petitioner intentionally submitted PT samples to a reference laboratory in violation of applicable law and regulations? 42 C.F.R. § 493.801.

2. Whether Petitioner engaged in inter-laboratory communications and collaboration in violation of 42 C.F.R. § 493.801(b)(3)?

3. Whether Petitioner failed to examine PT samples with its regular patient workload using the laboratory's routine methods in violation of 42 C.F.R. § 801(b)(1)?

4. Whether Petitioner met the condition for laboratory director pursuant to 42 C.F.R. §§ 1441 and 1445?

5. Whether Petitioner met the CLIA standard regarding test methods under 42 C.F.R. § 493.1205(E)(1)?

6. Whether Petitioner's actions justify revocation of its CLIA certificate and cancellation of approval to receive Medicare reimbursement?

VI. Findings of Fact and Conclusions of law

I hereby make the following findings of fact and conclusions of law:

1. Petitioner is a laboratory located in Garden City, Michigan, engaging in high complexity testing for routine chemistry and endocrinology and operating by virtue of a certificate of accreditation under CLIA. HCFA Ex. 6.
2. Nazar Sarafa, M.D. is Petitioner's laboratory director. HCFA Ex. 7.
3. Deborah Sabo performed high routine chemistry and endocrinology and PT for Petitioner and for other laboratories in the Detroit Metro area. HCFA Exs. 7, 11-13.
4. Some of the laboratories in the Detroit metro area participating in a PT program operated by AAB are: Garden City Medical Clinic; Oakland Medical Group; John Dunn, M.D.; Mark Hertzberg, M.D.; Rochester Rd. Clinic; Liptawat Family, PC; Lakeland Medical; Ecorse Med. Center; and Stanley Boykansky, M.D. HCFA Ex. 2.
5. AAB mails each laboratory participating in the PT program the same group of five specimens three times per year. The laboratories are required to test these specimens for analytes for which they did patient testing and mail their results to the AAB.
6. Testing samples for Petitioner included cholesterol, HDL cholesterol, triglycerides, glucose, TSH, T4, T3, FT4.
7. The affidavits and documentary evidence submitted by HCFA in support of its motion for summary judgment show that Petitioner reported PT results to the AAB in 1998 that were identical to the results of eight other Detroit area laboratories for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens.
8. From the multitude of identical results, as well as Petitioner's own admission, I find that Petitioner engaged in collaboration and inter-laboratory communications with other Detroit Metro area facilities in violation of 42 C.F.R. § 493.801(b)(3).
9. Petitioner did not arrive at identical results to that of eight other laboratories through human error or coincidence but by manipulation of PT results.

10. The PT scores reported by Petitioner to AAB in the testing events for 1998 were not obtained through onsite testing of specimens.
11. Petitioner did not treat PT samples in the routine manner in which it treated patient specimens. 42 C.F.R. § 493.801(b)(1).
12. Petitioner did not successfully participate in a PT program. 42 C.F.R. § 493.803.
13. Dr. Nazar Sarafa, as laboratory director, was responsible for Petitioner's overall operation and administration. His responsibilities included the employment of competent personnel to perform test procedures, record and report test results promptly, accurately and proficiently, and assuring compliance with applicable regulations.
14. Petitioner was in violation of the condition for laboratory director in failing to provide proper overall management and direction to the facility.
15. Petitioner did not meet the CLIA standards for test methods pursuant to 42 C.F.R. § 493.1205(e)(1).
16. Petitioner has submitted no affidavits or other documentary evidence that if taken as true would create a genuine issue of material fact that would require a hearing.
17. Pursuant to 42 U.S.C. § 263a(f), the Secretary is directed to ensure that certified clinical laboratories perform tests that are valid and reliable.
18. A laboratory that is issued a certificate of accreditation under CLIA must enroll in a PT program and comply with the requirements of 42 C.F.R. Part 493, Subpart H.
19. The facts on which I base this summary judgment are either not in dispute or uncontroverted. Thus, summary judgment is appropriate as a matter of law.
20. HCFA is authorized to revoke Petitioner's CLIA certificate for at least one year and cancel its approval to receive Medicare payment for its services.

VII. Discussion

A. *Petitioner's PT test results for the three testing events in 1998 were not obtained through referral to other laboratories.*

Petitioner contends that a finding of intentional referral is not appropriate inasmuch as HCFA made its finding based on a mere inference of collaboration. In this respect, it claims that no finding of referral is possible in the absence of evidence of a physical transfer from one laboratory to another. HCFA, on the other hand, contends that an inference of referral may be drawn from Petitioner's submission to AAB of proficiency testing results that demonstrably were not arrived at through testing samples on site. I need not determine here, however, whether evidence of physical transport is essential for a finding of referral in light of HCFA's own uncontradicted showing that referral did not occur.

The documentary evidence submitted by HCFA establishes that through an investigation conducted by Petitioner it was determined that an employee of Garden City Medical Clinic, whom also did testing for various other laboratories in the Detroit Metro area, used the data from tests done at one of the laboratories for all of her employers' proficiency examinations. *See* HCFA Ex. 17 at 2; HCFA Ex. 18 at 11-13. There is no dispute that nine laboratories in the Detroit Metro area submitted identical or near identical PT results to AAB in the three testing events for 1998. HCFA Ex. 16, Attachment C. From the facts of this case, I am unable to determine which of the nine facilities provided the results that the others followed. The affidavit of Richard A. Benson, nonetheless, clearly demonstrates that the PT results obtained by Petitioner were at variance with the results reported to AAB. *See* HCFA Ex. 16. *See also* HCFA

Ex. 3 at 7. Thus, Petitioner's claim that it did not refer PT samples to another laboratory, but rather, that Ms. Sabo relied on the testing performed at one of the other laboratories is credible.

> B. *Petitioner engaged in inter-laboratory communications in violation of 42 C.F.R. § 493.801(b)(3).*

Although there is no evidence of referral of PT samples, the facts, as presented by Petitioner do establish collaboration with other participating laboratories in the Detroit Metro area. An affidavit prepared by William E. Robertson, an investigator hired by Petitioner (HCFA Ex. 18), states that Deborah Sabo worked at approximately 11 laboratories and had the responsibility of performing PT at each of these. Furthermore, in a letter addressed to HCFA on July 22, 1999, counsel for Petitioner stated the following:

> [t]his case is most unusual in that one employee worked for a number of unaffiliated laboratories. This employee, acting on her own, without the knowledge of her employer allegedly used the data from tests done at one of the laboratories for all her employer's proficiency examinations. . .
>
> Dr. Sarafa has taken the corrective action of scheduling the termination of this employee and has requested an independent proficiency examination from the American Association of Bioanalysts (AAB). HCFA Ex. 17 at 2, 4.

This manipulation of PT results by Petitioner's employee explains the identical and near identical scores produced by at least nine participating laboratories in the Detroit, Michigan area during the 1998 testing events.[(4)] Such actions by Petitioner are plainly collaboration within the meaning of 42 C.F.R. § 493.801(b)(3).

Richard J. Benson, Chief, Laboratory Improvement Section, MDCIS, compiled a spread sheet from the PT testing results reported by nine laboratories for the three testing events in 1998 in the Detroit Metro area. *See* HCFA Ex. 16 at 23-25. Mr. Benson highlighted in bold the reported scores for those laboratories where Ms. Sabo was entrusted with the PT. The identical results in the reported analytes is inescapable. Moreover, the identical results reported by Petitioner and other laboratories where Ms. Sabo was not the person in charge of proficiency testing further magnifies the collusion with other participating facilities. These scores were reported to AAB even where they were known to be at variance from the results of local testing, and thus, incorrect. Again, the unequivocal conclusion is that Petitioner engaged in collaboration within the meaning of 42 C.F.R. § 493.801(b)(3).

The affidavit of Dr. Dennis W. Jay (HCFA Ex. 15), lends additional support for the finding of improper collaboration in light of the lack of variability in results submitted for triglycerides and total cholesterol. This was particularly unusual, stated Dr. Jay, because these assays typically show poor reproducibility from laboratory to laboratory when manually performed, as opposed to automated testing methods. Based upon his education and experience, given the imprecision on manual testing methodology and the range of acceptable results, Dr. Jay expected to see variations in results on the order of 10-20 percent for cholesterol and triglycerides. Instead identical values were reported by Petitioner and eight other Detroit area laboratories. Dr. Jay further opined that the chances of nine laboratories independently arriving at the same values by

happenstance for all five specimens for even two different tests are close to nil. *See* HCFA Ex. 15 at 3-4.

Dr. Jay's opinion is based not only on his expertise, but also on his personal examination and analysis of the data obtained from Petitioner's own records. Although some of his findings may be laced with statistical implications, the thrust of his declaration is more associated with the manner in which certain chemical properties will behave given specific testing conditions.

C. *Petitioner failed to examine PT samples with its regular patient workload using the laboratory's routine methods*.

Deviation from the standard practice of routine testing, handling and reporting of PT samples is a violation of the requirements at 42 C.F.R. § 403.801(b)(1) and (5). Petitioner concedes that its employee manipulated PT scores to agree with those obtained at another facility, and the results reported to the PT facility were not the product of testing performed at Garden City Medical Clinic. Consequently, the results of PT samples reported to AAB were not obtained through testing performed with the laboratory's regular patient workload.

Petitioner does not deny that Ms. Sabo engaged in improprieties in the handling and reporting of PT results. It claims, however, that she acted on her own, without the knowledge of her employer. Additionally, Petitioner alleges to have taken corrective action by terminating Ms. Sabo's employment and requesting an independent examination by AAB. This defense is not acceptable.

> 42 C.F.R. §§ 493.1840(a) and 493.1840(a)(3) clearly establish that HCFA may initiate adverse action to suspend, limit or revoke any CLIA certificate if HCFA finds that a laboratory owner or operator or one of its employees has failed to comply with the certificate requirements and performance standards. Neither the law nor the regulations allow room for exceptions in situations where the owner or operator is unaware of improprieties attributable to employees. Thus, even if for purposes of this summary judgment, I were to accept as true the operator's claim that he was unaware of Ms. Sabo's improprieties, and that he took corrective action as previously stated, that would not serve as a valid defense against the remedies imposed. *See Melvin C. Murphy, M.D., P.C.*, DAB CR590 (1999). *See also Southfield Medical Clinic*, DAB CR667 (2000).

D. *Petitioner did not meet the condition for laboratory director.*

A participating laboratory must have a director who provides overall direction and proper management for a laboratory pursuant to 42 C.F.R. §§ 493.1441 and 1445. The evidence of record, and Petitioner's own admissions, confirm that proficiency samples were not processed using the laboratory's regular testing procedures. In this regard, it is noted that the PT results reported to AAB, the PT agency, were not obtained through onsite testing, following the facility's routine methods. Dr. Sarafa's failure to ensure that the PT scores reported to AAB were the result of onsite testing, and not those obtained through testing at other participating laboratories are a clear indication that he was out of touch with the everyday operations of his laboratory. It was his ultimate responsibility to ascertain that proficiency testing and reporting was carried out in accordance with the requirements set forth at 42 C.F.R. § 493.801. It is noteworthy that Dr. Sarafa signed attestation sheets for the three testing events of 1998, documenting that the PT

samples were tested in the same manner as patient specimens, without the necessary corroboration in order to ascertain that the reported results were consistent with onsite testing that complied with CLIA requirements. This is a clear violation of 42 C.F.R. § 493.801(b)(5).

It is also the laboratory director's duty to ensure that stored controls and reagents do not exceed their expiration dates. As will be more particularly discussed in the following section, a review of records from 1997 to 1999 by the surveyor on March 3, 1999 revealed that Petitioner continued to store reagents and control materials beyond their expiration date. HCFA Ex. at 8.

Petitioner did not have a technical supervisor. It was, therefore, incumbent upon the laboratory director to establish a quality control program. Dr. Sarafa failed to do this. Such is evident from the surveyor's finding that the accuracy of testing could not be confirmed because the control materials were not available for review. *See* HCFA Ex. 3 at 9. Petitioner argues that these control materials were present and could have been shown to the surveyor had she asked for them. It fails to explain, however, why the surveyor was unable to find them or why assistance was not made available without the asking. Be that as it may, if the materials in question were in fact present at the time of the survey, the cooperative presence of the laboratory director would have made them available for review. Petitioner's argument at this juncture appears to be concoction in the aftermath. Needless to say, even without this additional deficiency, Dr. Sarafa did not meet the condition for laboratory director.

The regulations promulgated by the Secretary make the laboratory director responsible for assuring that a laboratory satisfies CLIA requirements. Petitioner's failure to meet those requirements points to the laboratory director's failure to properly discharge his duties. Moreover, Petitioner's laboratory director failed to meet his obligations under the standard at 42 C.F.R. § 493.1445 to such an extent that it constitutes a failure on the part of Petitioner to comply with the condition for laboratory director.

E. *Petitioner met did not meet the CLIA standard for test methods.*

42 C.F.R. § 493.1205(e)(1) requires that solutions, culture media, control materials, calibration materials and other supplies must be stored and handled in a manner to ensure that they are not used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. Based on a review of 1997 to 1999 records and observations, the surveyor (Lucy Estes) found that Petitioner continued to store three controls and reagents that had exceeded their expiration date.

Petitioner concedes the deficiency under the standard for test methods but downplays the nature of the violation by labeling it a "lesser problem" that has been corrected. *See* HCFA Ex. 17. It may be a lesser problem for Petitioner, but not for patients who rely on accurate laboratory testing for diagnosis and treatment of their medical conditions. One of the controls had expired in December 1998, yet the laboratory director had not exercised supervisory oversight to detect the deficiency.

F. *Petitioner's actions justify revocation of its CLIA certificate and cancellation of approval to receive Medicare reimbursement.*

Petitioner contends that the sanctions imposed and proposed are not appropriate according to the enforcement procedures set forth in the CLIA regulations. It points out

that the deficiencies alleged on the HCFA 2567 Statement of Deficiencies are not condition level. Consequently, Petitioner suggests that revocation of its CLIA certificate is not the proper remedy, but the requirement that it submit a plan of correction acceptable to HCFA. *See* HCFA Ex. 17.

The uncontroverted facts of this case leave no room for doubt that Petitioner failed to comply with the conditions of participation at 42 C.F.R. § 493.61(b), 42 C.F.R. Part 493, Subpart H, and 42 C.F.R. § 1441. HCFA relied on 42 C.F.R. § 493.61(b) to establish that by not treating proficiency samples in the same manner as patient samples, Petitioner could be subject to suspension or revocation of its certificate of accreditation or other alternative sanctions. By relying on, and reporting to AAB, PT results that were not obtained through the integration of proficiency specimens with its regular patient workload, Petitioner was in violation of the requirement for a certificate of accreditation. Petitioner's failure to satisfy the requirements under 42 C.F.R. § 493.801(b)(1), (3), and (5) is so egregious that it amounts to a violation of the condition for treatment of PT specimens and the condition requiring successful participation in an approved PT program under 42 C.F.R. § 493.803.

The failure to meet the condition regarding laboratory director is of such magnitude that this violation alone would suffice to support revocation of Petitioner's certificate for one year. Petitioner does not perceive the enormity of the deficiencies and thus suggests that a minor remedy, that includes a plan of correction, would be more appropriate. The thrust of Petitioner's argument is rooted in the lack of evidence pointing to referral of PT samples. However, even absent a finding that referral took place, there is a more than ample basis for revocation of its certificate of accreditation. Thus, HCFA has properly exercised its authority to impose principal sanctions, and Petitioner has no standing to claim that imposition of alternative sanctions is the appropriate remedy in this case.

VIII. Conclusion

Petitioner failed to comply with more than one laboratory condition of participation under CLIA. The presence of at least one condition level deficiency in Petitioner's operations authorizes HCFA to impose the remedies of suspension and revocation of Petitioner's CLIA certificate for at least one year, and cancel its approval to receive Medicare payment for its services, effective September 11, 1999. I hereby grant HCFA's motion for summary judgment.

JUDGE

Jose A. Anglada
Administrative Law Judge

FOOTNOTES

1. The score for a sample in routine chemistry is the score determined under either paragraph (c)(2) or (c)(3) of 42 C.F.R. § 493.931. The score for endocrinology is determined under paragraph (c)(2) or (c)(3) of 42 C.F.R. § 493.933.
2. These results were for the third quarter PT for 1998.
3. HCFA Ex. 2.
4. The identity of the PT scores cannot be explained by a mere unorthodox practice of rounding. This is exemplified by the illustration at HCFA Ex. 3 at 7.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT: Kaulson Laboratories, Inc.

Petitioner,
DATE: September 20, 2000
- v -

Health Care Financing Administration
Civil Remedies CR642
App. Div. Docket No. A-2000-55
Decision No. **1747 DECISION**

DECISION ON REVIEW OF ADMINISTRATIVE

LAW JUDGE DECISION AND ORDER OF REMAND

Kaulson Laboratories, Inc. (Petitioner) appealed a January 21, 2000 decision by Administrative Law Judge (ALJ) Jill S. Clifton that the Health Care Financing Administration (HCFA) was authorized to impose the remedies of suspension and revocation of Petitioner's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as the cancellation of Petitioner's approval to receive Medicare payments for its services. *Kaulson Laboratories, Inc.*, DAB CR642 (2000) (ALJ Decision). The ALJ found that Petitioner had failed to comply with four conditions for certification for laboratories set forth in the CLIA regulations at 42 C.F.R. Part 493.

On appeal to the Board, Petitioner challenged the ALJ's findings on the CLIA conditions and also raised a preliminary issue: Petitioner argued that it had not been properly informed of the issues addressed by the ALJ, and was not afforded an opportunity to brief and to present evidence on those issues. Petitioner further argued that it had agreed to forego presenting testimony at an in-person hearing based on the issue as identified in a prehearing conference. Petitioner argued that it was never clearly informed that issues beyond the issue identified in the prehearing conference and the ALJ's order confirming the prehearing conference would be considered by the ALJ.

As explained below, we conclude that HCFA agreed at the prehearing conference to a narrower statement of the issues than the issues HCFA subsequently briefed and the ALJ reached in her decision. HCFA also agreed to forego an in-person hearing, presumably based on the nature of the agreed-upon issue to be resolved. HCFA failed to provide any explanation for the manner in which it framed the issue in the prehearing conference.

Under applicable regulations, HCFA was bound by its agreement in the prehearing conference, absent facts showing that the agreement was unreasonable or inequitable. By expanding the issues beyond the prehearing order without requiring HCFA to make such a showing, without providing written notice to Petitioner, and without obtaining a

written waiver of an in-person hearing on the expanded set of issues, the ALJ failed to comply with the governing regulations. Those regulations require the ALJ to issue an order setting the issues to be resolved, and provide that agreements reached in a prehearing conference are binding on the parties. HCFA here did not object to the prehearing order within the established time period, nor subsequently seek to amend the issues, even though Petitioner, in its brief before the ALJ, objected to HCFA's having briefed issues not identified in the prehearing order.

While the ALJ may have had the authority to expand the issues, she could properly do so only in a way that complied with the governing regulations, which require written notice of the issues. No written notice was given, and most of the issues briefed by HCFA and addressed in the ALJ Decision were thus not properly before the ALJ. Moreover, even if oral notice and waiver of hearing rights were adequate (which they are not), the record does not support the ALJ's statement in her decision to the effect that Petitioner was given oral notice in a telephone conference held by her staff attorney.

The actions by HCFA and the ALJ resulted in substantial prejudice to Petitioner, which waived its right to an in-person hearing and submitted its briefs and documentary evidence without adequate notice that issues beyond those stated by HCFA in the prehearing conference would be considered by the ALJ. Moreover, HCFA still has not presented facts showing that HCFA should not be bound by its agreement in the prehearing conference, as the regulations provide.

Under the applicable regulations and the Board's guidelines, the Board has the authority to modify, reverse or remand the ALJ Decision when there has been a prejudicial error of procedure. Here, we remand the case to the ALJ for further proceedings as described below.

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. CLIA further grants the Secretary of this Department broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for a certificate. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N., 3828, 3829.

CLIA certification of a laboratory is dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. The regulations also set forth standards, the specific components of the conditions of laboratory certification that a laboratory must meet as part of achieving compliance with applicable conditions. Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). HCFA may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions,

and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R.
§ 493.1806.
A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations at 42 C.F.R. Part 493 incorporate by reference the hearing procedures in subpart D of Part 498 and the request for review provisions in subpart E of Part 498. 42 C.F.R.
§ 493.1844.
Regarding the conduct of ALJ hearings, and the degree of notice to be afforded petitioners as to the issues under review, Part 498 of 42 C.F.R. provides in relevant part:

§ 498.47 Prehearing conference.

(a) At any time before the hearing, the ALJ may call a prehearing conference for the purpose of delineating the issues in controversy, identifying the evidence and witnesses to be presented at the hearing, and obtaining stipulations accordingly.

§ 498.50 Record, order, and effect of prehearing conference.

(b) *Order and opportunity to object*.
(1) The ALJ issues an order setting forth the results of the prehearing conference, including the agreements made by the parties as to facts not in controversy, the matters to be considered at the hearing, and the issues to be resolved.

(2) Copies of the order are sent to all parties and the parties have 10 days to file objections to the order.

(3) After the 10 days have elapsed, the ALJ settles the order.

(c) *Effect of prehearing conference*. The agreements and stipulations entered into at the prehearing conference are binding on all parties, unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable.

§ 498.52 Time and place of hearing.

(a) The ALJ fixes a time and place for the hearing and gives the parties written notice at least 10 days before the scheduled date.

(b) The notice informs the parties of the general and specific issues to be resolved at the hearing.

§ 498.56 Hearing on new issues.

(a) *Basic rules*. (1) Within the time limits specified in paragraph (b) of this section, the ALJ may, at the request of either party, or on his or her own motion, provide a hearing on new issues that impinge on the rights of the affected party.

* * * *

(c) *Notice and conduct of hearing on new issues*. (1) Unless the affected party waives its right to appear and present evidence, notice of the time and place of hearing on any new issue will be given to the parties in accordance with § 498.52.

(2) After giving notice, the ALJ will, except as provided in paragraph (d) of this section, proceed to hearing on new issues in the same manner as on an issue raised in the request for hearing.

* * * *

§ 498.66 Waiver of right to appear and present evidence.

(a) *Waiver procedures*. (1) If an affected party wishes to waive its right to appear and present evidence at the hearing, it must file a written waiver with the ALJ.

The standard of review by the Board on a disputed factual issue is whether the ALJ decision is supported by substantial evidence in the whole record. The standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000); Board Guidelines -- Appellate Review of Decisions of Administrative Law Judges in Cases Under CLIA and Related Statutes, http://www.hhs.gov/dab/guidelines/clia.html. A prejudicial error of procedure may be a basis for modifying, reversing or remanding an ALJ decision. *Id*.

Background and arguments

Petitioner is a clinical laboratory located in West Caldwell, New Jersey that specializes in blood testing for lead poisoning. By letter dated December 8, 1997, HCFA advised Petitioner that its CLIA certificate and its approval to receive Medicare payments would be suspended effective December 22, 1997, for failure to meet the conditions of CLIA certification in the following four categories:

42 C.F.R. § 493.1101 Condition: Patient Test Management

42 C.F.R. § 493.1201 Condition: General Quality Control

42 C.F.R. § 493.1441 Condition: Laboratory Director High Complexity

42 C.F.R. § 493.1701 Condition: Quality Assurance

The December 8, 1997 letter, titled "Notice of Suspension of CLIA Certificate," stated that Petitioner's continued failure to correct the four conditions of certification would result in revocation of its CLIA certificate as of February 22, 1998. HCFA Exhibit (Ex.) 1. The notice indicated that HCFA's decision was based on a survey of Petitioner conducted by the New Jersey Department of Health and Senior Services (NJDHSS) on March 21, 1997, and stated that Petitioner had been informed in November 1997 that a plan of correction it submitted in August had been deemed unacceptable after review by NJDHSS. The notice referred to a 14-page statement of deficiencies resulting from the March 21, 1997 survey, which found Petitioner to be out of compliance with the four conditions of participation noted above, based on HCFA and NJDHSS's findings that Petitioner failed to comply with six specific CLIA standards for laboratories provided in the regulations. HCFA Ex. 17.

HCFA subsequently moved the effective date of the suspension of Petitioner's CLIA certificate from December 22, 1997 to January 23, 1998, to give HCFA and NJDHSS more time to evaluate the findings of a December revisit, but based on the revisit HCFA determined that Petitioner remained out of compliance with four conditions of CLIA certification. HCFA Ex. 3. HCFA informed Petitioner in a letter dated January 22 that the effective date of suspension of the laboratory's CLIA certificate and cancellation of Medicare payments remained as set for January 23, 1998. HCFA's January 22 letter did not state any specific noncompliance findings and did not refer to a statement of deficiencies or indicate that any was enclosed. *Id*.

Petitioner requested an ALJ hearing in a letter dated January 26, 1998. Petitioner's letter did not cite any of the deficiencies noted in HCFA's December 8, 1997 notice and did not offer any specific grounds for contesting the suspension of its CLIA certificate. Instead, Petitioner stated that it had not received a copy of the deficiencies but disagreed that it remained out of compliance. Before the ALJ, HCFA introduced a 22-page statement of deficiencies based on the revisit, dated December 29, 1997, that detailed Petitioner's failure to meet the four CLIA conditions, and referred to Petitioner's responses to the March 21, 1997 statement of deficiencies. HCFA Ex. 4. The survey found that Petitioner had failed to meet the same four CLIA conditions of participation as were noted in the March 21, 1997 statement of deficiencies. The alleged deficiencies involved the handling of patient specimens, accurate result reporting, the use of control procedures and a quality assurance program to monitor and evaluate the quality of the laboratory's total testing process, and the responsibility of the laboratory director to provide overall management and direction. In a letter dated April 27, 1998, HCFA requested that the appeal be stayed for settlement negotiations. By letter dated December 1, 1998, Petitioner reported that the settlement discussions had not been fruitful, and requested a hearing as soon as possible.

The ALJ then held a prehearing conference, on January 12, 1999, and issued an order memorializing the results of the prehearing conference that same day (ALJ Order). Regarding the issues under review, the ALJ Order stated:

> The issue, as framed by the Health Care Financing Administration (HCFA) during the January 12, 1999 prehearing conference, concerns Petitioner's method of determining blood lead levels by use of a filter paper method test. HCFA asserts that a condition-level deficiency exists, justifying Petitioner's CLIA suspension, because Petitioner was unable to explain to the New Jersey State surveyors or to HCFA how it calculated the results of the test.

ALJ Order at 1.

The ALJ Order gave the parties 10 days to object to the order, consistent with 42 C.F.R. § 498.50(b)(2). HCFA did not timely object. The record shows that HCFA nonetheless briefed a broader set of issues in its initial brief, addressing all of the deficiencies found in the survey. The record also shows that Petitioner pointed out in its initial brief before the ALJ that HCFA's brief went beyond the issue stated in the ALJ Order, which Petitioner referred to as resolution of the filter paper method; HCFA's response was to state that it had no authority to rule on the scientific validity of the filter paper test. Petitioner ALJ Brief (Br.) at 1; HCFA ALJ Reply Br. at 2. The record contains no indication that HCFA specifically sought a ruling from the ALJ to permit it to expand the issues beyond the issue statement in the ALJ Order.

The "filter paper method test" referred to in the ALJ Order is Petitioner's method for preserving and testing blood specimens for lead.[(1)] Petitioner maintained that the proposed suspension of its CLIA certificate resulted from NJDHSS's disapproval of the filter paper method. Petitioner ALJ Br. at 2-4; Petitioner Ex. 9. The ALJ Decision reflects the confusion that existed over whether that disapproval was the basis for HCFA's enforcement action:

> By order dated January 12, 1999, I established a schedule for the filing of documentary evidence and briefs. Regrettably, however, during the January 12, 1999 telephone prehearing conference that led to my order, HCFA mischaracterized the issue (a mischaracterization to which Petitioner acquiesced), suggesting that the controversy in this case centered on Petitioner's *employment* of a filter paper method test to determine blood lead levels, rather than Petitioner's alleged failure in its *performance* of the filter paper test to follow proper quality control standards and conditions as mandated by CLIA. Thus, my January 12, 1999 order mischaracterized the issue, indicating that the issue concerned the employment of the filter paper method, as opposed to the manner in which testing was performed. Neither party pointed out this mistake prior to submitting evidence and briefs. HCFA's opening brief focused on Petitioner's alleged failure to comply substantially with CLIA requirements. Petitioner's response brief, in contrast, contained an extensive defense of the filter paper test in general, leaving unaddressed HCFA's allegations that Petitioner had not properly performed its testing. In its reply brief, HCFA highlighted Petitioner's failure to address in its brief HCFA's specific allegations of deficiencies regarding Petitioner's performance of filter paper testing. In fact, only in Petitioner's reply brief did it begin to address the findings of the NJDHSS surveys, and then only in a cursory manner.
>
> At my direction, the Civil Remedies Division staff attorney assigned to work with me on this case conducted another prehearing conference with the parties on September 9, 1999. The staff attorney expressed my concern that Petitioner may have relied on the "Issue" paragraph from my January 12, 1999 order when it prepared its briefs, rather than addressing the actual findings of the NJDHSS surveys and HCFA. During the conference call, the parties were given the opportunity to clarify their positions and supplement the record, either by requesting an in-person hearing or by additional written submissions and/or documentary evidence. Both parties declined the opportunity.

ALJ Decision at 3-4.

The ALJ record does not contain a tape recording or transcript of the September 9, 1999 "prehearing conference," nor does it contain any notice of the conference or any correspondence confirming or describing what was discussed during the conference. The ALJ went on to find Petitioner out of compliance with the four CLIA conditions of participation noted in the December 8, 1997 notice of suspension and the two statements of deficiencies from March and December 1997. ALJ Decision, Findings of Fact and Conclusions of Law (FFCLs) 1-4. The ALJ found, however, that HCFA had not sufficiently established that Petitioner had failed to comply with one of the six CLIA standards noted in the statement of deficiencies. FFCL 2.a, ALJ Decision at 8-9. This standard, set forth at 42 C.F.R. § 493.1205, "Test methods, equipment, instrumentation, reagents, materials, and supplies," requires (among other things) that laboratories utilize test methods, equipment, and materials that provide accurate and reliable test results.

The ALJ's finding for Petitioner on this one standard did not alter the ALJ's overall determination that Petitioner failed to comply with the four CLIA conditions of participation noted in the statements of deficiencies.

Before the Board, Petitioner took issue with the ALJ's noncompliance findings, but, as an initial matter, denied having been informed that the issue presented in the ALJ Order did not comprise the entire issues upon which its case before the ALJ turned. Petitioner asserted that neither the ALJ nor the staff attorney advised it to present arguments or evidence on issues other than the issue of Petitioner's decision to use the filter paper method. Petitioner stated that the only conference call conducted with the parties other than the January 12 prehearing conference call that resulted in the ALJ Order was what Petitioner described as a routine call to its attorney asking if Petitioner felt that a hearing would be necessary. Petitioner further argued that the staff attorney misunderstood the purpose of the September phone conference and led the ALJ to believe that Petitioner had knowingly waived an opportunity to present evidence on what Petitioner called the non-filter paper issues. Had it been aware that the ALJ was seeking argument on the issues addressed in HCFA's briefs, Petitioner argued, it would have requested an in-person hearing.

HCFA did not deny here that it had framed the issue during the prehearing conference as stated in the ALJ Order. HCFA disagreed with Petitioner's claim that it was never informed that its appeal turned on issues other than that presented in the ALJ Order, and stated that "[d]espite Kaulson's repeated protests . . . when given another chance in a conference call . . . to supplement the record after the parties' briefs were received, Kaulson once again declined." HCFA Br. at 3. HCFA further asserted that the staff attorney who convened the conference call "could not have made it any plainer to Petitioner that the ALJ felt that Kaulson's brief did not respond to much of HCFA's case and that the ALJ wanted to give the lab another chance," and that Petitioner, with its counsel, "insisted on resting on what Kaulson had already filed." HCFA Br. at 3, n.2.

Conclusion

For the reasons stated above, we conclude that there was a prejudicial error of procedure in this case. When the Board concludes that there has been a prejudicial error of procedure, the Board may modify, reverse or remand an ALJ decision. Here, we have determined to remand the ALJ Decision for the ALJ to determine whether HCFA can present facts that would make the agreement on the issue to be resolved reached in the January 12, 1999 prehearing conference unreasonable or inequitable, as required by 42 C.F.R. § 498.50(c). HCFA has 10 days from the date it receives this decision to make such a showing.

The ALJ shall then determine whether HCFA has presented facts that would make the agreement on the issue to be resolved reached in the prehearing conference as reflected in the ALJ Order unreasonable or inequitable, as required by the regulations, and must issue her determination as to whether such a showing has been made in a written ruling. If the ALJ determines that HCFA has made the required showing, then she shall begin prehearing proceedings, including issuance of an amended prehearing order stating the issues to be resolved, and afford the parties an opportunity for an in-person hearing. The issues to be considered may include any and all issues raised by the HCFA determination under review (including the one issue on which the ALJ found in favor of Petitioner).

If the ALJ determines that the parties should be bound by the original agreement on the issue to be resolved because HCFA was unable to make the required showing in accordance with our decision, then the ALJ shall issue a modified decision addressing only the one issue stated in the ALJ Order. Since the only issue addressed in the ALJ Decision that was arguably encompassed within the issue stated in the prehearing conference and the ALJ Order was the one issue on which the ALJ found in favor of Petitioner, the modified decision should incorporate the ALJ's prior analysis and finding on that issue, and reverse all remedies against Petitioner.

The Board further concludes, under the circumstances here, that the remand proceedings should be expedited to prevent further prejudice to either party. The ALJ should develop the record as she determines necessary and issue her ruling on whether HCFA has timely made the required showing within 30 days of our decision, and, if she determines that HCFA has timely made the required showing, offer the parties an opportunity for a hearing to be held within 60 days of her ruling or such later time to which both parties agree, and issue a decision within 60 days after the record closes. If the ALJ determines that HCFA cannot make the required showing, she should issue her modified decision within 30 days of having issued her ruling. We do not decide here whether HCFA would have a right to appeal any finding in the ALJ's modified decision on the one issue on which the ALJ originally found in favor of Petitioner (FFCL 2.a). HCFA did not timely appeal that finding in this proceeding.

ANALYSIS

Under the procedural regulations promulgated by HCFA that govern the conduct of ALJ hearings in CLIA cases, one of the purposes of a prehearing conference is to clarify and narrow the issues for hearing. The regulations therefore provide that the issues the parties agree to in a prehearing conference and that are memorialized in an ALJ order setting forth the results of that conference are binding on the parties, "unless a party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable." 42 C.F.R. § 498.50(c). Although the regulations permit a party an opportunity to object to a prehearing order within 10 days, HCFA did not do that here. Moreover, the ALJ Order specifically stated that it was HCFA that framed the issue during the prehearing conference. Thus, HCFA was bound by its agreement on the issues, which effectively dropped other potential deficiencies as a basis for its determination, relying instead on the issue that "concerns Petitioner's method of determining blood lead levels by use of a filter paper method test" and HCFA's assertion "that a condition-level deficiency exists, justifying Petitioner's CLIA suspension, because Petitioner was unable to explain to the New Jersey State surveyors or to HCFA how it calculated the results of the test." ALJ Order at 1.

While this statement of the issue in the ALJ Order is arguably broader than the issue of the efficacy of the test itself, since it encompasses how Petitioner calculated the results of the test, it cannot reasonably be interpreted as encompassing all of the alleged deficiencies that HCFA briefed and the ALJ addressed in her decision.

Other issues addressed in the ALJ Decision that were not encompassed within the issue statement in the ALJ Order were not properly before the ALJ, unless she found the regulatory exception applied, as required by section 498.50. Here, however, HCFA

has not presented any facts that would show that it would be unreasonable or inequitable to hold it to its agreement reached in the prehearing conference. Instead, HCFA simply ignored its agreement, briefing a broader set of issues, even when Petitioner pointed out that this was inconsistent with the ALJ Order.

The essential requirement of the regulations as a whole is that parties be afforded written notice of issues to be resolved by the ALJ. While an ALJ is permitted to add issues that are "new," this must be done in accordance with the procedures at section 498.56.[(2)] To expand the issues beyond the issue statement in the ALJ Order, the ALJ was at a minimum required to issue a revised order correctly stating the issues so that the parties could submit briefing on the correct issues and seek an evidentiary hearing, if desired. The revised order would necessarily state whether the procedures previously agreed upon would have to be modified as a result of the restatement of the issues, and would provide the parties 10 days to file objections. Since these procedures were not observed, the other issues addressed by HCFA in its briefing were not properly before the ALJ.

Moreover, the record before us does not support the ALJ's finding that the parties received oral notice of the expanded issues or that Petitioner knowingly waived its opportunity to present argument and evidence at an in-person hearing on those issues.[(3)] The ALJ Decision states that the parties were advised during a September 1999 prehearing telephone conference convened by the staff attorney assigned to the case of the ALJ's concern that Petitioner had not addressed the allegations in HCFA's brief. As noted above, however, the record does not contain notice of such a conference, a tape recording or transcript of the conference, or any correspondence memorializing what was said during the conference. It is thus impossible to assess the parties' contentions concerning what occurred during the September 1999 conference. Even if we were to accept HCFA's version of what occurred in this conference, however, that version would not establish that Petitioner had sufficient oral notice that the issues were being expanded. HCFA asserted that the staff attorney conducting the telephone conference advised the parties that the ALJ felt that Petitioner's brief did not respond to much of HCFA's argument. HCFA did not allege that Petitioner was clearly informed that the ALJ intended to address all of the issues briefed by HCFA as issues to be resolved by the appeal, even though they went beyond the issue statement in the ALJ Order.

We also note that the ALJ's observations as to the paucity of Petitioner's arguments and evidence in response to HCFA's briefing (on issues other than that stated in the ALJ Order) are consistent with Petitioner's assertion that it was not advised of the expanded set of issues prior to or during the telephone conference, which occurred after briefing was complete. The ALJ noted the "meagerness" of the record on which she had to base her decision, and observed that "[i]n many instances, Petitioner's briefs did not touch on the allegations put forth by HCFA." ALJ Decision at 4. For two of the five CLIA standards for which the ALJ sustained HCFA's findings of noncompliance, the ALJ noted that Petitioner's defenses to HCFA's noncompliance findings were made only in its plan of correction (and not in its briefs). ALJ Decision at 6-11. Petitioner's failure to at least repeat the points it made in its plan of correction tends to support its argument that it was not aware that the ALJ would address these issues. It seems unlikely that Petitioner would not have repeated the responses to HCFA's findings that it presented

in its plan of correction if it knew that those findings were still possible grounds for the ALJ to uphold the suspension of its CLIA certificate.

The fact that the issues HCFA briefed were noted in its initial notice of suspension does not establish that Petitioner was necessarily aware that those were the issues on which the ALJ's decision would be based. The record indicates that HCFA and the state survey agency had previously voiced disapproval of Petitioner's filter paper method for preserving and testing blood specimens for lead. A 1995 survey of Petitioner was critical of the filter paper method, and a HCFA statement of deficiencies based on that survey referred to an enclosure titled "Kaulson Laboratories' Use of Filter Paper Lead Method That Did Not Assure Reliable Patient Test Results." Petitioner Ex. 3A. A May 16, 1996 letter from the New Jersey Department of Health reports that the state had initially refused to endorse Petitioner's use of the filter paper method on the grounds that it had not been supported by the Centers for Disease Control, that Petitioner had voluntarily suspended filter paper testing in 1995, and that the New Jersey Department of Health thereafter advised Petitioner that it could resume filter paper testing, as data submitted by Petitioner supported its theory that the filter paper method compared well with whole blood lead testing. Petitioner Ex. 6.

Petitioner also reported that during the settlement discussions that preceded the prehearing conference and the ALJ Order, it provided HCFA with information concerning the validity of the filter paper method, which it called the major issue in the case, and asserted that those discussions resulted in the filter paper issue remaining as the only issue to be resolved. Letter from Petitioner to Staff Attorney, December 1, 1998; Petitioner Br. at 1. Petitioner also asserted that it took corrective action on all deficiencies. Petitioner Response to HCFA ALJ Reply Br. at 1. Petitioner's view of the issue in dispute was confirmed during the January 12, 1999 prehearing telephone conference, when HCFA stated the issue as concerning Petitioner's filter paper method. HCFA did not dispute the ALJ's description of how it stated the issue during the telephone conference, or disagree with Petitioner's impression that the settlement negotiations had centered on the filter paper method. Thus, although HCFA's initial notice of suspension of Petitioner's CLIA certificate, dated December 8, 1997, cited deficiencies other than Petitioner's use of the filter paper method, Petitioner had reason to believe, one year later (after a lengthy period of negotiations and the January 12, 1999 prehearing conference), that the only remaining issue "concern[ed] Petitioner's method of determining blood lead levels by use of a filter paper method test" and that HCFA's basis for the suspension was HCFA's assertion "that a condition-level deficiency exists, justifying Petitioner's CLIA suspension, because Petitioner was unable to explain to the New Jersey State surveyors or to HCFA how it calculated the results of the test." ALJ Order at 1.[(4)] All the other issues addressed in the ALJ Decision were not properly before the ALJ because of the failure to provide the parties with notice of those issues as required by the regulations.

This failure to follow the regulations was not harmless procedural error, but instead resulted in substantial prejudice to Petitioner. The required notice provides the focus for the entire appeal by setting the issues that the parties are expected to address and informing their decisions to request or decline the opportunity for an in-person, evidentiary hearing. Here, based on the statement of the issues in the ALJ Order, Petitioner forsook its right to present evidence and to request an oral hearing to

challenge HCFA's determinations regarding other alleged deficiencies. As those other deficiencies were not properly before the ALJ, we conclude that the ALJ erred as a matter of law in ruling on them.

JUDGE

Judith A. Ballard
Cecilia Sparks Ford
Donald F. Garrett
Presiding Board Member

FOOTNOTES

1. The filter paper method involves preserving patient blood specimens in the form of drops spotted on filter paper. A disc of filter paper of measured dimension is punched out of the blood spots and put into sample cups for analysis. HCFA Ex. 19.

2. We do not necessarily imply here, however, that the expanded set of issues are "new" issues within the meaning of section 498.56. That section is directed primarily at issues arising from surveys subsequent to an initial determination by HCFA, whereas in this case all of the issues the ALJ addressed arose before HCFA's determination and before the prehearing conference. Moreover, the "new issues" provision has to be read together with the provision binding a party to the prehearing conference agreements, unless the party presents facts that, in the opinion of the ALJ, would make an agreement unreasonable or inequitable. 42 C.F.R. § 498.50(c).

3. A party that wishes to waive its right to appear and present evidence must do so in writing. 42 C.F.R. § 498.66(a).

4. The issue stated in the ALJ Order, about how Petitioner calculated the results of the test, was arguably encompassed by only one of the alleged deficiencies that HCFA briefed and that the ALJ considered in her decision, HCFA's determination that Petitioner failed to comply with the CLIA standard governing test methods, at 42 C.F.R. § 493.1205, "Test methods, equipment, instrumentation, reagents, materials, and supplies." The ALJ described this alleged deficiency as HCFA's claim "that Petitioner could not demonstrate on a continuing basis that it was calculating its filter paper lead results correctly." ALJ Decision at 8. While HCFA did not take timely exception to this FFCL, as required by the regulations, HCFA still disputed the ALJ's analysis and argued that it would have presented testimony on this issue had a hearing been held.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT:
Oakland Medical Group, P.C.,

Petitioner,
DATE: December 5, 2000
- v -

Health Care Financing Administration
Civil Remedies CR688
Docket No. A-2000-107
Decision No. **1755**
DECISION

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Oakland Medical Group, P.C.(Oakland/Petitioner) a Warren, Michigan, physician office laboratory, appealed a July 18, 2000 decision by Administrative Law Judge (ALJ) Jose A. Anglada granting summary judgment for the Health Care Financing Administration (HCFA). *Oakland Medical Group, P.C.*, DAB CR688 (2000) (ALJ Decision). There, the ALJ found that Oakland failed to meet condition level requirements for proficiency testing (PT) for testing events in 1998, failed to meet the condition level requirement for laboratory director and violated the standard for technical supervisor. Consequently, the ALJ determined that HCFA had properly revoked Oakland's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for one year and properly canceled Oakland's approval to receive Medicare payments for its services, effective October 1, 1999. ALJ Decision at 1, 7, and 22-23.

The ALJ Decision was based on 23 findings of fact and conclusions of law (FFCLs). Oakland took exception to 15 of those FFCLs.

Based on the analysis below, we sustain the ALJ Decision, affirming and adopting each of the ALJ's underlying FFCLs.

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*.[(1)] CLIA further grants the Secretary of this Department broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for a certificate. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N., 3828, 3829.

A laboratory's CLIA certification is generally dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. The regulations also set forth standards, the specific components of the conditions of laboratory certification that a laboratory must meet as part of achieving compliance with applicable conditions.

A key component to the statutory and regulatory program to assure that laboratories holding CLIA certificates are competent to perform tests of moderate and high complexity is the requirement for participation in a proficiency testing (PT) program that is approved by HCFA, as outlined in 42 C.F.R. Part 493, Subpart H. Among the requirements of that subpart are the following: each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493; a participating laboratory must test PT samples it receives in the same manner as it tests patient samples; must not communicate the results of its tests to other laboratories prior to the deadline for reporting results; must not intentionally refer PT samples to another laboratory for analysis; and must document and maintain documentation for the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 C.F.R. § 493.801. The condition at 42 C.F.R. § 493.803(a) specifically requires that a laboratory performing high complexity testing "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which it is certified under CLIA."

Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). HCFA may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.[(2)]

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations at 42 C.F.R. § 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E.

Background

This undisputed factual background is drawn from pages 3-6 of the ALJ Decision. Oakland conducted high complexity testing for routine chemistry and endocrinology. At the time in issue, Robert I. Moretsky, D.O., was Oakland's director, clinical consultant, technical supervisor, and general supervisor. HCFA Exs. 8 at 1; 14 at 1. Rene Wheatley was part of Oakland's testing personnel, as well as part of the personnel working at other laboratories in the general vicinity. HCFA Ex. 14. She performed high complexity routine chemistry and endocrinology testing, as well as PT for Oakland. *Id.* at 1.

Some of the laboratories in the Detroit metropolitan area participating in a PT program operated by the American Association of Bioanalysts (AAB) were Oakland Medical Group (also known as Moretsky/Trager/Flor); John Dunn, M.D.; Mark Hertzberg, M.D.; Rochester Road Clinic; Nazar Sarafa, M.D. (also known as Garden City Medical Clinic);

Liptawat Family, P.C.; Lakeland Medical; Ecorse Med Center; and Stanley Boykansky, M.D. HCFA Ex. 7. The AAB would mail to each laboratory participating in the PT program the same group of five specimens three times a year. The laboratories were required to test these specimens for analytes for which they did patient testing, and mail their results to the AAB by a date certain, approximately 10 days after receiving the samples. Oakland was required to test the specimens for cholesterol, HDL cholesterol, triglycerides, glucose, thyroid stimulating hormone, total thyroxine, triiodothyronine, and free thyroxine.

By letter dated January 4, 1999, Dennis W. Jay, Ph.D., Technical Director of the Proficiency Testing Service of the AAB, sent the Michigan Department of Consumer and Industry Services (MDCIS) some PT results for a group of Detroit area laboratories that he deemed suspect. HCFA Ex. 10. Specifically, the cover letter suggested that the same PT results were being submitted by several laboratories. The following five facilities submitted identical PT results during the third testing event of 1998 for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens: Oakland Medical Group, John Dunn, M.D., Mark Hertzberg, M.D., Rochester Road Clinic, and Nazar Sarafa, M.D. *Id.*

On January 14, 1999, the AAB notified MDCIS that it had discovered another four facilities reporting duplicate results and included their 1998 third quarter summaries and attestation sheets. These four facilities were: Liptawat Family, P.C., Lakeland Medical, Ecorse Med Center, and Stanley Boykansky, M.D. HCFA Ex. 7 at 1.

In response to the above information, on February 25, 1999, Richard J. Benson, Chief, Laboratory Improvement Section, Bureau of Health Systems, MDCIS, attempted an unannounced complaint investigation at Oakland. HCFA Ex. 11 at 3. He sought evidence regarding Oakland's PT for all three events of 1998. The Oakland staff present was unable to produce any testing records, nor was there anyone available who might have known their location. The director was not there that day, and Ms. Wheatley was not scheduled to come in at that time. Mr. Benson went away empty-handed. *Id.*

On March 2, 1999, Ms. Lucy Estes, Laboratory Evaluation Specialist, MDCIS, attempted to perform a complaint survey of Oakland's facilities. HCFA Ex. 15 at 2. Her first attempt failed. During the second attempt on the same day, the attending physician gave her copies of Oakland's records in response to a request to review quality control records, temperature records, graphs, patient testing records and PT records for 1998. *Id*. Based on her review of the testing records she received from Oakland, and information from the AAB concerning the similarity of PT results between Oakland and others in the Detroit area, Ms. Estes found that Oakland was not in compliance with the CLIA requirements under 42 C.F.R. § 493.801(b)(1), Testing of Proficiency Samples, and 42 C.F.R. § 493.1451(b)(4), Technical Supervisor Responsibilities. She completed and submitted HCFA Form 2567 to her supervisor, Mr. Benson, along with the aforementioned documents. *See* HCFA Ex. 15, Att. A.

By letter dated July 15, 1999, HCFA served on Oakland a Notice of Medicare Cancellation, Suspension, and Revocation of CLIA Certificate of Accreditation pursuant to MDCIS's referral of its case for imposition of enforcement action. Specifically, HCFA found that Oakland was not in compliance with the following CLIA statutory and regulatory requirements:

•The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4).

•Requirement for Certificate: The laboratory agrees to treat PT samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business. 42 U.S.C. § 263a(d)(E); 42 C.F.R. § 493.61(b)(1); 42 C.F.R. § 493.801(b)(1)-(3).

HCFA Ex. 1.

Because of Oakland's improper referral of PT samples to another laboratory for analysis, Oakland's failure to treat PT samples in the same manner as patient samples, and Oakland's refusal to permit MDCIS to survey its facilities, HCFA imposed the principal sanctions of suspension of Oakland's CLIA certificate of accreditation and cancellation of Oakland's approval to receive Medicare payment for its laboratory services, and proposed to revoke Oakland's CLIA certificate of accreditation. HCFA Ex. 1.

HCFA's July 15, 1999 letter provided Oakland with an opportunity to document that improper PT referral had not occurred. HCFA Ex. 1 at 4. On October 1, 1999, HCFA served Oakland with a final and more complete notice of adverse action, stating that HCFA had received nothing from Oakland to convince it that the relevant determinations in its July 15th letter were incorrect.[(3)]

HCFA Ex. 3 at 1. Addressed to Oakland's Director, Dr. Moretsky, the October 1, 1999 letter stated, in pertinent part:

> As set forth on the HCFA Form 2567 that was enclosed with our letter to you of July 15, 1999, the surveyors determined that with respect to the first three events of 1998, your laboratory's proficiency testing (PT) was not performed with the laboratory's regular workload using the laboratory's routine methods, in violation of the standard at 42 CFR § 493.801(b)(1). In our July 15, 1999, letter, we also stated that the evidence revealed that your laboratory referred certain PT samples to another laboratory for analysis in violation of the standard at 42 CFR § 493.801(b)(4). The evidence strongly suggests that the results of proficiency testing reported by your laboratory during the first, second, and third events of 1998 were obtained by improper referral and/or collaboration. Inter-laboratory communications pertaining to the results of proficiency testing samples, prior to the testing event reporting due date, are prohibited by the standard at 42 CFR § 493.801(b)(3).
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> * * *
>
> In addition, the standard at 42 CFR § 493.801(b)(5) requires that a laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. Further, the laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results. . . However, based on a review of the 1998 proficiency tests records and the patient sheets during the survey, it was determined that the PT samples were not examined or tested with the laboratory's regular patient work load. Since the survey findings show that integration did not occur, this violates the standard at 42 CFR § 493.801(b)(5).

> The findings from the survey also reveal that you, as laboratory director, have not fulfilled your responsibility to assure that PT samples are tested as required under 42 CFR § [Part] 493, subpart H. You, as technical supervisor, failed to assure that the manufacturer's quality control expected range inserts were available for each procedure performed in your laboratory. Therefore, normal and abnormal control material ranges were not available to determine whether quality control results were within the expected range of the manufacturer. The presence of the deficiencies cited in this letter and on the HCFA-2567 demonstrates that you have failed to take responsibility for the overall operation and administration of your laboratory. Therefore, the laboratory is out of compliance with the condition level requirement for a laboratory director at 42 CFR § 493.1441. Because your laboratory did not treat PT samples in the same manner as patient samples, it is in violation of the CLIA requirements at 42 CFR § 493.61 and 42 U.S.C. § 263a(d)(1)(E) and does not meet the requirements for a certificate of accreditation.
>
> * * *
>
> Because of your laboratory's failure to meet the conditions of Proficiency Testing and Laboratory Director, and because of your intentional referral of your laboratory's PT samples for the third testing event of 1998 to another laboratory for analysis, as set forth in our letter of July 15, 1998, we have imposed the following principal sanctions against your laboratory:
>
> •42 CFR § 493.1808(a) and 42 CFR § 493.1842(a)(1) - Principal Sanction: Cancellation of your laboratory's approval to receive Medicare payment for its services. This sanction will become effective on October 1, 1999, and will remain in effect until a hearing decision is rendered, or the end of the revocation period . . . .
>
> •42 U.S.C. § 263(a)(i)(4), 42 CFR §§ 493.1814(a) and 493.1840(b) - Principal Sanction: Revocation of your laboratory's CLIA certificate. . . .

HCFA Ex. 3.

On July 30, 1999, Oakland requested a hearing before an ALJ. In his decision, the ALJ found that Oakland failed to meet condition level requirements for PT events in 1998, failed to meet the condition level requirement for laboratory director, and violated the standard for technical supervisor. ALJ Decision at 22-23.

Standard of Review

Our standard of review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000).

ANALYSIS

As noted above, Oakland took exception to 15 of the ALJ's 23 FFCLs. Oakland filed, concurrently, both a Request for Review, listing all the FFCLs to which it excepted,

along with a Brief grouping some of those FFCLs within broader arguments. In presenting Oakland's position, we cite both its Request for Review and its Brief. We have considered each argument raised by Oakland as well as the entirety of evidence before the ALJ. Below, to the extent practical, we address each relevant argument relative to a disputed FFCL. We have concluded that the challenged FFCLs are not erroneous and are supported by substantial evidence on the record as a whole. Thus, any nuance of Oakland's contentions that we have not addressed specifically is subsumed in our analysis of its position and rejected.[(4)]

Exceptions to summary judgment

FFCL 22. Petitioner has submitted no affidavits or other documentary evidence that, if taken as true, would create a genuine issue of material fact that would require a hearing.

Fed. R. Civ. P. 56.

FFCL 23. The facts on which I base this decision are either not in dispute or uncontroverted. Thus, summary judgment is appropriate as a matter of law.

Both Petitioner and HCFA filed motions for summary judgment before the ALJ. Oakland contended that the ALJ erred in granting HCFA's motion for summary judgment because Oakland had submitted documentary evidence that created a genuine issue of material fact with respect to HCFA's allegations against Oakland, and because Oakland was not given an opportunity to request subpoenas. Oakland did not identify the issue of material fact to which it referred, nor did it state what the objects of any subpoena requests would be. In addition, rather than seeking remand of the case to the ALJ for further discovery or a hearing, Petitioner maintained that the Board should grant its motion for summary judgment and overturn the HCFA action. Oakland Request for Review at 5.

Upon review of the record before the ALJ, we conclude that Oakland's arguments are spurious. Of the three documents submitted by Oakland, only one was not a duplicate of a HCFA exhibit. That document -- a Form 1099 for Ms. Wheatley that was submitted to show that she was an independent contractor rather than an employee -- could be said to raise an issue of fact. However, as we find below, the ALJ correctly determined as a matter of law that Ms. Wheatley's alleged employment status was immaterial to Oakland's responsibility for compliance with CLIA requirements. Notably, Oakland did not supply affidavits from its laboratory director, Ms. Wheatley, or an independent expert to support its contentions about how its PT results came to be identical to those of other laboratories absent any referral or unlawful collaboration. Nor did Oakland specifically allege that it needed a subpoena to compel any potential witness to appear. Oakland also did not supply or offer to provide the missing documentation for the PT event of June 1998 or any other documents in its records that would support its defense. Consequently, we conclude that the ALJ's conclusion that summary judgment was appropriate is correct and we affirm and adopt FFCLs 22 and 23.

Exceptions to FFCLs about employees

FFCL 5. Ms. Deborah Sabo performed PT for Stanley Boykansky, M.D., John Dunn, M.D., Garden City Medical Clinic, and Mark Hertzberg, M.D. Ms. Sabo and Ms. Wheatley had a prior professional acquaintance as co-workers at Oakland General Hospital. HCFA Exs. 14 and 18.

Oakland asserted that this FFCL was irrelevant as there was no evidence that Ms. Sabo had any involvement in Oakland's 1998 PT, nor was there any evidence of contact between Ms. Sabo and Ms. Wheatley in 1998. Oakland Request for Review at 1-2. There is substantial evidence in the record supporting all aspects of this FFCL. There is no dispute that there was a prior professional relationship between these individuals. In a related case, Ms. Sabo testified that they knew each other "well" and that Ms. Wheatley was her supervisor at Oakland General Hospital. Ms. Sabo testified that Ms. Wheatley did perform PT at another laboratory involved in this situation. She nevertheless expressed her belief that the director of that laboratory incorrectly certified the time of Ms. Wheatley's employment and testified that Ms. Wheatley's employment occurred prior to 1998. HCFA Ex. 18 at 41-42. The ALJ stated, however, that his findings were not necessarily dependent on their common employment. ALJ Decision at 11, n.4.

FFCL 6. Petitioner represented that Ms. Rene Wheatley was an employee of Oakland whose duty it was to conduct high complexity testing for routine chemistry and endocrinology. Whether Ms. Wheatley was an independent contractor or not is irrelevant, inasmuch as Petitioner is responsible for the actions of all individuals it authorizes to perform chemistry testing at its facility on its behalf.

Oakland argued that this FFCL is not supported by substantial evidence and is clearly erroneous as the language of CLIA and its implementing regulations expressly distinguishes "employees" from others. Based on common law factors relied upon by the Internal Revenue Service and on the fact that she was paid by means of an Internal Revenue Service Form 1099, a common payment instrument for independent contractors, Oakland asserted that Ms. Wheatley was not an employee, but an independent contractor. Oakland contended that, contrary to the ALJ's finding, the applicable statutory and regulatory provisions do distinguish between "agents, persons and employees." Oakland insisted that the plain meaning of 42 C.F.R. §§ 493.1940(a) and (b) compelled a conclusion that a laboratory may be sanctioned based only upon the action of its owner, operator or employees. Oakland contended that it could not be sanctioned even if a referral occurred, as Ms. Wheatley was neither an owner, nor an operator or nor an employee. Noting that the CLIA statutory scheme distinguishes between employees and other personnel, Oakland also contended that both the ALJ and HCFA ignored the numerous other definitions of the term "employee" contained in the Social Security Act. As a result, Oakland contended, the ALJ glossed over an important distinction between "employee" and "independent contractor" which would have required a finding of standard level deficiencies at worst. Oakland Request for Review at 2; Oakland Br. at 7-12.

The ALJ's conclusion that Ms. Wheatley's employment status was irrelevant, since Petitioner was responsible for the actions of all individuals it authorizes to perform chemistry testing at its facility on its behalf, was not erroneous.

Regardless of the characterization of her employment status, there is no question that Oakland employed Ms. Wheatley to conduct clinical laboratory testing including PT. *See* Petitioner Br. at 11. As the ALJ noted, Oakland's CLIA Laboratory Personnel Report merely listed Ms. Wheatley as an employee. ALJ Decision at 11, citing HCFA Ex. 14. Signed by Oakland's Director (Dr. Moretsky), the Laboratory Personnel Report did not

distinguish between Ms. Wheatley, as an independent contractor, and her coworkers. They are all listed under the heading "Employee Names." The only distinguishing features for Ms. Wheatley's listing are her shift, part-time status and qualification to perform high complexity testing. HCFA Ex. 14 at 1. As the ALJ determined, the real issue was the responsibility of Oakland's operator (an owner as well as a director) for the safety and reliability of the laboratory's testing. As the ALJ noted, the regulation at 42 C.F.R. § 493.1445 establishes the director's responsibility for the overall operation and administration of the laboratory including the employment of competent testing personnel. The regulation specifically provides that delegation of those duties does not relieve directors of responsibility for their performance. 42 C.F.R. § 493.1445(b). Finally, the ALJ correctly concluded that 42 C.F.R. § 493.1840(b) did not place such a strained reading on the term laboratory so as to exclude from its sphere of import individuals hired by the facility who are not salaried employees. ALJ Decision at 11-12.

CLIA was designed to ensure accurate medical tests by clinical laboratories and to establish a single set of standards applicable to all laboratory services including those available to Medicare beneficiaries. ALJ Decision at 1. The ALJ correctly characterized as "strained" Oakland's reading of the program regulations in such a way as to preclude actions of an independent contractor from giving rise to a condition level deficiency. Although there is no suggestion that it was Oakland's intent to use Ms. Wheatley's independent contractor status as a shield from accountability for deficiencies, it is clear that Oakland's argument regarding her status, if accepted, would defeat the purpose of CLIA.

Oakland's reliance on the provision in 42 C.F.R. § 493.1840(a), which authorizes HCFA to take adverse action based on actions by a laboratory's "owner, operator or employees," is misplaced. The regulations make clear elsewhere that HCFA may impose principal or alternative sanctions on "a laboratory that is out of compliance with one or more of the CLIA conditions." 42 C.F.R. § 493.1806. Section 493.1840(a) provides HCFA additional authority to take adverse action based on a broad range of actions by certain individuals associated with laboratories and cannot reasonably be read in context as limiting HCFA's authority to act against a laboratory that does not meet the certification requirements.

Exceptions to FFCLs concerning Oakland's compliance with PT requirements

Oakland challenged the following FFCLs:

FFCL 9. The affidavits and documentary evidence submitted by HCFA in support of its motion to dismiss show that Petitioner reported PT results to the AAB in 1998 that were identical to the results of eight other Detroit area laboratories for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens.

FFCL 10. From the multitude of identical results, I draw the inference that Petitioner intentionally referred proficiency tests to another laboratory and/or engaged in inter-laboratory communications (collaboration) and then reported the results obtained to the AAB as Petitioner's own results. Additionally, although Petitioner reported PT results to the AAB for the second testing event in June 1998, it lacked records to substantiate the basis for the reported results.

FFCL 11. Petitioner's PT samples, particularly for the second testing event in June 1998, were not examined with the laboratory's regular patient workload in

violation of the condition level requirement set forth at 42 C.F.R. § 493.801 and 42 C.F.R. § 493.61.

FFCL 12. Petitioner did not arrive at PT results identical to that of eight other laboratories through human error or coincidence, but by intentional referral, collaboration, and manipulation of those results.

FFCL 18. Petitioner's PT results for the three testing events of 1998 were obtained through referral and/or inter-laboratory communications (collaboration) with other laboratories which constitutes a violation of 42 C.F.R. § 493.801.

FFCL 19. By failing to examine or test proficiency samples in the same manner as routine patient specimens, Petitioner violated the terms of 42 C.F.R. §§ 493.801, 493.801(b), and 493.61.

Oakland argued that the premise of FFCL 9, that Oakland's 1998 PT results were identical to those of eight other Detroit area laboratories, was not supported by substantial evidence in the record because the only evidence in the record indicating identical results was for the third quarter of 1998. Oakland Request for Review at 2.

Oakland argued that FFCL 10 was clearly erroneous and not supported by substantial evidence in the record because HCFA had not presented evidence to show that Oakland had physically transferred PT samples for any testing event or failed to perform PT at its clinical laboratory. Oakland contended that HCFA had offered nothing more than a belief that these events occurred as alleged. *Id.* at 2-3.

Oakland argued that FFCL 11 was clearly erroneous and not supported by substantial evidence in the record as there was no evidence presented to show that the June 1998 PT event was not performed with the regular patient workload. *Id.* at 3.

Oakland argued that FFCL 12 was clearly erroneous as it was a conclusion unsupported by any factual evidence. *Id*.

Oakland argued that FFCL 18 was clearly erroneous and not supported by substantial evidence in the record as there was no evidence presented to show that there was a referral of PT to any other laboratory and the clear language of 42 C.F.R. § 493.1840(b) does not include communication, collaboration or any other action short of an actual referral of PT samples to another laboratory as a violation. Oakland asserted that it performed its own PT at all relevant times. *Id.* at 4.

Oakland argued that FFCL 19 was clearly erroneous and not supported by substantial evidence in the record as there was no evidence presented to show that PT samples were not tested in the same manner as patient samples. *Id*.

Oakland's attacks on these FFCLs do not withstand close scrutiny. First and foremost, Oakland's assertion that FFCL 9 is incorrect because the evidence showed identical PT results for only the third quarter of 1998 is simply wrong. HCFA showed that Oakland reported identical results for many analytes in each of the three testing events. *See* HCFA Ex. 7. Thus, the ALJ properly concluded that HCFA made a prima facie case that Oakland failed to fulfill its CLIA responsibilities with respect to PT and focused on whether Oakland could meet its burden to demonstrate compliance for *all three events*. With respect to the June PT event, the ALJ examined the record before him and determined that:

> A review of Petitioner's Master Work Sheets for the second testing event of June 20, 1998 (98-2) revealed that the laboratory did not record any PT testing for this date for any of the analytes with any of the patient testing. HCFA Ex. 11, at 10, 44. Despite the

> absence of underlying data, Petitioner reported PT results for the second testing event for 1998 to the AAB. HCFA Ex. 11, at 10, 24-27. Petitioner claims to have complied with the proper testing and recording requirements, yet it has failed to make any documentary evidence available for my consideration that shows the existence of any underlying data for the second testing event . . . .

ALJ Decision at 18.

Oakland offered us no plausible explanation for why its records did not show that it did PT on June 20, 1998. On appeal, Oakland noted that it provided June PT results to AAB and that Ms. Wheatley attested that she performed that PT on the date indicated. Oakland Br. at 27-29.

In spite of Ms. Wheatley's attestation, Oakland has not pointed to any evidence of record purporting to be the underlying data for the June 1998 testing event. Absent supporting evidence, Ms. Wheatley's attestation of performance of the June 1998 PT and Oakland's assertions of correct testing procedures are largely self-serving, as to assert otherwise would be an admission of wrongdoing. Oakland was required to maintain for a period of two years from the date of the testing event "all records" necessary to document compliance with the PT process. 42 C.F.R. § 493.801(b)(5). Without them, Oakland cannot establish that it tested the PT samples for that event at all, much less that it performed the tests in accordance with the regulations or that the reason the results it obtained were identical to those of eight other laboratories was human error or coincidence. We therefore reject Oakland's assertions to the contrary as they pertain to this testing event.

With respect to the other 1998 PT events, the ALJ reviewed the testimony of two HCFA affiants and examined the records Oakland had produced to support the PT results reported for the March and October 1998 PT events. He relied on these affiants' opinions concerning the likelihood that identical results could be innocently reached, as well as his independent determination that the records contained data that was inconsistent with the results reported, in concluding that Oakland did not arrive at these results through human error or coincidence, but by intentional referral, collaboration, and manipulation of the results.

Oakland challenged the qualifications of the two HCFA affiants (the Technical Director, Proficiency Testing, AAB and the Chief, Laboratory Improvement Section, MDCIS) relied upon by the ALJ in reaching his decision. Oakland asserted that neither affiant's credentials include expertise or special knowledge in the area of statistical analysis. Thus, Oakland asserted that the ALJ's reliance on them was misplaced. Oakland Brief at 18-19.

We disagree. The ALJ did not rely on these individuals for statistical expertise. The ALJ stated:

> Their declarations (HCFA Exs. 11 and 16) are based not only on their expertise, but also on their personal examination and analysis of the data obtained from the AAB as well as Petitioner's records. Although some of their findings are laced with statistical implications, *the thrust of their declarations is more associated with the manner in which certain chemical properties will behave given specific testing conditions*. For example, based on their knowledge of the poor reproducibility of testing results for triglycerides and cholesterol, with an expected variation in results on the order of 10% to 20%, they are competent to voice an opinion as to the improbable likelihood that Petitioner's PT

> results for eight analytes, from each of the five specimens would be identical to the results reported by eight other laboratories in the same geographic area.

ALJ Decision at 14 (emphasis added).

Oakland also asserted that the affiants' declarations were suspect because they did not consider the totality of the testing process. Further, Oakland asserted that at least one of the affiants, as well as the ALJ, failed to understand that the reduction of the number of variables in a testing equation reduces the chances for dissimilarity of results. The more common elements the greater the chance for similar results. Here, Oakland noted, the laboratories participating in the AAB testing had the same samples and many used the same reagents and/or equipment. Oakland Br. at 25-27.

Contrary to Oakland's assertion, the ALJ discussed in significant detail the affiants' analytical process in determining that Oakland's reported PT results were not its own. This included a thorough review of Oakland's testing methodology and available worksheets and a comparison of that information to the PT results reported to AAB. ALJ Decision at 16-19. Oakland offered no specific argument or evidence to show that the affiants' statements were incorrect and thus that the relevant FFCLs were either unsupported by substantial evidence or erroneous.

In addition, Oakland did not even attempt to explain the discrepancies between the results reflected in its records and the results it reported to AAB. Consequently, it did not establish that it performed the tests in accordance with the regulations or that the results that it obtained that were identical to other laboratories' results were identical due to human error or coincidence. We therefore reject Oakland's exceptions to FFCLs 10, 12, 18, and 19.

Oakland also maintained that there was no direct or circumstantial evidence in the record which revealed that PT samples were removed from Oakland's clinical laboratory, so as to constitute an intentional referral within the meaning of the regulation. Oakland relied on an ALJ decision in *Southfield Medical Clinic*, DAB CR667 (2000), for the proposition that there can be no referral without physical transportation of the PT samples from one laboratory to another. Contrary to the reasoning of the ALJ in this case, Oakland contended that it was essential to give the applicable statutory and regulatory provisions their plain meaning that a referral occurs only when there is evidence of actual physical transport of PT samples to another laboratory. Oakland noted that, unlike other laboratories in cases involving referrals, it has not admitted referring the PT samples to another laboratory. The ALJ in this case did not have before him direct evidence that PT samples were in fact removed from Oakland in order to be tested elsewhere, but determined that referral was established through circumstantial evidence. ALJ Decision at 19. Oakland asserted that even if there were inter-laboratory communications regarding the PT samples, those communications would constitute nothing more than a standard level deficiency. Consequently, Oakland argued, the remedy selected by HCFA should have been a plan of correction, not the one-year revocation mandated by 42 U.S.C. § 263a(i)(4) and 42 C.F.R. § 493.801(b)(4). Oakland Br. at 21-24.

We have reviewed the ALJ decisions cited by the ALJ and both parties in this appeal, and we conclude that the ALJ's application of the referral regulation to the evidence before him in this case was not erroneous. The weight of the evidence demonstrated that the PT results that Oakland reported were not the result of its own testing, but were

obtained from another laboratory's testing. We therefore affirm the ALJ's factual determination here that referral was established through circumstantial evidence.

In addition, we agree with the ALJ in declining to follow the *Southfield* ALJ's analysis of the referral regulation as requiring that the actual physical transfer of the sample from one laboratory to another be established through direct evidence. As in the present case, the laboratory in *Southfield* reported PT results identical to those of another laboratory. In addition, in *Southfield* the same employee did the PT for both laboratories. In that case, the ALJ relied on the use of the word "send" in section 493.801(b)(4), and the fact that another subsection of the regulation, section 493.801(b)(3), specifically identifies inter-laboratory communication of PT results, for his conclusion that HCFA must show a physical transfer of the PT samples to establish intentional referral. He therefore held that the evidence before him supported only a finding of unlawful collaboration under section 493.801(b)(3).

The ALJ in *Southfield* focused on the wording of the provision at 42 C.F.R. § 493.801(b)(4), concluding that the wording indicates a physical transfer of the PT sample. We agree that the use of the word "send" in the first sentence of that section indicates a physical transfer. Contrary to what the ALJ in *Southfield* stated, however, that sentence is not presented as a definition of "intentional referral" but can be read as a separate prohibition. The second sentence of that section states: "Any laboratory that HCFA determines intentionally referred its . . . [PT] samples to another laboratory for analysis will have its certification revoked for at least one year." HCFA could reasonably read this sentence as applying to constructive referral as well as actual physical transfer, particularly in circumstances where the facts render physical transfer unnecessary for the outside analysis to take place. As noted by the ALJ in *Blanding Urgent Care Center Laboratory*, DAB CR438 (1996), the dictionary definition of "refer" includes "to direct the attention or thoughts of," and "to direct to a person, place, etc., for information or anything required." *Id.* at 21 citing Random House College Dictionary, revised ed. 1980, at 1108. HCFA established that the results reported by Oakland were not the product of its own PT. The mere fact that section 493.801(b)(3) prohibits inter-laboratory communications does not mean that communications about results could not constitute intentional referral, especially where the communication led to circumstances that are the substantial equivalent of a physical transfer with the transferring laboratory reporting the receiving laboratory's results as its own.

When the regulations are considered as a whole, reading section 493.801(b)(4) to encompass a constructive referral such as what occurred here is a better reading. Limiting the concept of a referral to a physical transfer is inconsistent with the underlying purposes of the condition for certification. Adopting the values achieved in another laboratory (either with or without having done the tests in one's own laboratory) clearly undercuts the general concept that the PT sample be tested in the same way as regular patient specimens in the laboratory are tested so that the results truly measure the proficiency of the laboratory reporting the PT results. The regulation requiring at least a one-year revocation of a certification where a laboratory intentionally referred PT samples to another laboratory can be considered notice of the seriousness with which any intentional circumvention of the requirements for PT would be regarded.

Finally, we reject Oakland's contention that a finding of intentional referral is essential to impose a one-year revocation of its CLIA certificate, and that a finding of inter-laboratory

communications would support only a standard level deficiency remedy. Even if only inter-laboratory communications were established, the record supports the ALJ's determination that Oakland was guilty of a wholesale failure to comply with PT requirements for all three 1998 PT events, and thus was out of compliance with the overall condition for participation in PT set forth in section 493.801. As we discuss below in our analysis of Oakland's exceptions concerning the remedies adopted by the ALJ, HCFA is authorized to impose a principal sanction on a laboratory that is out of compliance with one or more CLIA conditions. 42 C.F.R. § 493.1806.

Exceptions to the FFCLs concerning Oakland's laboratory director

FFCL 13. Dr. Robert I. Moretsky, as laboratory director and technical supervisor was responsible for Petitioner's overall operation and administration. His responsibilities included the employment of competent personnel to perform test procedures, the recording and the reporting of test results promptly, accurately and proficiently, and assuring compliance with applicable regulations. 42 C.F.R. §§ 493.1441 and 493.1445.

FFCL 14. Petitioner, through Dr. Robert I. Moretsky, was in violation of the condition for laboratory director in failing to provide proper overall management and direction to the facility and by not establishing and carrying out required quality control measures. 42 C.F.R. §§ 493.1441 and 493.1445.

FFCL 15. Petitioner, through Dr. Robert I. Moretsky, was in violation of the standard for technical supervisor in failing to establish a quality control program with parameters for acceptable levels of analytic performance, and ensuring that such levels are maintained throughout the entire testing process. 42 C.F.R. §§ 493.1449 and 493.1451.

Oakland argued that FFCL 13 was not supported by substantial evidence with regard to the finding that the laboratory director's responsibilities included employment of competent personnel. Oakland maintained that the implementing regulations do not require employees; rather, Oakland argued, laboratories may contract with testing personnel through independent contractor relationships as was the case here. Oakland Request for Review at 3.

Oakland argued that FFCLs 14 and 15 were clearly erroneous and not supported by substantial evidence in the record as there was no evidence presented to show that PT was not performed at Oakland's clinical laboratory. Thus, Oakland asserted, the FFCL regarding quality control measures was based on inferences and unsupported allegations. *Id.* at 3-4.

Oakland argued that the ALJ's conclusions related to Dr. Moretsky's supervision were clearly erroneous. Oakland asserted that "the only evidence relied on by the . . . [ALJ] is the inference that because there are standard level deficiencies, the laboratory director did not perform his responsibilities." Oakland Br. at 33.

Oakland asserted that FFCLs 13-15 were not based on substantial evidence because there were no allegations that Ms. Wheatley was incompetent, nor was there evidence presented to show that clinical testing was not performed on site. Indeed, Oakland claimed that it was illogical for the ALJ, or HCFA, to contend that Ms. Wheatley did not perform PT because there was no additional time burden placed on her to perform the tests, there was nothing to be gained by nonperformance, and there were no admissions from anyone connected with Oakland that the tests were not properly

performed. Oakland reasoned that since there had been no challenge to the routine patient testing at Oakland, and since indeed, Oakland claimed an unsullied history of PT and patient testing, the laboratory director had no reason to suspect deficiencies, at any level. Consequently, Oakland found it inconceivable that the director's performance could be considered deficient. Oakland also asserted that there was no evidence that the laboratory director knew or could have known of alleged improprieties in PT, even if he had stood next to the laboratory technician during testing. Finally, Oakland asserted that its alleged violation of 42 C.F.R. § 493.1451(b)(4) was only a standard level deficiency. Thus, Oakland again contended that HCFA was required to allow it the opportunity to remedy the deficiency pursuant to a plan of correction. Oakland Br. at 34-35.

The ALJ correctly noted that a laboratory must have a director who provides overall direction and proper management pursuant to 42 C.F.R. §§ 493.1441 and 493.1445. In reaching his decision, the ALJ found:

> Petitioner's laboratory records confirm that proficiency samples were not examined with the laboratory's regular workload; testing procedures were not documented; and prohibited collaboration with other laboratories occurred. . . .the MDCIS surveyor, found that the normal and abnormal control ranges were not available for the purpose of determining if quality control results for tests were within the manufacturer's expected ranges. HCFA Ex. 15, at 7. She also found that the laboratory could not verify quality control values for testing because the lot numbers, the expiration dates and the expected ranges were missing. *Id.*; HCFA Ex. 1, at 9.

ALJ Decision at 22.

The ALJ characterized Oakland's response to this deficiency as non-specific. The ALJ noted that although Oakland alleged it had performed the tests as required, it failed to produce any documentary evidence supporting its position even though it was required by regulation (42 C.F.R. § 493.801(b)(5)) to maintain such records. Finally, the ALJ determined that Oakland's technical supervisor (Dr. Moretsky) failed to establish a quality control program appropriate for the testing performed, and failed to establish the parameters for acceptable levels of analytic performance and to ensure that these levels were maintained throughout the entire testing process, from the initial receipt of the specimen through sample analysis and reporting of test results. Consequently, the ALJ found a violation of the standard at 42 C.F.R. § 494.1451(b)(4). ALJ Decision at 22.

In its appeal, Oakland did not dispute that its technical supervisor/director bore responsibility for ensuring that PT results were secured in accordance with the regulatory guidelines, nor did it provide evidence that Dr. Moretsky fulfilled his duties in this respect. Rather, Oakland challenged the notion that there was anything wrong with the PT results themselves. Since Oakland did not establish that its PT results were accurate and properly derived, however, it follows that Oakland's technical supervisor/director who attested to their accuracy did not fulfill his regulatory duties. We reject Oakland's implication that the laboratory director could not have discovered the PT deficiencies even if he had been standing next to the laboratory technician during testing, since it assumes that Ms. Wheatley did PT at Oakland for all three 1998 PT events. It bears repeating that Oakland produced no documentation substantiating testing for the June event, and the documentation it provided for the other two events did not support the results it reported. Adopting procedures to assure that required

documentation is produced, maintained, and checked for accuracy is certainly within the responsibilities of a laboratory director. *See* 42 C.F.R. § 493.1445(b)(4). Adherence to these requirements would have alerted Oakland's director to the problems with its PT. Moreover, such a wholesale failure to ensure compliance with PT requirements throughout all three 1998 testing events is certainly noncompliance with the conditions for laboratory director and technical supervisor, not just a standard level deficiency. We therefore conclude that Oakland has not demonstrated that the FFCLs in question here were erroneous or not supported by substantial evidence in the record.

Exceptions concerning the remedies proposed and imposed

FFCL 20. The revocation of Petitioner's CLIA certificate for a period of one year is not unreasonable in light of the failure to satisfy the condition level requirements mentioned above.

FFCL 21. HCFA properly canceled Petitioner's approval to receive Medicare payment for its services, effective October 1, 1999.

Oakland argued generally that revocation of its CLIA certificate was not authorized by the CLIA regulations because HCFA did not provide sufficient notice of the condition level deficiencies until the October 1, 1999 letter. Oakland also contended that the ALJ erred in finding that HCFA was not barred by the absence of reported deficiencies by the Commission on Office Laboratory Accreditation (COLA) from finding Oakland out of compliance with CLIA requirements. In addition, Oakland argued that HCFA was authorized to impose the principal sanction of revocation of its CLIA license only if HCFA established deficiencies in complying with items specifically identified in the regulations as conditions. According to Oakland, noncompliance with items identified as standards could never support imposition of a principal sanction, so that the appropriate sanction in its case was a plan of correction.

With respect to the numbered FFCLs, Oakland argued that FFCL 20 was clearly erroneous and not supported by substantial evidence in the record because revocation of its CLIA certificate for one year was unreasonable based upon HCFA's failure to prove any condition level requirements were unmet by Oakland. Oakland argued that FFCL 21 was clearly erroneous and not supported by substantial evidence in the record as HCFA did not properly cancel Oakland's approval to receive Medicare payments. Oakland Request for Review at 4-5.

The ALJ examined the notification time line in this case and determined that Oakland had ample notice that it had failed to meet requirements that were the basis for revocation of its CLIA certificate. ALJ Decision at 12. The ALJ characterized HCFA's October 1, 1999 letter to Oakland as a final and complete notice of adverse action. *Id.* at 5. As we noted earlier, the October 1st letter followed an opportunity for Oakland to demonstrate that the findings outlined in HCFA's July 15, 1999 letter, including the allegation of intentional referral, were incorrect. Moreover, as the ALJ noted throughout his decision, it is clear from the totality of the record that the alleged violations were so widespread as to amount to condition level deficiencies in Oakland's PT program. We therefore affirm the ALJ's determination that Oakland had sufficient notice of the charges against it to satisfy the notice requirements of the CLIA regulations.

The ALJ clearly did not err in rejecting Oakland's contention that HCFA could not find noncompliance with CLIA requirements because Oakland had passed a routine Commission on Office Laboratory Accreditation inspection. As he noted, HCFA may

always require an inspection where there has been a complaint. 42 C.F.R. § 493.1773(f). As a result of HCFA's inspection, Oakland was no longer deemed to meet the CLIA conditions by reason of its COLA accreditation. *See* 42 C.F.R. § 493.61.

We also reject Oakland's general contention that HCFA's citation to Oakland's deficiencies in meeting standards rather than overall conditions limited HCFA to alternative sanctions. It is indisputable that a laboratory can be so pervasively noncompliant with standards as to have failed to have complied with the overall condition. The record here supports the ALJ's determination that there was an absolute failure to comply with the CLIA requirements at 42 C.F.R. §§ 493.801, 493.801(b), and 493.61.

Finally, to the extent that Oakland's challenges to FFCLs 20 and 21 are based on its contention that no condition level deficiencies have been established, we have already affirmed the ALJ's FFCLs concerning the existence of condition level deficiencies, including the intentional referral of PT samples, for which revocation of Oakland's CLIA certificate is mandated.

We therefore reject Oakland's exceptions to these FFCLs and affirm and adopt them.

Conclusion

Based on the preceding analysis, we affirm and adopt each of the FFCLs underlying the ALJ Decision and sustain that decision in its entirety.

JUDGE

Judith A. Ballard
Donald F. Garrett
M. Terry Johnson
Presiding Board Member

FOOTNOTES

1. HCFA may deem a laboratory to meet all applicable CLIA program requirements if the laboratory obtains a certificate of accreditation, as required in 42 C.F.R. Part 493, Subpart D, and meets the other requirements listed in 42 C.F.R. § 493.551(b).

2. These remedies are also available if a laboratory with a certificate of accreditation fails to meet the requirements of 42 C.F.R. § 493.61, including the requirement that it treat the PT samples in the same manner as patient samples. 42 C.F.R. §§ 493.61(b)(1) and (c).

3. HCFA initially determined that Oakland had refused to permit an inspection and contemplated imposing a sanction on that basis. However, based on MDCIS's subsequent recommendation, HCFA withdrew that determination. HCFA Ex. 2.

4. For example, we found impossible to categorize as referring to any FFCL Oakland's contention that "the ALJ and HCFA have never alleged or presented any evidence or made any finding of fact related to patient testing not being properly performed at . . . [its] clinical laboratory." Oakland Br. at 34. Since we conclude below that the ALJ correctly determined that Oakland was out of compliance with CLIA requirements concerning PT participation and laboratory director, and that these deficiencies supported HCFA's imposition of principal sanctions, we need not consider contentions about Oakland's compliance with other CLIA requirements.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT: Stanley Boykansky, M.D.,

Petitioner,
DATE: December 21, 2000
- v -

Health Care Financing Administration
Civil Remedies CR690
Docket No.A-2000-108
Decision No. **1756 DECISION**

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Stanley Boykansky, M.D., a clinical laboratory (Petitioner), appealed a July 28, 2000 decision by Administrative Law Judge (ALJ) Steven T. Kessel. *Stanley Boykansky, M.D.*, DAB CR690 (2000) (ALJ Decision). The ALJ found that the Health Care Financing Administration (HCFA) properly imposed the remedies of suspension and revocation of Petitioner's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as the cancellation of Petitioner's approval to receive Medicare payments for its services.

On appeal to the Board, Petitioner excepted to all seven of the ALJ's findings of fact and conclusions of law (FFCLs). We have reviewed Petitioner's exceptions and conclude that the ALJ Decision should be affirmed.

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*.[(1)] CLIA further grants the Secretary of this Department broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for a certificate. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829.

A laboratory's CLIA certification is dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. The regulations also set forth standards, the specific components of the conditions of laboratory certification that a laboratory must meet as part of achieving compliance with applicable conditions.

A key component of the statutory and regulatory program to assure that laboratories holding CLIA certificates are competent to perform tests of moderate and high complexity is the requirement for participation in a proficiency testing (PT) program that is approved by HCFA, as outlined in 42 C.F.R. Part 493, Subpart H. Among the requirements of that subpart are the following: a participating laboratory must test PT samples it receives in the same manner as it tests patient samples; must not communicate the results of its tests to other laboratories prior to the deadline for reporting results; must not refer PT samples to another laboratory for analysis; and must document and maintain documentation for the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 C.F.R. § 493.801.

Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). HCFA may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations at 42 C.F.R. § 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E.

Background

This undisputed factual background is drawn from the ALJ Decision and the record below.

Petitioner is engaged in high complexity testing for routine chemistry and endocrinology in Farmington Hills, Michigan. Petitioner is owned and operated by Stanley Boykansky, M.D., who served as Petitioner's laboratory director, clinical consultant, technical supervisor and general supervisor. Petitioner employed Deborah Sabo. HCFA Ex. 9. Ms. Sabo performed high complexity routine chemistry and endocrinology testing, PT and tests billable to Medicare.

Some of the laboratories in the Detroit Metro area participating in a PT program operated by the American Association of Bioanalysts (AAB) were Stanley Boykansky, M.D.; Oakland Medical Group (also known as Moretsky/Trager/Flor); John Dunn, M.D.; Mark Hertzberg, M.D.; Rochester Road Clinic; Nazar Sarafa, M.D. (also known as Garden City Medical Clinic); Liptawat Family, P.C.; Lakeland Medical; and Ecorse Med Center. HCFA Ex. 1. The AAB would mail to each laboratory participating in the PT program an identical group of five specimens three times a year. The laboratories were required to test these specimens for analytes for which they did patient testing, and mail their results to the AAB by a date certain. Petitioner was required to test the specimens for cholesterol, HDL cholesterol, triglycerides, iron, thyroid stimulating hormone, total thyroxine, triiodothyronine, and thyroid uptake.

While working for Petitioner, Ms. Sabo also performed PT for the Dunn, Ecorse, Hertzberg and Garden City laboratories and worked for the Rochester Road laboratory as substitute testing personnel. Hearing Transcript (Tr.) at 42-43.

During this period, Rene Wheatley performed PT for the Rochester Road, Liptawat, Lakeland and Oakland laboratories. HCFA Exs. 1 and 2. Ms. Wheatley and Ms. Sabo had a prior professional relationship. Ms. Sabo testified that they knew each other "well" and that Ms. Wheatley had been her supervisor at Oakland General Hospital. Tr. at 41-42.

In early January 1999, Dennis W. Jay, Ph.D., Technical Director of the Proficiency Testing Service of the AAB, sent a letter to the Michigan Department of Consumer and Industry Services (MDCIS), the state survey agency, concerning PT results for a group of Detroit area laboratories that he deemed suspect. Specifically, the cover letter suggested that the same PT results were being submitted by nine laboratories including Petitioner. HCFA Exs. 15 at 2 and 13 at 2-3.

On February 25, 1999, MDCIS surveyors conducted a complaint investigation of Petitioner to determine whether Petitioner was complying with CLIA requirements. The surveyors determined that Petitioner's 1998 PT results were not obtained in compliance with CLIA requirements.[(2)] HCFA Ex. 15 at 3-4. Generally, the surveyors found that Petitioner's PT results for numerous tests were identical to PT results at some or all of eight other Detroit area laboratories, identified above, at which Ms. Sabo and Ms. Wheatley worked. Moreover, the underlying calculations ostensibly used to produce those results did not always support them.

The surveyors referred their findings to HCFA. HCFA Ex. 15 at 3-4. On May 13, 1999, HCFA notified Petitioner that it had been found to be deficient in complying with CLIA requirements. HCFA advised Petitioner that it would impose remedies against Petitioner which included cancellation of Petitioner's approval to receive Medicare payment for its services and revocation of Petitioner's CLIA certificate.

HCFA followed its May 13, 1999 notice with a second notice dated June 23, 1999. There HCFA advised Petitioner that its determination to impose remedies was based on its finding that Petitioner had referred PT samples to another laboratory for testing or had improperly collaborated with another laboratory in the administration of PT samples.

On July 15, 1999, Petitioner requested a hearing before an ALJ. HCFA sent a third notice to Petitioner, dated August 27, 1999. There HCFA reiterated and amplified its findings that Petitioner either had referred PT samples to another laboratory for testing or had collaborated with another laboratory in the PT event. In the August 27, 1999 notice, HCFA identified two specific CLIA conditions with which it asserted Petitioner had not complied. These conditions are stated at 42 C.F.R. §§ 493.801 (proficiency testing) and 493.1441 (laboratory director).

On April 12, 2000, the ALJ held an in-person hearing in Detroit, Michigan. There he heard the testimony of Ms. Sabo, who testified on behalf of Petitioner. The ALJ issued his decision on July 28, 2000. Petitioner timely appealed on September 21, 2000.

Standard of Review

Our standard of review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000).

ANALYSIS

Analysis

The ALJ Decision was premised on seven Findings of Fact and Conclusions of Law (FFCLs). As noted above, Petitioner took exception to each FFCL. Petitioner filed, concurrently, both a Request for Review, listing all the FFCLs to which it excepted, and a Brief grouping some of those FFCLs within broader arguments. In presenting Petitioner's position, we cite both its Request for Review and its Brief.

We have considered each argument raised by Petitioner as well as the entirety of evidence before the ALJ. Below, to the extent practical, we address each relevant argument relative to a disputed FFCL. We have concluded that the challenged FFCLs are not erroneous and are supported by substantial evidence on the record as a whole. Thus, any nuance of Petitioner's contentions that we have not addressed specifically is subsumed in our analysis of its position and rejected.

FFCL 1. HCFA gave Petitioner adequate notice of the basis for its determination to impose remedies.

Petitioner contended that this FFCL was clearly erroneous and not supported by substantial evidence in the record. Petitioner asserted that it did not receive proper notice of the condition-level deficiencies in accordance with 42 U.S.C. § 263a(i) and 42 C.F.R. § 493.1844(g). Petitioner alleged that it had suffered prejudice in that it had its Medicare payments canceled prior to receipt of notice of alleged condition-level deficiencies and, based on the ALJ's erroneous conclusion, could have its CLIA certificate revoked. Petitioner Request for Review at 1-2.

Petitioner asserted that HCFA's first Notice (May 13, 1999) alleged standard level deficiencies and that it was not until HCFA's August 27, 1999 Notice that allegations of condition-level deficiencies arose. Petitioner noted that the August 27th Notice cited condition-level deficiencies relative to 42 C.F.R. §§ 493.801 (testing of samples) and 493.1441 (laboratory director). However, Petitioner contended that HCFA's Form 2567 (Statement of Deficiencies) did not address section 493.1441, let alone violations of that provision. Rather, the Form 2567 pointed to violations of 42 C.F.R. § 493.1445, which, by definition, sets out standard level deficiencies relative to a laboratory director. Petitioner argued that HCFA, without authority, found a condition-level violation of section 493.1441, based on totally unsupported and previously undisclosed standard level deficiencies. Petitioner Br. at 5-6.

Petitioner contended that it received the August 27th Notice "after the sanctions were either imposed or appealed and provided no opportunity to respond or appeal . . . previously undisclosed deficiencies." Petitioner argued that the ALJ erred in finding that Petitioner had been provided with adequate notice. Specifically, according to Petitioner, the ALJ's reliance on 42 C.F.R. § 493.1842(b) (HCFA authorized to amend notices) was misplaced as that regulation also provided that neither cancellation nor revocation may occur without proper notice and opportunity to respond. Here, Petitioner asserted, HCFA imposed a condition level remedy, cancellation of payment, then raised the specter of condition level deficiencies. Additionally, Petitioner asserted, HCFA erroneously determined that it could cancel payments and revoke Petitioner's CLIA certificate based on an accumulation of standard level deficiencies justifying condition level sanctions. Petitioner Br. at 6-9.

We reject Petitioner's contention that it lacked timely notice of the basis for HCFA's determination because Petitioner admits in its Brief before us that, as early as the Notice and June 23 Letter, it knew that HCFA considered it to be so seriously out of compliance with CLIA requirements that principal sanctions were warranted. Petitioner stated, "HCFA . . . notified Petitioner that his approval to receive Medicare payments would be canceled and his CLIA certificate would be revoked based upon HCFA's determination that standard level deficiencies could provide a basis for a condition-level sanction if HCFA determined that such an unsupported determination was proper. Based upon the reasons and rationale underlying HCFA's decision with respect to the adverse action . . . Petitioner responded to the Notice and June 23 Letter." Petitioner Br. at 8. This admission confirms the ALJ's determinations that Petitioner had timely notice of the charges against it, and that the subsequent, more specific
August 27, 1999 notice was a permissible amendment of HCFA's May 13, 1999 Notice. ALJ Decision at 6. Moreover, one of the specific violations referenced in the May 13 Notice, the intentional referral of PT samples, by its own regulatory terms provides a basis for the principal sanction of certificate revocation. *See* 42 C.F.R. § 493.801(b)(4). In addition, as we discuss more extensively below, the egregious undermining of the PT system alleged by the May 13 Notice, which the ALJ found to exist in this case, certainly rises to the level of a condition level deficiency with the PT regulations.
We therefore affirm and adopt FFCL 1.

FFCL 2. HCFA is authorized to make independent determinations about the nature and severity of Petitioner's alleged noncompliance with CLIA requirements.

Petitioner asserted that this FFCL was clearly erroneous and not supported by substantial evidence in the record because, contrary to the ALJ's interpretation of its argument, it was not arguing that HCFA had no authority to either impose sanctions or find deficiencies. Rather, Petitioner argued that HCFA could not impose principal level sanctions unless it had properly alleged a condition level deficiency.
In reviewing Petitioner's arguments before the ALJ, we have concluded that the following statement in the ALJ Decision is accurate: "Petitioner seems to be arguing that HCFA lacks the authority to make findings that differ from those which its agents make in conducting CLIA compliance surveys by asserting that HCFA's determination that Petitioner manifested condition level deficiencies in its operations exceeded the findings that were made at the February 25, 1999 survey. From this, Petitioner appears to argue that HCFA's determinations in this case are invalid inasmuch as they differ from the findings of noncompliance that were made by the Michigan State survey agency surveyors." ALJ Decision at 6.
Petitioner did not contend before us that the ALJ's reasoning on this point was flawed. Rather, it contended that this FFCL does not adequately address its arguments about HCFA's authority to impose principal sanctions where the state surveyors had cited only standard level deficiencies. However, the ALJ addressed all aspects of Petitioner's contentions on this topic in FFCL 1, where he found that Petitioner had adequate notice, and FFCL 7, where he concluded that HCFA's imposition of principal sanctions was authorized. We have therefore placed our discussion of these arguments in the sections of this decision dealing with those FFCLs. Moreover, the ALJ's discussion of HCFA's authority to make independent determinations about the nature and severity of

Petitioner's noncompliance with CLIA requirements is legally sound, as it is based on the plain language of 42 C.F.R. § 493.1804. We therefore affirm and adopt FFCL 2 without further discussion.

FFCL 3. During 1998, Petitioner colluded with other clinical laboratories in the performance of proficiency testing.

Petitioner asserted that the ALJ's finding of collusion was not supported by "substantial facts presented." Petitioner Request for Review at 3. Petitioner argued that in reaching this FFCL, the ALJ ignored the only credible evidence of record, Ms. Sabo's testimony, and relied instead on the similarity of Petitioner's PT results to the results of other laboratories in the Detroit area. Petitioner contended that the ALJ's findings that Ms. Sabo and Ms. Wheatley were well-acquainted and that Ms. Sabo offered no explanation for similar or identical PT results were not supported by substantial evidence.

With respect to the evidence upon which the ALJ relied in reaching his decision, Petitioner challenged the qualifications of the three HCFA affiants (the Technical Director, Proficiency Testing, AAB; the Chief, Laboratory Improvement Section, MDCIS and the Medical Technologist, HCFA Survey and Certification Division). Petitioner asserted that these affiants' credentials did not include expertise or special knowledge in the area of statistical analysis, and thus, the ALJ's reliance on them was misplaced. Petitioner asserted that the affiants' declarations were suspect because they did not consider the totality of the testing process. Further, Petitioner contended that at least one of the affiants, as well as the ALJ, failed to understand that the reduction of the number of variables in a testing equation reduces the chances for dissimilarity of results. According to Petitioner, since the laboratories participating in the AAB testing had the same samples and many used the same reagents and/or equipment, the chance for similar results was increased. Petitioner Br. at 14-18.

Finally, Petitioner disputed that HCFA had met its burden regarding allegations of intentional referral, because all the cases cited by HCFA before the ALJ involved admissions of referrals by the laboratories. Petitioner contended that HCFA had relied on acts which were no more than simple rounding errors and inconsequential human error in an effort to bolster "unsupported allegations." Petitioner Br. at 13-14.

We have reviewed the ALJ's decision in light of Petitioner's contentions and conclude that this FFCL is supported by substantial evidence in the record. Our review of the transcript of the hearing revealed as baseless Petitioner's contentions that there was no evidence in the record to support the ALJ's findings that Ms. Sabo and Ms. Wheatley were well-acquainted and that Ms. Sabo offered no explanation for the similarity of testing results. In considering the ALJ's conclusions concerning Ms. Sabo's credibility, we defer, as we have previously stated is generally appropriate, to the assessment of witness credibility by the ALJ who has the opportunity to observe the witness' demeanor in testifying. *Edison Medical Laboratories, Inc.*, DAB 1713 at 21 (1999). Here, the ALJ explained his credibility determination and cited to overwhelming evidence that contradicted Ms. Sabo's assertion that these PT results were obtained by her performance of the analyses in the manner prescribed by the regulations: not only did the results match those of eight other laboratories to a degree that was highly improbable without collusion, but the records submitted to support Petitioner's PT results contained calculations that produced numbers different from the PT results reported.[(3)] ALJ Decision at 9-10.

Moreover, while the ALJ did not specifically address Petitioner's argument that Ms. Sabo had no motive to falsify the PT results for Petitioner because it would not save her any work, that argument does not avail Petitioner here. While motive, if proven, would have buttressed the ALJ's findings concerning Ms. Sabo's credibility, lack of motive does not undercut the evidence supporting the ALJ's finding that the PT results reported by Ms. Sabo simply did not match the records she made of the PT testing that she allegedly performed.

In addition to the lack of explanation from Ms. Sabo as to how all nine laboratories could innocently reach identical PT results in all three PT events for 1998, the ALJ relied on his analysis of the testimony of three HCFA affiants and his examination of the records Petitioner had produced to support the PT results reported. He relied on these affiants' opinions concerning the likelihood that identical results could be reached without collusion, as well as his independent determination that the records contained data that was inconsistent with the results reported, in concluding that Petitioner did not arrive at these results through human error or coincidence, but by intentional referral, collaboration, and manipulation of the results.

We also reject Petitioner's arguments about HCFA's affiants' alleged lack of credentials amd the similarity of test methods used by the laboratories who obtained identical testing results. Petitioner mischaracterizes the nature of the ALJ's reliance on the testimony of HCFA's experts. He addressed Petitioner's challenge to these individuals' statistical expertise as follows:

> None of these experts performed statistical analyses to obtain their conclusions. Rather, their conclusions were based on their training in their respective fields, their experience in those fields, and on the evidence which pertained to the specific PT results that are at issue in this case. Thus, for example, Dr. Jay [AAB Technical Director] concluded that the nine laboratories, including Petitioner, could not have independently reached identical results for cholesterol and triglyceride PT, because of the poor reproducibility of such tests. HCFA Ex. 13 at 2-3. *Dr. Jay plainly based that conclusion on his training and expertise and not on a statistical analysis of test results.*

ALJ Decision at 9 (emphasis added).

In addition, the ALJ specifically addressed Petitioner's allegation that the identical PT results for the nine laboratories could be due to the similar testing conditions for the laboratories. He stated:

> Although some of the laboratories had the same model spectrometer--a device that was used to perform proficiency testing--others had different models. Tr. at 77. All of the spectrometers were calibrated separately. *Id.* at 77-78. Each of the nine laboratories had its own supply of controls and reagents. *Id.* at 76-77. Room temperature varied from laboratory to laboratory. *Id.* at 78.

ALJ Decision at 9. Indeed, in making his finding that variability would be expected, the ALJ relied in part on Ms. Sabo's own testimony. *Id.* at 11.

We conclude that the ALJ properly weighed the evidence before him in reaching his finding that the results Petitioner reported for PT in 1998 were not its own. As we discuss below, we also conclude that he did not err in determining that this factual

finding meant that Petitioner had participated in unlawful communication of PT results in contravention of 42 C.F.R. § 493.801(b).

We reject Petitioner's contentions that the ALJ erred in affirming HCFA's finding of intentional referral here because HCFA relied on decisions where the laboratory in question had admitted referral and on documents showing what Petitioner characterized as rounding errors or inadvertent human error. The ALJ thoroughly discussed the evidence supporting his application of the referral and inter-laboratory communication regulations to the circumstances here, despite Petitioner's refusal to admit referral and its assertion that its discrepancies between its PT records and the results it reported were honest mistakes. *See* ALJ Decision at 7-9. As we have already stated, his analysis of these issues is supported by substantial evidence in the record.

We therefore affirm and adopt FFCL 3.

FFCL 4. During 1998, Petitioner did not test proficiency test samples in the same manner as it tested patients' specimens. Also during 1998, Petitioner engaged in inter-laboratory communications pertaining to the results of proficiency tests.

In challenging the evidentiary basis for this FFCL, Petitioner relied heavily on Ms. Sabo's "unequivocal testimony" that PT and patient testing were properly performed in 1998, and it contended that there was no reliable evidence that PT was not performed on site. Petitioner Br. at 25. Petitioner argued that not only was there no evidence before the ALJ that Petitioner had engaged in inter-laboratory communication, but also the relevant CLIA regulation, 42 C.F.R. §§ 493.801(b)(3) and (4), dictated that inter-laboratory communications be treated as a standard level deficiency, not sanctionable by revocation. Consequently, Petitioner concluded, since this Department and Congress intended that inter-laboratory communications be treated as a standard level deficiency, neither HCFA nor the ALJ had the authority to impose principal sanctions in this case. Petitioner Br. 24-25.

We have already discussed, in connection with our review of Petitioner's exceptions to FFCL 3, the substantial evidence in the record supporting the ALJ's finding that Petitioner's 1998 PT results were reached through collusion rather than through testing in accordance with the regulations. Based on the same analysis, we reject Petitioner's reliance on Ms. Sabo's testimony that PT testing was done properly on site.

We also reject Petitioner's regulatory analysis leading to its conclusion that HCFA is not authorized to impose a principal sanction for inter-laboratory communication. One of the subsections cited by Petitioner, 42 C.F.R. § 493.801(b)(4), specifically requires imposition of a principal sanction, revocation of a laboratory's CLIA certificate for one year, for any laboratory that HCFA determines intentionally referred its PT samples to another laboratory for analysis. This clearly contradicts Petitioner's assertion that the captioning of 42 C.F.R. § 493.801(b) as a standard evidences an intent to limit HCFA's authority to impose a principal sanction for violations of this provision. As we discuss below in reviewing Petitioner's exceptions to FFCL 7, HCFA is not limited to alternative sanctions where a laboratory's actions constitute an egregious violation of its PT responsibilities.

We therefore affirm and adopt FFCL 4.

FFCL 5. Petitioner failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

Petitioner asserted that the ALJ's analysis underlying this FFCL, that Petitioner deliberately attempted to frustrate the underlying purpose of PT, was not based on substantial evidence in the record. Petitioner insisted that the ALJ's finding that Petitioner had colluded with other laboratories on 1998 PT and his conclusion that collusion could rise to the level of an intentional referral under 42 C.F.R. § 493.801(b)(4) were clearly erroneous and not supported by substantial evidence in the record.[(4)] Petitioner argued that, based on a clear reading of the statute and regulation, there could be no referral without an actual transport of PT samples. Petitioner noted that although the ALJ had found no referral absent physical transport in his decision in *Southfield Medical Clinic*, DAB CR667 (2000), he ignored his *Southfield* holding in reaching his decision here. Petitioner argued that the ALJ's conclusion that an intentional referral of PT samples may occur under 42 U.S.C. § 263(a)(i)(4) without physical transport of the samples was clearly erroneous. Additionally, Petitioner argued that the ALJ incorrectly found that the laboratory director's failure to sign the PT attestation form was further evidence of collusion reaching the level of referral. Petitioner maintained that in reaching this finding, the ALJ ignored the evidence that Ms. Sabo was qualified to sign the attestation sheets in place of the laboratory director pursuant to 42 C.F.R. §§ 493.1411 and 493.1449. Petitioner Br. at 26-28.

We have already reviewed Petitioner's contentions concerning the ALJ's finding that Petitioner colluded with other laboratories and concluded that it is supported by substantial evidence in the record. In this section, we review Petitioner's contention concerning the legal effect of that finding. In arguing that the ALJ ignored his *Southfield* holding, Petitioner is mistaken, as the following excerpt from the ALJ Decision demonstrates:

> I disagree with HCFA's assertion and I disagree with the *Balding* (sic) [*Blanding Urgent Care Center Laboratory*, DAB CR438 (1996)] decision to the extent that it supports the proposition that an unlawful "referral" of a testing sample to another laboratory may occur without an actual physical transport of the sample from one laboratory to another. As I explained in *Southfield Medical Clinic*, DAB CR667 at 11 (2000), collusion and referral of testing samples are not the same thing.

ALJ Decision at 12. Thus, because there was no evidence of physical transfer in this case, the ALJ did not find intentional referral here. The ALJ went on to conclude, however, that the distinction between intentional referral and collusion was not important in this case because "the *effect* of Petitioner's collusion on the performance of its proficiency testing was indistinguishable from the effect resulting from other forms of cheating on proficiency testing, including referral of samples to another laboratory for testing. The effect was to invalidate completely Petitioner's proficiency testing." *Id.*, at 12-13.

We agree with the ALJ that Petitioner failed to comply with the CLIA condition at 42 C.F.R. § 493.801 because it reported PT results that were not its own. However, we have recently considered the two ALJ decisions cited by this ALJ, *Blanding* and *Southfield*, in another appellate decision, and we respectfully disagree with the ALJ that the regulation at section 493.801(b)(4) prohibiting intentional referral of PT samples is limited to cases where physical transfer is established. In *Oakland Medical Group, P.C.*, DAB No. 1755 (2000), we stated:

> The ALJ in *Southfield* focused on the wording of the provision at 42 C.F.R. § 493.801(b)(4), concluding that the wording indicates a physical transfer of the PT sample. We agree that the use of the word "send" in the first sentence of that section indicates a physical transfer. Contrary to what the ALJ in *Southfield* stated, however, that sentence is not presented as a definition of "intentional referral" but can be read as a separate prohibition. The second sentence of that section states: "Any laboratory that HCFA determines intentionally referred its . . . [PT] samples to another laboratory for analysis will have its certification revoked for at least one year." HCFA could reasonably read this sentence as applying to constructive referral as well as actual physical transfer, particularly in circumstances where the facts render physical transfer unnecessary for the outside analysis to take place. As noted by the ALJ in *Blanding* . . ., the dictionary definition of "refer" includes "to direct the attention or thoughts of," and "to direct to a person, place, etc., for information or anything required." *Id.* at 21 citing Random House College Dictionary, revised ed. 1980, at 1108.
>
> * * *
>
> When the regulations are considered as a whole, reading section 493.801(b)(4) to encompass a constructive referral such as what occurred here is a better reading. Limiting the concept of a referral to a physical transfer is inconsistent with the underlying purposes of the condition for certification. Adopting the values achieved in another laboratory (either with or without having done the tests in one's own laboratory) clearly undercuts the general concept that the PT sample be tested in the same way as regular patient specimens in the laboratory are tested so that the results truly measure the proficiency of the laboratory reporting the PT results.

Oakland at 17-18.

Consequently, we conclude that Petitioner violated 42 C.F.R. § 493.801(b)(4) specifically, as well as the overall condition at § 493.801. Since that provision codifies a statutory provision requiring HCFA to revoke Petitioner's CLIA certificate for one year, a sanction the ALJ had upheld based on his conclusion that Petitioner's actions violated the overall condition, we see no need to modify FFCL 5 to reflect that Petitioner also violated section 493.801(b)(4).[(5)]

As noted above, Petitioner also argued that the ALJ erred in relying on Petitioner's failure to rebut the allegation that its laboratory director failed to sign PT statements as further evidence of collusion, because Ms. Sabo was qualified to, and did, sign them as technical consultant or technical supervisor. However, the ALJ properly determined that the functions of technical supervisor and laboratory director are distinct under the regulations, and that at most, one could say that the technical supervisor's duties may be a component of the laboratory director's responsibilities. ALJ Decision at 13. Moreover, among the regulatory duties of the technical consultant and technical supervisor are the evaluation of the competency of all testing personnel to assure that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. 42 C.F.R. §§ 493.1414(b)(8) and 493.1451(b)(8). In addition, both positions bear responsibility for evaluating and documenting the performance of individuals responsible for testing.

42 C.F.R. §§ 493.1414(b)(9) and 493.1451(b)(9). These provisions indicate that the person holding these positions should not be the same individual responsible for testing, as was the case in Petitioner's laboratory.

We therefore affirm and adopt FFCL 5.

FFCL 6. Petitioner failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.1441.

Petitioner asserted that the ALJ's finding that Petitioner's laboratory director had not provided overall management and direction as required by 42 C.F.R. § 493.1441 was not supported by substantial evidence. Petitioner Request for Review at 5.

Petitioner asserted that the ALJ incorrectly relied on an inference that because there are standard level deficiencies, the laboratory director did not perform his responsibilities. Further, Petitioner noted that there was no evidence that Ms. Sabo was not competent to perform PT and no evidence that patient testing was not properly performed on site. Petitioner asserted that, absent evidence to the contrary, it defied logic to think that Ms. Sabo would not perform PT properly given that she had nothing to gain from not performing PT with routine patient testing. Petitioner noted that it had never received complaints concerning the quality of its patient testing, had not had its PT results rejected by AAB and had not had deficiencies cited by the Commission on Office Laboratory Accreditation (COLA). Petitioner characterized the similarity in PT results scores as emanating from small standard deviations from the mean on PT scores coupled with the work of a sloppy or absent-minded technician. Petitioner characterized as "absurd" what it interpreted as the ALJ's requirement that a laboratory director was required to look over the shoulder of a laboratory technician in order to demonstrate satisfactory direction. Petitioner Br. at 31. Petitioner argued that such stringent oversight would not prevent collusion. Rather, Petitioner argued, in order to function effectively, the director must be free to rely on his/her expert, i.e., the technician. Moreover, Petitioner argued that rather than being allowed to impose the draconian sanctions at issue, HCFA and the ALJ should be made to adhere to the letter of the CLIA statute and regulations. Thus, according to Petitioner, the most stringent sanction available should have been compelling Petitioner to adhere to a plan of correction. Petitioner Br. 29-32. Petitioner's argument is anomalous[(6)] and utterly lacking in merit. The ALJ's rationale is explicit and persuasive.

Specifically, he found:

> The evidence shows that, in 1998, Dr. Boykansky abdicated the supervisory authority that he had as Petitioner's laboratory director. This abdication of authority was so serious as to comprise a failure to comply with the laboratory director condition of participation under CLIA. The failure to supervise Ms. Sabo enabled her to collaborate with other laboratories in the performance of PT. Had Dr. Boykansky been more vigilant in supervising Ms. Sabo, the collusion that transpired between Petitioner and other laboratories might not have happened.
>
> * * *
>
> [T]here is ample evidence to show that he was remiss in supervising Ms. Sabo and that this lax supervision facilitated collusion between Petitioner and other laboratories.

> The collusion between Petitioner and other laboratories transpired over a period of approximately one year. . . During this entire period there is no evidence that Dr. Boykansky, acting as laboratory director of Petitioner and Ms. Sabo's supervisor, exercised any supervision of Ms. Sabo that would have exposed her actions. The inference I draw from his failure to intervene was that Dr. Boykansky was not providing required oversight of Ms. Sabo's work. My conclusion that Dr. Boykansky was not supervising Ms. Sabo is buttressed by Dr. Boykansky's failure to sign proficiency testing attestation statements. Rather, he permitted Ms. Sabo to sign these statements.

ALJ Decision at 14-15.

There is precious little room for dispute here. Petitioner has been unable to refute HCFA's case before the ALJ or the ALJ's rationale underlying the other FFCLs upon which his decision is based. This FFCL is the result of cumulative evidence before the ALJ. Faced with persuasive evidence of intentional referral of PT samples, Petitioner offered no credible evidence to show that PT was conducted properly. Consequently, Petitioner's arguments are totally unconvincing. We do not read this FFCL as requiring a laboratory director to stand over a technician's shoulder. As we discussed in our analysis of FFCL 5 above, the CLIA regulations provide for evaluation of testing personnel by the technical supervisor or technical consultant. 42 C.F.R.§§ 493.1414(b)(8) and 493.1451(b)(8). By permitting Ms. Sabo to sign in those capacities, Dr. Boykansky abdicated his responsibility for overall management and direction of the laboratory in accordance with the provisions of 42 C.F.R. § 493.1445. This regulation expressly provides that if a laboratory directory delegates responsibilities, he nonetheless remains responsible for ensuring that all duties are properly performed. 42 C.F.R. § 493.1445(b). Consequently, while he does not have to stand over his technician's shoulder, the laboratory director must ensure that PT is performed properly. 42 C.F.R. § 493.1445(e)(4). Here, there is ample evidence to show that the laboratory director failed to fulfill his responsibilities under 42 C.F.R. § 493.1445. Thus, the ALJ properly found a violation of the condition at 42 C.F.R. § 493.1441.

Further, Petitioner's argument that the lack of complaints about its prior performance in both PT and patient testing was evidence of its 1998 compliance with the regulation at issue is unavailing in the face of overwhelming evidence that its participation in these 1998 PT events was flawed. Thus, at most, Petitioner's prior compliance history is a factor HCFA could consider in choosing the appropriate sanction. *See* 42 C.F.R. § 493.1804(d)(6).

We therefore affirm and adopt FFCL 6.

FFCL 7. HCFA is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions of participation.

Petitioner asserted that this FFCL was clearly erroneous and not supported by substantial evidence. Petitioner Request for Review at 6. Petitioner asserted that it had submitted a valid plan of correction on May 28, 1999 with respect to the standard level deficiencies of which it had notice. Petitioner further asserted that Ms. Sabo's testimony addressed all those standard level deficiencies and that Petitioner, in its pleadings, had sufficiently explained "certain mistakes made by Ms. Sabo." Petitioner Br. at 32. Petitioner contended that HCFA's failure to properly allege condition level deficiencies meant that HCFA's choice of remedies was limited to those found at 42 C.F.R. §

493.1816. Petitioner asserted that, pursuant to the regulation, HCFA was compelled to provide it the opportunity to submit an acceptable plan of correction within 12 months of the last day of the inspection revealing the deficiencies.

Petitioner also asserted that the ALJ's and HCFA's theory that standard level deficiencies can amount to condition-level sanctions was baseless. In support, Petitioner pointed to 42 C.F.R. § 493.2, which provides that a condition-level deficiency constitutes noncompliance with one or more condition-level requirements. Petitioner asserted that neither CLIA nor the implementing regulations provide HCFA with the authority to find a condition-level violation in the circumstances present here. Moreover, Petitioner noted that both the legislative history and past ALJ decisions plainly distinguish between standard and condition-level deficiencies. Petitioner argued that, given these factors and since HCFA found only standard level deficiencies, the penalty imposed by HCFA was unwarranted. Petitioner Br. at 10-13.

Petitioner's contentions rest on its assertion that it was given timely notice only of standard level deficiencies, which we have already rejected, and on an overly technical reading of the regulations as restricting HCFA's authority to take action to protect patients from relying on laboratory results produced by laboratories which are found to be noncompliant with CLIA requirements. As we stated in *Oakland*, a case involving another of the group of laboratories found to have identical 1998 PT results, "[i]t is indisputable that a laboratory can be so pervasively noncompliant with standards as to have failed to have complied with the overall condition." *Id.* at 23. HCFA is not restricted by regulation to the use of a plan of correction, as urged by Petitioner, when "Petitioner's collusion was so egregious as to make its participation in proficiency testing meaningless." ALJ Decision at 14.

We therefore affirm and adopt FFCL 7.

JUDGE

Judith A. Ballard

Donald F. Garrett
M. Terry Johnson
Presiding Board Member

FOOTNOTES

1. HCFA may deem a laboratory to meet all applicable CLIA program requirements if the laboratory obtains a certificate of accreditation, as required in 42 C.F.R. Part 493, Subpart D, and meets the other requirements listed in 42 C.F.R. § 493.551(b).

2. We do not recount here each of Petitioner's questioned PT results. Those results were before the ALJ and their existence is not in question. Rather, the manner in which the PT results were obtained is at issue.

3. Petitioner also challenged the ALJ's credibility determination as not supported by substantial evidence because the ALJ ignored "undisputed evidence . . . that at nine out of thirteen laboratories that Ms. Sabo provided technician services, the 1998 . . . [PT] results are not at issue." Petitioner Request for Review at 3-4. However, the only information in the record concerning Ms. Sabo's performance of PT testing at the other laboratories where she worked was that those laboratories were not included in AAB's survey. Petitioner Br. at 19. Thus, there was no basis for Petitioner's suggested inference that since Ms. Sabo's 1998 performance had been thoroughly reviewed to

determine if every laboratory had identical PT results, the ALJ should have believed her when she said that the identical results found by AAB were merely a coincidence.
4. Petitioner also reiterated its position that standard level deficiencies alone could not constitute a condition-level violation and that there was no evidence in the record supporting the ALJ's conclusion to the contrary. Petitioner Request for Review at 5. We address this contention in our discussion of FFCL 7.
5. Moreover, while we agree with the ALJ's statement that there may be instances where collaboration is so minimal as not to warrant the imposition of a principal sanction, we do not agree that providing for a mandatory sanction for referral means that there cannot be more than one subsection applicable to activities that undercut the purpose of PT testing.
6. At one point, in consecutive sentences, Petitioner describes Ms. Sabo as both "highly qualified" and "a sloppy or absent-minded technician." Petitioner Br. at 31.

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Physicians Independent Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual,	CV 00-12209 SVW (CWx)
Plaintiffs,	ORDER DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION
vs.	
Donna Shalala, In Her Official Capacity As Secretary Of The United States Department Of Health and Human Services; Wayne Moon, In His official Capacity As Director of CLIA Operations, Health Care Financing Administration; Diana M. Bonta, R.N., Dr. P.H., Director of The California Department of Health Services.	
Defendants.	

I. Introduction

This is an action for preliminary injunctive relief pending an ALJ hearing brought by Plaintiffs, Physicians Independent Laboratory, Inc. ("PIL") and Sahibzada A. Akhtar (hereinafter "Plaintiffs" or “PIL” to require the Secretary of the United States Department of Health and Human Services ("the Secretary") to reverse its prior action that revoked the operating license of Mr. Akhtar's clinical laboratory (its "CLIA certificate") without first complying with the ALJ hearing requirements set forth in 42 C.F.R. 493-1840(d) (2).

Additionally, Plaintiffs ask the Court to order that any monies withheld from Medicare payments previously earned be immediately released to Plaintiffs and that any action to cancel Plaintiffs, approval to receive Medicare payments for services rendered be revoked and reinstated retroactively until such time as Plaintiffs receive a hearing before an ALJ.

Plaintiffs' motion for this Court to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstatement of its medicare reimbursements is denied.

II. Statement of Facts

The California Department of Health Services, Laboratory Field Services (the "State Survey Agency"), acting as the agent of the Secretary, conducted a survey of PIL between August 17, 1999 and December 13, 1999, which identified PIL's violation of nine separate CLIA "Conditions of Participation" and numerous “standard level' CLIA requirements.

Under cover of letter dated January 20, 2000, the State Survey Agency provided PIL with a 334-page report of the documented deficiencies. The subject line of the January 20, 2000 correspondence stated "Condition-Level Deficiencies and Not Immediate Jeopardy." The January 20, 2000 letter asked PIL to submit a “credible allegation of compliance” along with evidence documenting correction. PIL submitted what it believed to be a conforming plan of correction in April of 2000. By letter dated June 21, 2000, the State Survey Agency provided PIL with reasons why the April 2000 plan was not acceptable. A second correction plan, submitted by PIL on July 13, 2000, was also found to be unacceptable. PIL submitted a third correction plan dated July 25, 2000.

The State Survey Agency referred the matter to the Secretary. The Secretary accepted the State's recommendation for sanctions. Accordingly, by notice dated September 22, 2000, the Secretary informed PIL's director and owner that the Secretary was imposing certain sanctions including the suspension of the laboratory's CLIA certificate, effective October 6, 2000, and revocation of the laboratory's CLIA certificate, effective November 20, 2000. The September 22, 2000 notice informed PIL that even if it exercised its right to an ALJ hearing, the Secretary would maintain the CLIA certificate suspension prior to and during the hearing.

The September 22, 2000 notice, informing the Plaintiffs of the license suspension and revocation, stated "due to your failure to comply with reasonable requests for information that is necessary to determine your laboratory's compliance with performance standards set by law and its eligibility for a CLIA certificate of compliance" the suspension and revocation were imposed.

On October 2, 2000, PIL submitted materials directly to the Secretary in support of the laboratory's claim that the previously notice sanctions should not be imposed. The Secretary notified PIL, four days later by letter dated October 6, 2000, that "[w]e have carefully reviewed the materials your laboratory submitted on October 2, 2000 and determined that your laboratory has never come into compliance in correcting the deficiencies cited at the December 13, 1999 survey."

The Secretary notified PIL by letter dated October 17, 2000 that the submission was "entirely unacceptable as it failed to either address the deficiencies cited or to show that the alleged correction plan was every implemented." The sanctions were thereafter imposed in accordance with the schedule set forth in the September 22, 2000 notice, including the October 6, 2000 suspension of PIA's CLIA license.

III. State Defendants

It appears to be uncontroverted that the relief sought by Plaintiffs is within the sole authority of the Secretary. Therefore, for that reason, all state defendants and their agents are dismissed from this action, and the Court need not address the state defendants' Eleventh Amendment concerns.

IV. Jurisdiction Over Federal Defendants

The Secretary argues that this Court has no jurisdiction to issue equitable relief to the Plaintiffs because 42 U.S.C. § 263(a) (k) confers jurisdiction upon the Circuit Court for appeal of final agency action. 42 U.S.C. § 263(a)(k) states, in relevant part: "[a]ny laboratory which ... has had its certificate suspended, revoked, or limited ... may, at any time within 60 days after the date the action of the Secretary … becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principle place of business for judicial review of such action." 42 U.S.C. § 263a(k).

It is uncontroverted that the provision is applicable here, and it is equally clear that, by its language, that its grant of jurisdiction to the circuit court is not exclusive. There is no specific provision for alternative jurisdiction in the district court, although clearly the district court has general subject matter jurisdiction.. The Defendants argue that even though the grant of jurisdiction is not exclusive, the Ninth Circuit in Public Utility Commr. v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) mandates that this court read the permissive language of 42 U.S.C. § 263(a)(k) as conferring exclusive jurisdiction on the circuit court.

In Bonneville Power Administration, the Ninth Circuit held that in a rulemaking proceeding "'where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Public Utility Commr. v. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir., 1985). The Defendants are correct that the Ninth Circuit's holding is applicable even if the grant of jurisdiction to the circuit court is not exclusive. Id. at 625-628. However, the holding of the Ninth Circuit in Bonneville Power Administration is inapplicable here because the suit in this case does "not affect the court's future jurisdiction."

The plaintiff in Bonneville Power Administration challenged the constitutionality of ongoing agency rulemaking proceedings to revise certain rate formulas. Clearly, if the district court had ruled on the constitutionality of rate proceedings in Bonneville Power, the Ninth Circuit court's "future jurisdiction" would be affected in the sense that the Ninth Circuit would adjudicate these matters in an appellate posture and then only if the parties

appealed. Here, this Court is only being asked to grant temporary relief pending the outcome of an administrative proceeding, rather than determine whether a rulemaking proceeding is constitutional. Our relief in this case is confined to requiring the agency to following its own regulations, pending the outcome of an administrative proceeding that the agency failed to properly provide. PIL's appeal from any ALJ ruling would be to the Ninth circuit. Therefore, this Court has jurisdiction to grant plaintiffs a preliminary injunction pending an ALJ hearing.

V. Exhaustion of A,4-inistrative Remedies

In Darby **v.** Cisneros, 509 U.S. 137, 144-146 (1993), the Court explicitly held that federal courts have no authority to require plaintiffs to exhaust administrative remedies prior to seeking judicial review under the APA unless a statute or agency regulation specifically mandates exhaustion as a prerequisite to judicial review. See also, Ciba-Geigy Corp. v. E. P. A., 46 F.3d 1208, 1210 & n. 2 (D.C. Cir. 1995) (summarizing the holding of Darby as "courts cannot require exhaustion of administrative remedies where, as here, it is not expressly required by statute or agency rule").

The Supreme Court in Darby explained that "[a]gencies may avoid the finality of an initial decision, first, by adopting a rule that an agency appeal be taken before judicial review is available, and, second, by providing that the initial decision would be inoperative pending appeal." Darby, 509 U.S. at 137. Clearly, the agency has not provided that its initial decision would be inoperative.

As explained in Darby, "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by agency rule as a prerequisite to judicial review." Defendant argues that 42 U.S.C. § 263(a)(i) and the regulation promulgated in 42 C.F.R. § 493.1844 impose a statutory requirement of exhaustion. The Court disagrees. 42 U.S.C. § 263(a)(i) merely states that "[t]he opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation." 42 C.F.R. § 493.1844(f)(1) states "[a]ny laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its

services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing."

Without argument or citation, Defendants assume that these provisions specifically provide for exhaustion. However, an examination of other statutory provisions demonstrate the Congress was able, when it so desired, to clearly mandate exhaustion. For example, relating specifically to the Department of Agriculture and its agencies, 7 U.S.C. § 6912(e), titled, Exhaustion of Administrative Remedies, provides: "[n]otwithstanding any other provision of law, a person shall exhaust all administrative appeal procedures established by the Secretary or required by law before the person may bring an action in a court of competent jurisdiction against" the agency and its agents. 7 U.S.C. § 6912(e). Here, however, no such statutorily-mandated exhaustion requirement exists and under Darby none can be required by this Court.

VI. Finality of Agency Action

The APA permits "'non-statutory" judicial review only of "final agency action." 5 U.S.C. § 704. See, Bell v. New Jersy, 461 U.S. 773, 778 (1983) (.recognizing "strong presumption" that judicial review will be available only when agency action has become final). In order for agency action to be final, there must be a "direct and immediate impact." Franklin v. Massachusetts, 505 U.S. 788, 796-97 (1992). Two conditions.will satisfy this requirement. First, "the action must mark the consummation of the agency's decision making process ... [and] ... it must not be of a merely tentative or interlocutory nature ... second, the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." Bennett v. Spear, 520 U.S. 154, 177 (1997). Determination of finality of agency action for purposes of APA review is to be made in a pragmatic way. See, Pennzoil Co. v. Federal Energy Regulationry Comm'n, 645 F.2d 394, 399 (5th Cir. 1981).

Defendant has asserted that the revocation of the CLIA certification is not final agency action and that it will only become final agency action upon the exhaustion of administrative remedies.[1] Defendant confuses two analytically distinct doctrines. As the Supreme Court stated in Darby v. Cisneros, 509 U.S. 137, 144 "[T]he finality requirement is concerned with whether the initial decision maker has arrived at a definitive position on the issue that inflicts an actual, concrete injury; the exhaustion requirement generally refers to administrative and judicial procedures by which an injured party may seek review of an adverse decision and obtain a remedy if the decision is found to be.unlawful or otherwise inappropriate." See e.g., Association of National Advertisers v. FTC, 627 F. 2d 1151, 1157 (1980) ("'The jurisdictional difficulty arises out of the requirement of finality, a related

doctrine which also comes into play in this case, and which overlaps the requirement of exhaustion of administrative remedies but is analytically distinct.")

Here, Defendant does not assert that Plaintiff must proceed through an administrative review process. In fact, 42 U.S.C. § 263(a)(k) merely provides that "any laboratory ... may .. petition

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[1.] At oral argument, the Secretary stated chat because the imposition of its various sanctions including the license suspension was not final agency action, neither this court nor the Ninth Circuit could enjoin the agency from suspending plaintiff's license even if a violation of constitutional rights or the agency's own regulators had occurred. This represents a reversal of the Secretary's position taken at oral argument in. their opposition to the plaintiff's motion for a temporary restraining order when the Secretary represented that the action was final and that immediate relief was available from the Ninth Circuit. Either way, the court finds the Secretary's argument incorrect, and believes that this Court has jurisdiction to review the matter.

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for review." If administrative appeals are not mandated the action is final. Darby v. Cisneros, 509 U.S. 137, 137-138 (1993) ("[s]ince neither the National Housing Act nor applicable HUD regulations mandate further administrative appeals, the ALJ's decision was a 'final' agency action.") Therefore, the finality of an action is not affected by the. mere availability of an administrative remedy.

Additionally, from a pragmatic standpoint, the revocation of the CLIA license is final agency action. It is quite clear that the rights of the Plaintiff are dramatically affected by the revocation of its operating license and that the revocation "imposes an obligation, denies a right, or fixes a legal relationship." United States Dep't of Justice v. Fed. Labor Relation Auth., 727 F.2d 481, 493 (5th Cir. 1984). Therefore, the Court finds that revocation of the Plaintiff's CLIA certification was final agency action under the APA.

VII. A Pre-Deprivation Hearing Was Required

It seems clear to the Court, and Defendants do not argue to the contrary in their motions, that the suspension and revocation should have followed rather than proceeded a hearing.

The Code of Federal Regulations state that only in specific instances may an agency revoke a CLIA license prior to a hearing before an ALJ. Section 493-1840(d) states, in relevant part: "'HCFA does not suspend or limit a CLIA certificate until after an ALJ hearing decision that upholds suspension or limitation" except when "(i) The laboratory's deficiencies pose immediate jeopardy; (ii) The laboratory has refused a reasonable request for

information or work on material; (iii) The laboratory has refused permission for HCFA or a HCFA agent to inspect the laboratory or its operations."

It appears, at least from the record presented to the court that none of the sections of section 493.1840(d)(2) apply.

An agency may not rely on after the fact rationalizations to justify its actions. SEC v. Chenery Corp., 332 U.S. 194 (1947). Therefore, the statement submitted in the various declarations on behalf of Plaintiff now claiming that there may be other reasons, including health dangers for the suspension and revocation of the CLIA license, are not considered in our review of the Secretary's decisions.[2] At the time of the decision, the deficiencies cited in the Statement of Deficiencies issued by the State DHS as a result of the on-site inspection survey of the laboratory premises in August 1999 were determined by "State DHS" to be "not immediate jeopardy." Therefore, the Secretary cannot justify its decisions under the first exception by post-hoc submissions alleging potential health related harms.

An agency may "not proffer conclusory statements or unsubstantiated claims in defense of its decisions." National Treasury Employees Union v. Horner, 654 F. Supp. 1159, 1163 (D.C.

[2.] If the Secretary believes that there are genuine health issues and that it merely made a mistake in justifying its suspension and revocation of the license on a different grounds it may resort to 42 U.S.C. § 263(a)(j) which provides for injunctive remedies whenever "the Secretary has reason to believe that the continuation of any activity by a laboratory would constitute a significant hazard to the public health the secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity."

Cir. 1987). Yet the Secretary has done precisely that here. While it claims that "due to [PIA's] failure to comply with reasonable requests for information" the CLIA certificate was suspended, defendants in their submissions to this Court have not produced evidence of a single non-compliance with a request for information. Rather, the record establishes that Plaintiff was very forthcoming with information and that this information was the basis upon which the violations were found.[3]

It is quite clear that the allegation of failure to provide information is conclusory, as it is not mentioned in the Defendants' pleadings, declarations, and any other evidence before this Court. Therefore, the second exception is inapplicable.

Finally, the Secretary does not contest that the third exception is applicable. Because no exception applies, the Code of Federal Regulations required that PIA be granted a hearing prior to the revocation of its license.

VIII. Standard For Preliminary Injunction

The standard for a preliminary injunction balances the plaintiff's likelihood of success against the relative hardship to the parties. Sun Microsystems, Inc. v. Microsoft Corp., 188 F.3d 1115, 1118 (9th Cir. 1999). Generally, to obtain a preliminary injunction, plaintiff is required to demonstrate either: (1) a likelihood of success on the merits and the possibility of

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[3.] Defendants do not contest that over 2,300 pages of documentation responding to the deficiencies were filed. This does not include additional original business records of PIA.

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irreparable injury; or (2) that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor. Id. These two alternatives represent "extremes of a single continuum," rather than two separate tests. Id. (quoting Sega Enters, v. Accolade, Inc., 977 F.2d 1510, 1517 (9th Cir. 1992). Thus, the greater the relative hardship to plaintiff, the less probability of success must be shown. See, National Ctr-. For Immigrants Rights v. INS, 743 F.2d 1365, 1369 (9th Cir. 1984).

a. Irreparable Injury

Plaintiff alleges that, without its operating license, the laboratory will be forced to close, and its employees will have to find other work. Defendants direct our attention to cases holding that a preliminary injunction is an inappropriate remedy where the potential harm to the plaintiff is strictly financial. This is true as general rule, but an exception exists where the potential economic loss is so great as to threaten the existence of the plaintiff's business. See, Wright and Miller, Federal Practice and Procedure: Civil § 294B, Doran v. Salem Inn, Inc., 422 U.S. 922 (1975) (threat of bankruptcy constitutes irreparable harm); John B. Hull, Inc. v. Waterbury Petroleum, 588 E.2d 24 (2nd Cir. 1978), cert. denied, 440 U.S. 960 (1979) (possibility of going out of business is irreparable harm); Tri-State Generation v. Shoshone River-Power, Inc., 805 F.2d 351 (10th Cir. 1986) (threat to trade or business viability is irreparable harm; Milsen Co. v. Southland Corp., 454 F.2d 363 (7th Cir. 1971) (irreparable harm found where, without injunction, movants would lose businesses and their ability to carry on their lawsuit would have been crippled, if not destroyed.) However, Plaintiffs' claim that it is suffering irreparable harm is placed into question by the actions of Plaintiffs' to delay their ALJ hearing. Most recently, Plaintiffs' filed for a sixty day extension of the ALJ hearing previously scheduled for January 22, 2001. Although the Court finds that there is certainly a possibility of irreparable harm here, the Court need not decide this matter because the Plaintiffs have failed to prove a likelihood of success on the merits sufficient to warrant a grant of a preliminary injunction.

b. Likelihood of Success On The Merits Regarding CLIA Revocation

The Secretary makes a number of arguments as to why PIL will not succeed on the merits. First, the secretary argues that exhaustion is required. This argument is addressed and rejected in a previous section. Second, the Secretary argues that because PIA is likely to lose before the ALJ that it has little chance of success on the merits.

Plaintiffs do not allege that they have a high likelihood of retaining their CLIA license after a full hearing on the merits before an ALJ. Rather, Plaintiffs argue that the Court should not look to the probable resolution of the

ALJ hearing to determine likelihood of success on the merits, but rather look to the likelihood that Plaintiffs deserved a hearing prior to suspension and revocation of the CLIA license.

As previously discussed, the Court finds that a hearing was required prior to deprivation of the Plaintiff's CLIA certificate. However, Plaintiff is incorrect in his assertion that, in applying the likelihood of success on the merits standard in the context of preliminary injunctions, as opposed to a claim for other relief, Courts look only to the question of whether proper procedures were provided.

In Wheeler v. Office of the Controller Currency of The United States, 1998 WL 872945 (N.D. Tex. 1998), Plaintiff petitioned a federal district court for review of a Temporary Cease and Desist Order issued by the Office of the Controller of the Currency. Plaintiff sought preliminary and permanent injunctive relief to set aside the OCC's Order. Plaintiff alleged that the OCC was without authority to issue the Order against him, and, therefore, the issuance of the order should be enjoined. The Court found that, in the context of examining the likelihood of success for a preliminary injunction "the issue of whether the OCC had statutory authority to issue the Order is entwined with the issue of whether [Plaintiff] is likely to prevail on the merits of the underlying action." Id. at 6. c.f., D'Amico v. United States Svc. Indus., Inc., 867 F. Supp. 1075, 1088 (D.D.C. 1994) (stating, in dicta, that the "a substantial case or the merits in the underlying proceeding before the "Board" is required to meet the likelihood of success on the merits standard for a preliminary injunction).

Similar to the Plaintiff in wheeler, the Plaintiffs in this case have alleged failure to provide a pre-hearing deprivation is sufficient to grant a preliminary injunction, without regard to the success of the underlying claim. The Court in Wheeler disagreed with that assertion. Plaintiff cites no authority for the proposition that likelihood of success on the merits is to be judged by looking at a procedural matter rather than the substantive underlying issue. Plaintiff has, therefore, failed to meet his burden of proof that he has sufficient likelihood of success on the merits to warrant a grant of a preliminary injunction.

c. Likelihood of Success On The Merits Regarding Medicare Repayments

With regard to Plaintiff's request that this Court reinstate its eligibility to receive Medicare payments, the Court finds that the Plaintiff has not demonstrated that its has a right, either originating from due process or the Code of Federal Regulations, to a hearing prior to revocation of its eligibility to receive Medicare reimbursements.

ix. Conclusion

Therefore, Plaintiffs' motion for preliminary injunction to retroactively restore his CLIA license is denied. Plaintiffs' request that any Medicare monies withheld be released is denied at this time, subject to a supplementation to plaintiff's pleading that demonstrates a right to a hearing prior to the revocation of those benefits.

IT IS SO ORDERED.

DATED: 1/24/2001

STEPHEN V. WILSON

UNITED STATES DISTRICT JUDGE

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT:
Sentinel Medical Laboratories, Inc.,

Petitioner,
DATE: January 26, 2001
- v -

Health Care Financing Administation
Civil Remedies CR679
Docket No. A-2000-92
Decision No. **1762 DECISION**

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Dr. Sol Teitelbaum (Petitioner), the former director of Sentinel Medical Laboratories, Inc. (Sentinel, the laboratory), appealed a June 27, 2000 decision by Administrative Law Judge (ALJ) Edward D. Steinman sustaining the determination of the Health Care Financing Administration (HCFA) prohibiting Dr. Teitelbaum from owning or operating another laboratory for two years, including serving as laboratory director. *Sentinel Medical Laboratories, Inc.*, DAB CR679 (2000) (ALJ Decision). The determination followed the revocation of Sentinel's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as the cancellation of Sentinel's approval to receive Medicare payments for its services. In his decision, the ALJ found that Sentinel had failed to comply with five conditions for certification set forth in the CLIA regulations at 42 C.F.R. Part 493.

On appeal to the Board, Petitioner raised only legal objections to the ALJ Decision. The record in this appeal includes the parties' submissions and the transcript of oral argument conducted by telephone on September 25, 2000, as well as the record before the ALJ. As explained below, we affirm the ALJ Decision.

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CLIA certification of a laboratory is dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. CLIA grants the Secretary of this Department broad enforcement

authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.
The requirements of the statute are implemented in regulations at 42 C.F.R. Part 493. The regulations set forth standards, the specific components of the conditions of certification that a laboratory must meet to achieve compliance with applicable conditions. The regulations confer broad authority on HCFA to assure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. HCFA may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.
In addition to sanctions directed against laboratories, CLIA provides the following with respect to the owners and operators of non-compliant laboratories:

> (3) Ineligibility to own or operate laboratories after revocation.
>
> 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.

42 U.S.C. § 263a(i).
The regulations specifically include the laboratory director as an "operator" of a laboratory, if specified criteria are met. 42 C.F.R. § 493.2. The regulations require that any laboratory conducting moderate or high complexity testing must have a laboratory director who meets specific qualifications and has clear and specific responsibilities. 42 C.F.R. §§ 1403, 1405, 1407. Requirements include being a medical or osteopathic doctor, being certified in pathology and having requisite laboratory supervisory experience and/or training. The laboratory director is designated in the regulations as being --

> responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, [sic] and proficiently and for assuring compliance with the applicable regulations.

42 C.F.R. § 493.1407.
The director's responsibilities also include ensuring that appropriate test methodologies are used, that verification procedures are followed, that proficiency testing is complied with, that appropriate corrective actions are taken as necessary, that the laboratory follows quality control and quality assurance programs, etc. *Id*. The regulations subject to adverse action any laboratory that employs an individual who owned or operated a laboratory that had its CLIA certificate revoked within the previous two years. 42 C.F.R. § 493.1840(a)(8).
A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations incorporate by reference the hearing procedures in subpart D of Part 498 and the request for review provisions in subpart E of Part 498. 42 C.F.R. § 493.1844.

The Board's standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000); Board Guidelines -- Appellate Review of Decisions of Administrative Law Judges in Cases Under CLIA and Related Statutes (http://www.hhs.gov/dab/guidelines/clia.html).

Procedural Background

Laboratory field examiners from the California Department of Health Services, acting as agents for HCFA, began a complaint survey of Sentinel in August 1997. They terminated the survey on December 4, 1997 after Sentinel failed to supply records and other information the inspectors had requested. As a result of the inspectors' findings, HCFA by letter dated February 3, 1998 to Sentinel and its director, Dr. Teitelbaum, found Sentinel out of compliance with seven CLIA conditions of participation, and proposed sanctions including revocation of Sentinel's CLIA certificate, cancellation of its approval to receive Medicare payments, and imposition of a civil money penalty. The letter also notified Petitioner that if Sentinel's CLIA certificate was revoked, he would not be permitted to own or operate a laboratory, including being a laboratory director, for two years from the date of revocation of Sentinel's certificate. ALJ Decision at 3-5.

By letter dated February 7, 1998, Petitioner indicated that Sentinel had voluntarily ceased operations on December 29, 1997. Upon reviewing that letter and other submissions, HCFA decided by letter of February 24, 1998 to impose the sanctions it had outlined three weeks earlier. These included revocation of Sentinel's CLIA certificate, as well as barring any laboratory from hiring Petitioner, without substantial penalty, for two years. The proposed implementation date of these sanctions was April 14, 1998. *Id*.

Both Sentinel and Petitioner filed requests for a hearing and their appeals were consolidated. Subsequently, Sentinel, through one of its owners, Nida Madamba, withdrew its request for a hearing, and revocation of Sentinel's CLIA certificate was effectuated on November 30, 1998. Petitioner continued to pursue a right to a hearing on the two-year prohibition on his owning or operating a clinical laboratory.[(1)] Judge Steinman convened a hearing from November 30 through December 3, 1998. Before and during the hearing, HCFA objected to permitting Petitioner to proceed with his appeal, contending that a laboratory director had no separate standing, without the inclusion of the laboratory itself, to appeal the sanctions imposed on the laboratory or the two-year prohibition on his owning or operating another laboratory. Judge Steinman overruled HCFA's objections. *Id.* at 6-7.

In his decision, the ALJ rejected Petitioner's principal argument, that even though he was unquestionably Sentinel's laboratory director, he should not be held liable for Sentinel's deficiencies because he was only an employee of Sentinel, without authority to take or order actions necessary to bring the laboratory into compliance with CLIA standards. Pointing out that Petitioner was the laboratory director for three, possibly four, other CLIA laboratories and "knew or should have known what his obligations were," the ALJ found that if Petitioner was unable to perform his functions as a laboratory director, he should have resigned. *Id.* at 9-10. The ALJ rejected as self-serving Petitioner's testimony that he stayed on the job due to his obligation to the patients Sentinel served, in the face of his admission that he was aware of numerous questionable practices by the laboratory. *Id*.

The ALJ went on to dismiss Petitioner's arguments concerning the unconstitutionality of the CLIA regulations, rejecting his claims that they were vague, violated his right to due process, were "shocking and oppressive," and were applied in a discriminatory fashion. *Id.* at 10-13. The ALJ found that Petitioner's rights and duties under the regulations were clearly described, that he was being accorded full due process, that a two-year prohibition on his owning or operating another laboratory for his failure to perform his required duties was appropriate and in no way shocking or oppressive, and that there was no evidence that the sanctions were being applied in a discriminatory fashion. *Id.* at 8-13, 24.

The ALJ also rejected several contentions raised by Petitioner concerning the alleged failure to follow survey procedures, failure to receive adequate notice and other due process contentions. The ALJ also rejected the contention that since Sentinel ceased operations in December 1997, HCFA was precluded from imposing sanctions against either Sentinel or Petitioner. *Id.* at 24-30.

Regarding the substance of HCFA's deficiency findings, which were generally not contested during the hearing, the ALJ found that Sentinel was out of compliance with the CLIA conditions of participation for patient test management, general quality control, quality assurance, and the conditions for its laboratory director and for successful participation in proficiency testing.[(2)] The ALJ found that HCFA through extensive evidence demonstrated that Sentinel had failed to comply with CLIA conditions of participation, and that HCFA's evidence showed a pattern of noncompliance that was pervasive in scope and presented potential risks to patient health and safety. *Id.* at 13.

The ALJ Decision indicates that HCFA revoked Sentinel's CLIA certificate because of serious deficiencies in its operations that posed immediate jeopardy to the health and safety of the patients whose specimens it was paid to test. *Id.* at 6. Among its violations, Sentinel failed to demonstrate that it was capable of conducting accurate tests of human specimens, performed additional tests not requested by the physicians, and performed tests based on test requisitions from fictitious addresses. *Id.* at 17, n.18. Over 90 percent of patient records that the state surveyors examined showed that Sentinel had received an insufficient quantity of a patient's specimen to perform the requested tests. *Id.* at 16. Sentinel had no quality assurance program in place, as required by the CLIA regulations, and its staff were unable to produce any preventive maintenance protocols or documentation that it performed preventive maintenance on laboratory equipment. ALJ Decision at 20, 21. The evidence before the ALJ also showed that Sentinel was receiving questionable specimens from individuals for the purpose of allowing the laboratory to bill either Medicare or Medicaid for testing such specimens, and that these individuals received kickbacks from the laboratory. *Id.* at 9.

The ALJ's recitation of the evidence, which Petitioner did not dispute, also demonstrates that these deficiencies were not isolated occurrences but ongoing problems that Sentinel failed to correct despite ample notice via repeated requests for information from the state survey agency following its initial complaint survey of Sentinel in August 1997. Sentinel's failure to respond to these requests led the state survey agency to terminate its survey of Sentinel on December 4, 1997. Petitioner himself failed to respond to a December 27, 1997 letter to him from the survey team leader providing Sentinel one more chance to supply the needed documentation, and informing Petitioner that failure to supply the requested information by December 29, 1997, would

result in an action to suspend or revoke Sentinel's CLIA certificate. Despite these warnings, there was no evidence that the laboratory ever took any action to correct the identified deficiencies. *Id.* at 4-5.

The ALJ also noted that Petitioner was Sentinel's laboratory director during this entire period; as such, he bore primary responsibility for the overall operation and administration of the laboratory and for assuring compliance with the applicable regulations. *Id.* at 8-10, *citing* 42 C.F.R. § 493.1407.[(3)]

The ALJ Decision indicates that Petitioner did not fulfill his mandated responsibilities. Petitioner did not dispute the ALJ's finding that he took little action to discharge his duties (but continued to collect his paycheck), even in the face of growing evidence of the problems at Sentinel. *Id.* at 13. Nor did Petitioner take issue with the ALJ's observation that it was "difficult to imagine that Petitioner was exercising any of his CLIA responsibilities," given how widespread Sentinel's deficiencies were. *Id*. Petitioner also admitted to being aware that Sentinel was paying kickbacks to individuals who provided questionable specimens for the purpose of allowing the laboratory to bill Medicare or Medicaid for testing such specimens. *Id.* at 9.

The ALJ thus sustained HCFA's imposition of the two-year ban on Petitioner owning or operating another laboratory, effective on the date of the ALJ Decision, June 27, 2000.

ANALYSIS

Before the Board, Petitioner did not dispute the existence of numerous, serious deficiencies at Sentinel justifying the revocation of its CLIA certificate.[(4)] Petitioner made no effort to rebut what the ALJ described as extensive evidence of a pattern of noncompliance with CLIA requirements that was pervasive in scope and presented potential risks to patient health and safety. ALJ Decision at 13. Nor did Petitioner dispute that he had failed to fulfill his assigned responsibilities as Sentinel's laboratory director.

Instead, Petitioner attacked the constitutionality of the CLIA provisions and argued that the effectiveness of the two-year ban on his owning or operating another laboratory should be stayed until his appeal has been heard in federal court. Petitioner's arguments may be summarized as follows:

- The CLIA statute and regulation authorizing HCFA to bar the director of a sanctioned laboratory from directing any other clinical laboratory for two years are unconstitutional when applied to an employee laboratory director who is not the owner of the sanctioned laboratory. Barring him from his livelihood for two years based on Sentinel's CLIA deficiencies was shocking and oppressive for violating the principle of respondeat superior which, Petitioner argued, forbids holding an employee liable for the acts of his employer. Petitioner argued that, as Sentinel's employee, he was powerless to effect changes needed to correct Sentinel's deficiencies and comply with CLIA standards. He argued that the regulation as applied to him was unconstitutionally vague for failing to identify what actions an employee laboratory director must take if he is unable to force his employer to comply with CLIA standards.

- HCFA may not impose the sanction against him until he has received a hearing on his constitutional arguments. Because the ALJ concluded that he was not authorized to declare the CLIA regulations unconstitutional, the ALJ should have "recused" himself from the case and remanded it to federal court, the body authorized to overrule the statute or regulations on constitutional grounds. Petitioner's Brief (Br.) at 5. Petitioner further argued that, if the Board concludes that it, like the ALJ, is not authorized to declare the CLIA statute and regulations unconstitutional, then the Board should stay HCFA's action against him, so that he may argue his case in federal court.

As discussed below, we conclude that we are not empowered to declare the CLIA statute or regulations unconstitutional. However, we address Petitioner's arguments to the extent they suggest that HCFA applied otherwise valid provisions in an unconstitutional manner. We then go on to briefly address Petitioner's attacks on the validity of the CLIA provisions, arguments which Petitioner characterized as based on the Constitution; we agree with the ALJ's determination that they are without merit. Finally, we sustain the ALJ's finding regarding the timing of the two-year period during which a laboratory may not be certified if it hires Petitioner as its laboratory director.

1. *The ALJ and the Board are not authorized to declare the CLIA statute and regulations unconstitutional.*

It is well established that administrative forums, such as this Board and the Department's ALJs, do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional. A legislative rule is binding on the agency that issues it. 1 Kenneth Culp Davis and Richard J. Pierce, Jr., *Administrative Law Treatise*, § 6.5 (3rd ed. 1994), citing *U.S. v. Nixon*, 418 U.S. 683 (1974) (where the court noted that the executive branch was bound by the terms of a regulation it had issued, even though it was within its power to change that regulation). Federal courts have refused "to recognize in administrative officers any inherent power to nullify legislative [or executive] enactments because of personal belief that they contravene the [C]onstitution." *Gibas v. Saginaw Mining Co.*, 748 F.2d 1112, at 1117 (6th Cir. 1984) (citation omitted). Thus, courts have noted that challenges to the constitutionality of an agency regulation lie outside the cognizance of that agency, and that generally, an ALJ is bound by the regulations promulgated by his administrative agency. *Howard v. FAA*, 17 F.3d 1213, 1218 (9th Cir. 1994); *Stieberger v. Heckler*, 615 F.Supp. 1315, 1386 (S.D.N.Y. 1985), *citing D'Amico v. Schweiker*, 698 F.2d 903 (7th Cir. 1983). Challenges to the constitutionality of a statute or a regulation promulgated by an agency are generally beyond the power or the jurisdiction of an agency. *Gilbert v. National Transportation Safety Board*, 80 F.3d 364, at 366-67 (9th Cir. 1996); *Howard v. FAA*, *supra*. Accordingly, this Board (like the ALJ) has no authority to reverse the action against Petitioner on the basis that the CLIA statute or regulations are unconstitutional.

2. *Petitioner was required to exhaust his administrative remedies.*

The absence of authority to invalidate the CLIA regulations, however, did not require the ALJ to terminate proceedings so that Petitioner could take his appeal to federal court for review of his constitutional arguments. The Supreme Court has held that, when a constitutional challenge is made in an enforcement action, the doctrine of exhaustion of

administrative remedies requires that the administrative agency resolve all matters within its domain before the matter may be taken to federal court to proceed with any constitutional challenge. "The basic purpose of the exhaustion doctrine is to allow an administrative agency to perform functions within its special competence--to make a factual record, to apply its expertise, and to correct its own errors so as to moot judicial controversies." *Parisi v. Davidson*, 405 U.S. 34, 37 (1972) (citations omitted).

We reject the notion, raised by Petitioner, that the ALJ erred by following this long-established doctrine. We note that a federal district court has already declined to hear Petitioner's constitutional arguments during pendency of the ALJ proceeding. *Sol Teitelbaum, M.D. v. U.S. Dept. of Health and Human Services*, Ruling Granting Defendant's Motion to Dismiss; Denying Plaintiff's Motion for Summary Judgment as Moot; and Dismissing Action with Prejudice for Lack of Jurisdiction, SA CV 99-1040 (C.D. Cal. April 12, 2000). The court stated that the judicial review provision of 42 U.S.C. § 263a(k) is not triggered until exhaustion of the administrative review process. The court also found that Petitioner's "'constitutional' claims do not operate to trump or 'short circuit' what [Petitioner] may regard as an unfavorable administrative process." *Id.* at 2.

The statute cited by the court, 42 U.S.C. § 263a(k), provides for the federal court of appeals to review "final" agency decisions imposing CLIA sanctions. The CLIA regulations provide that revocation of a CLIA certificate (including revocation based on the laboratory's owner or operator having owned or operated a laboratory that had its CLIA certificate revoked during the preceding two years) is an initial determination, which (if appealed) becomes final only after being upheld by the ALJ and then (if further appealed) by the Board. 42 C.F.R. § 493.1844(a), (d)(4).[(5)]

3. *Petitioner was not denied due process*.

Although we do not have the power to declare a statute or regulation unconstitutional, we must, by necessity, evaluate some aspects of a claim of unconstitutionality to the extent it challenges the manner in which HCFA has interpreted or applied a regulation. Petitioner contended that the CLIA regulations as "applied to him as an employee laboratory director . . . are unconstitutional because they do not meet the standard of definiteness, they are vague, they are shocking, oppressive and violate due process . . . and they are not applied equally to all other employees of the laboratory." Petitioner's Br. at 7. The regulations are vague, Petitioner argued, for failing to identify what actions he could take to force his employer to comply with CLIA standards. Petitioner also argued that he was denied notice and an opportunity to be heard because the ALJ did not have authority to overrule the CLIA statute and regulations on the basis of Petitioner's constitutional challenges.

We find no merit in Petitioner's arguments. First, Petitioner has received ample due process from the Department. He received timely and adequate notice of the charges at issue; HCFA's challenge to his request for a hearing was rejected by the ALJ;[(6)] and he was given a full opportunity to present relevant evidence as well as to contest HCFA's evidence at an extensive hearing, during which he was represented by the person of his choosing. He thus has received notice and an opportunity to be heard as required by the Supreme Court case that Petitioner cited, *Garfield v. U.S. ex. rel. Goldsby*, 211 U.S. 249 (1908). Moreover, as we discussed above, Petitioner was not entitled to take his

claims to federal court before completing the administrative appeal process before the ALJ and this Board.

We also sustain the ALJ's determination that Petitioner's rights and duties were clearly spelled out. The regulations clearly list the responsibilities of the laboratory director, including assuring compliance with applicable regulations. Moreover, the statute and regulations put Petitioner on notice that failure to discharge his responsibilities could result in his being barred from directing CLIA laboratories for a period of two years. As the ALJ noted, rather than continue to tolerate the existence of CLIA deficiencies, Petitioner could have resigned as laboratory director. His resignation might have left Sentinel unable to continue operations, as the CLIA regulations require that the laboratory have a qualified laboratory director as a condition of the CLIA certificate. Petitioner's assertion that HCFA could have or would have held him responsible for Sentinel's deficiencies even if he had resigned (Tr. at 44-45) was pure conjecture, and nothing in the record indicates that such a concern informed Petitioner's decision to remain at Sentinel.

4. *Petitioner's reliance on the principle of respondeat superior is without merit.*

Petitioner's principal argument was that the CLIA regulations are unconstitutional because they violate the principle of respondeat superior by holding an employee laboratory director liable for the actions of his employer laboratory. Petitioner described respondeat superior as the "law of the land," arguing that Congress could not have intended to violate such established law and that any regulations which did were therefore unconstitutionally shocking. Petitioner's Br. at 7. He also argued that barring him from his chosen profession for two years was unconstitutionally oppressive. However, the principle of respondeat superior is inapplicable here and provides no basis for reversing the CLIA action against Petitioner.

Respondeat superior is a common law doctrine "whereby a master is liable for his servant's torts committed in the course and scope of his employment." *Burger Chef Systems, Inc. v. Govro*, 407 F.2d 921, 925 (8th Cir. 1969), *citing* Restatement of Agency, § 219. However, it is not a doctrine intended to protect employees. The authority for HCFA's action here springs not from common law tort principles, but from an act of Congress that specifically applies to the operator, as distinguished from the owner, of a CLIA laboratory. 42 U.S.C. § 263a(i). The statute does not hold the operator liable for damages, as in a tort action, but simply precludes eligibility to be the owner or operator of a laboratory for a period of time, where the owner or operator has proven himself untrustworthy or incompetent in the past. This is a remedial action intended to protect the public health. Congress's disjunctive use of the terms "owned" and "operated" in the section providing for the two-year ban clearly means that the operator of the laboratory may be someone other than the owner. HCFA was thus reasonable in including laboratory director within the regulatory definition of "operator," where the laboratory director oversees all facets of the operation of a laboratory and bears primary responsibility for the safety and reliability of the results of all specimen testing performed in the laboratory. 42 C.F.R. §§ 493.2, 493.1407.

The evidence before the ALJ does not support Petitioner's contention that he was a mere victim of the machinations of Sentinel's owners. Petitioner did not dispute the ALJ's finding that he failed to fulfill his responsibilities specified in the CLIA regulations, including responsibility for assuring compliance with applicable regulations. One of

HCFA's deficiency findings supporting revocation of Sentinel's CLIA certificate was that Sentinel failed to comply with the condition of participation for its laboratory director, Petitioner himself. Petitioner did not take issue with the ALJ's observation that in light of the widespread violations at Sentinel, of which Petitioner was aware, it was difficult to imagine that Petitioner was exercising any of his CLIA responsibilities. ALJ Decision at 9, 13. During 1997, which included the period during which Sentinel was being surveyed, Petitioner, who was also the laboratory director of three or four other clinical laboratories, visited Sentinel on an average of only two to three times per month through March, after which he visited the laboratory from five to six times per month and then, in the latter part of the year, up to ten times per month. ALJ Decision at 8, n.9. Thus, we question whether respondeat superior would in any circumstances offer Petitioner any relief, since the evidence suggests that Petitioner himself contributed to Sentinel's CLIA deficiencies, by not exercising the necessary oversight mandated by the regulations.

Additionally, the principle of respondeat superior, even if it were applicable, would offer no sanctuary to Petitioner in the face of a federal statute specifically providing a remedy affecting persons other than a laboratory's owners. Courts have held that congressional enactments can take precedence over principles of common law, including the principle of respondeat superior. *Price v. Westmoreland*, 727 F.2d 494 (5th Cir. 1984). The Supreme Court has stated that "the power of Congress to change the common-law rule is not to be doubted." *United States v. A & P Trucking Co.*, 358 U.S. 121, at 124 (1958).[(7)] Petitioner's argument that Congress could not have intended to hold non-owners responsible for a laboratory's deficiencies flies in the face of the plain language of the CLIA statute. Petitioner did not cite any legislative history to support this contention, and furthermore offered no evidence to document his claim that at the time that Congress passed CLIA, it was unusual for laboratory directors not to be owners of the laboratories they operated.

5. *The timing of the action against Petitioner was appropriate.*

HCFA's action against Petitioner became effective upon issuance of the ALJ Decision; shortly thereafter, HCFA contacted other laboratories that employed Petitioner as laboratory director and warned them that their CLIA certificates would be revoked if they continued to employ Petitioner as their laboratory director. Tr. at 29. Petitioner argued that HCFA could not take action against him until HCFA's action had been upheld in federal court, the only body authorized to declare the CLIA statute and regulations invalid on constitutional grounds.

The CLIA regulations provide that suspension, limitation or revocation of a CLIA certificate "is not effective until after a hearing decision by an ALJ is issued." 42 C.F.R. § 493.1844(d)(2).[(8)] The clear meaning of this provision is that, where a petitioner has requested an ALJ hearing, HCFA's action becomes effective upon issuance of an ALJ decision upholding that action. Because the same regulation also provides for the right to appeal an ALJ decision to the Board, the only reasonable reading of the regulation as a whole is that HCFA's action under CLIA, once upheld by an ALJ, is not postponed or stayed by further appeal to the Board. Accordingly, the ALJ did not commit an abuse of discretion, as Petitioner argued, by providing for the CLIA action to become effective upon issuance of his decision.

Permitting HCFA's action to take effect without delay upon issuance of the ALJ Decision is consistent with CLIA's purpose of ensuring the health and safety of persons undergoing laboratory tests. As HCFA noted in the preamble to the CLIA regulations, undue delay in the imposition of CLIA sanctions could mean further risk to the health and safety of the patients the laboratory serves and, in some instances, risk to the health of the general public. 57 *Fed*. *Reg*. 7224-25 (February 28, 1992).

During the oral argument, Petitioner cited provisions of the Administrative Procedure Act (APA) and the Federal Rules of Appellate Procedure (FRAP) in support of his argument that HCFA was without authority to take action against Petitioner upon issuance of the ALJ Decision. This action, however, is governed by the specific provisions of the CLIA regulations intended to govern CLIA actions, rather than by the more general provisions cited by Petitioner. Additionally, the cited provisions by their terms do not appear to be applicable here.

Petitioner relied on the APA, at 5 U.S.C. § 704, which provides that an agency may provide that its action is inoperative pending an appeal to a superior agency authority (such as this Board).[(9)] Tr. at 21. Here, however, the applicable regulations provide that HCFA's action is not rendered inoperative by an appeal to the Board. Moreover, the subsequent section of the APA, 5 U.S.C. § 705, which Petitioner did not cite, states that an agency *may* postpone the effective date of its action pending judicial review (which this agency has chosen not to do), which clearly means that an agency is not *required* to postpone enforcement of sanctions pending judicial review.

Petitioner also cited 28 U.S.C. §§ 2112 and 1296 and FRAP 15(b) during the oral argument. Section 2112(4) authorizes federal courts to stay the effective date of an agency order. That has not happened here, and, Petitioner's attempt to seek relief from HCFA's action was rejected by a federal court because Petitioner had not exhausted his administrative remedies. Section 1296 provides that the U.S. Court of Appeals for the Federal Circuit shall have jurisdiction "over a final decision under chapter 5 of title 3 . . . of an appropriate agency (as determined under section 454 of title 3)." Petitioner did not explain how this provision, even if applicable, could be interpreted to delay HCFA's action here. And finally, FRAP 15(b)(1) states that "application to enforce an agency order must be filed with the clerk of a court of appeals authorized to enforce the order." The language of FRAP Rule 15 as a whole makes clear that "applicants" filing such applications are not federal agencies but rather individuals affected by agency action, and that the federal agencies are deemed respondents who may file a response to such applications. This rule thus addresses non-agency parties who seek to enforce agency orders. It does not require that HCFA go to court in order to effectuate a determination that has already been upheld by an ALJ.

Petitioner's theory, that imposition of the statutory two-year prohibition on his owning or operating a laboratory must be stayed until a federal court has rejected his constitutional challenges, would enable clinical laboratories and laboratory directors (as well as health care providers facing exclusion from the Medicare and Medicaid programs) to delay for long periods of time the imposition of sanctions merely by raising constitutional claims beyond the authority of the Board. This is an absurd result which would thwart Congress's intent in passing CLIA of ensuring the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. Enforcing CLIA

sanctions upon issuance of the ALJ decision upholding those sanctions is consistent with the concern expressed by Congress in enacting CLIA. The Committee on Energy and Commerce stated that it was "concerned about cases remaining in litigation for months or years while substantial violations remain uncorrected." H.R. Rep. No. 899, 100th Cong. 2d Sess. 33 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3854.

Conclusion

For the reasons discussed above, we uphold the ALJ Decision. We affirm and adopt each of the ALJ's findings of fact and conclusions of law.

JUDGE

Judith A. Ballard
M. Terry Johnson
Marc R. Hillson
Presiding Board Member

FOOTNOTES

1. The ALJ opted to keep Sentinel as the captioned petitioner rather than substituting Petitioner.

2. The ALJ found that HCFA's evidence of these five deficiencies also supported HCFA's determination that Sentinel failed to comply with two additional conditions, the conditions for testing personnel in laboratories performing moderate complexity testing, and for inspection of laboratories requesting or issued a certificate of compliance. However, the ALJ did not discuss these findings in detail. ALJ Decision at 14, n.15.

3. By regulation, Petitioner's responsibilities at Sentinel included: overseeing proficiency testing and taking any corrective action necessary to address Sentinel's failure to pass proficiency tests; the establishment and maintenance of Sentinel's quality control and quality assurance programs (which the ALJ found were non-existent at Sentinel); and the employment of personnel competent to perform their duties. 42 C.F.R. § 493.1407. To the extent Petitioner delegated any of his duties to others, he remained responsible for ensuring that all of those duties were properly performed. 42 C.F.R. § 493.1407(b).

4. During the oral argument, Petitioner suggested that the problems at the laboratory were not as bad as argued by HCFA in its briefs, because HCFA had not sought a court order to close the laboratory immediately, as permitted by the CLIA statute and regulations. Transcript (Tr.) at 42-43. However, Petitioner did not specifically dispute any of the ALJ's factual findings concerning Sentinel's deficiencies.

5. As we explain later in this decision, HCFA's determination, while not final for purposes of judicial review prior to completion of the administrative appeals process, was effective upon issuance of the ALJ Decision.

6. HCFA contended before the ALJ that a laboratory director has no independent right to a hearing under the CLIA regulations, and argued that because Sentinel withdrew its challenge to the imposition of sanctions, Petitioner had to accept the two-year prohibition against him owning or operating a laboratory. The ALJ found that this would be a violation of Petitioner's right to due process, since he would be barred from the right to employment in his chosen field for two years without any recourse as regards challenging HCFA's findings. ALJ Decision at 6. The Department's ALJs have consistently ruled that a laboratory director has an independent right to a hearing, and HCFA wisely did not make this argument before the Board. *See Carlos A. Cervera,*

M.D., Docket No. C-99-797, Ruling Denying HCFA's Motion to Dismiss and Granting Extension of Time for Submission of Readiness Reports, December 21, 1999 (attached); *Allstate Medical Laboratory, Inc.*, Docket No. C-99-309, Ruling, October 6, 1999 (attached); and *Eugene R. Pocock, M.D.*, DAB CR527, at 5 (1998). We note that CLIA requires that HCFA, prior to taking action to revoke a laboratory's CLIA certificate, must offer the opportunity for a hearing to the laboratory's owner or operator, which includes the laboratory director. 42 U.S.C. § 263a(i)(1); 42 C.F.R. § 493.2.

7. In this respect, the federal court decision that Petitioner cited is not applicable here. *Jackson Marine Corp. v. Blue Fox*, 845 F.2d 1307, at 1310 (5th Cir. 1988) ("Although established rules of respondeat superior operate to impute fault up the employment hierarchy, these rules do not operate in the inverse to impute fault down the employment hierarchy."). That case involved application of this common law doctrine to resolve an issue that arose under other common law principles, the principles of maritime law. *Jackson Marine Corp.* provides no authority to conclude that Congress may not impose remedies against persons other than the owner of a laboratory.

8. In cases involving lesser, or alternative, sanctions (other than civil monetary penalties), and sanctions in situations posing immediate jeopardy, the imposition of sanctions on a laboratory is *not* delayed because the laboratory has appealed and the hearing or the hearing decision is pending. 42 C.F.R. § 493.1844(d)(1), (2)(ii).

9. 5 U.S.C. § 704 provides:

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

ATTACHMENT I:

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Departmental Appeals Board
Civil Remedies Division
Docket No. C-99-797

Date: Dec 21, 1999

In the Case Of: Carlos A. Cervera, M.D.,
Director, San Fernando Diagonostic Laboratory, Inc.
Petitioner
V.
Health Care Financing Administration.

RULING DENYING HCFA'S MOTION TO DISMISS AND GRANTING EXTENSION OF TIME FOR SUBMISSION OF READINESS REPORTS

In its motion, dated December 3, 1999, HCF contends that Dr. Cervera does not have the right to an appeal in a matter involving sanctions taken by HCF under the Clinical Laboratory Improvement, Amendments of 1988 (CLIA), against San Fernando Diagnostic Laboratory, Inc. HCF persists in its contention even though the letter imposing sanctions against the laboratory, dated June 17, 1999, was addressed to Dr. Cervera, and even though the sanctions proposed included a two year ban on his owning or directing a laboratory.

On August 1.0, 1999, Dr. Cervera appealed the HCF determination, and asked that his letter be considered a request for a hearing. Dr. Cervera essentially argued that he never acted as Director of the laboratory in question, that to his knowledge the laboratory never opened, and that he did not have a contract with the laboratory, among other statements in his letter.

The issues raised by this motion have been fully addressed by Judge Steinman in his order in *Allstate Medical Laboratory, Inc,* Docket No. C-99-309, October 6, 1999. (Copy attached). I adopt Judge Steinman's rationale in *Allstate.* In particular, I find that Dr. Cervera is an "affected party" within the meaning of 42 C.F.R. § 498.2, and that to cite Dr. Cervera as laboratory director and prohibit him from owning or operating a laboratory for two years, while at the same time denying him the same right to a hearing that the laboratory has raises significant issues of fairness and due process. Accordingly, HCF's motion is denied.

The parties are instructed to promptly submit the report of readiness to present evidence as per my September 30, 1999 Order in this case. Since recent correspondence has demonstrated that the parties are having some difficulties regarding communicating with each other I will extend the date of filing this report to **January 10, 2000.** L will set up a prehearing conference in this matter during the week of **January 24, 2000.**

It is so ordered.

Marc R. Hillson
Administrative Law Judge

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ATTACHMENT II:
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Departmental Appeals Board
Civil Remedies Division
In the Case of: Allstate Medical Laboratory, Inc.,
Petitioner,
v.
Health Care Financing Administration.
Docket No. C-99-309
DATE: October 6, 1999

RULING

The purpose of this ruling is to decide whether Pantaleon de Jesus, M.D., the director of Allstate Medical Laboratory, Inc., has a right to a hearing and, if so, the scope of that hearing right.

Forr the reasons set forth below, I have determined that Dr. de Jesus has a right to a hearing, which flows from the sanctions imposed by HCFA against Allstate Medical Laboratory, Inc. (Allstate). Accordingly, I deny HCFA's Motion to Dismiss.

Backqround

In a January 8, 1999 letter (Notice), HCFA informed Dr. de Jesus and Allstate that because it had not received any response from de Jesus as to why certain proposed sanctions should not be imposed, it was imposing the following sanctions as proposed in earlier letter dated December 23, 1998 [see footnote 1 below].

(1) a directed Plan of Correction of cease testing effective December 28, 1998, and submission of a client list of all clients since February 20, 1998;

(2) a civil money penalty of $10,000 per day for December 28 through December 30, 1998 for a total of $30,000;

(3) suspension of the laboratory's CLIA certificate and cancellation of Medicare and Medicaid payments effective December 31, 1998; and

(4) revocation of the laboratory's CLIA certificate effective February 21, 1999.

HCFA informed Dr. de Jesus further that, upon revocation of the laboratory's CLIA certificate, he would be prohibited from owning, operating, or directing a laboratory for at least two years from the date of the revocation. HCFA noted that Dr. de Jesus was currently directing five other laboratories besides Allstate, which was in itself a violation of the CLIA regulations.

Dr. de Jesus filed a request for hearing dated February 11, 1999 [see footnote 2 below]. His letter did not make any reference to the January 8, 1999 Notice letter sent by HCFA to Allstate, but stated at the end that it was a "formal request for a hearing on HCFA's actions affecting Dr. de Jesus." In his letter, Dr. de Jesus asserted, among other things, that "he [was] not responsible for the deficiencies listed in the survey report."

HCFA filed a motion to dismiss Dr. de Jesus, hearing request. In the alternative, and in accordance with numbered paragraph 2.D. of my June 18, 1999 Order, HCFA also filed its report of readiness to present evidence for adjudication of the case. Dr. de Jesus filed a response brief in which he opposed HCFA's motion.

The Parties' Positions

HCFA asserts that, under the CLIA statute and the regulations, Dr. de Jesus as an individual and in his capacity as the laboratory director is not a proper party to contest any of the sanctions imposed against the laboratory and does not otherwise have any right to a hearing to challenge the two-year prohibition against his owning or operating a laboratory. HCFA argues that only the laboratory is a proper party to challenge the sanctions imposed by HCFA. In response, Dr. de Jesus argues that he is an "affected party" under 42 C.F.R. § 498.2 and has the right to a hearing, which right flows from the sanctions imposed by HCFA against the laboratory. Dr. de Jesus relies on *Eugene R. Pocock, M.D.*, DAB CR527 (1998) to support his contention that a person who is alleged to be an "operator" of a laboratory under the regulations has a direct right to appeal the prohibition against owning or operating (or directing) a laboratory for at least two years, resulting from a CLIA revocation.

DISCUSSION

I have considered the arguments of the parties and the applicable statutory and regulatory provisions. My analysis begins with an examination of HCFA's Notice dated January 8, 1999. HCFA's Notice is addressed to "Pantaleon De Jesus, M.D., Director" and "Allstate Medical Laboratory, Inc." Thus, on its face, the Notice names Dr. de Jesus as one of the addressees, and refers to him in his capacity as the laboratory director. The principal sanction affecting Dr. de Jesus as an individual is that he is now prohibited from owning or operating (or directing) a laboratory for at least two years from the date of Allstate's CLIA certificate revocation, which became effective February 21, 1999. Dr. de Jesus' ability to have any meaningful involvement with any other laboratory as a director is now effectively suspended for a two-year period.

In its brief, HCFA recognizes that under 42 U.S.C. § 263a(i)(1), reasonable notice and opportunity for hearing must be given to the owner or operator of the laboratory before a laboratory's certificate may be suspended, revoked, or limited. HCFA contends, however, that the statute does not give any hearing rights to laboratory owners and operators who become prohibited from owning or operating other laboratories for two years following a CLIA certificate revocation. See 42 U.S.C. 263a(i)(3). HCFA asserts that only laboratories have been afforded hearing rights under-the CLIA statute and regulations.

In light of my analysis in *Pocock*, I find that HCFA's assertion that only laboratories are the proper parties to request a hearing to challenge HCFA's sanctions is without merit. The fact that the statutory provision at 42 U.S.C. § 263a(i)(1) references the laboratory's owner or operator signifies that these individuals have standing and would be parties in interest in proceedings which affect a laboratory's CLIA certificate. Simply put, in an administrative proceeding such as the one before me, a laboratory is merely a legal entity. For this reason, a laboratory and its owner and operator are essentially one and the same for purposes of contesting any adverse actions initiated by HCFA. A laboratory's owner and/or operator are the only individuals who could possibly represent its interests. Accordingly, I conclude that a laboratory, its owner, and its operator, all have equal standing and all possess a right to be heard on sanctions imposed by HCFA against the laboratory. I conclude further that a laboratory owner or operator has a right to a hearing to challenge the mandatory two-year prohibition against owning or operating a laboratory, as set forth in 42 U.S.C. § 263a(i)(3).

Moreover, I disagree with HCFA's argument that Dr. de Jesus is not an "affected party" within the meaning of 42 C.F.R. § 498.2. The regulation at 42 C.F.R. 498.2 defines the term "affected party" as follows:

. . . a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part . . . .

Because Dr. de Jesus is a physician, there can be no dispute that he is also a "practitioner." HCFA's determination to impose sanctions against Allstate adversely affects Dr. de Jesus' rights since, as a result, he will be prohibited for two years from owning or operating a laboratory. Thus, due to HCFA's sanctions, Dr. de Jesus can be characterized as a "practitioner that is affected by an initial determination issued under this part," and therefore falls within the definition of "affected party" under 42 C.F.R. § 498.2. Because Dr. de Jesus is an "affected party," he is entitled to a hearing under 42 C.F.R. §§ 498.40 and 498.42.

It is nonsensical to state that when the statute and the regulations refer to adverse actions taken against the "laboratory", that no individual has a right to a hearing. HCFA's attempt to "play down" the role of a laboratory's owner or operator in the context of appealing adverse actions is contrary to what is reasonable or fair. A laboratory's owner and operator play essential roles in the functioning and conduct of the laboratory. To exclude a laboratory's owner and operator from having hearing rights would cause an outcome that is unacceptable and raises questions of fairness and due process. The regulation at 42 C.F.R. § 493.2 defines the term "operator" to include "[a] director of the laboratory if he or she meets the stated criteria." HCFA, in its Notice, has named Dr. de Jesus, indicating that he is the director of the laboratory. Were I to accept HCFA's position that Dr. de Jesus, as Allstate's director, is not a proper party and is without any right to a hearing, he would be precluded from asserting in these proceedings that he is not an "operator," as that term is defined in the regulations.

In conclusion, as I interpret 42 C.F.R. § 498.2, Dr. de Jesus has the status of an "affected party" and therefore, has a right to a hearing under 42 C.F.R. § 498.40. The scope of Dr. de Jesus's hearing right encompasses the following issues:

1) whether or not Dr. de Jesus is an "operator" as defined in the regulations;

2) whether any of the laboratory activities which are alleged to be deficiencies were in violation of federal regulatory standards for a laboratory;

- whether any of the alleged deficiencies, if proven, are

subject to sanctions; and

4) whether any of the alleged deficiencies occurred while Dr. de Jesus was an operator, assuming he is found to be an operator.

Edward D. Steinman
Administrative Law Judge

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ATTACHMENT II RULING FOOTNOTES:

(1) In its earlier letter dated December 23, 1998, HCFA informed Dr. de Jesus and Allstate that it concurred with the State agency's November 12, 1998 survey findings and its recommendations, and would be imposing sanctions against Allstate. HCFA recounted that at the November 12, 1998 survey, the State agency had found Allstate to be out of compliance with several conditions under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), as well as numerous standard-level deficiencies. Based on these findings, the State agency had determined that immediate jeopardy to patient health and safety existed and directed Allstate to take immediate action to remove the jeopardy situation. HCFA stated in this letter that "due to your failure to remove jeopardy and correct all cited deficiencies, and your failure to properly report a change in ownership within the 30 day time frame as required by 42 C.F.R. § 493.51," it would impose the sanctions of a civil money penalty, directed plan of correction, suspension and revocation of Allstate's CLIA certificate, and cancellation of Allstate's approval to receive Medicare payments. HCFA stated further that under 42 U.S.C. § 263a(i)(3) and 42 C.F.R.§ 493.1840(a)(8), the present owner or operator (including director) would be prohibited from owning or operating (or directing) a laboratory for at least two years from the date of the CLIA certificate revocation. HCFA concluded the letter by giving ten calendar days to Allstate to submit any written evidence or other information against the imposition of the proposed sanctions.

(2). Allstate, through its owner, also filed a request for hearing dated January 14, 1999, which contested only the imposition of the CMP. As a result, revocation of Allstate's CLIA certificate became effective February 21, 1999.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT:
Garden City Medical Clinic,

Petitioner,
DATE: January 30, 2001
- v -

Health Care Financing Administration.
Civil Remedies CR698
Docket No. A-2000-14
Decision No. **1763 DECISION**

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Garden City Medical Clinic (Garden City/Petitioner), a physician office laboratory located in metropolitan Detroit, Michigan, appealed a September 11, 2000 decision by Administrative Law Judge (ALJ) Jose A. Anglada granting summary judgment for the Health Care Financing Administration (HCFA). *Garden City Medical Clinic*, DAB CR698 (2000) (ALJ Decision). There, the ALJ found that Garden City failed to meet condition level requirements for proficiency testing (PT) for testing events in 1998, and failed to meet the condition level requirement for laboratory director. Consequently, the ALJ determined that HCFA had properly revoked Garden City's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for one year and properly canceled Garden City's approval to receive Medicare payments for its services, effective September 11, 1999. ALJ Decision at 1.

The ALJ Decision was based on 20 findings of fact and conclusions of law (FFCLs). Garden City filed seven general exceptions to the ALJ Decision, including an argument that summary judgment was inappropriate.

We have determined that Garden City's contention that summary judgment was inappropriate has merit. Consequently, we reverse and remand this case to the ALJ for further proceedings. Since those proceedings could change the record for decision before the ALJ, we need not delve further into the merits of Garden City's exceptions to the substance of the ALJ Decision.[(1)]

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*.[(2)] CLIA further grants the Secretary of this Department broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for a certificate. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and

hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N., 3828, 3829.

A laboratory's CLIA certification is generally dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. The regulations also set forth standards, the specific components of the conditions of laboratory certification that a laboratory must meet as part of achieving compliance with applicable conditions.

A key component to the statutory and regulatory program to assure that laboratories holding CLIA certificates are competent to perform tests of moderate and high complexity is the requirement for participation in a PT program that is approved by HCFA, as outlined in 42 C.F.R. Part 493, Subpart H. Among the requirements of that subpart are the following: each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493; a participating laboratory must test PT samples it receives in the same manner as it tests patient samples; must not communicate the results of its tests to other laboratories prior to the deadline for reporting results; must not intentionally refer PT samples to another laboratory for analysis; and must document and maintain documentation for the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 C.F.R. § 493.801. The condition at 42 C.F.R. § 493.803(a) specifically requires that a laboratory performing high complexity testing "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which it is certified under CLIA."

Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997); 42 C.F.R. § 493.2. HCFA may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.[(3)]

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations at 42 C.F.R. § 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E.

Background

The following background information is drawn from the ALJ Decision and the record before him.

Garden City conducted high complexity testing for routine chemistry and endocrinology. At the time in issue, Nazar Sarafa, M.D., was Garden City's laboratory director. HCFA Ex. 7; ALJ Decision at 10. Debra Sabo was a member of Garden City's testing personnel, as well as part of the personnel working at other laboratories in the general vicinity. HCFA Ex. 7. She performed high complexity routine chemistry and endocrinology testing, as well as PT for Garden City. HCFA Exs. 7, 11-13.

Some of the laboratories in the Detroit metropolitan area participating in a PT program operated by the American Association of Bioanalysts (AAB) were Garden City; Mark Hertzberg, M.D. (also known as Millenium Medical Group); Oakland Medical Group (also known as Moretsky/Trager/Flor); John Dunn, M.D.; Rochester Road Clinic; Liptawat Family, P.C.; Lakeland Medical; Ecorse Med Center; and Stanley Boykansky, M.D. HCFA Ex. 2. The AAB would mail to each laboratory participating in the PT program the same group of five specimens three times a year. The laboratories were required to test these specimens for analytes for which they did patient testing, and mail their results to the AAB by a date certain, approximately 10 days after receiving the samples. Garden City was required to test the specimens for cholesterol, HDL cholesterol, triglycerides, glucose, thyroid stimulating hormone, total thyroxine, triiodothyronine, and free thyroxine.

By letter dated January 4, 1999, Dennis W. Jay, Ph.D., Technical Director of the Proficiency Testing Service of the AAB, sent the Michigan Department of Consumer and Industry Services (MDCIS) some PT results for a group of Detroit area laboratories that he deemed suspect. HCFA Ex. 1 at 3-8. Specifically, the cover letter suggested that the same PT results were being submitted by several laboratories. The following five facilities submitted identical PT results during the third testing event of 1998 for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens: Oakland Medical Group, John Dunn, M.D., Mark Hertzberg, M.D., Rochester Road Clinic, and Nazar Sarafa, M.D. (Garden City). HCFA Ex. 1.

On January 14, 1999, the AAB notified MDCIS that it had discovered another four facilities reporting duplicate results and included their 1998 third quarter summaries and attestation sheets. These four facilities were: Liptawat Family, P.C., Lakeland Medical, Ecorse Med Center, and Stanley Boykansky, M.D. HCFA Ex. 2.

Based on the above information, on March 2, 1999, Lucy Estes, Laboratory Evaluation Specialist, MDCIS, performed a complaint survey at Garden City. Based on her review of the testing records she received from Petitioner, and information from the AAB concerning the similarity of PT results between Petitioner and others in the Detroit area, Ms. Estes found that Petitioner was not in compliance with the CLIA requirements under 42 C.F.R. § 493.801(b)(1), Testing of proficiency samples; 42 C.F.R. § 493.1205(e)(1); and 42 C.F.R. § 493.1451(b)(4), Technical Supervisor Responsibilities. She completed and submitted HCFA Form 2567 to her supervisor, Richard J. Benson, along with the aforementioned documents. *See* ALJ Decision at 4-5; HCFA Ex. 3 at 6-10.

By letter dated July 9, 1999, HCFA served on Garden City a Notice of Medicare Cancellation, Suspension, and Revocation of CLIA Certificate of Accreditation pursuant to the MDCIS's referral of its case for imposition of enforcement action. Specifically, HCFA found that Garden City was not in compliance with the following CLIA statutory and regulatory requirements:

- •The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4).
- •Requirement for Certificate: The laboratory agrees to treat PT samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the

ordinary course of business. 42 U.S.C. § 263a(d)(E); 42 C.F.R. § 493.61(b)(1); 42 C.F.R. § 493.801(b)(1)-(3).

HCFA Ex. 3.

Because of what it then characterized as Garden City's improper referral of PT samples to another laboratory for analysis and other serious deficient test practices found during the survey, HCFA imposed the principal sanctions of cancellation of Garden City's approval to receive Medicare payment for its laboratory services and revocation of Garden City's CLIA certificate of accreditation. HCFA Ex. 3.

On October 15, 1999, HCFA served Garden City with a final and more complete notice of adverse action. Addressed to Dr. Sarafa, this letter stated, in pertinent part:

> As set forth on the HCFA Form 2567 that was enclosed with our letter to you of July 9, 1999, the surveyors determined that with respect to the first three events of 1998, your laboratory's proficiency testing (PT) was not performed with the laboratory's regular workload using the laboratory's routine methods, in violation of the standard at 42 CFR § 493.801(b)(1). We also stated that the evidence revealed that your laboratory referred certain PT samples to another laboratory for analysis in violation of the standard at 42 CFR § 493.801(b)(4). The evidence strongly suggests that the results of proficiency testing reported by your laboratory during the first, second, and third events of 1998 were obtained by improper referral and/or collaboration. Inter-laboratory communications pertaining to the results of proficiency testing samples, prior to the testing event reporting due date, are prohibited by the standard at 42 CFR § 493.801(b)(3).
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> * * *
>
> In addition, the standard at 42 CFR § 493.801(b)(5) requires that a laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. . . based on a review of the 1998 proficiency tests records and the patient sheets during the survey, it was determined that PT samples were not examined or tested with the laboratory's regular patient work load. Since the survey findings show that integration did not occur, this violates the standard at 42 CFR § 493.801(b)(5).
>
> The findings from the survey also reveal that you, as laboratory director, have not fulfilled your responsibility to assure that PT samples are tested as required under 42 CFR . . . [Part] 493, subpart H. It was determined that the laboratory's personnel were not testing and reporting proficiency testing results using the laboratory's routine methods; that you failed to assure that the reagents and control materials were not stored beyond their expiration dates; and that you failed to assure that the parameters for acceptable analytical performance were available for consultation and confirmation. The presence of the deficiencies cited in this letter and on the HCFA-2567 demonstrates that you have failed to take responsibility for the overall operation and administration of your laboratory. Therefore, the laboratory is out of compliance with the condition level requirement for a laboratory director at 42 CFR § 493.1441. Because your laboratory did not treat PT samples in the same manner as patient samples, it is in violation of the CLIA requirements at 42 CFR § 493.61 and 42 U.S.C. §

263a(d)(1)(E) and does not meet the requirements for a certificate of accreditation.

* * *

Because of your laboratory's failure to meet the conditions of Proficiency Testing and Laboratory Director, and because of your intentional referral of your laboratory's PT samples for the third testing event of 1998 to another laboratory for analysis, as set forth in our letter of July 9, 1998, we have imposed the following principal sanctions against your laboratory:

- •42 CFR § 493.1808(a) and 42 CFR § 493.1842(a)(1) - Principal Sanction: Cancellation of your laboratory's approval to receive Medicare payment for its services. This sanction became effective on September 11, 1999, and will remain in effect until a hearing decision is rendered, or the end of the revocation period. Medicare payments will not be made for services provided by your laboratory on or after September 11, 1999, the effective date of the cancellation.

- •42 U.S.C. § 263(a)(i)(4), 42 CFR §§ 493.1814(a) and 493.1840(b) - Principal Sanction: Revocation of your laboratory's CLIA certificate. . . will become effective following the administrative hearing decision if we prevail in our determination of noncompliance.

HCFA Ex. 5 at 1-3.

On August 18, 1999, Garden City requested a hearing before an ALJ. On September 23, 1999, the ALJ issued his initial order in this case (ALJ Order).

In response to the ALJ Order, on October 19, 1999, Garden City submitted "Petitioner's Report of Readiness to Present Evidence for Adjudication of the Case" (Garden City Report). There, Garden City took the position that there was a need for testimonial evidence before the ALJ. Garden City asserted that both the statute and regulations provided it with a right to a hearing. Specifically, Garden City noted that HCFA relied almost exclusively on the affidavits of two individuals. Garden City asserted that the "allegations" in those affidavits relied on statistical analysis and data which had to be reviewed in the context of a procedure providing cross-examination. Garden City argued that cross-examination was both contemplated by the applicable regulation and necessary to a full exploration of the allegations offered by HCFA. Garden City Report (unpaginated) at ¶ VI.

HCFA's November 22, 1999, response to the ALJ Order clearly indicated that HCFA would seek summary judgment of Garden City's appeal.

After considering the parties' written submissions, the ALJ concluded that all inferences drawn from the evidence before him cast "no doubt" as to the propriety of granting HCFA's motion for summary judgment as there was no issue of material fact to be tried. He found that HCFA's motion was properly supported by documentary evidence while Garden City relied on mere allegations and denials, thus "falling short of a showing" that

there was a genuine issue for hearing. More significantly, the ALJ determined that the facts upon which he relied in granting HCFA's motion were conceded or not disputed by Garden City. ALJ Decision at 7-8.

In particular, the ALJ relied upon affidavits from Dennis W. Jay, Ph.D., DABCC, Technical Director of AAB's PT Service and Richard J. Benson, Chief, Laboratory Improvement Section, Bureau of Health Systems, MDCIS. HCFA Exs. 15 and 16. The ALJ found that these affiants based their declarations not only on their expertise, but on their personal examination and analysis of data obtained from the AAB and Garden City's records, as well as data from the other eight metropolitan Detroit laboratories with questionable PT results. The ALJ noted that, although some of Dr. Jay's findings are laced with statistical implications, the thrust of his declaration is more associated with the manner in which certain chemical properties will behave given specific testing conditions. ALJ Decision at 12-13.

In his decision, the ALJ found that Garden City generally failed to meet the condition level requirements for PT events pursuant to 42 C.F.R. Part 493, Subpart H; failed to satisfy the standard for test methods under 42 C.F.R. § 493.1205(e)(1); and failed to satisfy the requirements for accreditation pursuant to 42 C.F.R. § 493.61. ALJ Decision at 7.

FFCLs

The ALJ Decision was based on the following 20 FFCLs:

1. Petitioner is a laboratory located in Garden City, Michigan, engaging in high complexity testing for routine chemistry and endocrinology and operating by virtue of a certificate of accreditation under CLIA. HCFA Ex. 6.

2. Nazar Sarafa, M.D. is Petitioner's laboratory director. HCFA Ex. 7.

3. Deborah Sabo performed high routine chemistry and endocrinology and PT for Petitioner and for other laboratories in the Detroit Metro area. HCFA Exs. 7, 11-13.

4. Some of the laboratories in the Detroit metro area participating in a PT program operated by AAB are: Garden City Medical Clinic; Oakland Medical Group; John Dunn, M.D.; Mark Hertzberg, M.D.; Rochester Rd. Clinic; Liptawat Family, PC; Lakeland Medical; Ecorse Med. Center; and Stanley Boykansky, M.D. HCFA Ex. 2.

5. AAB mails each laboratory participating in the PT program the same group of five specimens three times per year. The laboratories are required to test these specimens for analytes for which they did patient testing and mail their results to the AAB.

6. Testing samples for Petitioner included cholesterol, HDL cholesterol, triglycerides, glucose, TSH, T4, T3, FT4.

7. The affidavits and documentary evidence submitted by HCFA in support of its motion for summary judgment show that Petitioner reported PT results to the AAB in 1998 that

were identical to the results of eight other Detroit area laboratories for cholesterol, HDL cholesterol, triglycerides, and glucose with respect to five different specimens.

8. From the multitude of identical results, as well as Petitioner's own admission, I find that Petitioner engaged in collaboration and inter-laboratory communications with other Detroit Metro area facilities in violation of 42 C.F.R.§ 493.801(b)(3).

9. Petitioner did not arrive at identical results to that of eight other laboratories through human error or coincidence but by manipulation of PT results.

10. The PT scores reported by Petitioner to AAB in the testing events for 1998 were not obtained through onsite testing of specimens.

11. Petitioner did not treat PT samples in the routine manner in which it treated patient specimens. 42 C.F.R. § 493.801(b)(1).

12. Petitioner did not successfully participate in a PT program. 42 C.F.R. § 493.803.

13. Dr. Nazar Sarafa, as laboratory director, was responsible for Petitioner's overall operation and administration. His responsibilities included the employment of competent personnel to perform test procedures, record and report test results promptly, accurately and proficiently, and assuring compliance with applicable regulations.

14. Petitioner was in violation of the condition for laboratory director in failing to provide proper overall management and direction to the facility.

15. Petitioner did not meet the CLIA standards for test methods pursuant to 42 C.F.R. § 493.1205(e)(1).

16. Petitioner has submitted no affidavits or other documentary evidence that if taken as true would create a genuine issue of material fact that would require a hearing.

17. Pursuant to 42 U.S.C. § 263a(f), the Secretary is directed to ensure that certified clinical laboratories perform tests that are valid and reliable.

18. A laboratory that is issued a certificate of accreditation under CLIA must enroll in a PT program and comply with the requirements of 42 C.F.R. Part 493, Subpart H.

19. The facts on which I base this summary judgment are either not in dispute or uncontroverted. Thus, summary judgment is appropriate as a matter of law.

20. HCFA is authorized to revoke Petitioner's CLIA certificate for at least one year and cancel its approval to receive Medicare payment for its services.

ALJ Decision at 9-10.

Garden City filed seven exceptions to the ALJ Decision but did not specifically identify FFCLs to which it excepted. In those exceptions, Garden City disputed all the findings of fact critical to the ALJ's determination that Garden City had failed to meet CLIA conditions of participation.

Standard of Review

Our standard of review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000). The bases for modifying, reversing or remanding an ALJ decision include the following: a finding of material fact necessary to the outcome of the decision is not supported by substantial evidence; a legal conclusion necessary to the outcome of the decision is erroneous; the decision is contrary to law or applicable regulations; a prejudicial error of procedure (including an abuse of discretion under the law or applicable regulations) was committed. *See* DAB Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, at The Review Process at the Board.

ANALYSIS

Before the Board, Garden City labeled as "simply false" HCFA's assertions that Garden City had never asked to call witnesses, never submitted affidavits, never asked to cross-examine witnesses, and never challenged the authenticity or relevance of HCFA's exhibits. Garden City noted that it had proposed an evidentiary hearing for the purposes of cross-examining witnesses and was denied that right by the ALJ. Garden City asserted that the ALJ's action denied it the opportunity to cross-examine HCFA's witnesses and test the reliability of their testimony. Garden City Reply Br. at 1-2. We conclude that there is merit to Garden City's argument.

The ALJ committed a procedural error that prejudiced Garden City when he denied its request for an evidentiary hearing on the ground that Garden City raised no genuine dispute of material fact. Both the statute and the regulations confer upon a provider who has received an initial determination the right to a hearing. *See* section 353 of the Public Health Service Act; 42 U.S.C. § 263a(i)(1); 42 C.F.R.§ 493.1844(a). The Board has interpreted these provisions as giving an appellant the right to an opportunity for an in-person hearing where the appellant shows that there are material facts in dispute for which testimonial evidence is required. *Everett Rehabilitation and Medical Center*, DAB No. 1628 at 3 (1997), citing *Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994). In the present case, the failure to permit cross-examination of affiants whose testimony was challenged reduces the reliability of that testimony such that, unless there is other substantial evidence supporting the ALJ's decision, we must reverse and remand the case. As we explain below, there is not sufficient other evidence to support the ALJ's FFCLs, and we therefore reverse and remand.

In his discussion of why he found summary judgment appropriate for this case, the ALJ did not address Garden City's assertion in its Readiness Report that it was requesting an evidentiary hearing to cross-examine the two witnesses, one an employee of HCFA and the other an employee of the AAB, upon whose statements HCFA and the ALJ relied in reaching the conclusion that Petitioner was out of compliance with CLIA requirements. Several of the contentions raised by Garden City in its response to HCFA's motion for summary judgment made it clear that Garden City disputed the facts

alleged in the affidavits provided by HCFA as support for its position and raised questions about the affiants' qualifications and the data upon which they based their opinions. Garden City Medical Clinic's Reply to HCFA's Motion for Summary Affirmance at 19-23. While an ALJ may rely upon written statements as evidence where an appellant has not availed itself of the opportunity for cross-examination provided in the applicable administrative procedures, *Richardson v. Perales*, 402 U.S. 389 (1971), once cross-examination is requested, the ALJ must either grant the request or explain why cross-examination is not required.[(4)] Failing that, the ALJ could not reasonably rely upon the affiants' testimony as "undisputed." Consequently, we must remand this case to the ALJ unless there exists other substantial evidence supporting his FFCLs.

There were two other items of evidence cited by the ALJ in support of his conclusion that Garden City engaged in unlawful collaboration with other laboratories (which in turn supported his conclusion as to Garden City's noncompliance with the laboratory director condition).[(5)] These were the alleged inconsistency of Garden City's work papers with its reported PT results and its alleged admission that its laboratory employee had used the data from another laboratory as Garden City's PT results. ALJ Decision at 13-15. Neither of these items is sufficient to support the ALJ's conclusion.

With respect to Garden City's work papers, the ALJ's finding that they are inconsistent with its reported PT results is also based upon testimony of an affiant. *See* ALJ Decision at 11 (citing HCFA Ex. 16). Although Garden City did not challenge the authenticity of the work papers, the affiant's opinion was based in part upon calculations performed by him using Garden City's data, not just a simple comparison of numbers listed as results. HCFA Ex. 16 at 5-8. In light of Garden City's request to cross-examine the affiant as to the data supporting his opinion, and lacking any indication that the ALJ performed these calculations for himself, we cannot sustain this finding.

Finally, we agree with Garden City that the statement by Garden City's counsel that the ALJ held to be an admission by Garden City that it had engaged in collaboration and inter-laboratory communications was not an admission. That statement, contained in a July 22, 1999 letter to HCFA, was: "This case is most unusual in that one employee worked for a number of unaffiliated laboratories. This employee, acting on her own, without the knowledge of her employer, *allegedly* used the data from tests done at one of the laboratories for all of her employers' proficiency examinations." HCFA Ex. 17 at 2 (emphasis added). It is clear from the context of this letter and the overall context of the proceedings before the ALJ that this statement, which contains the word "allegedly," was made as a part of Garden City's argument in the alternative that, even if HCFA successfully established that the employee had behaved in this manner, a lesser penalty should be imposed upon Garden City. Elsewhere, in this letter and in the pleadings before the ALJ and this Board, however, Garden City has repeatedly asserted that the PT tests in question were performed by its employee in the same manner as all patient testing and that she signed PT reporting forms reporting the results properly. Garden City Br. at 17. Consequently, we conclude that this statement is not an admission by Garden City that it collaborated with other laboratories during the 1998 PT testing events.

Consequently, we reverse the ALJ Decision and remand this case to the ALJ for further proceedings. Given the heavy reliance placed by the ALJ on the testimony of HCFA's affiants, the ALJ should address Garden City's request for an opportunity to cross-

examine those witnesses. We, therefore, remand this case for further proceedings in accordance with our decision.

JUDGE

Judith A. Ballard
Donald F. Garrett
M. Terry Johnson
Presiding Board Member

FOOTNOTES

1. We note that this is the third appeal to come before us based on HCFA's finding of irregularities in 1998 PT results reported by nine physician laboratories in the metropolitan Detroit area. *See Oakland Medical Group, P.C.*, DAB No. 1755 (2000) and *Stanley Boykansky, M.D.*, DAB No. 1756 (2000). Some of the issues raised in Garden City's current exceptions to the substance of the ALJ Decision are similar to those raised and resolved in *Oakland* and *Boykansky*.

2. HCFA may deem a laboratory to meet all applicable CLIA program requirements if the laboratory obtains a certificate of accreditation, as required in 42 C.F.R. Part 493, Subpart D, and meets the other requirements listed in 42 C.F.R. § 493.551(b).

3. These remedies are also available if a laboratory with a certificate of accreditation fails to meet the requirements of 42 C.F.R. § 493.61, including the requirement that it treat the PT samples in the same manner as patient samples. 42 C.F.R. §§ 493.61(b)(1) and (c).

4. We note that in *Richardson v. Perales* the appellant had asked for cross-examination of witnesses whose written statements were cited by the ALJ but had not requested subpoenas. The Court determined that failure to request subpoenas in that case amounted to a waiver of cross-examination. In this case, the ALJ did not address Garden City's request for cross-examination, much less determine that it had been waived.

5. The ALJ also relied upon the failure of Garden City to proffer affidavits or other documentary evidence that if taken as true would create a genuine issue of material fact that would require a hearing. FFCL 16. However, the record before the ALJ included PT test reporting documents submitted by HCFA (HCFA Exs. 8-13) that all include the following statement, signed by the laboratory employee that Garden City alleged properly performed the testing: "THE UNDERSIGNED ANALYST ATTESTS THAT SAMPLES WERE TESTED IN THE SAME MANNER AS PATIENT SAMPLES." *See*, *e.g.*, HCFA Ex. 8, at 2 (capitalization in original). Garden City's laboratory director signed these documents as well. The characterization of the act of signing such documents as attesting to specific facts was sufficient to put into dispute HCFA's expert's testimony that testing was not performed as required.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 00-3138

EDISON MEDICAL LAB., INC.,

Petitioner

v.

HEALTH CARE FINANCING ADMINISTRATION

ON APPEAL FROM THE DEPARTNMNT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL APPEALS BOARD APPELLATE DIVISION
(DAB App. Div. No. A-99-96)

Argued: January 25, 2001
Before: NYGAARD, ALITO, and RENDELL, Circuit -Judges.

JUDGMENT

This cause carne to be heard on the record from the Department of Health and Human Services Departmental Appeals Board Appellate Division on January 25, 2001.

After careful review and consideration of all contentions raised by the appellant, it is hereby ORDERED and ADJUDGED that the judgment of the Department of Health and Human Services entered on December 23, 1999, be and is hereby affirmed, all in accordance with the opinion of this Court.

Costs taxed against appellant

ATTEST:

Clerk

DATED: February 15, 2001

Certified as a true copy and issued in lieu of a formal mandate on April 9, 2001.

Teste:

Clerk, United States Court of Appeals for the Third Circuit

UNREPORTED / NOT PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 00-3138

EDISON MEDICAL LAB., INC.,

Petitioner

V.

HEALTH CARE FINANCING ADMINISTRATION,
Respondent

ON APPEAL FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTNENTAL APPEALS BOARD APPELLATE DIVISION

(DAB App. Div. No. A-99-96)

Argued: January 25, 2001

Before: NYGAARD, ALITO, and RENDELL, Circuit Judges.

(Opinion Filed: February 15, 2001)

MEMORANDUM OPINION OF THE COURT

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Counsel for Respondent

ALITO, Circuit Judge:

Petitioner Edison Medical Laboratories, Inc. appeals the December 23, 1999 decision of the Department of Health and Human Services Departmental Appeals Board upholding the suspension and subsequent revocation of Petitioner's certificate of accreditation for failure to meet condition-level requirements of the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a, and regulations promulgated thereunder at 42 C.F.R. Part 493. After careful review of the record and arguments advanced by Petitioner, we have determined that the findings of the Departmental Appeals Board are supported by substantial evidence. Accordingly, pursuant to our jurisdiction under 42 U.S.C. § 263a(k) (3), we affirm the action of the Department of Health and Human Services in revoking Petitioner's certificate of accreditation.

TO TBE CLERK OF THE COURT:

Kindly file the foregoing Opinion.

/s/Samuel A. Alito

Circuit Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Union City Diagnostic Laboratory,

Petitioner,
DATE: March 6, 2001
- v -

Health Care Financing Administration
Docket No.C-99-831
Decision No. **CR749 DECISION**

I sustain the determination of the Health Care Financing Administration (HCFA) to impose principal administrative remedies against Petitioner, Union City Diagnostic Laboratory, based on Petitioner's failure to comply with the Clinical Laboratory Improvement Amendments of 1988, section 353 of the Public Health Services Act, 42 U.S.C. § 263(a) (CLIA), and with implementing regulations published at 42 C.F.R. Part 493. The remedies which I sustain are as follows:

- Pursuant to 42 C.F.R. §§ 493.1807 and 493.1840(d)(2)(i), suspension of Petitioner's CLIA certificate effective August 13, 1999.

- Pursuant to 42 C.F.R. §§ 493.1806 and 493.1842, cancellation of Petitioner's approval to receive Medicare payments for laboratory services effective August 13, 1999.

- Pursuant to 42 C.F.R. §§ 493.1806 and 493.1840(e)(1), revocation of Petitioner's CLIA certificate.

I. Background

A. Procedural History

Petitioner is a clinical laboratory that is located in Union City, New Jersey. On August 5, 1999, HCFA notified Petitioner that it had determined to impose principal remedies against Petitioner based on findings that were made at a survey of Petitioner that was conducted by the New Jersey Department of Health and Senior Services (NJDHSS). The NJDHSS survey was completed on June 14, 1999 (June 1999 survey). HCFA determined, based on the findings that were made at this survey, that Petitioner had failed to comply with six CLIA conditions of participation. HCFA determined additionally that Petitioner's noncompliance was of so serious a nature as to constitute immediate jeopardy to patient health and safety.

Petitioner requested a hearing to contest HCFA's findings and remedy determinations. The case was assigned at first to other administrative law judges, but, eventually, was transferred to me. I conducted a hearing in Newark, New Jersey, on September 19 and 20, 1999. At the hearing, HCFA presented testimony from the following witnesses:

• *Joan Mikita (Tr. at 19 - 116).* Ms. Mikita is employed by NJDHSS as a supervising clinical laboratory evaluator.

• *Bhavna Patel (Tr. at 116 - 139).* Ms. Patel is employed by NJDHSS as a clinical laboratory evaluator II.

• *Joseph Mierzwicki (Tr. at 140 - 157).* Mr. Mierzwicki is employed by NJDHSS as a quality assurance and quality control specialist.

All of HCFA's witnesses participated as surveyors in the June 1999 survey of Petitioner's facility.

Petitioner presented testimony from the following witnesses:

• *Pravin Patel (Tr. at 159 - 268).* Mr. Patel is the owner of Petitioner.

• *Dharmishtha Kanuga, M.D. (Tr. at 274 - 306).* Dr. Kanuga currently is the forensic director of Petitioner's facility.

At the hearing I received into evidence from HCFA exhibits consisting of HCFA Ex. 1 - HCFA Ex. 57. I received into evidence from Petitioner exhibits consisting of P. Ex. 1 - P. Ex. 65.

B. Governing law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens, and certify through the issuance of a certificate, that a laboratory meets those requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as general requirements which must be met in order that a laboratory qualify under CLIA. For example, under 42 C.F.R. § 493.1201 (general quality control for tests of moderate or high complexity), the condition of participation is stated to include the requirement that a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each testing method to assure the accuracy and reliability of patient test results and reports.

Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. For example, under 42 C.F.R. § 493.1202 (standards for moderate or high complexity testing or both), specific requirements are set forth which govern the way such moderate or high complexity tests must be performed by a laboratory.

The CLIA regulations authorize HCFA or its designee (such as NJDHSS) 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 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* remedies against the laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a) and (b). HCFA may also impose *alternative* remedies against a noncompliant laboratory in lieu of or in addition to principal remedies. 42 C.F.R. § 493.1806(c). 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that HCFA may remove alternative remedies that have been imposed against the laboratory. 42 C.F.R. § 493.1810(e). A laboratory may make an allegation of compliance once it believes it has corrected the deficiencies. HCFA will verify whether the deficiencies have been corrected if it finds the allegation of compliance to be credible and will lift alternative sanctions effective as of the correction date. *Id*. However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, remedies lifted based on self-correction of deficiencies and an allegation of compliance by the laboratory. Nor is HCFA obligated to accept as credible a laboratory's allegation of compliance. The determination to accept or not accept a noncompliant laboratory's allegation of compliance is a matter of discretion for HCFA to exercise.

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 that upholds 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 after HCFA gives notice of its determination and in advance of a hearing and decision by an administrative law judge. 42 C.F.R. § 493.1844(d)(2)(ii). A suspension automatically becomes a revocation of the laboratory's CLIA certificate in a case where an administrative law judge upholds 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. 42 C.F.R. § 493.1844(d)(4)(ii).

A laboratory that has been found to be posing immediate jeopardy to patients may appeal the finding or findings of condition-level deficiencies which are the basis for the imposition of remedies against that laboratory. But, the laboratory may not appeal HCFA's determination that the deficiencies pose immediate jeopardy to patients. 42 C.F.R. § 493.1844(c)(6). Nor may a laboratory appeal a determination by HCFA not to rescind a suspension of that laboratory based on the laboratory's allegations of compliance where HCFA has concluded that the reason for the suspension has not been removed or that there is insufficient assurance that the reason for the suspension will not recur. 42 C.F.R. § 493.1844(c)(3).

The standard of proof that is employed at a hearing concerning HCFA's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. HCFA has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by HCFA. *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

II. ISSUES, FINDINGS OF FACT AND CONCLUSIONS OF LAW

A. Issue

The issue in this case is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving HCFA the authority to impose principal remedies.

In this decision I do not address the question of whether Petitioner's deficiencies - to the extent that it had deficiencies - were at an immediate jeopardy level of noncompliance. As I discuss above, at Part I.B. of this decision, a finding by HCFA that a laboratory manifests immediate jeopardy level deficiencies may not be appealed by the laboratory. Nor do I address the question of whether HCFA should have accepted any of the several plans of correction that Petitioner submitted to address the deficiencies that were identified by NJDHSS at the June 1999 survey. HCFA based its remedy determination in this case on findings by NJDHSS that Petitioner had condition level deficiencies as of the June 1999 survey. As I explain at Part I.B., a laboratory is not entitled to submit a plan of correction to address condition level deficiencies. Moreover, HCFA has discretion to accept or reject any plan of correction that a laboratory submits. I do not have authority to hear and decide whether HCFA used its discretion appropriately to reject a plan of correction.

B. Findings of fact and conclusions of law (Findings)

I make Findings to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. Petitioner failed to comply substantially with the CLIA condition that is stated at 42 C.F.R. § 493.1101.

The CLIA condition that is stated at 42 C.F.R. § 493.1101 requires a clinical laboratory that performs moderate or high complexity testing, or both, to employ and maintain a system that provides for: proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and, accurate result reporting. This system must assure optimum patient specimen integrity and positive identification throughout the pre-analytic, analytic, and post-analytic process and it must satisfy the specific compliance standards that are set forth as part of the overall condition of participation.

Petitioner failed to comply with the condition governing patient test management of moderate or high complexity testing. Specifically, Petitioner failed to maintain systems for accurate processing and reporting of test results. This is made evident by Petitioner's systematic altering of hematology test results and its reporting of these altered results to patients' physicians. Physicians depended on Petitioner to produce

accurate hematology test results as an aid in diagnosing patients' medical conditions and illnesses. Petitioner's systematic reporting of altered results rendered the results it produced useless, or worse, misleading.
Hematology is the study of blood. Tr. at 27. It includes the study of the different cells that are components of blood and their function and structure. Blood cells consist of red and white blood cells. There are several different types of white blood cells. *Id.* at 28. White blood cells include a group of cells known as "mid cells." Mid cells include a combination of less common varieties of white blood cells. *Id.* at 31. Increases and decreases in various types of mid cells may signal to a physician the presence of a variety of diseases, including heart disease, tuberculosis, allergies, parasitic diseases and colitis. Tr. at 29; 36 - 38.
Hematology testing mainly consists of the counting of quantities of cells in blood, the analysis of different cell types, and the determination of whether observed cells are normal or abnormal. Tr. at 27. Commonly conducted blood tests include a complete blood count (CBC) in which the numbers of major types of blood cells in a known quantity of blood are counted. *Id.* at 29. A differential test is often done in conjunction with a CBC. *Id.* at 30. A differential test is designed to break down categories of white blood cells into subgroups of designated cell types. *Id*. A partial leukocyte differential test examines a specific subgroup of white blood cells. *Id*. A CBC with a partial leukocyte differential test are among the most commonly performed medical laboratory hematology tests. *Id.* at 31.

A CBC test is almost always an automated test, meaning that the test is performed by an instrument which mechanically analyzes a sample of blood. Tr. at 31. A partial leukocyte differential test may be done via an automated procedure. Alternatively, the test may be done by hand counting cells in a prepared slide of a specimen of blood observed through a microscope. *Id.* at 31 - 32.

Petitioner utilized a blood analyzer machine known as a Cell-Dyn 1600 analyzer. Tr. at 32. This machine enabled Petitioner to do both an automated CBC and an automated partial leukocyte differential. *Id.* at 32 - 33. The machine uses a method for counting blood cells known as the electrical impedance method. Tr. at 35. The machine operates by sending an electrical pulse through a sample of blood. Different types of blood cells produce changes in the electrical field depending on their size. *Id.* at 34. The machine aggregates blood cells by size and counts them electrically. *Id.* at 34 - 35.

HCFA offered persuasive evidence to show that Petitioner systematically and inexplicably altered the printout of test results it obtained from the Cell-Dyn 1600 analyzer to produce fictitious test results. Tr. at 40; HCFA Ex. 2 at 2 - 3. The surveyors selected at random from Petitioner's records for review 82 patient test records that Petitioner generated between January 1998 and May 1999. Of those results, 96.3% of lymphocyte results, 100% of mid cell results, and 80.5% of granulocyte results that Petitioner reported to patients' physicians did not reflect the results generated by the analyzer. HCFA Ex. 2 at 2.

These inaccuracies became apparent when surveyors compared the printouts

generated by Petitioner's Cell-Dyn 1600 analyzer for individual patient tests with the reports that Petitioner generated and sent to patients' physicians. Tr. at 41 - 42. There were systematic discrepancies between the results that the Cell-Dyn 1600 analyzer produced and the test results reports that Petitioner generated and sent to physicians. For example, in the 82 patient records that the surveyors reviewed Petitioner always reported mid cell test results as comprising either one or two percent of the cells counted regardless of the results that were generated by the Cell-Dyn 1600 analyzer. Tr. at 47.

The mid cell results that Petitioner reported to physicians were at best meaningless and at worst misleading. Of the 82 records reviewed, Petitioner reported mid cells as comprising one percent of total cells counted in 67 of them and as comprising two percent of total cells counted in 15 of them. HCFA Ex. 2 at 3; HCFA Ex. 5. The percentages of mid cells reported by Petitioner had no relationship to the percentages that were counted by Petitioner's Cell-Dyn 1600 analyzer. Petitioner was unable to produce documentation to show that the percentages of mid cells that it reported had been determined based on accurate manual cell counts. Petitioner could not explain why it disregarded the results obtained from the Cell-Dyn 1600 analyzer and replaced them with what appeared to be arbitrary results. Nor could Petitioner explain rationally why it always found that specimens contained either one percent or two percent mid cells when the normal range of mid cells in a patient exceed one or two percent.

HCFA offered additional persuasive evidence of Petitioner's failure to employ a system for proper processing and reporting of hematology test results. The manufacturer's operating manual for the Cell-Dyn 1600 analyzer states that, in order to obtain the most accurate hematology test results, specimens must be processed within eight hours of their collection. Tr. at 65; HCFA Ex. 40 at 33. However, Petitioner on at least one occasion held specimens for as long as 48 hours before processing them. Tr. at 64 - 65; HCFA Ex. 2 at 4.

Finally, HCFA offered evidence which showed that Petitioner employed a flawed methodology for assuring the accuracy of its hematology tests. Under CLIA regulations, a laboratory is required to establish a pertinent reference range for tests as an accuracy check for its test results. 42 C.F.R. § 493.1109(d). Petitioner employed an incorrect reference range for mid cell testing utilizing the Cell-Dyn 1600 analyzer. HCFA Ex. 2 at 4.

Petitioner's use of an incorrect reference range for mid cell testing is a standard level deficiency. In and of itself, the deficiency does not show that Petitioner failed to comply with the overall condition that is stated under 42 C.F.R. § 493.1101. However, Petitioner's failure to comply with the standard underscores the overall failure by Petitioner to employ a system which assured accurate hematology testing. The evidence offered by HCFA establishes, in sum, that Petitioner simply was not performing hematology tests accurately, nor was it reporting accurate hematology test results.

Petitioner did not respond directly to nor deny the evidence that HCFA offered. Indeed, in conversations with the NJDHSS surveyors, Mr. Patel, who is Petitioner's owner and proprietor, essentially admitted to some of the practices that the surveyors discovered. For example, Mr. Patel admitted to the surveyors that he had altered the Cell-Dyn 1600 analyzer counts of mid cells to show results of one or two percent of total cells counted. HCFA Ex. 2 at 3. The explanation that Mr. Patel offered to the surveyors for making this systematic alteration in test results was that all mid cells looked to him like lymphocytes. Tr. at 122. Therefore, he apparently altered the machine test results to account for his own observations.

Petitioner offered a variety of additional explanations for its practices. These explanations are contained in the written plans of correction that Petitioner filed in response to the surveyors' findings and in Mr. Patel's testimony at the hearing. I find these explanations to be confusing, contradictory, and, ultimately, unpersuasive.

For example, Mr. Patel testified that his manual counts of mid cells were of superior accuracy to those that were generated by the Cell-Dyn 1600 analyzer. Tr. at 194 and 196. He asserted also that some doctors insisted that manual counts of cells be performed. But, he did not explain why he would *always* make manual partial differentials of mid cells despite the fact that the analyzer was capable of performing the differentials automatically.

Furthermore, Mr. Patel not only failed to persuade me that his manual counts were more accurate than those that were performed by the Cell-Dyn 1600 analyzer, he failed to persuade me that his manual counts were objective and reliable. He did not offer any rational explanation as to how Petitioner's manual counts of mid cells always tallied at one or two percent of total cells when the standard range of mid cells allowed for the possibility that, in individual cases, counts of mid cells would greatly exceed two percent. *See* Tr. at 249 - 250. The explanation that Mr. Patel offered to the surveyors (that all mid cells looked to him like lymphocytes) not only shows a lack of training and understanding of hematology testing by Mr. Patel, but it demonstrates an inadequate understanding on his part of cell appearance and anatomy. Moreover, I do not understand from Mr. Patel's explanations why he would insist on overriding the results that were produced by the Cell-Dyn 1600 analyzer without at least discussing with the machine's manufacturer his discomfort with the results that the analyzer was producing. Yet, Petitioner produced no evidence that Mr. Patel ever participated in such a discussion.

Mr. Patel suggested, at one point in his testimony, that some of the test reports that the surveyors had not reviewed showed mid cell counts of three or four percent. But, Petitioner failed to produce any of these alleged test results as evidence. *See Id.*

2. Petitioner failed to comply substantially with the CLIA condition that is stated at 42 C.F.R. § 493.1201.

The CLIA condition that is stated at 42 C.F.R. § 493.1201 requires a laboratory to establish and follow written quality control procedures for monitoring and evaluating the

accuracy and reliability of patient test results and reports. Petitioner failed to comply with this condition. Petitioner failed to follow established quality control procedures in operating laboratory testing machinery, thereby, producing and reporting test results that were inaccurate or misleading. In particular, Petitioner failed to ensure that its Cell-Dyn 1600 analyzer was operated according to the quality control procedures established by the machine's manufacturer. Additionally, Petitioner failed to properly calibrate testing equipment and failed to check test results that suggested inaccuracies in the testing processes.

The Cell-Dyn 1600 analyzer is programmed to "flag" test results that are suspect. Tr. at 77 - 78. A flag is recorded by the analyzer as a marginal notation on a test results printout which tells the operator that there is something wrong with the test result that may require some intervention or further action by the laboratory. *Id*. The Cell-Dyn 1600 operator's manual tells the operator what a particular flag potentially may mean. HCFA Ex. 2 at 7 - 9. The manual gives instructions for further action to be taken depending on the specific flag or flags that are present in the test results report. HCFA Ex. 40 at 27 - 31. Typically, the manual directs that slides of specimens be examined manually to resolve the problem that is indicated by a flag.

Petitioner failed systematically to perform the manual reviews that were indicated by flags as being necessary. Tr. at 78 - 79. HCFA identified numerous instances where Petitioner and its staff ignored flags. For example, on February 19, 1999, a test performed on patient specimen # 90216619 produced test results with a flag designation of "R3". HCFA Ex. 5 at 3. The operator's manual for the Cell-Dyn 1600 analyzer tells the operator that, in the case of an R3 flag, a manual differential must be performed. HCFA Ex. 40 at 30; Tr. at 82. However, in this instance, Petitioner failed to perform the indicated manual differential.

In another instance, on April 14, 1998, a test performed on patient # 180 produced a flag designation of "URI." The Cell-Dyn 1600 analyzer operator's manual tells the operator that, in the instance of a URI flag, the test result is suspect. HCFA Ex. 40 at 28 - 29. Yet, in this instance, Petitioner reported the flagged result to the patient's physician without determining the cause of the URI flag. Tr. at 84 - 86.

Petitioner offered several explanations of the way in which it dealt with flagged test results. As with other explanations that Petitioner offered for its actions, I find these explanations to be confusing, contradictory, and ultimately, unpersuasive. For example, Mr. Patel told the surveyors that it is not his usual practice to do many manual differentials. Tr. at 122 - 123. But, in a plan of correction, Petitioner stated that it performed manual differentials to confirm automated results, suggesting that it performed these differentials in all instances. HCFA Ex. 9 at 2. Then, in another statement in the same document, Petitioner asserts that it performed manual differentials to check flagged results. *Id*.

These contradictory statements were contradicted or confused even further by Mr. Patel's testimony at the hearing. He testified that he performed manual differentials with *all* patient test results regardless whether the automated results were flagged. Tr. at 188 - 189. I find this testimony contradicts Mr. Patel's prior statement to the surveyors that he seldom performed manual differentials. Moreover, his testimony that he always performed manual differentials is self-serving and without any corroboration in the

record. Petitioner did not produce any corroborating evidence to show that it had performed manual differentials in all cases. *See* Tr. at 194.

Petitioner's failures to deal appropriately with flagged test results is not the only evidence to show that Petitioner failed to follow prescribed quality control procedures. As another example, Petitioner failed to properly calibrate its Cell-Dyn 1600 analyzer. HCFA Ex. 2 at 10; Tr. at 137. The manufacturer's specifications require an operator to check the accuracy of the Cell-Dyn 1600 analyzer by first performing a precision test and then by running the calibrators 11 times. Tr. at 130. Petitioner failed to do precision testing. And, in calibrating the analyzer, it ran the calibrators only three times. *Id*. Petitioner also failed to perform basic maintenance checks on its analyzers. HCFA Ex. 2 at 11; Tr. at 132. It failed to calibrate properly another instrument known as the Technicon RA 1000. Tr. at 144 - 147. And, it failed to check results that were produced by the Technicon RA 1000 that were biased. Tr. at 150 - 152.

3. Petitioner failed to comply substantially with the CLIA condition that is stated at 42 C.F.R. § 493.1253.

The CLIA condition that is stated at 42 C.F.R. § 493.1253 requires that a clinical laboratory performing hematology testing meet the quality control requirements of 42 C.F.R. §§ 493.1201 through 493.1221 along with the specific requirements that are set forth at subparts (a) through (d) of 42 C.F.R. § 493.1253. Petitioner failed to comply with the requirements of this condition inasmuch as Petitioner failed to comply with the requirements of the conditions that are stated at 42 C.F.R. § 493.1201. Finding 2.

4. Petitioner failed to comply substantially with the CLIA condition that is stated at 42 C.F.R. § 493.1441.

The CLIA condition that is stated at 42 C.F.R. § 493.1441 requires, among other things, that a laboratory must have a director that provides overall management and direction in accordance with the requirements of 42 C.F.R. § 493.1445. Section 493.1445 provides, in general, that the laboratory director is responsible for the laboratory's overall operation and administration including employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with applicable regulations.

Petitioner failed to comply with these requirements. The evidence in this case establishes a generalized failure by Petitioner to perform competently hematology testing. The inescapable inference that is created by the evidence of incompetent testing at Petitioner's laboratory is that its laboratory director failed to provide the direction that is required by 42 C.F.R. §§ 493.1441 and 493.1445. As I discuss above, at Findings 1 and 2, Petitioner provided no meaningful rebuttal to overcome this inference.

5. Petitioner failed to comply substantially with the CLIA condition that is stated at 42 C.F.R. § 493.1447.

The CLIA condition that is stated at 42 C.F.R. § 493.1447 requires, among other things, that a clinical laboratory have a technical supervisor who provides technical supervision in accordance with the requirements of 42 C.F.R. § 493.1451. Section 493.1451

requires, generally, that a laboratory's technical supervisor is responsible for the technical and scientific oversight of the laboratory. It provides that the supervisor is not required to be on a laboratory's premises at all times. However, a technical supervisor must be available to provide necessary supervision of a laboratory's operations. The regulation requires that a technical supervisor be responsible for resolving a laboratory's technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. 42 C.F.R. § 493.1451(b)(5).

Petitioner failed to comply with this condition. There was a manifest failure by Petitioner to provide adequate supervision of the performance of hematology testing. Indeed, the evidence in this case shows that what supervision that may have been provided resulted in gross mismanagement of hematology tests. As I discuss at Finding 1, Petitioner apparently had a policy of altering its automated hematology test results to produce mid cell counts that were inaccurate and misleading. The reasons Petitioner adhered to this policy are inexplicable. Petitioner has offered no cogent explanation for its policy.

6. Petitioner failed to comply substantially with the CLIA condition that is stated at 42 C.F.R. § 493.1701.

The CLIA condition that is stated at 42 C.F.R. § 493.1701 requires a clinical laboratory performing moderate or high complexity testing to establish and follow written policies and procedures for a comprehensive quality assurance program that is designed to monitor and evaluate the ongoing and overall quality of the laboratory's total testing process. The quality assurance program must: evaluate the effectiveness of a laboratory's policies and procedures; identify and correct problems; assure the accurate, reliable and prompt reporting of test results, and; assure the adequacy and competency of staff. A laboratory must revise policies and procedures, as may be necessary, based on the results of its evaluations.

Petitioner failed to comply with this condition. That is apparent from the systematic failures in the conduct of hematology testing by Petitioner. Finding 1. What is apparent from these failures, which extended over a period of at least several months, is that Petitioner was deficient in applying any quality control policies that it may have had to identify and correct erroneous testing practices. At the hearing of this case, Petitioner asserted that it had quality control policies and manuals which the NJDHSS surveyors had failed to obtain or review. I pointed out then, and I reiterate now, that the issue is not whether Petitioner had quality control policies, but whether it implemented them.

7. A basis exists for HCFA to impose principal remedies against Petitioner.

HCFA is authorized to impose principal remedies against a laboratory where that laboratory fails to comply with one or more CLIA conditions. 42 C.F.R. § 493.1806(a). In this case, Petitioner failed to comply with six CLIA conditions. Therefore, HCFA was authorized to impose principal remedies against Petitioner. The principal remedies that HCFA determined to impose in this case - cancellation of Petitioner's approval to receive Medicare reimbursement for its services, suspension of Petitioner's CLIA certificate pending a decision in this case, and revocation of Petitioner's CLIA certificate

- are specifically authorized by regulation. 42 C.F.R. §§ 493.1806(b); 493.1807(a); *see* 493.1812(b).

JUDGE

Steven T. Kessel
Administrative Law Judge

MAY 10 2001

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

Physicians independent Laboratory, Inc., a California corporation; Sahibzada A. Akhtar, an individual,

Plaintiffs,

vs.

Donna Shalala, In Her Official Capacity As Secretary Of The United States Department of Health and Human Services; Wayne Moon, In His Official Capacity As Director of CLIA Operations, Health Care Financing Administration; Diana M. Bonta, R.N., Dr. P.H., Director of The California Department of Health Services.

Defendants.

CV 00-12209 SVW (CWx)

ORDER GRANTING DEFENDANTS, MOTION TO DISMISS

I. Introduction

Plaintiff Physician's Independent Laboratory, Inc. (“PIL") and Akhtar filed this action on November 16, 2000, seeking preliminary injunctive relief pending an ALJ hearing, to require the Secretary of the United States Department of Health and Human Services (“the Secretary”) to reverse its prior action that revoked the operating license of Mr. Akhtar's clinical laboratory (its “CLIA certificates”) without first complying with the ALJ hearing requirements set forth in 42 C.F.R. 493.1840(d) (2).

Additionally, Plaintiffs asked this Court to order that any monies withheld from Medicare payments previously earned be immediately released to Plaintiffs and that any action to cancel Plaintiffs approval to receive

Medicare payments for services rendered be revoked and reinstated retroactively until such time as Plaintiffs receive a hearing before an ALJ.

This Court denied in our January 25, 2001 (the "January 25, 2001 Order") Plaintiffs' request to issue a mandatory injunction to retroactively restore Plaintiffs' CLIA certification and reinstate its medicare reimbursements because Plaintiffs did not demonstrate a substantial likelihood of success of the merits after an ALJ hearing.

In its second amended complaint now pending before the court, Plaintiffs, seek money damage against Donna Shalala and Wayne Moon and Mary Jew as Federal employees acting in their official capacities. Defendants bring a motion to dismiss all causes of action in the second amended complaint arguing that this Court is without jurisdiction to grant the relief sought by the Plaintiffs, that a Bivens action is not available to Plaintiffs, and that Plaintiffs must exhaust administrative remedies. Defendant motion to dismiss is granted.

II. Statement of Facts

The California Department of Health Services, Laboratory Field Services (the "State Survey Agency), acting as the agent of the Secretary, conducted a survey of PIL between August 17, 1999 and December 13, 1999, which identified PIL's violation of nine separate CLIA “Conditions of Participation” and numerous "standard level" CLIA requirements.

Under cover of letter dated January 20, 2000, the State, Survey Agency provided PIL with a 334-page report of the documented deficiencies. The subject line of the January 20, 2000 correspondence stated "Condition-Level Deficiencies and Not Immediate Jeopardy." The January 20, 2000 letter asked PIL to submit a “credible allegation of compliance” along with evidence documenting correction. PIL submitted what it believed to be a conforming plan of correction in April of 2000. By letter dated June 21, 2000, the State Survey Agency provided PIL with reasons why the April 2000 plan was not acceptable. A second correction plan, submitted by PIL on July 13, 2000, was also found to be unacceptable. PIL submitted a third correction plan dated July 25, 2000.

The State Survey Agency referred the matter to the Secretary. The Secretary accepted the State’s recommendation for sanctions. Accordingly, by notice dated September 22, 2000, the Secretary informed PIL's director and owner that the Secretary was imposing certain sanctions including the suspension of the laboratory's CLIA certificate, effective October 6, 2000, and revocation of the laboratory’s CLIA certificate, effective November 20, 2000. The September 22, 2000 notice informed PIL that even if it exercised its right to an ALJ hearing, the Secretary would maintain the CLIA certificate suspension prior to and during the hearing.

The September 22, 2000 notice, informing the Plaintiffs of the license suspension and revocation, stated "due to your failure to comply with reasonable requests for information that is necessary to determine your laboratory's compliance with performance standards set by law and its eligibility for a CLIA certificate of compliance" the suspension and revocation were imposed.

On October 2, 2000, PIL submitted materials directly to the Secretary in support of the laboratory's claim that the previously notice sanctions should not be imposed. The Secretary notified PIL, four days later by letter dated October 6, 2000, that "[w]e have carefully reviewed the materials your laboratory submitted on October 2, 2000 and determined that your laboratory has never come into compliance in correcting the deficiencies cited at the December 13, 1999 survey."

The Secretary notified PIL by letter dated October 17, 2000 that the submission was "entirely unacceptable as it failed to either address the deficiencies cited or to show that the alleged correction plan was every implemented." The sanctions were thereafter imposed in accordance with the schedule set forth in the September 22, 2000 notice, including the October 6, 2000 suspension of PIA's (sic) CLIA license.

In a letter dated November 7, 2000, from PIL's attorney, which was received by HCFA on November 20**,** 2001, PIL requested a hearing before an ALJ. In a letter dated November 21, 2000**,** HCFA requested that an administrative law judge be assigned to this administrative action. The matter was set for a hearing on January 22, 2001.

However, Plaintiffs refused to participate in an ALJ hearing. On or about January 18, 2000, PIL requested a continuance of the administrative hearing or, in the alternative, withdrawal of its request for a hearing. The administrative law judge issued an Order Dismissing the Case on January 23, 2001. This Order has become final.

III. discussion

a. Jurisdiction Over Federal Defendants

Plaintiffs previously brought a motion for a preliminary injunction which this Court denied in our January 25, 2001 Order. In opposition to Plaintiffs' motion for a preliminary injunction Defendants argued that this Court has no jurisdiction to grant equitable relief to the Plaintiffs because 42 U.S.C. § 263(a) (k) confers jurisdiction only upon the Circuit Court for appeal of final agency action under the CLIA. The Court found that "this Court has jurisdiction to grant Plaintiffs a preliminary injunction pending an ALJ hearing." See January 25, 2001 order.

Defendants now argue that, because Plaintiffs have declined to participate in any ALJ hearing and seek monetary rather than preliminary injunctive relief pending an ALJ hearing, that this Court no longer has jurisdiction over this matter. Defendants are correct.

42 U.S.C. § 263(a) (k) of the Clinical Laboratory Services Amendment of 1988 states, in relevant part: "[a]ny laboratory which ... has had its certificate suspended, revoked, or limited ... may, at any time within 60 days after the date the action of the Secretary …becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has it principle place of business for judicial review of such action." 42 U.S.C. § 263a(k).

It is uncontroverted that the provision is applicable here, and it is equally clear that, by its language, its grant of jurisdiction to the circuit court is not exclusive. There is no specific provision for alternative jurisdiction in the district court, although the district court has general subject matter jurisdiction.

The Defendants argue that even though the grant of jurisdiction in 42 U.S.C. § 263(a) (k) is not exclusive, the Ninth Circuit in Public Utility Commr. V. Bonneville Power Administration, 767 F.2d 622, 626 (9th Cir. 1985) mandates that this court read the permissive language as conferring exclusive jurisdiction on the circuit court. The Ninth Circuit in Bonneville Power stated that "where a statute commits review of final agency action to the court of appeals, any suit seeking relief that might affect the court's future jurisdiction is subject to its exclusive review." Id. Jurisdiction is exclusive in the Court of Appeals "even in the absence of an express statutory command of exclusiveness." Id. citing Central Lincoln Peoples Utility District v. Johnson, 735 F.2d 1101, 1109 (9th Cir. 1984) (Central Lincoln II); Assure Competitive Transportation, Inc. v. United States, 629 F. 2d 467, 470-72 (7th Cir. 1980),cert. denied, 449 U.S. 1124 (1981); Nevada Airlines, Inc. v. Bond, 622 F.2d 1017, 1020 (9th Cir. 1980); City of Rochester v. Bond, 603 F. 2d 927, 935 (D.C. Cir. 1979); UMC Industries v. Seagorg, 439 f. 2d 953, 955 (9th Cir. 1971).

This Court acknowledged Bonneville Power in Plaintiffs' motion for a preliminary injunction but found Bonneville Power to be inapplicable to a request for a preliminary injunction pending an ALJ hearing because the Ninth Circuit would receive Plaintiffs' appeal from an ALJ hearing in the same posture as it otherwise would whether or not the district court granted temporary relief.

Although granting temporary relief would not affect the posture of this case before the Ninth Circuit, allowing Plaintiffs to proceed in this action would deprive the Ninth Circuit of the experrtise of the ALJ in

this matter because Plaintiffs' appeal would, of course, be directly to the Ninth Circuit. Plaintiffs in this case, as the Plaintiffs in Bonneville Power attempted to do, seek to challenge agency proceedings on constitutional grounds in the district court. Bonneville Power provides that a statutory review mechanism providing for an ALJ hearing followed by an appeal within the agency, and subsequent appeal to the Ninth Circuit is Plaintiffs' exclusive remedy even if the statutory language is only permissive.

Therefore, this Court lacks jurisdiction over Plaintiffs, causes of action.

b. Exhaustion of Administrative Remedies

Previously, Defendants argued that the CLIA requires exhaustion of administrative remedies prior to judicial review of any kind - including a request for preliminary injunctive relief under the APA. This Court found, citing the United States Supreme Court in Darby v. Cisneros, 509 U.S. 137, 144-146 (1993), that federal courts have no authority to require plaintiffs to exhaust administrative remedies prior to seeking judicial review under the APA unless a statute or agency regulation specifically mandates exhaustion as a prerequisite to judicial review. As explained in Darby, "the exhaustion doctrine continues to exist under the APA to the extent that it is required by statute or by the agency rule as a prerequisite to judicial review." Id.

Although the judicially created doctrine of exhaustion cannot be applied to actions brought under the APA, "the exhaustion doctrine continues to apply as a matter of judicial discretion in cases not governed by the APA." Id. Therefore, in Bivens actions, a district court has discretion in its application of the judicially created exhaustion doctrine. See Stauffer Chemical Co. V. FDA, 670 F. 2d 106, 107 (9th Cir. 1982); SEC v. G.C. George Securities, Inc., 637 F. 2d 685, 687-88 (9th Cir. 1981) ; Reid v. Engen, 765 F. 2d at 1462; United States v. California Care Corp., 709.F. 2d at 1248; Southeast Alaska Conservation Council, Inc. V. Watson, 697 F. 2d 1305, 1309 (9th.Cir. 1983); Aleknagik Natives Ltd. v. Andrus, 648 F. 2d 496, 500 (9th Cir. 1980).

The Ninth Circuit, in Montgomery v. Rumsfeld, 572 F. 2d 250, 252-53 (9th Cir. 1978), explained that exhaustion of administrative remedies was either "specifically required by statute" or "judicially developed." Id. In Montgomery, the Ninth Circuit stated that, in determining whether to apply the judicially developed doctrine of exhaustion "[t]he district judge should carefully weigh the need for an administrative record for proper judicial review, the agency's interests in applying its expertise, in correcting its own errors, and preserving the efficacy and independence of its administrative system, and particularly, the district court should carefully consider "whether

allowing all similarly situated individuals to bypass the administrative avenue in question would seriously impair the agency's ability to perform its functions." Id. at 254.

In applying these factors, the Court finds that Plaintiffs must exhaust their administrative remedies and seek its appeals through the process described in 42 U.S.C. § 263(a) (k).

First, the Court finds that there is a significant need for an administrative record and a strong interest in the agency applying its expertise. Plaintiffs argues that the revocation of its license prior to an ALJ hearing was forbidden by 42 C.F.R. § 493.1840(d). Defendants argue that their revocation was proper because under, Section 493.1840 (d) , "the laboratory [had] refused a reasonable request for information or work an material." Deciding whether a laboratory has sufficiently complied with requests for information seeking to probe its safety and compliance with complex regulations is a task significantly better suited for an ALJ.

Second, allowing all similarly situated individuals to bypass the statutory procedures by refusing to attend an ALJ hearing significantly undermines the Clinical Laboratory Amendment of 1998, 42 U.S.C. § 263, which clearly states that violations of regulations promulgated under it should receive initial scrutiny by an ALJ. Therefore, even if the Court could properly exercise jurisdiction in this matter, it would require Plaintiffs to exhaust their administrative remedies before appealing an adverse decision as set forth in 42 U.S. C. § 263 (a) (k).

III. Conclusion

Defendants' motion to dismiss is granted.

IT IS SO ORDERBD.

DATED: *5/9/2001*

STEPHEN V. WILSON

UNITED STATES DISTRICT JUDGE

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
American Women's Center,

Petitioner,
DATE: May 14, 2001
- v -

Health Care Financing Administration
Docket No.C-99-830
Decision No. **CR773 DECISION**

DECISION

I hereby dismiss the request for hearing filed by American Women's Center (AWC) regarding the Phillipsburg and Elizabeth facilities. I deny HCFA's motion to dismiss as to the Voorhees facility and remand the portion of this case concerning the Vorrhees facility to HCFA for further proceedings consistent with this ruling.

I. **Background**

Petitioner, AWC, performs laboratory testing in conjunction with the provision of abortion services at three New Jersey facilities located in Elizabeth, Voorhees, and Phillipsburg. The New Jersey Department of Health and Senior Services (NJDOHSS) conducted surveys at the Elizabeth, Voorhees, and Phillipsburg facilities of AWC, on June 24, 1996, July 25, 1996, and August 30, 1996, respectively. NJDOHSS found the same condition level deficiency at all three laboratories, in that they had failed to enroll in a statutorily mandated proficiency testing program. 42 C.F.R. § 493.801. HCFA claims that on May 8, 1997, it notified each of the AWC New Jersey facilities by certified mail, of that agency's determination to suspend their Clinical Laboratory Improvement Amendments (CLIA) certificates, effective May 23, 1997.

The notices also advised the three facilities of an additional opportunity to file an acceptable plan of correction by July 21, 1997, and of the right to seek an administrative hearing. According to HCFA, none of the AWC facilities filed acceptable plans of corrections or hearing requests. Consequently, HCFA claims that on August 27, 1997 it served notice on each of the three laboratories subject of these proceedings, by regular mail, that their CLIA certificates would be revoked effective September 10, 1997. According to HCFA, sometime in 1999, it learned that these three AWC facilities had nevertheless continued laboratory testing of human specimens after their CLIA certificates were revoked in 1997. Thus, HCFA sent them a notice on August 9, 1999, that they must cease and desist laboratory testing because the laboratories were operating without CLIA certificates.

AWC filed a request for hearing on September 20, 1999, in response to the August 9, 1999 notices to cease and desist, seeking a hearing for each of the three facilities with regard to the suspension and revocation actions undertaken by HCFA in 1997.

On July 31, 2000, HCFA filed a motion to dismiss Petitioner's hearing request supported by a memorandum of law and four proposed exhibits. HCFA had labeled these as attachments "A" through "D", but I have re-designated them exhibits 1 - 4 (HCFA Exs. 1 - 4). Petitioner filed a response memorandum on September 18, 2000, accompanied by sixteen exhibits. I have admitted these into evidence as Petitioner's exhibits 1 - 16 (P. Exs. 1 - 16). I entertained argument by the parties over the telephone on February 21, 2001. The transcript (Tr.) of the February 21, 2001 oral argument forms part of the record. Subsequent to the oral argument, HCFA submitted a four page exhibit consisting of the CLIA application for the Elizabeth, New Jersey facility of ACW. I have admitted this additional exhibit as HCFA exhibit 5 (HCFA Ex. 5). Petitioner supplemented the record with three additional exhibits that have been admitted as Petitioner's exhibits 17 - 19 (P. Exs. 17 - 19).

After consideration of the written and oral arguments and documentary evidence submitted by the parties, I grant HCFA's motion to dismiss as to the facilities of AWC at Elizabeth and Phillipsburg. I deny HCFA's motion as to the Voorhees facility. In arriving at my decision I find that the hearing request was untimely filed as to the Elizabeth and Phillipsburg facilities, and that the time for filing a request for hearing should not be extended, inasmuch as Petitioner has not shown good cause for the failure of these laboratories to file a timely hearing request. On the other hand, I conclude that Petitioner had good cause for late filing of the Voorhees request for hearing, and an extension of the time for requesting a hearing is in order.

II. Issue

The issues in this case are:

a. Whether Petitioner filed a timely request for hearing; and

b. Whether Petitioner has shown good cause for extending the time period within which it should be allowed to file a request for hearing.

III. Applicable Law and Regulations

CLIA was designed to promote accurate medical tests by clinical laboratories. Congress' goal was to establish a single set of standards applicable to all laboratory services, including those provided to Medicare beneficiaries. *See* H.R. Rep. 899, 100th. Cong., 2nd. Sess. 8 (1988), *reprinted in*1998 U.S.C.C.A.N. 3828.

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. The Act 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). The Act 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).

The standards for operation of clinical laboratories promulgated by the Secretary pursuant to the enabling legislation are found at 42 C.F.R. Part 493. Regulations governing the performance of proficiency tests by clinical laboratories are found at 42 C.F.R. § 493.801. A clinical laboratory must enroll in an approved proficiency testing program. It must notify the Department of Health and Human Services of each program

or programs in which it chooses to participate to meet proficiency testing standards. Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for imposition of remedies including suspension or revocation of its CLIA certificate.

A laboratory that is not satisfied with the imposition of remedies by HCFA may request a hearing before an Administrative Law Judge (ALJ). 42 C.F.R. § 493.1844. A party is entitled to a hearing if that party files its request for hearing within the time limits established by 42 C.F.R. § 498.40(a)(2), unless the time period for filing is extended. In order to be entitled to a hearing, a party must file its request within 60 days from the receipt of a determination by HCFA imposing a remedy. An ALJ may extend the time within which a hearing request may be filed based on a showing of good cause justifying an extension of time. 42 C.F.R. § 498.40(c)(2). An ALJ may dismiss a request for hearing which is not timely filed. 42 C.F.R. § 498.70(c).

IV. HCFA's Contentions

HCFA contends that the orders to cease and desist do not constitute an appealable action pursuant to 42 C.F.R. § 493.1844(b). Furthermore, it contends that the request for hearing filed on September 20, 1999 was untimely, coming two years after HCFA's sanctions were imposed. HCFA adds that regardless of whether the facilities, individually, received notice, it cannot be disputed that AWC knowingly continued to violate federal law by performing patient testing despite the fact that its laboratories were not enrolled in statutorily required proficiency testing programs.

V. Petitioner's Contentions[(1)]

Petitioner asserts that HCFA has failed to produce evidence to show that the Elizabeth and Phillipsburg facilities received the notices of suspension and revocation issued in May and August 1997. Thus, it argues that the facilities timely requested a hearing within 60 days after they first learned of HCFA's suspension and revocation actions by virtue of the cease and desist notice dated August 9, 1999. In effect, it argues that the absence of adequate notice tolled the time for requesting a hearing. Petitioner admits that the Voorhees facility received the notice of suspension of its CLIA certificate, but alleges that HCFA ignored the fact that the facility responded, providing documents evidencing enrollment in a proficiency testing program.

VI. Findings and Discussion

I make the findings of fact and conclusions of law (Findings) to support my decision. Each Finding is noted below, in bold face and italics, followed by a discussion of the finding.

1. Petitioner did not file a timely request for hearing.

HCFA may suspend and revoke a laboratory's CLIA certificate when a laboratory is found to be out of compliance with a condition level requirement. 42 C.F.R. § 493.1842. Each laboratory must meet the condition level requirement of enrollment in an approved proficiency testing program. 42 C.F.R. § 493.801. In the case at hand, HCFA took action to suspend and revoke Petitioner's CLIA certificate for failure to comply with 42 C.F.R. § 493.801. In furtherance of those enforcement actions, HCFA generated the letters dated May 8, 1997, found at Petitioner's Exs. 17 - 19. Afterwards, HCFA sent Petitioner the notice of revocation dated August 27, 1997, found at P. Ex. 16. It was the

notice of May 8, 1997, that granted Petitioner 60 days within which to request a hearing before an ALJ. Thus, the time for seeking a hearing expired in July 1997.
42 C.F.R. § 498.40(a)(2) expressly provides that:

> [An] affected party or its legal representative or other authorized official must file the request for hearing in writing within 60 days from the receipt of the notice of initial, reconsidered, or revised determination unless that period is extended . . .

Petitioner filed its request for hearing on September 20, 1999, clearly beyond the 60 days stipulated in the regulations.

2. Petitioner is not entitled to an extension of time to file a request for hearing with respect to its Elizabeth and Phillipsburg facilities.

As stated earlier, Petitioner contends that HCFA's failure to provide adequate notice and opportunity to respond to the letters of suspension and revocation of its CLIA certificates tolled the time for the filing of its request for hearing. In effect, Petitioner suggests that HCFA's alleged failure prevented it from seeking a hearing timely.
Petitioner argues that HCFA has been unable to produce documentary evidence showing that the Elizabeth facility received notice of either suspension or revocation. P. Br., at 10. As to the *suspension* notice, Petitioner asserts that whereas HCFA possesses a returned envelope indicating the address did not exist, it mysteriously produced a certified mail delivery receipt (green card) for the same envelope. Additionally, Petitioner claims that the signature on the delivery receipt does not belong to anyone on the staff of the Elizabeth facility. Concerning the *revocation* notice, Petitioner claims that no receipt of delivery exists, and the letter lacks an official date stamp.
As to the Phillipsburg facility, it is Petitioner's position that HCFA has been unable to produce any document showing that it received notice of either the suspension or the revocation. Petitioner places reliance for this assertion on the absence of a signed receipt of delivery (green card). Moreover, it alleges that the envelope that HCFA claims contained the notice was returned as undelivered. As to the revocation notice, Petitioner states that there is no official date stamped, signed copy of the letter sent to the Phillipsburg facility.

HCFA's May 8, 1997 notice of suspension, addressed to the Elizabeth facility was sent to:

> 1134 East Jersey Street, Elizabeth, NJ 07201.

Petitioner argues in its brief that such an address does not exist. P. Br., at 10. Allegedly, the correct address street address is 1139 East Jersey Street. *See* Petitioner's Report of Readiness dated April 3, 2000, at 1. What Petitioner fails to mention, however, is that the notice was sent to the address for the Elizabeth facility reported by AWC in its CLIA application dated January 24, 1996. HCFA Ex. 5 at 1. It requires no strain of the imagination to reason that the Elizabeth laboratory's CLIA application generated a response and written communications from the appropriate governmental agency, yet the record is devoid of any need to make an address correction during the approximately 15-month period that followed. Notwithstanding, a second attempt

yielded positive results, as can be gleaned from HCFA Ex. 2. That exhibit refers to the certified mail delivery receipt signed by an agent of the Elizabeth facility and dated May 21, 1997. Petitioner characterizes as mysterious HCFA's production of the delivery receipt signed by an agent of the laboratory. This mere characterization, however, falls short of constituting convincing evidence that the notice of imposition of sanctions was not delivered to AWC's Elizabeth facility. In analogous cases it has been established that "[a] simple denial by an excluded individual that he or she received a notice, in the face of proof that the notice was delivered to the individual's address, will not suffice to overcome the presumption of receipt that flows from proof of delivery of a notice." *Julio M. Soto, M.D.*, DAB CR418, at 4 (1996).

In *Soto*, as HCFA did in the case before me, the Inspector General sent the notice by certified mail, return receipt requested, and someone at Petitioner's address signed for the documents. Nonetheless, Petitioner asserted that neither he nor anyone in his household signed for the notice. In dismissing the argument, the ALJ in that case held that "the fact that someone other than Petitioner, his wife, or children may have signed the return receipt does not vitiate the proof . . . " *Id.* at 5. Similarly, in this case, the bare assertion that the signature on the delivery receipt does not belong to any "staff member" at the Elizabeth facility, does not overcome the presumption of receipt. *See also Ronald J. Crisp, M.D.*, DAB CR724 (2000).

Petitioner also claims that there is no evidence (i.e., no green card) that a notice of revocation was received by the Elizabeth facility and that the letter lacked a date stamp. This assertion overlooks the fact that the regulations merely require that written notice be given.

Petitioner's contention that HCFA has been unable to produce any document showing that the Phillipsburg facility received notice of either the suspension or revocation is unpersuasive. There is no legal requirement that HCFA show that the laboratory actually received the sanction letter. The only specific requirement of the regulation as to the notice is that it be in writing. 42 C.F.R. § 493.1810. To require HCFA to prove that the laboratory actually received the notice of sanction undercuts not only the effectiveness of the enforcement mechanisms but also the purpose of the Congressional intent to protect the general public. 42 C.F.R. § 493.1804.

The letter of imposition of sanctions was sent to the AWC Phillipsburg facility at 157 South Main Street, Phillipsburg, NJ 08865. Petitioner does not deny that this is the facility's correct address. The delivery envelope shows that Post Office notices went to the addressee on May 29 and June 10, 1997. HCFA Ex. 4. The mail was returned to sender after the U.S. Postal Service attempted delivery twice and failed to produce a response from the facility. Interestingly enough, the Phillipsburg letter was marked "unclaimed' by the U.S. Postal Service after the other two AWC facilities involved in these proceedings received their notices on May 21, 1997. I infer from this that Petitioner chose not to claim the certified mail at the Post Office as a strategy to avoid being held responsible for its contents. If Petitioner were allowed to prevail by way of such stratagem, it would make a mockery of the purpose behind CLIA. I should also note that Petitioner's argument that the notice of revocation copies lacked an official date stamp also fails to overcome the regulatory presumption of receipt.

In view of the foregoing, I conclude that Petitioner has not shown good cause for extension of time to file the request for hearing regarding the imposition of sanctions against its laboratories in Elizabeth and Phillipsburg.

3. Good cause exists for extending the Voorhees facility's time to file a request for hearing.

The Voorhees facility was sent the May 8, 1997 notice of suspension of its CLIA certificate via certified mail. P. Ex. 18, HCFA Ex. 2. On July 5, 1997, the laboratory responded stating that on June 6, 1997, the necessary proficiency testing kits had been ordered from the American Association of Bioanalysts.[(2)] P. Ex. 9. The laboratory expected the Basic Immunology kit to be received by September 23, 1997. Voorhees also forwarded a copy of the certificate attesting to their enrollment in a proficiency testing program, and requested to be contacted as to the status of their possible reinstatement. P. Ex. 9. HCFA did not respond to the Voorhees letter although the facility purportedly attached a copy of the certificate evidencing their enrollment in a proficiency testing program. The facility was responsive to HCFA's May 8, 1997 notice of suspension, but HCFA did not acknowledge the response.[(3)] I note further that Voorhees indicated in its letter of July 5, 1997, that it was unaware that there was a problem with the requirement regarding enrollment and testing samples. This claim rings true inasmuch as NJDOHSS had previously notified the facility that no significant deficiencies were noted as a result of the survey of July 25, 1996. P. Ex. 10. In spite of this report, the suspension notice says that in light of that same survey conducted by NJDOHSS on July 25, 1996, a condition level deficiency was found.[(4)]

In accordance with regulatory requirements, HCFA afforded the facility a ten day period within which to respond to the notice of imposition of proposed sanctions. 42 C.F.R. § 493.1810(b), and (c). HCFA argued that the response has to be either a request for hearing or a plan of correction. Tr. at 65, HCFA Br., at 7. The language of the regulation does not support that view. The regulation allows the laboratory to submit "evidence or other information against the imposition of the proposed sanction or sanctions." 42 C.F.R. §1810(b). Once the laboratory avails itself of that opportunity, HCFA has to provide written notice that acknowledges "any evidence or information received." 42 C.F.R. §1810(c). HCFA failed to do that in this case. I realize that the facility responded well beyond the ten days granted by HCFA, but nonetheless, an acknowledgment should have been forthcoming.

HCFA posits that enforcement actions against all AWC laboratories is also appropriate because they have continued to operate without the required CLIA certificates. However true that may be, it is only a reflection of their character. That does nothing to relieve HCFA of its duty to accord Petitioner the due process of law to which it is entitled. In this regard, HCFA should be mindful that the law is not self executing.

In view of the foregoing, I find no merit in HCFA's motion to dismiss the request for hearing as to the Voorhees facility. The AWC Voorhees facility is entitled to an extension of time to file its request for hearing. However, inasmuch as HCFA did not consider the merits of the Voorhees facility's response to its notice of suspension prior to revocation of its CLIA certificate, it is appropriate to remand this portion of the case to HCFA for further proceedings consistent with this ruling.

VII. Conclusion

Based on the applicable law and undisputed facts, I conclude that Petitioner's hearing request as to its Elizabeth and Phillipsburg facilities was untimely filed and good cause does not exist to extend the time for filing. As to these facilities, HCFA's motion to dismiss is granted. However, I deny HCFA's motion to dismiss the hearing request as to the Voorhees facility. This portion of the case concerning the Voorhees facility is remanded to HCFA for further proceedings.

JUDGE

José A. Anglada
Administrative Law Judge

FOOTNOTES

1. HCFA asserts, and Petitioner concedes, that the cease and desist order of August 9. 1999, is not an initial determination subject to a hearing request. 42 C.F.R. § 493.1844(b). Petitioner is requesting a hearing on HCFA's imposition of remedies in 1997.
2. The American Association of Bioanalysts is a proficiency testing agency approved by the Department of Health and Human Services.
3. I am not persuaded by HCFA's suggestion that the Voorhees response was a mere act of playing dumb. Tr. at 65.
4. HCFA implies that the facility had to know that it was not enrolled in a proficiency testing program. At first blush that seems to be a reasonable assumption, however, not all CLIA certificates require such enrollment.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Evette Elsenety, M.D., Et. Al.,

Petitioner,
DATE: June 12, 2001
- v -

Health Care Financing Administration
Docket No.C-01-218 thru C-01-233
Decision No. **CR779 DECISION**

DECISION

I sustain the determinations of the Health Care Financing Administration (HCFA) to revoke the Clinical Laboratory Improvement Amendments (CLIA) certificates of each of the Petitioners (Evette Elsenety, M.D., Docket No. C-01-218; Harold Margolis, D.O., Docket No. C-01-219; Mary C. Ferris, D.O., Docket No. C-01-220; Gregory O. Claque, D.O., Docket No. C-01-221; Gary B. Lungnas, D.O., Docket No. C-01-222; Ronald I. Rothenberg, D.O., Docket No. C-01-223; Thomas J. Chwierut, D.O., Docket No. C-01-224; Kenneth S. Meyers, D.O., Docket No. C-01-225; Jeffrey H. Soffa, D.O., Docket No. C-01-226; Dudley Roberts, III, M.D., Docket No. C-01-227; James M. Kohlenberg, M.D., Docket No. C-01-228; Stanley H. Remer, D.O., Docket No. C-01-229; Harold Margolis, D.O., Docket No. C-01-230; Phillip Newman, D.O., Docket No. C-01-231; Daniel Jebens, D.O., Docket No. C-01-232; and Gary L. Berg, D.O., Docket No. C-01-233) in these cases. The undisputed material facts of these cases establish that each of these Petitioners is a clinical laboratory that is owned by an entity, Oakland Medical Group, P.C. (Oakland Medical Group), whose CLIA certificate was revoked within the past two years. As a matter of law the CLIA certificates of these Petitioners must be revoked because CLIA prohibits an entity whose CLIA certificate has been revoked from owning or operating another laboratory during the two-year period from the date of revocation of the CLIA certificate.

I. Background

On November 7, 2000 HCFA sent a notice to each Petitioner in these cases. In each notice HCFA advised each Petitioner of its intent to revoke that Petitioner's CLIA certificate. HCFA asserted that it was acting to revoke the CLIA certificates at issue because it had determined that each Petitioner was owned or operated by Oakland Medical Group and because Oakland Medical Group's CLIA certificate had been revoked.

Each Petitioner requested a hearing and all of the cases were assigned to me for a hearing and a decision. I held a consolidated prehearing conference at which HCFA advised me that it intended to move for summary disposition. HCFA then moved for

summary disposition and Petitioners opposed HCFA's motion with a consolidated response.
HCFA submitted four proposed exhibits (HCFA Ex. 1 - HCFA Ex. 4) in support of its motion. Petitioners, in their consolidated response to the motion, submitted four proposed exhibits (P. Ex. 1 - P. Ex. 4). I am receiving into evidence HCFA Ex. 1 - HCFA Ex. 4 and P. Ex. 1 - P. Ex. 4.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in these cases are whether:

1. Summary dispositions are appropriate; and

2. Petitioners' CLIA certificates must be revoked as a matter of law based on the undisputed material facts.

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. I discuss each Finding in detail.

1. Summary dispositions are appropriate in these cases.

Generally, summary disposition is appropriate in a case if there are no disputed issues of material fact. I find that there are no disputed issues of material fact in these cases. Consequently, summary dispositions are appropriate here.
A party who opposes a motion for summary disposition must do more than to deny the facts that are alleged as support for the motion. The party who opposes the motion must offer facts which, if true, would refute the facts that are relied on by the moving party. I would not find these cases appropriate for summary disposition had Petitioners offered any facts which, if true, called into doubt the material facts relied on by HCFA to support its motions for summary disposition in these cases. But, Petitioners did not do so.
HCFA rests its motion for summary disposition on two assertions of fact. First, it asserts that each Petitioner is owned by Oakland Medical Group. Second, it asserts that Oakland Medical Group's CLIA certificate was revoked within the past two years. As I discuss below, there is no genuine dispute as to these material facts.

a. Each Petitioner is owned by Oakland Medical Group.

There is no genuine dispute that each Petitioner is owned by Oakland Medical Group. Oakland Medical Group's ownership of Petitioners is established by a letter dated October 24, 1998 from Petitioners' counsel to HCFA's counsel. HCFA Ex. 3. In that letter counsel attaches a list of "the addresses and CLIA numbers of the laboratories *owned by* The Oakland Medical Group, P.C. . . ." *Id.* at 1 (emphasis added). The attached list includes the business address, along with the CLIA certificate number, of each of the Petitioners in these cases. *Id.* at 4 - 5.
Petitioners contend that HCFA presented no evidence that they are owned by Oakland Medical Group. Petitioners assert that the letter that HCFA relies on is erroneously dated "October 24, 1998" when, in fact, it actually was authored on October 24, 2000.

Moreover, according to Petitioners, the letter was sent as part of settlement discussions between Petitioners and HCFA and, "[a]t no time has . . . [Oakland Medical Group] or counsel for . . . [Oakland Medical Group] indicated to HCFA or HCFA counsel that such letter was sent for any reason other than settlement." Petitioners' brief at 3.
These assertions by Petitioners are no basis for me to conclude that there is any genuine dispute as to whether Petitioners are owned by Oakland Medical Group. The letter is an admission made on behalf of Petitioners by their counsel that they are owned by Oakland Medical Group. That it may have been misdated does not detract from the significance of the contents of the letter. Nor is the letter made less probative by the fact that it was sent to HCFA as part of settlement discussions. Petitioners have not averred that they stated untruths to HCFA in order to settle these cases and there is no reason for me to assume that they would do so.

b. Oakland Medical Group's CLIA certificate was revoked within the past two years.

There is no dispute that Oakland Medical Group's CLIA certificate was revoked within the last two years. HCFA made a determination to revoke Oakland Medical Group's CLIA certificate. That determination was sustained after an administrative hearing by an administrative law judge and, on appeal, by the Departmental Appeals Board. *Oakland Medical Group, P.C.*, DAB CR688 (2000), *aff'd* DAB No. 1755 (2000). Revocation of Oakland Medical Group's CLIA certificate was made effective July 19, 2000. HCFA Ex. 2.

2. Petitioners' CLIA certificates must be revoked as a matter of law based on the undisputed material facts.

The undisputed material facts of this case are that Petitioners all are owned by an entity, Oakland Medical Group, whose CLIA certificate was revoked within the past two years. I find that, as a matter of law and in light of the undisputed material facts, HCFA must revoke Petitioners' CLIA certificates.
CLIA provides that any "person" whose CLIA certificate has been revoked is prohibited from owning another laboratory within a two-year period from the date of revocation:

> [n]o 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.

42 U.S.C. § 263(a)(i)(3). Regulations authorize HCFA to enforce this section by initiating adverse action to, among other things, revoke a laboratory's CLIA certificate where that laboratory's owner or operator has owned or operated another laboratory whose CLIA certificate was revoked during the preceding two-year period. 42 C.F.R. § 493.1840(a)(8).
Oakland Medical Group - whose CLIA certificate was revoked effective July 19, 2000 - is by law prohibited from owning any CLIA-certified laboratories for two years from that date. HCFA plainly was authorized to revoke Petitioners' CLIA certificates inasmuch as they are all owned by Oakland Medical Group. As a matter of law I must sustain HCFA's determination to do so.

Petitioners argue that revocation of their CLIA certificates is antithetical to the purpose of CLIA. Moreover, according to Petitioners, their organization and ownership is dictated by law enacted subsequent to the enactment of CLIA. Petitioners assert that it was not Congress' intent that laboratory owners be penalized for complying with this subsequently enacted law. Yet, according to Petitioners, that is the consequence of applying the requirements of CLIA to these cases. Petitioners' brief at 3 - 6.

The essence of Petitioners' argument is that they are organized as subsidiaries of Oakland Medical Group because jointly owned clinical laboratories may not be operated lawfully unless they are organized as part of a group practice. Petitioners assert that the manner of their organization is dictated by 42 U.S.C. § 1395nn(b)(2) which was enacted after the enactment of CLIA. However, according to Petitioners, the reality is that each of them continue to function as a discrete and independently operated laboratory. They assert that to revoke their CLIA certificates would frustrate the intent of legislation which requires that they be organized as part of a group practice. Moreover, they argue that common sense dictates that their CLIA certificates not be revoked inasmuch as they had nothing to do with the activities that resulted in the revocation of Oakland Medical Group's CLIA certificate.

The problem with Petitioners' argument is that it does not deal with the express requirements of CLIA. CLIA strictly prohibits a person whose CLIA certificate has been revoked from owning another laboratory during the two-year period after the date of revocation. It does not contain exceptions or permit a case-by-case analysis as Petitioners suggest is appropriate. Consequently, I may not consider the essentially equitable arguments made by Petitioners. Furthermore, Petitioners have not offered anything which would suggest that Congress intended to modify CLIA with the enactment of subsequent legislation.

I note that the word "person" is not defined in CLIA and I have considered the question of whether Oakland Medical Group is a "person" within the meaning of CLIA. If the word "person" meant only an individual then, arguably, there would be no statutory prohibition against Oakland Medical Group owning CLIA-certified laboratories despite the revocation of its CLIA certificate. The general rules of construction of the United States Code, of which CLIA is a part, are that the word "person" in any statute contained in the United States Code be interpreted to include a corporation or a company unless the context of the statute indicates otherwise. 1 U.S.C.A. § 1 (West 2001). I find nothing in CLIA to suggest that Congress intended the word "person" to mean only individuals and not corporations or companies. Thus, the general rule of construction that "person" means a corporation or a company applies to CLIA's use of the word "person."

JUDGE

Steven T. Kessel
Administrative Law Judge

United States Attorney
STUART A. MINKOWITZ
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2925
SAM-2692

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,
Plaintiff,

v.

EDISON MEDICAL LABORATORY SERVICE CORPORATION,
Defendant.

Hon.

Civil Action No. 01-2872 [(k?)sh]

ORDER TO SHOW CAUSE AND TEMPORARY RESTRAINING ORDER (Fed. R. Civ. P. 65(a), (b); 42 U.S.C. § 263a(j) and 42 C.F.R. § 493.1846)

TO: KENNETH B. FALK, ESQ.
Deutch & Falk
843 Rahway Ave.
Woodbridge, NJ 07095-3699

THIS MATTER HAVING BEEN opened by the plaintiff, by and through its counsel, Robert J. Cleary, United States Attorney for the District of New Jersey (Stuart A. Minkowitz, Assistant U.S. Attorney appearing), upon an application for an Order to Show Cause and a Temporary Restraining Order, and the Court having considered the Complaint and the papers filed therewith, and it appearing to the Court that defendants continue to commit the acts specified in this Order, and that unless restrained by the Court, the defendants will cause a significant hazard to the public health before notice can be given and the defendant or defendant's attorney can be heard in opposition to the granting of a temporary restraining order, and for good cause having been shown; therefore

IT IS on this **18th** day of June, 2001 at **4:00** a.m/**[p.m,]**

ORDERED THAT:

1. Plaintiff's application for an Order to Show Cause and a Temporary Restraining Order be and is hereby granted.

2. Pursuant to 42 U. S.C. § 263 a(j) and 42 C.F.R. § 493.1846, and pending a hearing on the preliminary injunction, defendant, its owners, operators, employees, agents, representatives, successors or assigns, and all persons in active concert or participation with them are hereby restrained from operating a clinical laboratory, or soliciting or accepting materials derived from the human body for laboratory examination or other procedure without certification pursuant to the requirements of the Clinical Laboratories Improvement Amendments of 1988 ("CLIA") (Public Law 100-578), and as set forth in 42 C.F.R. § 493, et seq.

3. The foregoing temporary restraints shall remain in force until the close of business on the **2nd** day of **July**, 2001, or at such later date as may be set by the Court or agreed upon by the parties.

4. Defendants she show cause before this Court on the **2nd** day of **July**, 2001 at **2:00p.m**. why an Order granting a preliminary injunction in the form annexed hereto should not be granted.

5. Written opposition by defendant, if any, to plaintiff's application shall be filed with this Court and received by the United States Attorney on or before the **25th** day of **June**, 2001.

6. The plaintiff may file, and serve upon defendant, a reply to any opposition filed by defendant no later than the **29th** day of **June**, 2001. *by 12:00 pm*

7. True copies of this Order to Show Cause with Temporary Restraining Order, together with the other papers filed with this application shall be served upon defendant or their attorney within **I** days of the date of this Order, Service of these documents may be effected by sending the same via next-day mail or by hand delivery. a*nd by fax.*

8. Pursuant to 42 U.S.C. § 263a(j), the plamff need not post a bond.

HON.

UNITED STATES DISTRICT JUDGE

ROBERT J. CLEARY
United States Attorney
STUART A. MINKOWITZ
Assistant United States Attorney
970 Broad Street, Suite 700
Newark, New Jersey 07102
(973) 645-2925
SAM-2692

UNITED STATES OF AMERICA,
Plaintiff,

v.

EDISON MEDICAL
LABORATORY SERVICE
CORPORATION,
Defendant.

Hon. Katharine S. Hayden

Civil Action No. 01-2872 (KSH)

CONSENT DECREE

WHEREAS, Plaintiff, the United States of America, on behalf of its agencies the Department of Health and Human Services and Centers for Medicare and Medicaid Services ("CMS") (formerly the Health Care Financing Administration ("HCFA")) (collectively "the Government"), having filed its complaint against the defendant, Edison Medical Laboratory Service Corporation ("EMLS"); seeking to permanently enjoin defendant, owners, operators, employees, agents, assigns and/or successors from violating the Clinical Laboratories Improvement Act Of 1967; Clinical Laboratories Improvement Amendments of 1988 ("CLIA") (42 U.S.C. § 263a(b) and (j) and its associated regulations (42 C.F.R. 493.1846); and

WHEREAS, the parties have engaged in discussions in an effort to resolve all issues raised by the Complaint; and

WHEREAS, the defendant has consented to entry of this Decree without contest and the Government has consented to the entry of this Decree; therefore,.

NOW, it is hereby ORDERED, ADJUDGED AND DECREED as follows:

1. The Court has subject matter jurisdiction over this ation under 28 U.S.C. § 1345, 42 U.S.C. § 263a(j) and 42 C.F.R. § 493.1946, and its general equity and ancillary jurisdiction.

2. Venue lies in the District of New Jersey under 28 US.C. § 1391(b) and (c) and 42 U.S.C. § 2634a(j), as the place where the claims arose and where the defendant's laboratory is located.

3. The Complaint states a valid claim against the defendant under CLIA.

4. Defendant does not contest the allegations contained in the Complaint.

5. Defendant, EMLS, and its owners, operators, employees, agents. assigns and/or successors, are hereby permanently enjoined and restrained from soliciting or accepting materials derived from the human body for laboratory examination or other procedure unless and until there is in effect for the laboratory a valid certificate issued by the Secretary of HHS under 42 U.S.C. § 263a. The permanent restraint includes, but is not limited to, (1) the diagnosis, prevention or treatment of any human disease or impairment, or (2) the assessment of the of health of any person, (3) procedures to determine, measure, or otherwise describe the presence or absence of substances or organisms in the human body, or (4) the taking of specimens or samples derived from the human body.

6. Defendant, its owners, operators, employees., agents, assigns and/or successors agree that HHS, CMS or New Jersey Department of Health and Senior Services, or their agents, may periodically inspect EMLS, unannounced, at any time during regular business hours to verify that the laboratory has not resumed diagnostic testing without a valid CLIA certificate. Defendant, its owners, operators, employees., agents, assigns and/or successors consent to such periodic inspections and acknowledge that they may be required to bear the cost of each inspection, if the defendant is found to be in violation of this Consent Decree.

7. In the event EMLS, its owners, operators, employees., agents, assigns and/or successors, violate any provision of this Consent Decree, upon notice by HHS, CMS or the New Jersey Department of Health and Senior Services, EMLS, it owners, operators, employees., agents, assigns and/or successors shall, within 10 days of receipt of such notice, pay a penalty of $5, 000.00 per violation. In addition, EMLS, it owners, operators, employees., agents, assigns and/or successors, shall pay $500.00 per day for each day the violation continues beyond the date of the receipt of the notice of a violation. The penalties shall be made payable to the United States Department of

Justice. This remedy is not in lieu of, but in addition to any other remedy available to the Government by statute, regulation or the common law, including an order for contempt. If EMLS, it owners, operators, employees., agents, assigns and/or successors disagree with the findings of HHS, CMS, or the New Jersey Department of Health and Senior Services, that there has been a violation of this Consent Decree, it shall be entitled to challenge such findings in this Court, but solely on the grounds that the violation did not occur and by demonstrating the nonoccurrence by a preponderance of the evidence.

8. Without leave of Court, the Government may take discovery reasonably calculated to determine whether persons or entities bound by this Consent Decree are in full compliance with the provisions of this Consent Decree.

9. If any person or entity bound by this Consent Decree fails to comply with any provision of this Consent Decree or is found in civil or criminal contempt thereof, that defendant shall, in addition to other relief, reimburse the Govenment for its reasonable attorney's fees, investigational expenses and costs.

10. Nothing in this Consent Decree shall be deemed to excuse defendant, it owners, operators, employees., agents, assigns and/or successors , from hereinafter complying with CLIA and the regulations promulgated thereunder, or any other obligations under applicable law or regulation.

11. If the present owners or operators of EMLS become affiliated as an owner, operator or otherwise, with any laboratory other than EMLS, or applies for a CLIA certificate on behalf of any laboratory, they must notify the Government within seven days, identifying the name, address, owners, officers and nature of the laboratory.

12. All notices and corespondence required by this Consent Decree shall be sent by first class mail to the parties at the following addresses, and, if possible, by facsimile unless otherwise indicated:

<u>To the Government</u>

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Jacob K. Javits Federal Bldg.
26 Federal Pza., Rm. 3809
Now York, NY 10278

With a copy to:

U.S. Department of Health and Human Services
Office of the General Counsel, Region II
Jacob K. Javits Federal Bldg.
26 Federal Pza., Rm. 3908
New York, NY 10278
Fax: (212) 264-6364

Chief, Civil Division
United States Attorney's Office
970 Broad St., Ste. 700
Newark, NJ 07102
Fax: (973) 297-2010

To the-Defendant

Kenneth B. Falk, Esq.
Deutch & Falk, P.C.
843 Rahway Ave.
Woodbridge, NJ 07095-3699
Fax: (732) 636-3575

Edison Medical Laboratory Services Corporation
1692 Oak Tree Pza.
Edison, NJ 08820

The parties will notify each other promptly upon any change in the above information.

13. This Consent Decree shall be binding upon defendant, it owners, operators, officers, agents, employees, lessess, assigns, successors in interest, and those persons who are in acitive concert or participation with them directly or indirectly.

14. The individuals executing this Consent Decree on behalf of EMLS represent that they are duly authorized to execute this Consent Decree on EMLS's behalf.

15. Nothing herein shall be deemed to limit the Government's ability to enforce CLIA and its regulations.

16. This Court shall retain jurisdiction for the purpose of enforcing or modifying this Consent Decree, and for the purpose of granting such addiional relief as may hereafter appear neccessary or appropriate.

17. With the exception of inspection costs outlined in paragraph 6, above, each party shall bear its own costs, including attorney's fees.

18. The Government reserves the right to seek costs, investigation and attorney's fees against defendant, its owners, operators, employees, agents, assigns, and/or successors, should defendant violate the terms and conditions of this Consent Decree.

19. If any provision of this Consent Decree is declared invalid, such declaration shall not effect the validity of any other provision herein.

IT IS SO ORDERED,

Dated: *7/6/01*

HON. KATHARINE S. HAYDEN
United States District Judge

AGREED AND CONSENTED TO:

For the Plaintiff, United States of America

ROBERT J. CLEARY
United States Attorney
District of New Jersey

By: STUART A. MINKOWITZ
Assistant U.S. Attorney

Dated: *7/2/01*

For theDefendant, Edison Medical Laboratory Service Corporation

DEUTCH & FALK, P.C.

By: Kenneth B. Falk, Esq.
Attorney(s) for Edison Medical Laboratory Service Corporation

Dated: *6/28/01*

EDISON MEDICAL LABORATORY
SERVICE CORPORATION

By: Dated: *6/26/2001*
Name: Edison Medical Laboratory Services Corporation
Title: President

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT Of MICHIGAN

SOUTHERN DIVISION

PREFERRED FAMILY MEDICINE, P.C.
A Michigan Professional Corporation,
MARC WEISMAN, D.O. and
JASON TALBERT, M.D.

v.

Case No-. 01 -72447
Honorable Victoria A. Roberts

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, and THOMAS SCULLY, ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID SERVICES, formerly known as the Health Care Financing Administration

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OPINION & ORDER DENYING PLAI ITIFF'S MOTION FOR INJUNCTIVE RELIEF AND REQUEST FOR DECLARATORY JUDGMENT AND MANDAMUS, AND GRANTING DEFENDANTS' MOTION TO DISMISS

I. Introduction

This matter is before the Court on Plaintiff s' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief, as well as their Motion for a Temporary Restraining Order and Preliminary Injunction pursuant to Fed. R. Civ. P. 65(a) and (b).

Plaintiffs contend that they are entitled to injunctive relief in order to prevent Defendants from canceling Preferred Family Medicine's ("PFM") approval to receive Medicare payments for its laboratory services. This cancellation went into effect or, July 2, 2001, pursuant to 42 C.F.R. § 493.1808(a), 493.1842(o) (1) and 493.1844(d) (3). Additionally, Plaintiffs are requesting injunctive relief to prevent the revocation of their CLIA

("Clinical Laboratory Improvement Amendment") Certificate of Accreditation. Plaintiffs maintain that if either of these two events occur, it would effectively force the closure of PFM's laboratory and cause irreparable harrn to Plaintiffs and numerous Medicare and other patients. Plaintiffs also seek declaratory relief and relief in the form of a writ of mandamus.

Secondly, Plaintiffs argue that this Court has subject matter jurisdiction even though they have not exhausted their administrative remedies prior to judicial review, as required by 42 U.S.C. § 405(h). Plaintiffs state that the waiver exception under 42 U.S.C. § 405(g) applies to their factual circumstances, thus giving this Court jurisdiction.

Defendants' response is two-fold. First, they assert that this Court does not have subject matter jurisdiction, thereby requiring the dismissal of Plaintiffs' claim without reaching the merits. Defendants also maintain that Plaintiffs are not entitled to a writ of mandamus or declaratory relief because the facts and circumstances of this case do not warrant such extraordinary relief.

Second, if this Court reviews Plaintiffs' Motion on the merits. Defendants argue that Plaintiffs are not entitled to injunctive relief because this matter does not meet the requisite factors before injunctive relief con be granted.[1]

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(1) whether the movant has a "strong" likelihood of success on the merits; (2)whether the movant would otherwise suffer irreparable injury; (3) whether

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Defendants claim that: (1) nonpayment of Medicare claims for laboratory services is not irreparable harm; (2) the public interest would be disserved by requiring the Secretary to continue Medicare payments to a laboratory that engaged in such serious misconduct with respect to the handling of proficiency testing samples; and, (3) the balance of the equities weighs against granting injunctive relief.

For the reasons set forth below, Plaintiffs' Motion for Injunctive Relief is **DENIED**, Plaintiffs' request for declaratory judgment and mandamus is **DENIED**; and, Defendants Motion to Dismiss is **GRANTED**.

II. Background

A. The Parties

PFM provides family/primary care physician services including laboratory testing. Plaintiffs, Drs. Weisman and Talbert, are practicing physicians with PFM and are also the President and Director, respectively, of PFM. Defendant, Secretary Health and Human Services, through the Centers for Medicare and Medicaid Services (CMS - a component of the Department of Health and

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issuance of a preliminary injunction would cause substantial harm to others; and (4) whether the public interest would be served by issuance of a preliminary injunction. *United Food & Commercial Workers Union,* Local *1099 v. Southwest Ohio Regional Transit Auth.,* 163 F.3d. 341, 347 (6th Cir. 1998)

Human Services)[2] is responsible for operating the Medicare Program and is statutorily empowered with enforcement authority for the regulations regarding clinical laboratories. Defendant, Administrator of CMS, is responsible for the administration of the Medicare Program and shares responsibility for the proposed actions by CMS against Plaintiffs which are at issue here.

B. PFM Accreditation

As a clinical laboratory, PFM is required to comply with the provisions of the Social Security Act and with CLIA regulations. PFM is entitled to payment from Medicare for medically necessary, covered laboratory services it renders to its Medicare patients so long as PFM is deemed to be compliant with the above referenced statutory law. In order to assist in the compliance with and enforcement of the CLIA requirements, CMS has approved COLA (formerly the Commission on Office Laboratory Accreditation) as an accreditation organization for laboratories under the CLIA program.

Prior to such approval, HCFA conducted a detailed and in-depth comparison on COLA's requirements[3] for its laboratories to those of CLIA and

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[2] CMS was formerly known as the Health Care Financing Administration (HFCA).

[3] The COLA Accreditation Manual was created to inform persons involved with laboratory medicine how COLA works. The Manual also includes the following references to the CLIA and HCFA: (1) "COLA has been approved by the federal government as a private non-profit accrediting organization for CLIA purposes;" (2) "COLA accreditation has been deemed by the federal government to be equivalent to the CLIA regulations. (3) 'Deeming authority' (i.e.,

dermined that it should grant approved status to COLA as a private nonprofit organization for accrediting laboratories under CLIA for specific specialty or subspecialty areas of human specimen testing.[4]

On July 31, 1992, HCFA issued a final rule (57 FR 33992). Under section 353(e)(2) of the Public Health Service Act (PHSA), HCFA may approve a private nonprofit organization to accredit clinical laboratories (an "approved accreditation organization") under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) program if the organization meets certain requirements.

An organization's requirements for accredited laboratories must be equal to, or more stringent than, the applicable CLIA program requirements in 42 Code of Federal Regulations (CFR), part 493 (Laboratory Requirements). Therefore, a laboratory accredited by an approved

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equivalent standard) is a COLA status recognized by HCFA; (3) Laboratories accredited by COLA are 'deemed' to meet the government standards; and COLA-accredited labs are not routinely inspected by the government; (4) "As a result of being granted deeming authority, some COLA criteria now mirror federal CLIA requirements;" (5) Once a laboratory applies to COLA for accreditation, HCFA recognizes the lab as a COLA-accredited laboratory; and (7) Although it's useful to see the relationship between the COLA and CLIA standards, COLA-accredited laboratories are quartered to meet COLA standards, not CLIA. *COLA* Accreditation *Manua[, §3*

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[4] Baciedology, mycobacteriology, mycology, parasitology, virology, syphilis serology, general immunology, routine chemistry, endocrinology, toxicology, urinalysis, and hematology, immunohematology.

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accreditation organization that meets and continues to meet all of the accreditation organization's requirements would be considered to meet CLIA condition level requirements if it were inspected against CLIA regulations. The regulations listed in subpart E (Accreditation by a Private, Nonprofit Accreditation Organization or Exemption Under an Approved State Laboratory Program) of part 493 specify the requirements an accreditation organization must meet to by an approved accreditation organization. HCFA approves an accreditation organization for a period not exceed 6 years. 65 FR 64966.

In establishing laboratory compliance with CLIA requirements, COLA must, among other conditions and requirements (1) use inspectors qualified to evaluate laboratory performance and agree to inspect laboratories with the frequency determined by CMS; (2) apply standards and criteria that are equal to or more stringent than CMS

requirements; (3) provide reasonable assurance that these standards and criteria are continually met by its accredited laboratories; (4) provide CMS with the name of any laboratory that had its accreditation denied, suspended, withdrawn, limited, or revoked within 30 days of the action; (5) notify CMS in writing at least 30 days before the effective date of any proposed changes in its standards; and, (6) if CMS withdraws its approval, notify the accredited laboratories of the withdrawal within 10 days of the withdrawal. *65 FR* 64966 (October *31, 2000).* COLA's requirements for PT are equivalent to those of CLIA. ld.

C. September 3,1999 COLA Letter to PFM

In a letter dated September 3, 1999 PFM was first notified by COLA of a pending denial of COLA accreditation due to PFM's complicity in proficiency test (PT) averaging, resulting in an improper referral, collaboration, and integration at PFM's laboratory in 1998 and 1999. (See September 3, 1999 Letter from COLA to Plaintiff Talbert attached to Plaintiffs' Verified Complaint as Exhibit B). Upon receipt of the Letter, Plaintiffs Weisman and Talbert contend that they conducted an immediate investigation into the allegations by COLA and learned that while PFM's laboratory technician, Marilyn Nichols, had properly tested the proficiency of PFM's laboratory as required by COLA and CLIA, she had averaged the test results with test results she had obtained at two other laboratories where she worked. She then reported the averaged test results to Medical Laboratory Evaluation (MLE), a COLA and CMS approved proficiency test program.

On or about October 19,1999, COLA denied PFM's COLA accreditation based upon "knowingly comparing results of proficiency test prior to the proficiency test program end-date for receipt of the results." (See October 19, 1999 letter from COLA to Plaintiff Talbert attached to Plaintiffs' Verified Complaint as Exhibit). At some point after the PT averaging discovery, Plaintiffs terminated Marilyn Nichols and hired Lawrence S. Michaelski, a certified chemist with over thirty years of clinical laboratory experience and the Chemistry Supervisor of Crittenton Hospital in Rochester, Michigan. After hiring Mr. Michaelski, Plaintiffs designed and implemented a Quality Assurance Program which has been in place at PFM since January 2000. Plaintiffs submitted proof of their remedial efforts to COLA and requested a reconsideration of the denial of COLA accreditation. Ultimately, after a hearing on February 19, 2000, the COLA Accreditation Committee voted to reverse the initial decision to deny accreditation (reversal "constitutes the final action of the Accreditation Committee") and notified Plaintiffs in a letter dated March 3, 2000. (See March 3, 2000 letter from COLA to Plaintiff Tolbert attached to Plaintiffs' Verified

Complaint as Exhibit J). From early March 2000 until the present, Plaintiffs allege that PFM has been fully compliant with all applicable CLIA and COLA requirements.

Defendants have not presented any evidence to the contrary. Plaintiffs further allege that during an on-site survey at PFM in April 2001, no new deficiencies were noted[5] ; only the violation of which PFM was notified by COLA in September of 1999, and determined by COLA in March 2000 not to warrant the revocation of the laboratory accreditation.

D. May 29, 2001 CMS Letter to PFM

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[5] On April 10, 2001, a complaint investigation survey was conducted by Lucy Estes, CLS, MSA, who is a laboratory evaluation specialist and employed by the Michigan Department of Consumer and industry Services (MDICS), Laboratory Improvement and Special Projects Section. (Declaration of *Lucy Estes, CLS, MSA)*

Despite this compliance, Quality Assurance Program and "final action of the Accreditation Committee" to not deny accreditation, based on the 1998 and 1999 testing events, Plaintiffs were informed in a letter dated May 29, 2001 from HCFA (CMS) that the Michigan Department of Consumer and Industry Services (MDCIS) conducted a complaint investigation survey at PFM on April 10, 2001 to determine whether "improper referral, collaboration, and integration occurred at PFM's laboratory during proficiency testing events of 1998 and 1999." (See May *29, 2001* letter from HCFA *to Plaintiff Talbert attached to Plaintiffs' Verified* Complaint *as Exhibit K).*

In the May 29, 2001 letter, HCFA (CMS) alleged that PFM'S laboratory was not in compliance with CLIA as a result of an "improper referral, collaboration, and non-integration [which] occurred during specific 1998-1999 testing events;" and, therefore, PFM was deemed non-compliant with 42 C.F.R. § 493.1441, 493.61 (b) (1); and 493.801 (b) (3) and 42U.S.C.§ 263a(d) (1) (E). Consequently, certain penalties were imposed: (1) cancelling PFM's laboratory's approval to receive Medicare payment for services effective July 2, 2001; and (2) the future revocation of PFM's CLIA Certificate of Accreditation.

E. Procedural Process Undertaken By Plaintiffs In Response To The May 29, 2001 Letter

On June 14, 2001, Plaintiffs presented their request to Defendant Secretary of Health and Human Services to reverse CMS' determination to impose these additional sanctions upon PFM. (See *Plaintiffs' Verified* Complaint, pg. 13*, ¶46).* Plaintiffs allege that they have no idea when the procedural process will get underway. Plaintiffs

allege that they requested an expedited hearing with the Administrative Law Judge (ALJ) on June 18, 2001, and were told by Jacqueline Williams, Chief of the Civil Remedies Division at CMS, "it happens [the hearing] when it happens." Id. *at ¶47.* On June 27, 2001, Plaintiff filed a request for a hearing before an ALJ of the Department of Health and Human Services pursuant to 42 C.F.R. § 493.1844. Id. *at ¶48.*

F. Pendency ot ALJ Hearing

Plaintiffs acknowledge that revocation of PFM'S CLIA Certificate of Accreditation will not take effect until a decision is rendered by the ALJ of the Department of Health Services pursuant to 42 C.F.R. § 493.1844(d)(2). However, the effective date of the cancellation of PFM's approval to receive Medicare payment for its laboratory services, July 2, 2001, was prior to any opportunity for an ALJ decision. Moreover, Defendants are permitted to publish in a local newspaper and in the laboratory registry, information about PFM and its directors being sanctioned. 42 C. F. R. § 1844 (g) (1).

G. The CMS Complaint lnvestigation

CMS imposed its sanction determination based on a complaint investigation survey performed at Plaintiffs' laboratory by the MDCIS at CMS's request. CMS requested the survey of PFM after inspections by MDCIS of two other Detroit-area laboratories employing the same laboratory technician for proficiency testing as PFM (Marilyn Nichols). This investigation uncovered the alleged prohibited referral and/or collaboration of PT results. PFM was identified as the third laboratory involved in this alleged unlawful conduct detailed above which occurred in 1998 and 1999. (See *Declaration of Richard J.* Benson ¶ 9-18 attached to Defendants' Memorandum of Low *in* Opposition *to Plaintiffs'* TRO *Motion as Exhibit 1).* It is important to point out that COLA had an obligation to notify CMS in September 1999 when it made the decision to deny accreditation to PFM. 65 *FR* 64966 (October 31, 2000). Plaintiffs have presented no evidence that COLA did that, and Defendants state that COLA did not notify CMS about its withdrawal of Plaintiff' accreditation status. (Defendants' Motion to *Dismiss, pp. 7-12).*

III. Standard of Review

A. Subject Matter Jurisdiction

Pursuant to Federal Rule of Civil Procedure 12(b) (1), when "considering a motion to dismiss for lack of subject matter jurisdiction, the person asserting jurisdiction bears the burden of showing that the case is properly before the court at all stages of the litigations." *Fed. Realty Inv. Trust v.* Juniper Props. *Group*, No. 99-3389, 2000 WL 45996, at 3 (E.D.Pa.2000) (citing Packard *v. Provident Nat'l Bank, 994* F.2d 1*039, 1045 (3d Cir. 1993), cert.*

denied, 51 0 U.S. 964, 114 S.Ct. 440, 126 L.Ed.2d 373 (1993)). The district court, when reviewing a motion to dismiss for lack of subject matter jurisdiction, "must accept as true the allegations contained in the plaintiff's complaint, except to the extent federal jurisdiction is dependent on certain facts." Id. *(citing Hoydo v. Amerikohl Mining,* Inc., 830 F.2d 494, 496 (3d Cir. 1987)).

The district court is not confined to the face of the pleadings when deciding whether subject matter jurisdiction exists. Id. *(citing Armstrong World Indus.* v. *Adams,* 961 F.2d 405, 410, n. 10 (3d Cir.1 992)). "in assessing a Rule 12 (b) (1) motion, the parties may submit and the court may consider affidavits and other relevant evidence outside of the pleadings." *Id. (citing Berardi v.* Swanson Mem'l Lodge No. *48 of Fraternal Order* of Police, 920 F.2d 198, 200 (3d Cir. 1 990)). In the case where the defendant attacks jurisdiction with supporting affidavits, "the plaintiff has the burden of responding to the facts so stated." Id. "A conclusory response or a restatement of the allegations of the complaint is not sufficient." Id. *(citing lnt'i Ass'n* of Machinists & Aerospace Workers v. *Northwest Airlines,* Inc., 673 F.2d 700, 711 (3d Cir. 1982)).

IV. Finding of Fact

For purposes of resolving the issues before the Court, the following are accepted as fact:

1. While COLA is an approved accreditation organization for laboratories under the CLIA program, CMS reserves the right to conduct validation and complaint investigation surveys in order to ensure compliance with CLIA requirements. 65. *FR 64966.*

2. The language in the COLA Accreditation Manual conflicts with 65 FR 64966 (October 31, 2000) to the extent that in the COLA Manual, CMS appears to confer full authority upon COLA to work through noncompliance issues. However, in the Federal Register, it is recognized that although a COLA accreditation "provides reasonable assurance that the laboratories accredited by it meet the conditions required by CLIA law and regulations," these accredited laboratories remain subject to federal validation and complaint investigation surveys. Id.

3. COLA cited PFM for PT Violations and denied PFM an accreditation as a result. After reconsideration by COLA and implementation of a Plan of Correction which has been followed by PFM, CMS was never notified in accordance with 65 FR 64966 by COLA about PFM's alleged PT deficiencies and the process that followed.

4. If COLA had given CMS notice of its accreditation activity with PFM, CMS would have been able to begin its investigation sooner, especially since CMS was already investigating two other Detroit laboratories which also had PT deficiencies and which also employed Marilyn Nichols.[6]

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[6] Accredited laboratories (i.e., COLA) are obligated pursuant to 65 FR 64966-01 to "[p]rovide HCFA with the name of any laboratory that has had its accreditation denied, suspended, withdrawn limited, or revoked within 30 days of the action taken.

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5. CMS and COLA View the issue of "intent" differently when determining whether a laboratory should be held responsible for "knowingly comparing results of proficiency tests prior to the PT program end-date for receipt of results."

6. In reversing itself, COLA did not impute the actions of PFM's laboratory technician to the laboratory director. On the other hand, CMS holds the laboratory and its director accountable for all business activity related to the functioning of the laboratory.

V. Conclusions of Law

A. Subject Matter Jurisdiction

The express language of 42 U.S.C. § 405(h) bars district court jurisdiction over an action to compel payment of Medicare reimbursement because the

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[7] During the COLA investigation process, it determined that "the knowledge of the lab technician should not be imputed to the laboratory itself," *(Exhibit* J of *Plaintiffs' Verified.Compliaint for* Declaratory *Judgment, Mcindamus and Injunctive Relief).* Conversely, CMS imputes the actions of a laboratory technician upon the laboratory director and the laboratory itself by indicating that "as laboratory director, [you] have not fulfilled your responsibility of assuring that PT samples are tested as required under 42 CFR 493, subpart H. The deficiencies noted in this letter and the HCFA-2567 demonstrate that you have failed to fulfill your responsibility for the overall operation and administration of your laboratory. Therefore, the *condition* level *requirement for* a laboratory director *is out* of compliance *at 42* CFR § 4930.1441." Exhibit K of Plaintiffs' Verified Complaint for Declaratory Judgment, Mandamus and Injunctive Relief).

Medicare Act requires exhaustion of administrative remedies before judicial review.

Since Plaintiffs' claim arises under the Medicare Act, the general rule is that this Court does not have subject matter jurisdiction. *Shalala V. Illinois Couvncil* on Long *Term* Care, Inc. 529 U.S. 1. 10 (2000); *Heckler v. Ringer, 466* U.S. 602 (1984); *Weinberger v. Salfi,* 422 U.S. 749 (1975); *Cathedral Rock of North* College *Hill v.* Shalala, 223 F.3d 354 (6th Cir. 2000); *Michigan Association of* Homes and Services for *the Aging v. Shalala,* 127 F.3d 496, 500-01 (6th Cir. 199*7); Monakee* Professional Medical *Transfer* Service, Inc. v. *Shalala, 71* F.3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue* Shielct of *Michigan,* 24 F.3d 853 (6th Cir. *1994); Livingston* Care Center *v.* United States, 934 F.2d 719, 721 (6th Cir.), cert. denied., 502 U.S. 1003 (1991).

Having concluded that this Court lacks subject matter jurisdiction, it is unnecessary and inappropriate, for the Court to reach the other issues raised by Plaintiffs.

Conclusion

Even though this Court finds in favor of Defendants, the Court is troubled that the law allows COLA to make determinations concerning violations; communicate with PFM about the problem; and, work out a Corrective Plan, yet CMS can enter the picture over a year later and, in effect, vitiate COLA's entire investigation and efforts to reinstate accreditation for P FM, which has remained in compliance with CLIA requirements. There are several references in the Federal Register as to how comparable and “equivalent" COLA accreditation standards are to those of CLIA.[8]

However, the law also seems to allow CMS to completely ignore the COLA finding and the Corrective Plan that is in place, as well as impose stiffer sanctions for the some conduct in however long a time frame it desires.

This Court finds that PFM justifiably believed that it had resolved its accreditation problems based upon the fact that it had been in compliance with its Corrective Plan for over a year; and, because COLA represented its actions to be final.

Therefore, it is unfortunate that PFM, must in effect, be subjected to the entire validation and complaint investigation all over again.

However, the Court finds that, despite the apparent inequity of the matter, the express language of 42 U.S.C. § 405(h) and the above cited case low bars

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[8] COLA has been approved as an accreditation organization for laboratories under the CLIA programrm; COLA requirements for PT are equivalent to those of CLIA according to the Federal Register; accreditation and approval of a laboratory by COLA meets the applicable CLIA condition level requirements for laboratories as indicated in the Federal Register; COLA has complied with the requirements under CLIA for approval as an accreditation organization according to the Federal Register; COLA's requirements are equal to the CLIA requirements; and COLA's laboratory enforcement and appeal policies are essentially equivalent to the requirements of the Federal Register as they apply to accreditation organizations.

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this Court from compelling payment of Medicare reimbursement, under either 28 U.S.C. § 1 331 or 28 U.S.C. § 1346. Therefore, upon consideration of the Verified Complaint and motions and briefs of the parties, it is hereby **ORDERED** that Plaintiffs' Motion for Temporary Restraining Order & Preliminary Injunction [**Doc. # 2-1**] is **DENIED**.

IT IS fURTHER ORDERED THAT this Court is without subject matter jurisdiction and that accordingly, Defendants' Motion to Dismiss [**Doc. #6-1**] is **GRANTED**.

IT IS FURTHER ORDERED THAT Plaintiffs' request for declaratory relief and request for a mandamus action in Plaintiffs' Verified Complaint [**Doc. #1 –1**] is **DENIED**.

IT IS SO ORDERED.

Victoria A. Roberts

United States District Judge

DATED: **JUL 31 2001**

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Mark Gary Hertzberg, M.D., P.C.,

Petitioner,
DATE: August 3, 2001
- v -

Centers for Medicare & Medicaid Services
Docket No.C-99-763
Decision No. **CR805 DECISION**

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS)[(1)] to impose remedies against Petitioner, a physician-owned laboratory known as Mark Gary Hertzberg, M.D., P.C., pursuant to the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a *et seq.* (CLIA). The remedies which I sustain include: (1) cancellation of Petitioner's approval to receive Medicare payment for its services beginning 60 days from Petitioner's receipt of CMS's June 23, 1999 remedy determination notice and continuing until the date of this decision; and (2) revocation of Petitioner's CLIA certificate effective the date of this decision.

I. BACKGROUND

A. Background facts

As I discuss more fully below, CMS submitted 27 exhibits (CMS Exs. 1 - 27) and Petitioner submitted five exhibits (P. Exs. 1 - 5) during the course of these proceedings. I receive into evidence CMS Exs. 1 - 27 and P. Exs. 1 - 5. In receiving these exhibits into evidence, I overrule any objection the parties made to making them part of the record.

Petitioner is a clinical laboratory that is located in Southfield, Michigan. Petitioner is owned and operated by Mark Gary Hertzberg, M.D. Dr. Hertzberg serves as Petitioner's laboratory director. On February 25, 1999, surveyors employed by the Michigan Department of Consumer and Industry Services (Michigan State survey agency) conducted a complaint investigation of Petitioner to determine whether Petitioner was complying with CLIA requirements. The surveyors made findings which were referred to CMS. On June 23, 1999, CMS notified Petitioner that CMS had determined that Petitioner had intentionally referred its proficiency testing samples to another laboratory for analysis and it had been found to be deficient in complying with CLIA requirements. CMS Ex. 4. CMS advised Petitioner that it had determined to impose remedies against Petitioner which included cancellation of Petitioner's approval to receive Medicare payment for its services and revocation of Petitioner's CLIA certificate for at least one year.

Petitioner responded to CMS's notice with letters dated June 28, 1999, and August 9, 1999. CMS Exs. 20 and 21. Petitioner denied CMS's allegations and contended that CMS had misunderstood the manner in which the laboratory dated its worksheets.
CMS responded to Petitioner's letters on August 17, 1999. CMS Ex. 22. CMS clarified and set forth in more detail its basis for imposing CLIA sanctions on Petitioner. In this second notice, CMS advised Petitioner that it had based its determination to impose remedies on its finding that Petitioner had referred proficiency testing samples to another laboratory for testing or had improperly collaborated with another laboratory in the testing of proficiency testing samples. CMS asserted that this conduct constituted noncompliance with 42 C.F.R.§ 493.801, the CLIA condition concerning proficiency testing. CMS provided a point by point response to Petitioner's arguments concerning the laboratory records. CMS also withdrew one of the deficiencies not related to the proficiency testing.
Petitioner requested a hearing on August 19, 1999, and the case was assigned to me on September 30, 1999 for a hearing and a decision.
On September 3, 1999, CMS forwarded to Petitioner certain additional evidence upon which it had based it determinations. This evidence was a spread sheet that compared the proficiency testing results reported by Petitioner in 1998 with the identical (and nearly identical) results reported by eight other area laboratories. CMS Ex. 23. The nine laboratories at issue in this case employed either Deborah Sabo or Rene Wheatley as testing personnel. CMS Ex. 25 at 3.
CMS moved for summary disposition. CMS's motion was accompanied by 25 exhibits which I identify as CMS Exs. 1 - 25. Petitioner filed a response brief in opposition to CMS's motion. Attached to Petitioner's brief were three documents labeled P. Exs. 1 - 3. CMS filed a reply in support of its motion for summary disposition. Petitioner then moved to file a surreply. I granted Petitioner's request and accepted Petitioner's accompanying surreply into the record.
On May 16, 2000, CMS submitted additional documents, including the transcript of the in-person hearing in the case of *Stanley Boykansky, M.D.*, DAB CR690 (2000) and CMS's posthearing brief in *Boykansky*.[(2)] I identify the transcript as CMS Ex. 26, and the copy of the brief as CMS Ex. 27. Petitioner objected to the admission of these submissions, but offered Boykansky's posthearing brief in *Boykansky* should CMS's posthearing brief be admitted. (Petitioner and Boykansky were represented by the same counsel.) I identify Boykansky's posthearing brief in *Boykansky* as P. Ex. 4.
On May 31, 2000, Petitioner filed a motion for summary disposition with a supporting brief. CMS then filed a response in opposition to Petitioner's motion accompanied by one attachment. Petitioner filed a reply.
On September 25, 2000, I convened a prehearing conference in which I informed the parties that I was denying Petitioner's motion for summary disposition, and that I would address Petitioner's arguments in my written decision in this case. Pursuant to Petitioner's request, I scheduled an in-person hearing for November 8, 2000. On November 2, 2000, this hearing was canceled at the request of the parties, and the parties were given additional time to submit written documents which they said would obviate the need to take in-person testimony.
On November 2, 2000, the parties filed a stipulation that if Ms. Sabo, the testing personnel for Petitioner and the Boykansky laboratory, were to testify in this matter, her

testimony would be the same as her April 12, 2000 testimony given in the hearing before the ALJ in *Boykansky* and contained in the transcript from that proceeding (CMS Ex. 26). Petitioner subsequently submitted a supplemental affidavit by Ms. Sabo. I mark this document as P. Ex. 5. CMS and Petitioner simultaneously filed concluding briefs and waived the filing of response briefs.

B. Governing law

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*.[(3)] The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. CLIA grants the Secretary of the United States Department of Health and Human Services broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for a certificate.

A laboratory's CLIA certification is dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. The CLIA regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as broadly stated general requirements which must be met in order for a laboratory to qualify under CLIA. Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. Standards are subparts of the more broadly stated conditions. A failure by a laboratory to comply with one or more standards may be so serious as to constitute failure to comply with the condition of which the standards are subparts. *Stanley Boykansky, M.D.*, DAB No. 1756, at 18 - 19 (2000).

A key component of the statutory and regulatory program to assure that laboratories holding CLIA certificates are competent to perform tests of moderate and high complexity is the requirement for participation in a proficiency testing program that is approved by CMS, as outlined in 42 C.F.R. Part 493, Subpart H. Among the requirements of that subpart are the following: a participating laboratory must test proficiency testing samples it receives in the same manner as it tests patient samples; must not communicate the results of its tests to other laboratories prior to the deadline for reporting results; must not refer proficiency testing samples to another laboratory for analysis; and must document and maintain documentation for the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. 42 C.F.R. § 493.801.

The CLIA regulations authorize CMS or its designee (in this case the Michigan State survey agency) 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 enforcement authority on CMS in order to assure that laboratories comply with CLIA. 42 C.F.R. § 493.1800. Where CMS determines that a laboratory is not complying with one or more CLIA conditions, CMS may impose as remedies *principal* sanctions against the laboratory

which may include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). CMS may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). Additionally, CMS 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).

A laboratory that is dissatisfied with a determination by CMS to impose sanctions against it may request a hearing before an administrative law judge to contest CMS's determination. 42 C.F.R. § 493.1844. The CLIA regulations at 42 C.F.R. § 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E.

The standard of proof that is employed at a hearing concerning CMS's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. CMS has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by CMS. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

II. ISSUE, FINDINGS OF FACTS AND CONCLUSIONS OF LAW

A. Issue

The issue in this case is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving CMS the authority to impose remedies against Petitioner, including canceling Petitioner's approval to receive Medicare payments and revoking Petitioner's CLIA certificate.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail and address Petitioner's arguments.

1. CMS properly notified Petitioner of condition-level deficiencies.

Petitioner asserts that CMS did not give it proper notice of condition-level deficiencies in accordance with 42 U.S.C. § 263a(i), 42 C.F.R. § 493.1842(b), and 42 C.F.R. § 493.1844(g). Petitioner argues that, as a result of this alleged failure, CMS is without authority to impose principal sanctions against Petitioner.

First, Petitioner argues that the initial (June 23, 1999) notice was improper because it imposed principal sanctions, but did not cite any condition-level deficiencies and was based on the attached Statement of Deficiencies (HCFA Form 2567). The Statement of Deficiencies also listed only standard-level deficiencies cited by the surveyors.

Petitioner asserts that CMS cannot impose principal sanctions pursuant to a finding of only standard-level deficiencies. Petitioner argues that the "surveyors found no condition level deficiencies, and they cannot simply be created by HCFA as a result of the standard level violations alleged." Brief in support of Petitioner's motion for summary disposition at 9.

Petitioner's assertions that CMS cannot impose principal sanctions for standard-level deficiencies and that CMS is limited to the surveyors' findings is premised on a misreading of the CLIA sanction process. Appellate panels of the Departmental Appeals Board have repeatedly ruled that "a laboratory can be so pervasively noncompliant with standards as to have failed to have complied with the overall condition." *Boykansky*, DAB No. 1756, at 18 - 19. Therefore, the violation of a standard may constitute violation of a condition. Further, CMS is not limited to the surveyors' findings. Rather, CMS is authorized to make independent determinations about the nature and severity of a laboratory's noncompliance with CLIA requirements.[(4)] *Boykansky*, DAB No. 1756, at 7.

In the first notice, CMS informed Petitioner that CMS had determined that Petitioner had referred proficiency testing samples to another laboratory for analysis and that, based on this failure, it proposed sanctions of cancellation of Petitioner's approval to receive Medicare payments and revocation of Petitioner's CLIA certificate. CMS Ex. 4. In the first notice, CMS expressly cited 42 C.F.R. § 493.801(b)(4), the CLIA standard concerning intentional referral of proficiency testing samples. This standard specifically mandates the principal sanction of certificate revocation. Therefore, the fact that the specific regulatory provisions cited in the attached Statement of Deficiencies concerned only standard level deficiencies does not make the notice inadequate to impose principal sanctions.

Second, while Petitioner acknowledges that the second notice (August 17, 1999) cited a condition-level deficiency for noncompliance with 42 C.F.R. § 493.801 (enrollment and testing of samples), and two new standard-level deficiencies, 42 C.F.R.§ 493.801(b)(3) and 42 C.F.R. § 493.801(b)(5), Petitioner argues that the second notice is deficient because it was received after the sanctions were imposed and provided no opportunity to respond or appeal previously undisclosed deficiencies.

I disagree. An appellate panel has determined that CMS may subsequently amend its initial notice to impose CLIA sanctions.[(5)]

Boykansky, DAB No. 1756, at 6. CMS issued its second notice prior to Petitioner's request for a hearing which was dated August 19, 1999 (although Petitioner did not receive the second notice prior to submitting its request). CMS inadvertently failed to enclose the chart of the nine laboratories' results on which it based its determination of referral or collusion. This omission was corrected by a September 3, 1999 mailing. Petitioner was fully informed of CMS's position and had a copy of the evidence upon which CMS based its decision prior to any substantive development of the record in this case. Petitioner has had a full opportunity to develop its rebuttal to CMS's allegations. Thus, the second notice constitutes an acceptable amendment of the first notice.

Petitioner argues that it was prejudiced by this sequence of events because: (1) the date of the termination of its Medicare payments was based on the allegedly invalid first notice and was therefore miscalculated; and (2) Petitioner was not given an opportunity to respond to the second notice prior to the termination of Medicare payments.

Neither of these factors constitutes prejudice in this case. Since I conclude that the first notice was valid, the date of the termination of Medicare payments was properly calculated. Furthermore, pursuant to the information in the first notice, Petitioner was given an opportunity to respond to the determinative allegation that it had referred proficiency testing samples to another laboratory for testing. While I agree that Petitioner may have theoretically been in a better position to respond had it been given

all of CMS's information as of June 23, 1999, including the chart of coincidental results from the nine laboratories, CMS's failure to provide the information at that time made no practical difference in this case. Though Petitioner has denied collusion or referral, it has offered no persuasive evidence to rebut CMS's findings or to show in any way that the amended notice hampered its ability to rebut CMS's findings. Therefore, Petitioner has failed to show any prejudice resulting from CMS's amended notice.

2. During 1998, Petitioner colluded with other clinical laboratories in the performance of proficiency testing.

Petitioner colluded with other laboratories during 1998 in the performance of proficiency testing. The evidence in this case provides overwhelming support for this conclusion. Petitioner did not rebut the evidence of collusion.

The condition of participation that is stated at 42 C.F.R. § 493.801 requires that a clinical laboratory must enroll in a proficiency testing program that meets defined criteria and which is approved by the United States Department of Health and Human Services. It also requires laboratories to test the proficiency testing samples in the same manner as patients' specimens.

Petitioner enrolled in an approved proficiency testing program that is operated by the American Association of Bioanalysts (AAB). *See* CMS Ex. 24. Petitioner received a group of proficiency testing samples from the AAB at regular intervals each year. Other clinical laboratories who were enrolled in the AAB proficiency testing program received the same samples at the same time. I take notice of the fact that the AAB refers to each mailing of samples to laboratories for proficiency testing as an "event."

The object of the proficiency testing exercise is for each participating laboratory to test its samples independently as if they are patient specimens and to report the results of its tests to the AAB. The laboratories were required to test five samples for each analyte. The AAB scores the results for the tests that are performed for each event and rates each laboratory's testing competency for that event based on the scores that the laboratory obtains. Petitioner was required to test for cholesterol, HDL cholesterol, glucose, triglycerides, iron, thyroid stimulating hormone (TSH), total thyroxine, triiodothyronine, and thyroid uptake. CMS Ex. 8, CMS Ex. 25 at 3.

For many of the proficiency tests that Petitioner and other laboratories were asked to perform in 1998, there was no such thing as a single "correct" score. CMS Ex. 24 at 3 - 4. For these tests, the AAB accepts scores that fall within a range of possible scores as "correct" because of the wide range of variables that are involved in the testing process. *Id*. For example, the third testing event of 1998 included testing triglyceride samples. CMS Ex. 25 at 39. For the first sample of that event, a laboratory would receive a passing score if it identified a triglyceride level which fell anywhere in a range of values of between 140 to 233. *Id*. For the fourth sample, acceptable values ranged between 96 to 160. *Id*.

During 1998, Petitioner and eight other laboratories located in the Detroit, Michigan area submitted proficiency test results that were virtually identical. CMS Ex. 24 at 3. Indeed, on numerous tests, Petitioner and the other eight laboratories submitted scores that were precisely identical. *Id*. The inference that arises from Petitioner and eight other laboratories submitting virtually identical proficiency testing results for numerous samples in three testing events during a single year - especially given the variable

factors that were at play - is that Petitioner and the other laboratories colluded with each other to produce those results. There is no reasonable likelihood that nine laboratories independently would produce nearly identical results on numerous proficiency tests for three events in a single year. CMS Ex. 24 at 4; CMS Ex. 25 at 4 - 5.

The evidence which supports my conclusion that Petitioner and eight other laboratories colluded with each other to produce nearly identical proficiency testing results in 1998 includes the declarations of two experts: Dennis W. Jay, Ph.D., DABCC, Technical Director of the AAB Proficiency Testing Service (CMS Ex. 24) and Richard J. Benson, CLS, MT, Chief, Laboratory Improvement Section, Bureau of Health Systems, of the Michigan State survey agency (CMS Ex. 25). I find these experts to be well-qualified and their opinions to be persuasive.

As to the testing for triglycerides and total cholesterol, Dr. Jay stated in his declaration:

> The lack of variability in results submitted for triglycerides and total cholesterol was particularly unusual since these assays typically show poorer reproducibility from laboratory to laboratory when compared to other routinely performed tests. This is particularly so in the case of Hertzberg and the eight neighboring laboratories, given that the methods used by these laboratories are preformed manually. Manually performed methods show poorer reproducibility when compared to automated methods. Based upon my education and experience, given the imprecision of the testing methodology and the range of acceptable results, I would expect to see variation in results on the order of 10-20% for these assays. Instead, for cholesterol and triglycerides the exact same values were reported by all nine laboratories.

CMS Ex. 24 at 3 - 4.

Dr. Jay concluded:

> In my professional opinion, the chances of nine laboratories independently arriving at the same values by happenstance for all five specimens for even two different tests are close to nil. The identity of the Hertzberg's reported results for nine analytes, five specimens each, with nearly every result reported by as many as eight other laboratories in the same geographic area leads to the inescapable conclusion that the results that were reported to AAB were arrived at through referral, or collaboration, or both.

Id. at 4.

Mr. Benson came to the same conclusion. CMS 25 at 4 - 5. In his letter recommending the revocation of Petitioner's CLIA certificate, Mr. Benson wrote:

> [T]he possibility of nine testing locations arriving at **one** identical result that is obtained in the course of manual diluting, incubating, measuring and calculating of standards followed by further calculation of patient values is a strain on the premise of coincidence. In many instances, the results reported are triple digit whole numbers. The *slightest* variation in technique or calculation would result in numerical diversity. For nine testing locations to arrive at identical results for a set of **five** values defies belief. For testing locations to arrive at identical results for a **no less than 20** results (each facility exactly matched cholesterol, high density lipoprotein, triglyceride and thyroid stimulation hormone) is absurd.

CMS Ex. 2 at 2.

> Petitioner challenges these experts' opinions on the ground that they have not demonstrated any background or training in statistics sufficient to enable them to opine as to the probability of different laboratories attaining identical proficiency testing results. I do not find Petitioner's argument to be persuasive. These experts did not perform statistical analyses to obtain their conclusions. Rather, their conclusions were based on their training in their respective fields, their experience in those fields, and on the evidence which pertained to the specific proficiency tests that are at issue in this case. Thus, for example, when Dr. Jay concluded that the nine laboratories, including Petitioner, could not have independently reached identical results for cholesterol and triglyceride proficiency testing, because of the poor reproducibility of such tests, he plainly based that conclusion on his training and expertise and not on a statistical analysis of test results.

I find reinforcement for my conclusion that there existed no reasonable probability that the nine laboratories would independently arrive at identical proficiency testing results on multiple occasions by the existence of differences in testing conditions among the laboratories which would have affected the test results produced by each laboratory. Although some of the laboratories had the same model spectrometer - a device that was used to perform proficiency testing - others had different models. CMS Ex. 26 at 77. All of the spectrometers were calibrated separately. *Id*. at 77 - 78. Each of the nine laboratories had its own supply of controls and reagents. *Id*. at 76 - 77. Room temperature varied from laboratory to laboratory. *Id*. at 78.

The evidence which I have discussed so far indicates that Petitioner and the other eight laboratories colluded in 1998 to produce nearly identical proficiency testing results. Additionally, the following evidence supports my finding that these laboratories engaged in collusion.

First, the evidence establishes that the opportunity for collusion existed. All nine of the laboratories submitting identical proficiency testing results employed as testing personnel one of two individuals, Ms. Sabo and Ms. Wheatley. CMS Ex. 25 at 3. During 1998, Petitioner employed Ms. Sabo. CMS Ex. 26 at 42. Ms. Sabo and Ms. Wheatley are well-acquainted. *Id*. at 42.

In the *Boykansky* hearing, Ms. Sabo denied colluding with other laboratories or individuals. CMS Ex. 26 at 21. She asserted that she performed each proficiency test for the Boykansky laboratory in the same manner that she performed tests on patients' specimens and that she integrated her proficiency testing into her routine specimen testing. *Id*. at 18 - 19, 20. Ms Sabo averred that discrepancies between proficiency testing data and the results that she reported for proficiency testing could be explained as simple errors on her part. *Id*. at 30 - 39.

The ALJ in *Boykansky*, found that Ms. Sabo's denials of complicity in collusion were not credible. He wrote:

> If anything, Ms. Sabo's testimony confirms my conclusion that collusion is the *only reasonable* explanation for the nearly identical proficiency test results that were produced by the nine laboratories. Ms. Sabo's testimony consisted, essentially, of unsupported denials of wrongdoing. Moreover, it failed to explain the overwhelming evidence that collusion occurred. Ms. Sabo was unable to provide any credible explanation how nine

> laboratories could produce identical proficiency testing results on many tests over a lengthy period of time.
>
> Ms. Sabo acknowledged that the testing she performed was subject to a large number of variables that would be likely to produce different results at different laboratories assuming that samples were tested individually at these laboratories. Tr. at 74 - 80. She admitted that, given these variable factors, it would be surprising if identical test results were produced at different laboratories. *Id*. She offered no explanation for the virtually identical proficiency testing scores produced by the nine laboratories given the acknowledged variables in the testing process. *See Id*. at 76 - 80.

Boykansky, DAB CR690, at 11.

My review of the transcript of Ms. Sabo's testimony supports the ALJ's conclusions in *Boykansky*. Further, Petitioner has introduced no evidence or arguments in this case that would cause me to reject the ALJ's conclusions as to the significance of Ms. Sabo's testimony in this case.

Second, the evidence shows that the proficiency testing results that Petitioner submitted were not consistent with Petitioner's own records of its proficiency tests. Such evidence strongly supports a conclusion that Petitioner manipulated its proficiency testing results in order to submit results that conformed to those which were submitted by the other eight laboratories. The evidence shows that Petitioner rounded proficiency testing values in a manner that is inconsistent with accepted practice in order to produce results that conformed with the results obtained by the other eight laboratories. CMS Ex. 25 at 8 - 11. Thus, in March 1998, Petitioner recorded 162.5 and reported 163; but it also recorded its fourth triglyceride sample as 182.5 and reported it as 182. *Id*. at 8 - 9. In June, Petitioner recorded 187.5 and reported 188; but it also recorded its first glucose sample as 178.5 and reported it as 178. *Id*. at 9-10. In October, Petitioner recorded 22.7 and reported 23, but it also recorded 25.7 for its first HDL sample and reported it 25. *Id*. at 11.

These rounding practices are logically inconsistent, but each one results in a figure which matches values reported by other Sabo/Wheatley laboratories. In March 1998, Petitioner reported 182 as its result for the fourth AAB triglyceride sample and so did six of the eight Sabo/Wheatley laboratories. CMS Ex. 23 at 2. In June 1998, Petitioner reported 178 as its result for the first glucose sample and so did four of the eight Sabo/Wheatley laboratories that test for that analyte. CMS Ex. 23 at 3. In October 1998, Petitioner reported 25 as its result for the first HDL sample and so did all eight of the other Sabo/Wheatley laboratories. CMS Ex. 23 at 4.

The logical inference is that the values Petitioner reported were obtained in whole or in part from analysis of samples in the other eight laboratories. This inference is supported by other anomalies in its worksheets. For example, in June 1998, like the six other laboratories testing for triiodothyronine, Petitioner reported a result of 700 for the third proficiency test sample. However, according to its own laboratory worksheet, its test result was 701, not 700. CMS Ex. 23 at 3, CMS Ex. 25 at 11 - 12.

Third, the evidence shows that Petitioner did not document its testing of proficiency testing samples in the same manner as it documented the testing process for patient samples. Patient results for cholesterol, HDL, triglycerides, and glucose are almost always expressed as integers in the worksheets. However, proficiency testing results

are carried out to one decimal place. CMS Ex. 25 at 8 - 10 . This raises additional questions as to whether the proficiency testing was done as part of Petitioner's regular workload.

In rebuttal, Petitioner asserts that "results received by AAB represent small standard deviations and thus a high probability that multiple laboratories produced the same figures." Petitioner brief in response to CMS memorandum of law in support of summary affirmance at 13. In support of this representation, Petitioner relies on the summary of proficiency testing results for TSH and triglycerides submitted to AAB for the third quadrimester of 1998. P. Ex. 3.

This exhibit does not support Petitioner's arguments for the following reasons:

- Petitioner has not accompanied its argument with any evidence as to the mathematical significance of the amount of a standard deviation.

- Petitioner cites to the standard deviations for TSH and triglycerides as supporting "a high probability that multiple laboratories produced the same figures." However, even if Petitioner's representations were supported, they address only 2 of the 9 analytes for one of the three quadrimesters in which these laboratories had coincidental results.

Petitioner also argues that Ms. Sabo had no motive to falsify the proficiency testing results for Petitioner because it would not save her any work. However, that argument is not persuasive in this context. As the appellate panel concluded in *Boykansky*:

> [L]ack of motive does not undercut the evidence supporting the ALJ's finding that the [proficiency testing] results reported by Ms. Sabo simply did not match the records she made of the [proficiency testing] that she allegedly performed.

Boykansky, DAB No. 1257, at 9.

Finally, Petitioner argues that although Ms. Sabo testified that she performed laboratory technician services in 13 laboratories in 1998, only four of these were cited for collusion. Petitioner asserted that CMS has ignored the fact that Ms. Sabo worked at twice as many laboratories that did not have the same results as Petitioner and this fact "clearly shows that neither Ms. Sabo nor Petitioner intentionally referred any proficiency testing samples to another laboratory as contemplated by CLIA." Petitioner reply to CMS response to Petitioner motion for summary disposition at 3 - 4.

I do not find this argument persuasive for the following reasons. First, the record is silent as to the test results of these laboratories. Second, even if it is assumed that these laboratories filed different results, there is no way to know whether there were factors as to these laboratories which would have interfered with collusion. For example, perhaps these laboratories were not enrolled in the AAB program; perhaps they used significantly different equipment or methods; or perhaps the laboratory directors supervised the proficiency testing process more diligently. If the circumstances and testing results of these laboratories were relevant, Petitioner had the burden to produce such evidence and it has failed to do so.

Identical proficiency testing results submitted by up to nine laboratories, coupled with discrepancies between laboratory worksheets and reported proficiency testing results and the opportunity for collusion is persuasive evidence of collaboration among laboratories. *Boykansky*, DAB No. 1756, at 8 - 11. Therefore, I conclude that CMS has

adduced persuasive evidence that Petitioner engaged in collusion with other laboratories in testing proficiency testing samples and Petitioner has offered no persuasive arguments or evidence which rebut CMS's showing of collusion.

> ***3. Petitioner's conduct in colluding with other laboratories as to the testing of proficiency testing samples during 1998 constitutes a violation of the following standards concerning proficiency testing set forth at 42 C.F.R. § 493.801(b): section 493.801(b)(1) (failing to test proficiency testing samples in the same manner as it tests patients' specimens); section 493.801(b)(3) (engaging in inter-laboratory communications pertaining to the results of proficiency testing samples); and section 493.801(b)(4) (intentionally referring proficiency testing samples to another laboratory for analysis).***

The standards for the CLIA condition of participation regarding testing of proficiency testing samples set forth at 42 C.F.R. § 493.801 require that a clinical laboratory must test proficiency test samples in the same manner as it tests patients' specimens; must not engage in inter-laboratory communications pertaining to the results of proficiency testing; and must not refer proficiency testing samples to other laboratories for analysis. 42 C.F.R. § 493.801(b)(1), (3), and (4). Petitioner did not comply with these standards during 1998.

The manner in which Petitioner performed proficiency testing - by colluding with other laboratories to obtain a collectively determined result - clearly was a departure from standard procedures for testing patients' specimens and involved communicating with other laboratories about the results of proficiency testing. This behavior was a violation of 42 C.F.R. § 493.801(b)(1) and (3).

I also find that Petitioner's conduct constitutes a violation of 42 C.F.R. § 493.801(b)(4) which prohibits intentional referral of testing samples to another laboratory. In doing so, I reject Petitioner's argument that section 493.801(b)(4) is limited to cases where physical transfer of the testing sample is established.

The question of physical transport was addressed by an appellate panel in *Oakland*, DAB No. 1755 (2000). It concluded that, while use of the word "send" in the first sentence of 42 C.F.R. § 493.801(b)(4) indicates a physical transfer, that sentence was not presented as a definition of "intentional referral" but could be read as a separate prohibition.

The appellate panel noted that the second sentence of that section states: "Any laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year." Therefore, the appellate panel concluded as follows:

> HCFA could reasonably read this sentence as applying to constructive referral as well as actual physical transfer, particularly in circumstances where the facts render physical transfer unnecessary for the outside analysis to take place. As noted by the ALJ in *Blanding Urgent Care Center Laboratory*, DAB CR438 (1996), the dictionary definition of 'refer' includes 'to direct the attention or thoughts of,' and 'to direct to a person, place, etc., for information or anything required.' *Id*. at 21 citing Random House College Dictionary, revised ed. 1980, at 1108.

* * *

> When the regulations are considered as a whole, reading section 493.801(b)(4) to encompass a constructive referral such as what occurred here is a better reading. Limiting the concept of a referral to a physical transfer is inconsistent with the underlying purposes of the condition for certification. Adopting the values achieved in another laboratory (either with or without having done the tests in one's own laboratory) clearly undercuts the general concept that the [proficiency testing] sample be tested in the same way as regular patient specimens in the laboratory are tested so that the results truly measure the proficiency of the laboratory reporting the [proficiency testing] results.

Oakland , DAB No. 1755, at 21 - 22.

Consequently, I conclude that Petitioner violated 42 C.F.R. § 493.801(b)(4). That provision codifies a statutory provision, found at 42 U.S.C. § 263(a)(i)(4), requiring CMS to revoke Petitioner's CLIA certificate for at least one year.

4. Petitioner failed to comply with the standard set forth at 42 C.F.R. § 493.801(b)(5) which requires the clinical laboratory's director to sign proficiency testing attestations.

Petitioner's owner and laboratory director, Dr. Hertzberg, did not sign the attestation statements that were submitted as part of the three proficiency testing events in 1998 in violation of the standard that is stated at 42 C.F.R. § 493.801(b)(5). CMS Exs. 8, 10, 12. That standard requires that a clinical laboratory's director must sign proficiency testing attestations. CMS asserts that Ms. Sabo, who was employed by Petitioner as its testing personnel and not as Petitioner's laboratory director, signed the statements.[(6)] Petitioner did not dispute this assertion.

5. Petitioner's failure to comply with the standards set forth in 42 C.F.R. § 493.801(b) constitutes a failure to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

If standard level deficiencies are sufficiently egregious, they will constitute a failure by a laboratory to comply with the overall condition of which the standards are subparts. *Boykansky*, DAB No. 1756, at 18 - 19. That is certainly the case here.

I conclude that Petitioner's violation of the standards for testing of samples in a proficiency testing program set forth in 42 C.F.R. § 493.801(b) constitutes failure to comply with the condition of participation stated at 42 C.F.R. § 493.801. Petitioner's collusion in the performance of proficiency testing was a deliberate effort to frustrate the purpose of proficiency testing, which is to assure that a clinical laboratory establishes its competence through an impartial proficiency testing process. Petitioner's collusion was so egregious as to make its participation in a proficiency testing program meaningless. Petitioner's collusion undermined the integrity of the proficiency testing process for other laboratories.[(7)] Furthermore, such collusion by Petitioner meant that Petitioner was not performing its proficiency tests in the manner that it normally tested patients' specimens, was engaging in inter-laboratory communication about proficiency testing samples, and was referring proficiency testing samples to other laboratories. Finally, Petitioner's owner and laboratory director failed to sign required attestation statements that it submitted as part of the first three proficiency testing events in 1998.

6. CMS is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions of participation.

CMS is authorized to impose principal sanctions, including revocation of a laboratory's CLIA certificate, as remedies for a laboratory's failure to comply with one or more CLIA conditions. 42 C.F.R. § 493.1806(a), (b). CMS may impose the additional remedy of cancellation of a laboratory's approval to receive Medicare payment for its services where the laboratory has not complied with one or more CLIA conditions. 42 C.F.R. § 493.1807.

As discussed above, the evidence in this case establishes that Petitioner failed to comply with a CLIA condition of participation. Therefore, CMS is authorized to cancel Petitioner's approval to receive Medicare payment for its services and to revoke Petitioner's CLIA certificate.

JUDGE

Alfonso J. Montano
Administrative Law Judge

FOOTNOTES

1. The Health Care Financing Administration (HCFA) has been renamed Centers for Medicare & Medicaid Services (CMS). For purposes of this decision, reference to either name will constitute reference to the same entity. In this regard, I point out, for example, that the CMS exhibits are marked with the acronym "HCFA". I have renamed these exhibits by substituting CMS for HCFA, and I refer to them as CMS exhibits.

2. With this submission as well as at other times during the proceedings, CMS submitted copies of Civil Remedies Division decisions. Since these decisions were submitted for my convenience, I do not consider them to be proposed exhibits. Both parties were given ample opportunity to address the legal significance of these decisions throughout the extensive briefing process in this case.

3. CMS may deem a laboratory to meet all applicable CLIA program requirements if the laboratory obtains a certificate of accreditation, as required in 42 C.F.R. Part 493, Subpart D, and meets the other requirements listed in 42 C.F.R. § 493.551(b).

4. As the ALJ in *Boykansky* reasoned:

> The plain meaning of [42 C.F.R. § 493.1804(b)(1)] is that HCFA has the final say on determining whether or not to impose sanctions against a laboratory. It is HCFA's decision and not that of the State survey agency which controls. Moreover, the language of the regulation is equally plain in stating that HCFA may determine independently whether a laboratory is not complying with CLIA requirements and the extent of that noncompliance. Under the regulation, HCFA finds the presence of deficiencies based on the results of inspections. *Boykansky*, DAB CR690, at 7.

5. As explained by the ALJ in *Stanley Boykansky, M.D.*, DAB CR690, at 6, the regulations which govern CLIA enforcement by CMS and hearings involving an alleged failure by a clinical laboratory to comply with CLIA requirements do not prohibit CMS

from amending or superseding a notice of an initial determination. *See* 42 C.F.R. Part 493, Subpart R.; 42 C.F.R. Part 498, Subpart D; 42 C.F.R. § 493.1844(a)(2).

6. At the in-person hearing in *Boykansky*, Boykansky and Petitioner's counsel asked Ms. Sabo if she had served as Boykansky's "technical supervisor." CMS Ex. 26 at 26. The ALJ in Boykansky surmised that counsel was trying to elicit testimony from Ms. Sabo to the effect that she served as the functional equivalent of a laboratory director. The ALJ rejected this approach, writing:

> [C]ounsel's question did not address the issue of who was Petitioner's laboratory director. Petitioner laid no foundation to show that a 'technical supervisor' at Petitioner's laboratory performed the functions of a laboratory director. I note that regulations which define the role of laboratory director state that a laboratory director may function as a laboratory's technical supervisor as part of his or her broader responsibilities. 42 C.F.R. § 493.1445(a). But, this regulation does not suggest that a laboratory director and a technical supervisor have interchangeable roles. To the contrary, the regulation suggests that a technical supervisor's duties are, at most, a component of a laboratory director's responsibilities. Furthermore, Ms. Sabo answered the question equivocally, by asserting first that she was the "testing personnel" for the laboratory and then, by saying that she might have at times been referred to as "technical supervisor" because of her degree. Tr. at 26.

Boykansky, DAB CR690 at 13 - 14.

7. As Dr. Jay states:

When, as occurred here, a group of laboratories reports [proficiency testing] results that were not obtained as required, *i.e.*, through independent testing of samples in the same manner as patient samples are tested, the integrity of the entire proficiency testing program is undermined. This is because proficiency testing is graded on a "curve." To determine what constitutes a "passing grade" for a particular analyte, results from laboratories using the same methodology and equipment are grouped together. The average value reported determines the range of "correct" responses. Because any collaboration among laboratories necessarily skews the calculation of the average, collaboration or referral corrupts the grading range against which all laboratories in the given group are evaluated.

Consequently, referral and/or collaboration not only helps insure those who engage in this improper activity obtain a passing grade, regardless of the quality of their proficiency testing; but it also may so disrupt the average values against which all other similarly situated laboratories are rated as to make other laboratories appear to have performed poorly when, in fact, they may be reporting results well within what should be tolerable limits of accuracy. In addition, false information concerning the reproducibility of the method is displayed to the public, which could cause errors in judgment when evaluating laboratory tests.

CMS Ex. 24 at 4 - 5.

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

PREFERRED FAMILY MEDICINE, P.C.,
a Michigan Professional Corporation,
MARC WEISMAN, D.O. and
JASON TALBERT, M D.,

Plaintiffs

vs

Case No: 01-72447

Honorable Victoria A. Roberts

TOMMY G. THOMSON, SFCRETARY OF HEALTH
AND HUMAN SERVI'IES and THOMAS SCULLY,
ADMINISTRATOR OF THE CENTERS FOR
MEDICARE AND MEDICAID SERVICES, formerly
known as HEALTH CARE FINANCING
ADMINISTRATION.

Defendants.

SUPPLEMENTAL OPINION & ORDER DENYING PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF AND REQUEST FOR DECLARATORY JUDGMENT AND MANDAMUS, AND GRANTING DEFENDANS' MOTION TO DISMISS

1. Introduction

On July 31, 2001, this Court entered an Order denying Plaintiff s Motion for Temporary Restraining Order & Preliminary Injunction. The Court also denied Plaintiff's request for declaratory relief and request for a mandamus action. Accordingly, Defendant's Motion to Dismiss was granted. Upon review of the July 31, 2001 Opinion and Order, the Court finds that clarification is warranted concerning the issue of whether the factual circumstances of this case come within the exception to the general rule that district courts do not have original

subject matter jurisdiction over claims arising under the Medicare Act. The Court found that this matter did not fall within the exception, thus precluding this Court from having subject matter jurisdiction rule upon the issues presented by Plaintiff. The rationale of the Courts ruling on this issue is detailed below.

II. applicable Law & Analysis

A. Subject Matter Jurisdiction

Plaintiffs argue that this Court has subject matter jurisdiction of this matter, even though they admittedly have not exhausted their administrative remedies prior to judicial review as required by 42 U.S.C. § 405(h). Plaintiffs state that the waiver exception under 42 U.S.C. § 405(g) applies to their factual circumstances, thus giving this Court jurisdiction.

Defendants' response is that this Court does not have subject matter jurisdiction to hear this matter, thereby requiring the dismissal of Plaintiff s claim without reaching the merits.

The express language of 42 U.S.C. § 405(h) bars district court jurisdiction over an action to compel payment of Medicare reimbursement because the Medicare Act requires exhaustion of administrative remedies before judicial review. Since Plaintiff's claim arises under the Medicare Act, the general rule is that this Court does not have subject matter jurisdiction. *Shalala v. Illinois Council on Long Term Care, Inc*. 529 U.S. 1, (?)0 (2000); *Heckler v. Ringer*, 466 U.S. 602 (1984); *Weinberger v. Salfi*, 422 U.S. 749 (1975); *Cathedral Rock of North College Hill v. Shalala*, 223 F.3d 354 (6th Cir. 2000); *Michigan. 4ssociation of Homes* and *Services for* the Aging v. *Shalala,* 127 F.3d 496, 500-01 (6th Cir. 1997); Manakee *Professional Medical Transfer Service, Inc. v. Shalala,* 1 F 3d 574 (6th Cir. 1995); *Farkas v. Blue Cross & Blue Shield of Michigan,* 24 F.3d (?)53 (6th Cir. 1994); *Livingston Care Center* v. *United States,* 934 F.2d. 719, 721 ((?)th Cir.), *cert. denied*., 502 U.S. 1003 (1991).

Based upon the evidence presented, Plaintiffs have not met the waiver requirements set forth in *Matthews v. Eldridge,* 424 U.S. 319 (1976). Pursuant to *Matthews* and its progeny, the exhaustion of administrative remedies may be waived where the plaintiff: (1) raises a colorable constitutional claim collateral to the substantive claim of entitlement (2) shows that irreparable harm would result from exhaustion; and (3) shows that the purposes of exhaustion would not be served by requiring further administrative procedures, i.e., futility. *Matthews,* at 330-31.

First, this Court finds that Plaintiff s Verified Complaint does not raise any colorable constitutional claim, and especially not one "wholly collateral to a claim for benefits." *Id*. Plaintiffs' claim is squarely one for continued Medicare payments. It is well settled that procedures that provide for a hearing before an administrative law judge

after the effective date of a determination which cancels Medicare payments, meet the requirements of due process. See *Cathedral Rock, supra* (termination of nursing home's provider agreement); Lavapies *v. Bowen,* 883 F.2d 465 (6th Cir. 1989) (exclusion of physician from Medicare participation); *Nothlake Community Hospital v. United States,* 654 F.2d 1234 (7th Cir. 1981) (termination of Hospital Medicare provider agreement).

Plaintiff's attempt to rebut this by claiming that administrative res judicata applies in this case because COLA already conducted an investigation, instituted discipline and assisted in implementing a Corrective Plan. Therefore, Plaintiffs contend that to repeat this process with CMS for the same alleged wrongful conduct. would in effect be res judicata. Since this Court finds as a matter of fact that COLA is not an administrative arm of CMS and has no authority over CMS. COLA's findings are immaterial to CMS' present complaint investigation.

Since this Court finds that there is no colorable constitutional claim, Plaintiffs' ability to come within the *Matthews* exhaustion exception and 42 U.S.C. § 405(g) is not possible. However, this Court further finds, addressing the second prong of the waiver exhaustion requirement, that Plaintiffs have not shown that they will be irreparably harmed if a temporary restraining order is not put into place. Plaintiffs claim that their business will likely fold; and, as a result their patients will be harmed due to the potential severance of the physician/patient relationship. Moreover, Plaintiffs allege that they will lose a significant amount of money if they do not receive Medicare payments. Finally, Plaintiffs maintain that they will suffer irreparable harm in the form of damage to their reputation, based upon the publication of the sanctions.

The Sixth Circuit has concluded that injuries stemming from stoppage of Medicare payments are avoidable, and thus not irreparable. *Livingston*, 934 F.2d at 721. Subsequently, thie Sixth Circuit stated that such injuries are not necessarily irreparable even if they force a health care provider out of business. *Manakee*, 71 F.3d at 581. Regarding the physician/patient relationship harm, this Court agrees with Defendants in that such a claim is speculative and such claims do not constitute irreparable harm. *War(ner?)* v. *Central Trust Co.,* 715 F.2d 1121, 1123 (6th Cir. 1983). Finally, regarding the harm to Plaintiffs' reputation, courts have recognized that Plaintiffs have an opportunity to clear their names through the administrative appeal process. *A(?)nett v. Kennedy,* 416 U.S. 134, 157 (1974).

Thus, the Court finds that Plaintiffs have not shown that exhausting administrative remedies would be futile or that it would not serve the purpose of the exhaustion requirement.

As a result of the foregoing, this Court finds that it is bound by 42 U.S.C. § 405(h) and that Plaintiffs do not come within the exception under 42 U.S.C. § 405(g). Consequently, this Court does not have subject matter jurisdiction. The Court's July 31, 2001 Order is affirmed as clarified.

IT IS SO ORDERED.

Victoria A. Roberts
United States District Judge

Dated: **AUG 2 8 2001**

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
RNA Laboratories, Inc.,
and,
Ter-Zakarian Medical Clinic,

Petitioner,
DATE: October 23, 2001
- v -

Centers for Medicare & Medicaid Services.
Docket No.C-01-336
Docket No.C-01-337
Decision No. **CR829**
DECISION

DECISION

I sustain the determinations of the Centers for Medicare & Medicaid Services (CMS, formerly known as the Health Care Financing Administration or "HCFA") to impose sanctions pursuant to the Clinical Laboratory Improvement Amendments (CLIA), 24 U.S.C. § 263a and implementing regulations at 42 C.F.R. Part 493, against Petitioners, RNA Laboratories, Inc. (Petitioner RNA) and Ter-Zakarian Medical Clinic (Petitioner Ter-Zakarian). These sanctions consist of the following:

1. Revocation of each Petitioner's CLIA certificate effective the date of this decision;

2. Cancellation of each Petitioner's approval to receive Medicare payments for services that the laboratory performed on or after December 9, 2000; and

3. Imposition of alternative sanctions against each Petitioner consisting of civil money penalties.

During the two-year period which follows the revocation of the CLIA certificate of Petitioner RNA or Petitioner Ter-Zakarian, CMS may revoke the CLIA certificate of any laboratory that is owned or operated by a person who owned or operated Petitioner RNA or Petitioner Ter-Zakarian. Effectively, my decision precludes Hovanes Ter-Zakarian, M.D., the owner of Petitioner Ter-Zakarian and the medical director of Petitioners RNA and Ter-Zakarian, from owning or operating another laboratory during the two-year period which follows the revocation of the CLIA certificates of Petitioners RNA and Ter-Zakarian.

I base my decision in these cases on my findings that Petitioners did not comply with regulatory conditions which governed their participation in CLIA. CMS established a prima facie case, which Petitioner did not rebut, that Petitioners RNA and Ter-Zakarian

each failed to comply with conditions of participation that are stated at 42 C.F.R. §§ 493.801 and 493.1403.

I. Background

The facts and law that I recite in this background section are not disputed by the parties. These two cases involve enforcement actions taken against Petitioners by CMS pursuant to CLIA and regulations that are published at 42 C.F.R. Part 493. A laboratory must comply with CLIA participation requirements in order to be eligible for payment from the federal Medicare program for services that it provides to beneficiaries of that program. 24 U.S.C. § 263a; 42 C.F.R. Part 493.

CLIA participation requirements are set forth in applicable regulations at 42 C.F.R. Part 493 as conditions and standards of participation. A *condition* of participation is a broadly stated general requirement that a laboratory must meet in order to qualify to participate under CLIA. A *standard* of participation sets forth the specific requirements which must be met by a laboratory in order to satisfy the more general requirement of a condition of participation.

The Secretary of the United States Department of Health and Human Services (Secretary) is charged with enforcing the requirements of CLIA. The Secretary has delegated his CLIA enforcement authority to CMS. The regulations at 42 C.F.R. Part 493 establish sanctions that CMS may impose against a laboratory that fails to comply with one or more CLIA conditions. CMS may impose *principal* sanctions against a noncompliant laboratory which include revocation of that laboratory's CLIA certificate. 42 C.F.R. § 493.1806(b). It may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). CMS may also 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). Additionally, CMS may suspend or revoke a laboratory's CLIA certificate if that laboratory is owned or operated by an individual who, within the previous two years, owned or operated a laboratory whose CLIA certificate was revoked. 42 C.F.R. § 493.1840(a)(8).

Each Petitioner is a clinical laboratory that is located in the Los Angeles, California area. Petitioner RNA's mailing address is in North Hollywood, California, and Petitioner Ter-Zakarian's mailing address is in Santa Monica, California. Petitioner Ter-Zakarian is owned by Dr. Ter-Zakarian. Dr. Ter-Zakarian serves as the medical director of Petitioner Ter-Zakarian in addition to being its owner. Dr. Ter-Zakarian also served as the medical director of Petitioner RNA. Petitioner RNA was owned by a corporation that was owned by Dr. Ter-Zakarian's brother, Vahe Ter-Zakarian.

Each Petitioner was inspected on behalf of CMS in order to determine its compliance with CLIA requirements. CMS determined that each Petitioner failed to comply with CLIA conditions of participation. CMS determined to impose principal sanctions against each Petitioner which included revocation of that Petitioner's CLIA certificate and cancellation of each Petitioner's authority to receive payments for Medicare services performed by that Petitioner. CMS also determined to impose alternative sanctions against Petitioners. These included imposition of civil money penalties against each Petitioner.

A laboratory that is dissatisfied with a determination by CMS to impose sanctions against it may request a hearing before an administrative law judge to contest CMS's

determination. 42 C.F.R. § 493.1844(a)(3). Hearing requests were filed on behalf of Petitioners RNA and Ter-Zakarian. Each of these requests was assigned a separate docket number and each case was assigned to me. I decided to conduct a consolidated hearing in these two cases inasmuch as they involved similar issues and common evidence. I did not formally consolidate the cases due to the fact that the parties requesting hearings in the two cases were not the same entities.

After the hearing requests were filed, Dr. Ter-Zakarian asserted through his counsel that he was the real party in interest in the hearing request filed by Petitioner Ter-Zakarian. Dr. Ter-Zakarian sought to challenge - insofar as it might apply to him - a statement in CMS's notice of remedies to Petitioner Ter-Zakarian which advised Dr. Ter-Zakarian, in his capacity as director and owner of Petitioner Ter-Zakarian, that CLIA and implementing regulations prohibit the owners, operators, and directors of a laboratory whose CLIA certificate is revoked from owning, operating, and directing any laboratory for at least two years from the date of the revocation. Notice from CMS to Dr. Ter-Zakarian as director and owner of Petitioner Ter-Zakarian, dated December 7, 2000.

I reserved deciding whether Dr. Ter-Zakarian had a hearing right independent of that of Petitioner Ter-Zakarian. I conducted an in-person hearing in Los Angeles, California, on March 21 and 22, 2001 in which I permitted both Petitioners and Dr. Ter-Zakarian to participate. I recessed the hearing until March 27, 2001 when I received additional testimony by telephone. At the hearing I received into evidence exhibits from CMS which are identified as HCFA Ex. 1 - HCFA Ex. 18. I received exhibits into evidence from Petitioners which are identified as P. Ex. 1 - P. Ex. 23. I also identified but did not receive into evidence exhibits from Petitioners which are identified as P. Ex. 24 and P. Ex. 25.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. Dr. Ter-Zakarian has a right to a hearing;

2. Petitioner RNA or Petitioner Ter-Zakarian failed to comply with a CLIA condition or conditions of participation; and

3. A basis exists to sustain the imposition of principal and alternative sanctions against either Petitioner RNA or Petitioner Ter-Zakarian based on that Petitioner's failure to comply with a CLIA condition or conditions of participation.

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 separately numbered heading.

1. Dr. Ter-Zakarian has a right to a hearing.

CMS's notice, in which it announced its intention of imposing sanctions against Petitioner Ter-Zakarian, was addressed to Dr. Ter-Zakarian as "Director and Owner."

Letter from CMS to Dr. Ter-Zakarian dated December 7, 2000. It contained the following statement:

> We remind you that once revoked, CLIA regulations at 42 U.S.C. 263a(i)(3) and 42 C.F.R. 493.1840(a)(8) prohibit the owners, operators and director of the laboratory from owning, operating and directing any laboratory for at least two years from the date of the revocation.

Id. Dr. Ter-Zakarian asserts that this language is a sanction determination that is aimed at him, personally, and that he is entitled to a hearing to contest that determination.

CMS asserts that Dr. Ter-Zakarian has "no standing" to contest any prohibition against his owning, operating, or directing a laboratory that might result as a collateral consequence of the revocation of the CLIA certificates of Petitioner RNA or Petitioner Ter-Zakarian. CMS's posthearing brief at 33. CMS does not elaborate on this assertion. Other administrative law judges have held that a laboratory owner or director has a right to a hearing to challenge revocation of a laboratory's CLIA certificate. *Carlos A. Cervera, M.D.*, Docket No. C-99-797, Ruling Denying HCFA's Motion to Dismiss and Granting Extension of Time for Submission of Readiness Reports, December 21, 1999; *Allstate Medical Laboratory, Inc.*, Docket No. C-99-309, Ruling, October 6, 1999; *Eugene R. Pocock, M.D.*, DAB CR527 at 5 (1998). These rulings and decision have been cited favorably by the Departmental Appeals Board in *Sentinel Medical Laboratories, Inc.*, DAB No. 1762 at n.6 (2001). I follow these rulings and decisions and hold that Dr. Ter-Zakarian has a right to a hearing to challenge the effect that a revocation of Petitioners' CLIA certificates may have on him.

In their post hearing brief Petitioners made the suggestion that I should "defer ruling on. . . [CMS's] sanction action pending a separate hearing for Dr. Ter-Zakarian . . . ." Petitioners' post hearing brief at 21. Petitioners did not elaborate on this suggestion and I am unsure as to what they are requesting. I have given Dr. Ter-Zakarian a hearing in this case. Although I reserved deciding what hearing rights he was entitled to until after the in-person hearing, I allowed him to participate in that hearing and to give testimony and present evidence. Petitioners have not asserted that there are issues that affect Dr. Ter-Zakarian that have not been aired fully or that they or Dr. Ter-Zakarian have been denied the opportunity to present relevant evidence.

2. Petitioners RNA and Ter-Zakarian failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

The CLIA condition of participation that is set forth at 42 C.F.R. § 493.801 provides for mandatory enrollment of a clinical laboratory in an approved proficiency testing program and governs the manner in which a laboratory will conduct its proficiency testing. The purpose of proficiency testing is to measure the competence of a laboratory's clinical testing. Tr. at 74. The CLIA condition of participation which governs proficiency testing states explicitly that a laboratory must test its proficiency testing samples in the same manner as it tests patients' specimens. 42 C.F.R. § 493.801(a). A laboratory must perform its proficiency testing exactly as it tests patients' specimens if proficiency testing is to be a measure of the laboratory's competence. Proficiency testing would be meaningless if a laboratory tested its proficiency testing samples differently from patient

specimens because, under that circumstance, proficiency testing would not measure the laboratory's competence to handle patient test specimens.
Testing proficiency testing samples in the same manner as patients' specimens means that the proficiency testing samples must be integrated fully into the laboratory's testing regime. The requirement for full integration is spelled out in the standards that are stated at 42 C.F.R. § 493.801(b). The laboratory must use the same techniques to test proficiency testing samples and patient specimens. 42 C.F.R. § 493.801(b)(1). A laboratory must not test proficiency testing samples a greater or fewer number of times than it tests patient specimens. 42 C.F.R. § 493.801(b)(2). The laboratory must not collaborate with any other individual or entity in the performance of proficiency testing. 42 C.F.R. § 493.801(b)(3). It must maintain complete and accurate documentation of all proficiency testing. 42 C.F.R. § 493.801(b)(5).
Both Petitioner RNA and Petitioner Ter-Zakarian enrolled in an approved proficiency testing program that is operated by the American Association of Bioanalysts Proficiency Testing Service (AAB). Petitioner RNA and Petitioner Ter-Zakarian received the same proficiency testing samples from AAB at the same times. At regular intervals throughout the year, AAB sends to all of its enrollees a group of five proficiency testing samples for each of the tests for which proficiency testing is required. Each laboratory that is enrolled with AAB receives identical samples from AAB for each test for which the laboratory is enrolled for proficiency testing. Tr. at 69 - 70. I take notice of the fact that the AAB refers to each mailing of samples to enrolled laboratories as an "event."
Each laboratory that receives proficiency testing samples from AAB for an event is required to perform its proficiency testing within a specified period of time and to mail its testing results back to AAB. AAB provides each enrolled laboratory with a form that the laboratory completes in conjunction with its proficiency testing. The laboratory inserts appropriate codes to indicate the reagents it used to perform its tests and the type of equipment that it used. It also verifies the name of the individual who performed the proficiency testing. Tr. at 71 - 72.
CMS alleges that Petitioners RNA and Ter-Zakarian failed to comply with the CLIA condition at 42 C.F.R. § 493.801 in that these laboratories failed to test proficiency testing samples in the same manner as patients' specimens. More specifically, CMS asserts that Petitioners failed to comply with several of the standards that are a part of this condition and that their failures to comply with these standards were so egregious as to comprise a failure by each of them to comply with the overall condition.
CMS made a prima facie case to support its allegations which Petitioners did not rebut. The evidence offered by CMS establishes such a high degree of irregularity in the manner in which Petitioners conducted their proficiency testing as to establish a failure by Petitioners to comply with the overall condition of participation that is stated at 42 C.F.R. § 493.801(a).
Most significantly, the evidence shows that Petitioners engaged in prohibited inter-laboratory communications about proficiency test samples prior to reporting test results. Additionally, the evidence demonstrates other failures by one or both of Petitioners to conduct proficiency tests in the same manner as they tested patients' specimens. These additional failures included failure by Petitioner RNA to document the handling, preparation, processing, examination, and each step of proficiency testing and failure by

Petitioner Ter-Zakarian to test proficiency test samples the same number of times that it tested regular patient test samples.

a. Petitioners RNA and Ter-Zakarian engaged in prohibited inter-laboratory communications about proficiency testing.

A laboratory which is engaged in proficiency testing:

> must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) . . . .

42 C.F.R. § 493.801(b)(3).

It is important that a laboratory conduct its proficiency testing honestly. Communications between laboratory personnel about ongoing proficiency testing frustrates the premise of proficiency testing that proficiency testing samples are to be tested in the same manner as are patients' specimens. Proficiency testing results that have been tainted by inter-laboratory communications are not a meaningful measure of a laboratory's competence to do testing. Tr. at 75.

The evidence offered by CMS establishes that, for the third proficiency testing event in 1999, Petitioner RNA and Petitioner Ter-Zakarian submitted identical proficiency testing results for all five samples tested in each of nine different categories of tests. Tr. at 90 - 91; 94; HCFA Ex. 9 at 5 - 6. Both laboratories reported identical test results for all five samples tested in each of the testing categories of: cholesterol, glucose, triglycerides bicarbonate, chloride, creatinine, potassium, sodium, and, urea nitrogen. *Ids.* In total, Petitioner RNA and Petitioner Ter-Zakarian reported identical testing results for 45 separate samples tested in nine separate categories. *Ids.*

The evidence of identical proficiency testing results on so many tests is powerful circumstantial proof that Petitioners engaged in prohibited communications with each other in conducting proficiency testing. As is made clear by the expert testimony of Dennis Jay, Ph.D., the technical director of AAB's proficiency testing program, there is no rational explanation for the identical test results submitted by Petitioners other than prohibited communication between the two laboratories. That is so given: the identical results reported by the two laboratories in 45 separate instances; and, the presence of many variables that logically would render extraordinarily unlikely the submission of identical results in so many instances without a prohibited information exchange occurring between the two laboratories. Tr. at 60, 70 - 101.

Dr. Jay has extensive experience in laboratory operations. In his capacity as the technical director of AAB's proficiency testing program he has reviewed numerous proficiency testing reports submitted by many laboratories. The essential point that Dr. Jay made in his testimony is that, based on his experience, two independently operated laboratories generally would not be likely to produce identical proficiency testing results for any given sample.

A proficiency testing score may be affected by the chemical reagent that the laboratory uses to perform testing. Tr. at 73. It might be affected by the make of analyzer which a laboratory uses to process a particular type of test. *Id.* The test result may be affected by temperature within an analyzer. *Id.* at 76. It might be affected by the skills of the technician who performs the test. *Id.* It may also be affected by the physical environment of the laboratory in which the test is performed. *Id.*

Given all of these variables, there is a high likelihood that test results will vary among samples tested within a single laboratory and among samples tested between different laboratories. Tr. at 77. Indeed, the proficiency testing program operates on the assumption that identical results would be an aberration and not the norm. AAB has acknowledged the high likelihood of variance by deciding that there is no such thing as one "correct" proficiency testing result. AAB grades an individual proficiency testing score based on the proximity of that score to a mean score for the sample at issue. Tr. at 72 - 73. A "passing" score on a proficiency test is one that falls within grading limits that are calculated based on the mean score. *Id.*

It is highly implausible that two laboratories could produce identical test results for multiple samples in a range of tests without communicating with each other about test results. *See* Tr. at 98 - 101. When two laboratories produce identical test results in multiple samples and in different tests the logical inference to be drawn is that they collaborated in obtaining or reporting the results.

The inference that Petitioners engaged in prohibited communications is reinforced by their close geographic and management relationship. Dr. Jay's experience is that two laboratories which produce identical proficiency testing scores on multiple samples invariably are located in close physical proximity to each other. In this case the two laboratories were located only a few miles from each other and had the same medical director, Dr. Ter-Zakarian.

The inference of collaboration between Petitioner RNA and Petitioner Ter-Zakarian also is reinforced by the failure of Petitioner RNA to produce any analyzer printouts which would show actual testing results. The absence of such documents lends support to a conclusion that Petitioner RNA did not actually conduct proficiency testing on the samples for which it reported identical findings as were obtained by Petitioner Ter-Zakarian.

Petitioners did not offer persuasive evidence or arguments that rebutted the evidence introduced by CMS showing a prohibited exchange of information between Petitioner RNA and Petitioner Ter-Zakarian. Petitioners argue, first, that Dr. Jay's testimony is not credible because it is based on "bad science." They assert that his testimony must be disregarded because it is "anecdotal" and not based on any statistical analysis. I agree with Petitioners that no evidence was offered by CMS which establishes the statistical probability that the 45 identical test results were tainted by collusion. But, I do not agree with Petitioners that statistical analysis is necessary to reach the conclusion that a prohibited exchange of information lay behind the identical test results.

Dr. Jay's testimony was credible and persuasive. I find here, as I did in *Stanley Boykansky, M.D.*, DAB CR690 (2000), that Dr. Jay's opinion is based not on statistical evidence but on his practical experience and knowledge of laboratory operations. It is not necessary to establish the statistical probability of two laboratories producing identical results in any given test in order to find that it is highly unlikely that they would produce those identical results independently. Dr. Jay testified persuasively that the many variable factors that could affect test results made it extraordinarily unlikely that two laboratories independently would produce so many identical test results. Dr. Jay's opinion was buttressed by his experience. Dr. Jay testified that he had never found identical proficiency testing results in specified tests except with laboratories that were located in close geographic proximity to each other. Tr. at 96.

Second, Petitioners argue that, in fact, Petitioner Ter-Zakarian conducted its proficiency tests successfully for the third testing event in 1999. As evidence for that assertion they point to analyzer printouts that were generated by Petitioner Ter-Zakarian that confirmed the proficiency test values that this Petitioner reported. P. Ex. 5 at 20 - 28. However, the likelihood that Petitioner Ter-Zakarian may actually have performed its proficiency tests begs the question of whether it engaged in prohibited communications with Petitioner RNA. Petitioners have not produced any credible evidence showing that Petitioner RNA independently came up with the identical test results that were obtained by Petitioner Ter-Zakarian in 45 separate tests.

Third, Petitioners argue that Petitioner RNA performed its proficiency testing independently of Petitioner Ter-Zakarian for the third testing event in 1999. They argue that Petitioner RNA scored successfully for 115 values on chemical analytes that were not reported or tested by Petitioner Ter-Zakarian. They reason that it would be illogical for Petitioner RNA to conduct these tests independently from Petitioner Ter-Zakarian but then to engage in prohibited communications with Petitioner Ter-Zakarian concerning the 45 tests in which identical results were obtained by the two laboratories. I find this argument to be unpersuasive. The fact that Petitioner RNA may have performed *some* of its proficiency testing independently from Petitioner Ter-Zakarian is not a basis to conclude that it performed *all* of its proficiency testing independently.

b. Petitioner RNA failed to comply with documentation and record keeping requirements in its conduct of proficiency testing.

A clinical laboratory is required to:

> document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results . . . .

42 C.F.R. § 493.801(b)(5).

The evidence offered by CMS establishes that Petitioner RNA failed to produce documents which were necessary to verify the accuracy of its proficiency testing. HCFA Ex. 5 at 4; Tr. at 265. Petitioner RNA concedes that it has not produced the analyzer reports that would show actual proficiency testing results. Petitioners' post hearing brief at 10. It suggests that its failure to do so is not a significant failure to comply with CLIA requirements because it produced the testing report forms that it used to record proficiency testing results.

However, the regulation requires a laboratory to produce *all* of its records and to document each step in the testing and reporting of proficiency testing results. 42 C.F.R. § 493.801(b)(5). Production of a partial set of records does not satisfy this requirement. Moreover, the records that are missing are precisely the records that would be necessary to establish whether Petitioner RNA performed proficiency testing honestly. The analyzer reports contain the raw data and test results that a laboratory produces when it conducts a proficiency test. In the absence of this information, there is no way to verify the accuracy of Petitioner RNA's testing report forms.

c. Petitioner Ter-Zakarian did not test proficiency testing samples the same number of times that it routinely tested patient samples.

The proficiency testing requirements include the requirement that a clinical laboratory:

> must test [proficiency testing] samples the same number of times that it routinely tests patient samples.

42 C.F.R. § 493.801(b)(2).

The purpose of this requirement is to assure that proficiency testing samples do not receive special handling by a laboratory but are integrated into the laboratory's regular workload. That makes proficiency testing a true measure of a laboratory's testing competence.

CMS presented a prima facie case that established a pattern in the way Petitioner Ter-Zakarian conducted its proficiency testing. When Petitioner Ter-Zakarian conducted proficiency testing it often ran tests of proficiency testing samples multiple times. In contrast, Petitioner Ter-Zakarian routinely tested patients' specimens only once. For example, evidence introduced by CMS shows that, in the third proficiency testing event of 1999, Petitioner Ter-Zakarian ran proficiency tests for routine chemistry twice (back to back) on October 21, 1999 and then tested them a third time later on that same day. HCFA Ex. 11 at 13 - 16. It tested proficiency testing samples for glyco-hemoglobin twice on October 19, 1999 whereas it tested patient samples only one time on that date. *Id.* at 17 - 19; *see* Tr. at 256. Evidence introduced by CMS shows that Petitioner also ran proficiency tests more times than it ran patients' specimens for samples tested in the other 1999 proficiency testing events and in the 2000 proficiency testing events as well. HCFA Ex. 5 at 4 - 6; HCFA Ex. 10 at 12 - 20; HCFA Ex. 12 at 4 - 8; HCFA Ex. 13 at 5 - 9.

From this evidence I infer that Petitioner Ter-Zakarian was concerned that it might not be conducting proficiency tests competently and, so, ran them multiple times. *See* Tr. at 258. I also infer that Petitioner Ter-Zakarian often and egregiously contravened the requirement that it test proficiency testing samples and patients' specimens the same number of times.

Petitioners argue that Petitioner Ter-Zakarian tested proficiency testing samples in the same *manner* as it tested patients' specimens because it used the same equipment and testing techniques for both types of tests. Petitioners' post hearing brief at 14 - 15. This argument does not address the allegations or the evidence offered by CMS. The issue here is whether Petitioner invalidated proficiency testing by testing proficiency testing samples more times than it tested patients' specimens. It is not whether Petitioner used different types of equipment or techniques to perform proficiency tests than it used to test patients' specimens.

d. The failures by Petitioner RNA and Petitioner Ter-Zakarian to conduct proficiency testing in the same manner as the testing of patients' specimens were so egregious as to be failures by these Petitioners to comply with the condition of participation that is stated at 42 C.F.R. § 493.801(a).

The failures by Petitioners RNA and Ter-Zakarian to comply with standards of participation set forth at 42 C.F.R. § 493.801(b) were so egregious as to be failures by these two Petitioners to comply with the overall condition that is stated at 42 C.F.R. § 493.801(a). These failures so compromised the proficiency testing results that

Petitioners reported that they made proficiency testing useless as measures of the laboratories' competency.

Petitioners RNA and Ter-Zakarian did not conduct proficiency testing honestly during the third event in 1999. Their collaboration in producing test results renders meaningless the results that they submitted. Indeed, for the 9 tests and the 45 samples that are at issue it is not possible to discern whether Petitioner RNA conducted proficiency testing at all. Petitioner RNA's failure to maintain its original testing data made it impossible to verify what that Petitioner did or did not do as proficiency testing. And, the fact that Petitioner Ter-Zakarian tested proficiency testing samples two or three times whereas it tested patients' specimens only once invalidated the results that this Petitioner obtained on its proficiency tests.

Petitioners argue that the deficiencies established by CMS are only minor standard level deficiencies. I disagree with this contention for the reasons that I have just stated. Petitioners' deficiencies fundamentally affected the validity of their proficiency testing.

Petitioners also argue that CMS did not make a prima facie showing that Petitioner RNA sent any proficiency testing samples to Petitioner Ter-Zakarian for analysis or that Petitioner Ter-Zakarian sent any proficiency testing samples to Petitioner RNA for analysis in violation of the requirements of 42 C.F.R. § 493.801(b)(4). They argue that Petitioners may not be found to have contravened the condition at 42 C.F.R. § 493.801(a) inasmuch as CMS did not establish an unlawful referral of proficiency testing samples from one Petitioner to the other.

I am not persuaded by this argument. The improper exchange of information between Petitioners would be an unlawful "referral" of proficiency testing samples under the holdings of *Oakland Medical Group*, DAB No. 1755 (2000) and *Stanley Boykansky, M.D.*, DAB No. 1756 (2000). But, I do not need to find an unlawful referral of proficiency testing samples by one Petitioner to the other in order to find that these Petitioners failed to comply with the CLIA condition that is set forth at 42 C.F.R. § 493.801(a). The egregious failures by both Petitioners to comply with the standard that is set forth at 42 C.F.R. § 493.801(b)(1), by Petitioner RNA to comply with the standard that is set forth at 42 C.F.R. § 493.801(b)(5), and by Petitioner Ter-Zakarian to comply with the standard that is set forth at 42 C.F.R. § 493.801(b)(2), is sufficient basis for me to find condition-level noncompliance by these Petitioners.

3. Petitioners RNA and Ter-Zakarian failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.1403.

The condition of participation that is set forth at 42 C.F.R. § 493.1403 requires a clinical laboratory to have a director who is responsible for the overall management and direction of the laboratory. It requires that the laboratory director provide management and direction that comports with standards set forth at 42 C.F.R. § 493.1407. Under this latter regulation a laboratory director must, among other things, assure that proficiency testing is conducted in compliance with the requirements of all applicable regulations. The laboratory director is the individual who bears responsibility for assuring that a clinical laboratory meets the quality control standards that are at the heart of CLIA requirements. Tr. at 280 - 281. Ultimately, the laboratory director is the person who assures that a clinical laboratory does a competent job testing patients' specimens. It is no exaggeration to say that the success or failure of a laboratory director in discharging

his or her responsibilities may have life or death consequences for many patients who rely on a laboratory to perform clinical testing of their specimens.
CMS introduced evidence which establishes a prima facie case that both Petitioners RNA and Ter-Zakarian failed to comply with the condition governing the performance of the laboratory director. The evidence supports findings of egregious failures by Petitioners to comply with the standards that are set forth at 42 C.F.R. § 493.1407. I may infer from this evidence of noncompliance that the failures of Petitioners to comply with these standards were so serious as to violate the overall condition governing the position of laboratory director.
I find that Petitioners failed to rebut this evidence. Indeed, Petitioners offered no meaningful response to CMS' allegations and evidence except to aver that they complied with the condition governing proficiency testing. As I discuss above, at Finding 2, Petitioners did not comply with the condition governing proficiency testing. The failures by Petitioners to comply with the proficiency testing condition also are failures to comply with the laboratory director condition because these failures establish the absence of proper management of the laboratories' activities. Furthermore, the unrebutted evidence offered by CMS with respect to Petitioner Ter-Zakarian establishes that this Petitioner's management failures involved more than its failures to conduct proficiency testing according to the requirements of 42 C.F.R. § 493.801.

a. Petitioner RNA did not comply with the laboratory director condition.

CMS offered evidence to establish a prima facie case that Petitioner RNA did not comply with the laboratory director condition. In the case of Petitioner RNA, the prima facie evidence of its failure to comply with the laboratory director condition is its failure to comply with the proficiency testing condition. As I discuss above, at Finding 2, Petitioner RNA engaged in a prohibited exchange of information with Petitioner Ter-Zakarian and failed to maintain records of its proficiency testing. I find that this evidence establishes a failure by Petitioner RNA's laboratory director to exercise the oversight and management responsibilities that are his responsibilities.
Petitioner RNA did not rebut this prima facie evidence of its failure to comply with the laboratory director condition. At Finding 2, I discuss why I do not find to be persuasive Petitioner's arguments which address allegations that it did not comply with the proficiency testing condition. Petitioner makes the additional assertion with respect to the laboratory director condition that it was the fault of Petitioner RNA or its owner, and not of the laboratory director if Petitioner RNA failed to produce proficiency testing documentation. I find this argument not to be persuasive because creation and preservation of records of proficiency testing were tasks that were within the scope of the laboratory director's responsibilities.

b. Petitioner Ter-Zakarian did not comply with the laboratory director condition.

CMS offered evidence that Petitioner Ter-Zakarian failed to comply with the laboratory director condition by failing to comply with the condition governing proficiency testing. Additionally, CMS offered evidence to show that Petitioner Ter-Zakarian failed in other respects to comply with the laboratory director condition. This additional evidence consisted of the following:

• Petitioner Ter-Zakarian was conducting patients' specimen tests for TSH. However, its laboratory director had not enrolled it in a proficiency testing program for this substance, in violation of the requirements of 42 C.F.R. §§ 493.1407(e)(4) and 493.801(a). HCFA Ex. 2 at 25.

• Petitioner Ter-Zakarian had received proficiency testing reports for the third proficiency testing event of 1999 which showed that the laboratory had tested unsuccessfully for creatinine, one of the samples in the proficiency testing event. However, it failed to produce any evidence to show that its laboratory director had reviewed and evaluated these reports or had undertaken any corrective action, in violation of the requirements of 42 C.F.R. § 493.1407(e)(4)(iii). HCFA Ex. 25 at 27.

• Petitioner Ter-Zakarian's laboratory director permitted staff to run proficiency tests multiple times. However, he established no quality controls which instructed staff as to how to distinguish correct from erroneous proficiency test results. Furthermore, he permitted results to be reported which did not accurately state the findings that were produced by his laboratory's proficiency testing. For example, in the first proficiency testing event of 1999, instrument printouts produced readings of 177 and 136 for a total cholesterol test. Yet, Petitioner Ter-Zakarian reported a result of 172 for that test. HCFA Ex. 13 at 2. This and other examples constituted evidence of a failure by the laboratory director to implement quality control requirements as is required by 42 C.F.R. § 493.1407(e)(5). HCFA Ex. 2 at 29 - 30.

The evidence offered by CMS is prima facie proof that Petitioner Ter-Zakarian did not comply with the laboratory director condition. It establishes a wholesale failure by Petitioner's laboratory director to manage or direct the laboratory in compliance with applicable requirements. Petitioner offered no evidence which persuasively rebutted the proof offered by CMS and I find, therefore, that Petitioner Ter-Zakarian failed to comply with the laboratory director condition.

4. CMS withdrew its allegations that Petitioners failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.1773.

In its posthearing brief, CMS urges that I find that Petitioners RNA and Ter-Zakarian failed to comply with the requirements that are set forth at 42 C.F.R. § 493.1773. However, at the in-person hearing, I asked counsel for CMS what allegations CMS intended to pursue and counsel offered the following statement:

> they [CMS] found the condition for inspection [the condition stated at 42 C.F.R. § 493.1773] - at that time, that has - is not going to be addressed because ultimately the laboratory did supply more information.

Tr. at 16. This statement by counsel is ambiguous but it may be interpreted reasonably to mean that CMS was not pursuing allegations that it had made concerning Petitioners' failure to comply with the requirements of 42 C.F.R. § 493.1773. I interpreted the statement to mean that and so did Petitioners.

In light of that I find that CMS withdrew its allegations that Petitioners failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.1773. However, this withdrawal has no affect on my decision in this case inasmuch as it is unnecessary

that CMS establish that Petitioners failed to comply with more than one CLIA condition in order for there to be a basis for CMS to impose the remedies that CMS determined to impose.

5. A basis exists to impose remedies against Petitioners RNA and Ter-Zakarian.

CMS determined to impose the following remedies against Petitioners RNA and Ter-Zakarian:

- Cancellation of each Petitioner's approval to receive reimbursement from Medicare for tests performed for Medicare beneficiaries;
- Revocation of each Petitioner's CLIA certificate; and,
- Alternative sanctions consisting of civil money penalties.

CMS may impose each or all of these remedies that in any instance where a laboratory has failed to comply with one or more CLIA conditions. 42 C.F.R. §§ 493.1814; 493.1834. There is a basis for imposition of these remedies here in that I have found that Petitioners each failed to comply with CLIA conditions.

I have no authority in these cases to decide whether any of the remedies that CMS determined to impose is appropriate. CMS's *choice* of remedy, as opposed to its authority to impose a remedy, is not an issue which I may hear and decide. *See*, *e.g.*,42 C.F.R. § 493.1844(b)(3). A laboratory's right to a hearing, or that of a laboratory's owner or operator, is a right to assert that a basis does not exist to impose remedies.

CMS's remedy determinations do not directly affect Dr. Ter-Zakarian. However, there is a significant indirect consequence for Dr. Ter-Zakarian which results from my decision to uphold the revocation of Petitioners' CLIA certificates. The due process implications of this indirect effect are the basis for my decision to grant Dr. Ter-Zakarian a hearing. *See* Finding 1 above.

Applicable regulations provide for the revocation of a laboratory's CLIA certificate where that laboratory's owner or operator owned or operated a laboratory whose CLIA certificate has been revoked within the preceding two-year period. 42 C.F.R. § 493.1840(a)(8). The regulation does not specifically prohibit such an individual from owning or operating a laboratory. However, that is the practical effect of the regulation. Thus, CMS may revoke the CLIA certificate of any laboratory that Dr. Ter-Zakarian owns or operates within a two-year period from the date of revocation of the CLIA certificate of Petitioner RNA or of Petitioner Ter-Zakarian.

6. I deny Petitioners' motions.

Prior to the hearing of this case Petitioners made four motions. These motions are: (1) Petitioners' Motion to Exclude Evidence of Identical or Very Similar Proficiency Testing Events as Improper "Probability of Guilt" Evidence; (2) Petitioners' Motion to Preclude Dennis W. Jay, Ph.D., DABCC, from Giving Testimony Concerning Statistical Analysis and Probability; (3) Petitioner Ter-Zakarian Medical Clinic's Motion to Dismiss for Lack of Jurisdiction; and (4) Petitioners' and Real Party in Interest Request for Consideration of Due Process Violations. I reserved deciding these motions. Petitioner withdrew motion (3) and has renewed its request that I decide motions (1), (2), and (4).

I now deny these motions. I have dealt with Petitioners' arguments concerning motions (1) and (2) above, at Finding 2. I find that neither Petitioners nor Dr. Ter-Zakarian has been denied due process and, therefore, I deny motion (4).

JUDGE

Steven T. Kessel
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division
IN THE CASE OF

SUBJECT: Evette Elsenety, M.D., et al.

Petitioner,
DATE: November 8, 2001
- v -

Health Care Financing Administration
Civil Remedies No. CR779
Docket No. A-2001-103
Decision No. 1796 **DECISION**

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Oakland Medical Group, P.C. (Oakland) a Warren, Michigan, physician office laboratory, appealed a June 12, 2001 decision by Administrative Law Judge (ALJ) Steven T. Kessel granting summary disposition for the Health Care Financing Administration (HCFA).[(1)] *Evette Elsenety, M.D., et. al*, DAB CR779 (2001) (ALJ Decision). The ALJ Decision involved 16 Petitioners,[(2)] each a clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Based on "undisputed material facts," the ALJ found that Oakland owned each Petitioner and that Oakland's CLIA certificate had been revoked within the past two years. Therefore, the ALJ concluded, the law required HCFA to revoke each Petitioner's CLIA certificate. ALJ Decision at 4.

Based on the analysis below, we sustain the ALJ Decision, affirming and adopting each of the ALJ's underlying FFCLs.

Background

I. The Oakland Decision

HCFA's action against the 16 Petitioners stemmed from an earlier CLIA action involving Oakland. HCFA revoked Oakland's CLIA certificate in 1999. An ALJ sustained HCFA's action in *Oakland Medical Group, P.C.*, DAB CR688 (2000). Essentially, the ALJ found that Oakland failed to meet condition level requirements for proficiency testing for testing events in 1998, failed to meet the condition level requirement for laboratory director and violated the standard for technical supervisor. Consequently, the ALJ determined that HCFA properly revoked Oakland's CLIA certification for one year and canceled Oakland's approval to receive Medicare payments for its services, effective October 1, 1999. This Board affirmed the ALJ Decision in *Oakland Medical Group, P.C.*, DAB No. 1755 (2000).

II. Facts and Law

The pertinent section of the CLIA statute, 42 U.S.C. § 263a(i), provides:

> (3) Ineligibility to own or operate laboratories after revocation
>
> 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. . . .

On November 7, 2000, HCFA advised each Petitioner that Oakland's CLIA certificate had been revoked and that, since Oakland owned or operated each Petitioner, HCFA was also required to revoke each Petitioner's CLIA certificate. Each Petitioner requested a hearing before an ALJ and their appeals were consolidated into a single proceeding.

III. The ALJ Decision

The ALJ Decision was based on the following two findings of fact and conclusions of law (FFCLs):

1. Summary dispositions are appropriate in these cases.

> a. Each Petitioner is owned by Oakland Medical Group.
>
> b. Oakland Medical Group's CLIA certificate was revoked within the past two years.

2. Petitioners' CLIA certificates must be revoked as a matter of law based on the undisputed material facts.

ALJ Decision at 2-4.

Oakland, on behalf of Petitioners, took exception to both FFCLs.

ANALYSIS

Our standard of review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000).

1. Summary dispositions are appropriate in these cases.

> **a. Each Petitioner is owned by Oakland Medical Group.**
>
> **b. Oakland Medical Group's CLIA certificate was revoked within the past two years.**

Oakland conceded that it had provided HCFA with a letter demonstrating Oakland's ownership of the 16 Petitioners. However, Oakland asserted that upon receipt of this letter, HCFA broke off settlement discussions and revoked Petitioners' certifications. Oakland contended that this letter had been a product of settlement discussions and, pursuant to Rule 408 of the Federal Rules of Evidence, was not admissible into evidence or at least not worthy of substantial weight. Oakland argued that, at a minimum, HCFA should have been required to rehabilitate this letter with additional evidence of Petitioners' ownership. Oakland maintained that since this "clearly

inadmissible evidence" was HCFA's only proof of ownership, the ALJ Decision should be reversed. Oakland Br. at 5-6; Oakland Reply Br. at 3-4.

As the ALJ noted, summary disposition is appropriate where there are no disputed issues of material fact. A party opposing summary disposition must allege facts which, if true, would refute the facts relied upon by the moving party. ALJ Decision at 2-3. The facts of this case are not in dispute. Oakland has offered no facts which would refute those relied upon by HCFA in moving for summary disposition.

a. Each Petitioner is owned by Oakland.

Oakland asserted that the ALJ erred when he relied on HCFA Exhibit 3 as a basis for this finding. Oakland complained that the letter was incorrectly dated October 24, 1998 instead of October 24, 2000. Further, Oakland argued the letter was a product of settlement negotiations and thus should be excluded from evidence pursuant to Rule 408 of the Federal Rules of Evidence. Oakland's arguments have no merit.

The ALJ considered the arguments relative to the misdating and the settlement aspect of the letter as follows:

> That it may have been misdated does not detract from the significance of the contents of the letter. Nor is the letter made less probative by the fact that it was sent to HCFA as part of settlement discussions. Petitioners have not averred that they stated untruths to HCFA in order to settle these cases and there is no reason for me to assume that they would do so.

ALJ Decision at 3.

The ALJ did not err in his determination that the letter was misdated as it is clear from the context in which the letter was written (described below) that the letter was produced after the revocation of Oakland's CLIA certificate in 1999. As HCFA noted, Oakland's facsimile produced a "10/24/00" date stamp on the letter, thus resolving any confusion about the date. HCFA Br. at 3, n.1; *see also* HCFA Ex. 3 at 1.

In addition, we reject Oakland's assertion that the ALJ erred in failing to exclude Oakland's letter pursuant to Rule 408 of the Federal Rules of Evidence. Petitioners did not raise this issue before the ALJ.[(3)] Petitioners did not challenge the admission of this letter at all; their arguments focused on the issues of authenticity and credibility. As noted above, the ALJ considered these arguments and rejected them. Since there was no issue of admissibility under the Federal Rules of Evidence before the ALJ, there is, of course, no error in his failure to address the question.[(4)]

Moreover, since Petitioners did not contend before the ALJ that the letter should be excluded from the record as the product of settlement negotiations, the ALJ did not require them to address this issue as part of an analysis of the applicability of the privilege. Thus, other than Oakland's assertion here, there is no support in the record for such a conclusion. On October 17, 2000, HCFA wrote to Oakland explaining the consequences flowing from revocation of Oakland's CLIA certificate. HCFA noted the potential for criminal liability if Oakland operated a laboratory within two years of the date of revocation. HCFA continued:

> . . . if you own or operate any other laboratory, we rely on you to provide the name and address of that laboratory so that we may initiate enforcement action against the laboratory pursuant to the . . . statutory and regulatory requirement.

HCFA Ex. 2 at 1-2.
Faced with potential criminal liability, Oakland provided the requested information to HCFA within seven days. HCFA Ex. 3. There is no indication on the face of the letter that Oakland considered the information to be proffered as part of any settlement negotiations.

b. Oakland Medical Group's CLIA certificate was revoked within the past two years.

Although it generally questioned the propriety of HCFA's action underlying the revocation, Oakland did not deny that its certification had been revoked within the past two years.
Accordingly, the ALJ did not err in finding that this matter was appropriate for summary disposition.

2. Petitioners' CLIA certificates must be revoked as a matter of law based on the undisputed material facts.

Oakland argued that ALJ erred by expanding the plain meaning of the word "person" in 42 U.S.C. § 263a(i)(3) to include corporations and companies. Oakland stated that section 263a(i)(1)(A)-(G) set out actions which, if performed by an employee, owner, or operator, jeopardize CLIA certification. However, Oakland asserted, these actions are attributable only to an individual, not to a corporation or an organization. Thus, Oakland reasoned, since an "individual" was meant to be a person in one part of the statute, that term could not be read differently later in that same statutory section. Additionally, Oakland relied on the statute's enforcement regulation, 42 C.F.R. § 493.1840(a)(8). Oakland asserted that the regulation limited its application and recognized the injustice of extending punishment for a CLIA violation to the entire organization, rather than just the individual location which violated the CLIA statute. Specifically, Oakland noted that the regulation's application was limited to "only **the** owner or operator, ***not*** all of the laboratory's employees." Oakland Br. at 6-7 (emphasis in original).
Oakland also asserted that the ALJ's expansive reading of the term "person" and the resultant conclusion that section 263a(i)(3) required revocation of Petitioners' CLIA certificates would frustrate the intent of 42 U.S.C. § 1395nn(b)(2), requiring group practice organization.
The statute at 42 U.S.C. § 1395nn, more commonly known as the Stark Amendment, was enacted in 1992 in order to combat kickbacks stemming from referrals for clinical laboratory work to laboratories often owned by the referring physician. Oakland Br. at 8-9. Oakland asserted that -

> [t]he purpose of the provision set forth at 42 U.S.C. § 263a(i) . . . was in keeping with the intent of CLIA to ensure accurate and reliable clinical laboratory testing. That subsection . . . as with CLIA generally, was implemented prior to the Stark legislation during a period when multiple location physician owned practices were virtually nonexistent. Congress implemented that provision to avoid a situation in which a physician who was an owner or operator of a clinical laboratory . . . [whose CLIA certificate had been revoked] would be allowed to reapply for a new CLIA certificate and begin clinical laboratory testing all over again in the same location.

Oakland Br. at 10.
Oakland indicated that it was not attempting to reapply for CLIA certification. Rather, Oakland argued, HCFA was punishing laboratories not involved in the circumstances leading to revocation of Oakland's certificate, but who were merely part of the Oakland group practice. Thus, according to Oakland, HCFA was clearly practicing guilt by association. Oakland Br. at 10-11; Oakland Reply Br. at 5-7.
Oakland's position is without merit. The ALJ stated that, if the word "person" meant only an individual, there would be some merit to Petitioners' position. However, as he noted, CLIA is found in the United States Code. The general rules of construction applied to the Code are that, unless otherwise indicated, the word "person" includes a company or corporation. ALJ Decision at 5, citing 1 U.S.C.A. § 1 (West 2001). There is no indication in section 263a(i)(3) that a different construction of the term was intended.
If "person" referred only to an individual, a group with a revoked certificate, such as Oakland here, could simply restart its operation in another laboratory. That interpretation would undercut the purpose of section 263a(i)(3). Congress intended that --

> an owner or operator whose conduct has precipitated a revocation not be allowed simply to begin operating a new or existing laboratory . . . , when such person bore ultimate responsibility for the conduct giving rise to the revocation.

H.R. Rep. No. 899, 100th Cong. 2d Sess. 35 (1988).
Where the group, rather than an individual, bore collective responsibility for the conduct, the provision must apply to the group in order to meet this intent.
Consequently, we agree with the ALJ that Petitioners' interpretation was invalid.

Conclusion

Based on the preceding analysis, we affirm and adopt each of the FFCLs underlying the ALJ Decision and sustain that decision in its entirety.

JUDGE

Judith A. Ballard
Donald F. Garrett
M. Terry Johnson
Presiding Board Member

FOOTNOTES

1. Although HCFA has been renamed the Centers for Medicare & Medicaid Services, we continue to use "HCFA" below since that acronym was used to refer to the agency at the time the actions at issue were taken. *See* 66 Fed. Reg. 35437 (July 5, 2001).
2. Petitioner parties before the ALJ were: Evette Elsenety, M.D., [Civil Remedies Docket No.] C-01-218; Harold Margolis, D.O., C-01-219; Mary C. Ferris, D.O., C-01-220; Gregory O. Claque, D.O., C-01-221; Gary B. Lungnas, D.O., C-01-222; Ronald I. Rothenberg, D.O.; C-01-223; Thomas J. Chwierut, D.O., C-01-224; Kenneth S. Meyers, D.O., C-01-225; Jeffrey H. Soffa, D.O., C-01-226; Dudley Roberts, III, M.D., C-01-227; James M. Kohlenberg, M.D., C-01-228; Stanley H. Remer, D.O., C-01-229; Harold Margolis, D.O., C-01-230; Phillip Newman, D.O., C-01-231; Daniel Jebens, D.O., C-01-232; and Gary L. Berg, D.O., C-01-233.

3. Oakland did not explain why Petitioners did not raise this issue before the ALJ. Generally, this "Board will not consider issues not raised in the request for review, nor issues which could have been presented to the ALJ, but were not." *Guidelines - Appellate Review of Decisions of Administrative Law Judges Affecting Provider's Participation in the Medicare and Medicaid Programs* at 4, § 4(c).
4. Additionally, the program regulations governing conduct of a hearing before an ALJ provide that "[e]vidence may be received at the hearing even though inadmissible under the rules of evidence applicable to court procedure. The ALJ rules on the admissibility of evidence." 42 C.F.R. §498.61.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division
IN THE CASE OF

SUBJECT:
Edward Ming-Che Lai, M.D.,

Petitioner,
DATE: December 17, 2001
- v -

Centers for Medicare & Medicaid Services
Docket No.C-01-288
Decision No. **CR848 DECISION**

DECISION

I decide that the Centers for Medicare & Medicaid Services (CMS, formerly known as the Health Care Financing Administration or HCFA) is not authorized to impose sanctions against Petitioner, Edward Ming-Che Lai, M.D. I do so because I find that Petitioner was not serving as the laboratory director of Polymedic Clinical Laboratory, Inc. (Polymedic) in May 2000 when Polymedic failed to comply with a condition for certification pursuant to regulations that implement the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (CLIA).

I. Background

This case emanates from sanction determinations that CMS made against Polymedic. The sanctions that CMS imposed against Polymedic include revocation of Polymedic's CLIA certificate. Polymedic has not requested a hearing to contest those sanctions. Petitioner requested a hearing in order to challenge CMS's determination that, as a consequence of being Polymedic's laboratory director, he was precluded from owning, operating, or directing a clinical laboratory for at least two years from the date that Polymedic's CLIA certificate was revoked by CMS. Petitioner has not argued that CMS lacks a basis for revoking Polymedic's CLIA certificate or for imposing other sanctions against it.

The case was assigned to me for a hearing and a decision. I held an in-person hearing in Los Angeles, California on August 2, 2001. The parties each called witnesses to testify. CMS offered and I accepted exhibits consisting of HCFA Ex. 1 - HCFA Ex. 10 (the exhibits each were identified with the acronym "HCFA" and, therefore, I refer to them by that acronym in order to avoid confusion). Petitioner offered and I accepted exhibits consisting of P. Ex. 1 - P. Ex. 3.

II. Undisputed facts and law

The facts and law that I discuss in this section are not disputed.

Polymedic was a clinical laboratory that was located in El Monte, California. It had obtained a CLIA certificate which allowed it to perform clinical tests on patients' specimens. In order to maintain its CLIA certificate, Polymedic was required to comply with CLIA conditions of participation.

The Secretary of the United States Department of Health and Human Services (Secretary) is charged with enforcing the requirements of CLIA. The Secretary published implementing regulations at 42 C.F.R. Part 493 and delegated his CLIA enforcement authority to CMS. CMS assures that clinical laboratories are inspected at regular intervals in order to determine their compliance with CLIA requirements. CMS has the authority to impose remedies (sanctions) against laboratories that are found not to be complying with CLIA requirements. These sanctions may include revocation of a laboratory's CLIA certificate in the circumstance where the laboratory is found not to be complying with one or more CLIA conditions.

On May 5, 2000, examiners employed by the California Department of Health Services, Laboratory Field Services (LFS), acting as agents of CMS, went to Polymedic's business address in order to conduct an inspection. Transcript (Tr.) 29. The examiners found no laboratory operating at that location. They then reviewed the file that the State of California maintained on Polymedic and found nothing which indicated a change of address for the laboratory. However, on May 22, 2000, the laboratory's owner advised LFS that the laboratory's address had changed and that it was now located down the street from its previous location. Tr. 30.

The examiners then went to the new address that had been supplied by the laboratory's owner in order to conduct an inspection of those premises. However, they found no laboratory at this address. Tr. 30 - 31. The inspectors left their business cards at the new address, along with a letter which requested that the laboratory contact them so that they could conduct an inspection. Tr. 31 - 32. They received no response to the letter. *Id*.

LFS recommended that CMS revoke Polymedic's CLIA certificate. Tr. 33. LFS based its recommendation on Polymedic's failure to comply with the CLIA condition that is stated at 42 C.F.R. § 493.1777 (now recodified at 42 C.F.R. § 493.1773). This section requires a laboratory to make its premises accessible for an inspection and to provide information that is requested of it by examiners.

On October 20, 2000, CMS sent a letter to Polymedic's owner and to Petitioner as director of Polymedic. HCFA Ex. 1. The letter advised them that CMS was imposing sanctions against Polymedic due to Polymedic's violation of CLIA provisions by its failure to permit immediate access for inspection and by its failure to report a change in location. The October 20, 2000 letter described a range of sanctions that CMS intended to impose against Polymedic, including revocation of Polymedic's CLIA certificate.

On October 30, 2000, Petitioner responded to CMS's October 20, 2000 letter. HCFA Ex. 2. Petitioner denied that he was Polymedic's laboratory director. He averred that he was approached by Polymedic's owner in August 1999. He acknowledged having a meeting with Polymedic's owner. At that meeting the owner requested Petitioner to serve as laboratory director of Polymedic. Petitioner acknowledged agreeing verbally to the "general terms" for becoming laboratory director. He also acknowledged signing a form for changing the laboratory's directorship. *Id*. However, according to Petitioner, his verbal agreement was never finalized in writing and his directorship was never established officially. *Id*. Petitioner attested that he had no additional contact with Polymedic's owner until December 1999 when the owner called him. He stated that the owner advised him that the laboratory had not received certification from Medicare or MediCal (California's Medicaid program) and that the laboratory would not continue in

existence. Petitioner asserted that he had always assumed that his directorship of the laboratory was not finalized because he had not entered into a final agreement to direct Polymedic, had not received any payment from Polymedic, and had not had any follow-up communications with the laboratory's owner until December 1999. *Id*.

CMS sent an additional letter to Polymedic's owner and to Petitioner on November 16, 2000. HCFA Ex. 3. The letter noted that mail directed to Polymedic had been returned as undeliverable. The letter advised Polymedic's owner and Petitioner that it was a formal notice of imposition of sanctions.

The November 16, 2000 letter asserted that Petitioner had served as director of numerous laboratories and should have known that, by signing on as laboratory director of Polymedic, he was assuming the directorship responsibilities for the laboratory. It asserted further that Petitioner could not relieve himself of his responsibilities as director by failing to fulfill his responsibilities or by not being aware of what was happening at Polymedic. The November 16, 2000 letter confirmed that CMS was imposing the sanctions that had been described in the October 20, 2000 letter. Additionally, it advised Petitioner that 42 C.F.R. § 493.1840(a)(8) prohibits the owner, operator, or laboratory director of a clinical laboratory whose CLIA certificate has been revoked from owning, operating, or directing another laboratory for at least two years from the date of revocation. HCFA Ex. 3 at 1 - 2.

III. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. Petitioner is entitled to a hearing;

2. Petitioner was the director of Polymedic as of May 2000; and

3. CMS is authorized to impose sanctions against Petitioner.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding as a separate heading. I discuss each Finding in detail.

1. Petitioner, in effect, will be prohibited from owning or operating a clinical laboratory if Petitioner was Polymedic's laboratory director as of the dates when LFS attempted to inspect Polymedic.

The regulations which implement CLIA provide, at 42 C.F.R. § 493.1840(a)(8), that CMS may suspend, limit, or revoke any laboratory's CLIA certificate if CMS finds that the laboratory's owner or operator has:

> Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked.

The regulation does not explicitly prohibit the owner, operator, or laboratory director of a clinical laboratory whose CLIA certificate is revoked from owning, operating, or directing another laboratory within a two year period from the revocation date (CMS argues that a laboratory's director is the "operator" of that laboratory within the meaning of CLIA and

implementing regulations and Petitioner does not challenge that position). However, that is the practical effect of the regulation.

If I find that Petitioner was the laboratory director of Polymedic as of the dates in May 2000 when LFS attempted unsuccessfully to inspect Polymedic, then Petitioner effectively would be prohibited from owning or operating another clinical laboratory for at least two years from the date Polymedic's CLIA certificate was revoked. It is unlikely that any laboratory would allow Petitioner to serve as an owner, operator, or director, because his ownership or operation of the laboratory would cause that laboratory's CLIA certificate to be revoked.

2. Petitioner is entitled to a hearing.

CMS asserts that Petitioner has no standing to contest any prohibition against his owning, operating, or directing a laboratory, as a collateral consequence of the revocation of Polymedic's CLIA certificate. CMS argues that regulations which confer hearing rights in cases involving CLIA enforcement actions give those rights to laboratories and not to individuals. *See*, *e.g.*, 42 C.F.R. § 493.1844. CMS argues further that the fact that there may be collateral consequences for a laboratory's owner, operator, or laboratory director resulting from imposition of sanctions against a laboratory does not mean that these individuals have appeal rights. CMS post-hearing brief at 12.

It is true that the regulations only grant hearings to laboratories who are affected by sanctions and do not explicitly confer hearing rights on laboratory owners, operators, and directors. However, although the regulations may be silent on the subject, CLIA is not. CLIA provides expressly that the Secretary may suspend, revoke, or limit a laboratory's CLIA certificate only after giving "reasonable notice and opportunity for hearing to the *owner or operator of the laboratory* . . . . " 42 U.S.C. § 263a(i)(1) (emphasis added).

Consistent with that statutory requirement, administrative law judges have held that CLIA provides a laboratory owner, operator, or director with a right to a hearing to contest the consequences of revocation of the laboratory's CLIA certificate. *RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic*, DAB CR829, at 5 (2001); *Carlos A. Cervera, M.D.*, Docket No. C-99-797, Ruling Denying HCFA's Motion to Dismiss and Granting Extension of Time for Submission of Readiness Reports, December 21, 1999; *Allstate Medical Laboratory, Inc.*, Docket No. C-99-309, Ruling, October 6, 1999; *Eugene R. Pocock, M.D.*, DAB CR 527 (1998). These rulings and decisions were cited favorably by an appellate panel of the Departmental Appeals Board in *Sentinal Medical Laboratories, Inc.*, DAB No. 1762, at n.6 (2001), which observed that CMS "wisely" opted not to argue before the Board that an owner or operator of a laboratory had no right to a hearing to challenge a sanctions determination made against the laboratory. I follow these rulings and decisions and hold that Petitioner has a right to a hearing to challenge the effect that revocation of Polymedic's CLIA certificate may have on him.

3. Petitioner was not serving as director of Polymedic as of May 2000.

CMS makes two allegations in this case. The first allegation, which is not challenged by Petitioner, is that Polymedic violated a CLIA condition in May 2000 when the examiners attempted unsuccessfully to inspect Polymedic, thereby justifying CMS's determination

to revoke Polymedic's CLIA certificate. The second allegation, which Petitioner does challenge, is that he was serving as Polymedic's laboratory director, or at least had agreed to be Polymedic's laboratory director, at the time of the May 2000 inspection attempts. CMS argues that, based on prima facie evidence addressing these two allegations, Petitioner is precluded, as Polymedic's laboratory director, from owning or operating another laboratory for the two year period that begins with CMS's revocation of Polymedic's CLIA certificate.

I do not find CMS's arguments as to its second allegation to be persuasive, because the preponderance of the evidence supports the conclusion that Petitioner was not performing any duties as Polymedic's laboratory director in May 2000 and had not agreed to serve as laboratory director as of that date. The evidence shows that Petitioner informally agreed to become Polymedic's laboratory director in late August or early September 1999. He acted as Polymedic's director when he executed a CLIA certificate application on Polymedic's behalf in September 1999. But, thereafter, he assumed none of the director's responsibilities and exercised none of the director's authority. He entered into no agreement with Polymedic to provide continued service to Polymedic as its laboratory director. Polymedic failed to offer a contract to Petitioner or to negotiate the terms of compensation with him. And, Petitioner and Polymedic's owner came to a clear understanding in December 1999 that Petitioner would have no further dealings with Polymedic.

Under CLIA, a laboratory director has the principal responsibility for management and operation of a clinical laboratory. 42 C.F.R. § 493.1407. Whether an individual actually is a laboratory's director is a question of fact. An individual may be deemed to be a laboratory's director under two circumstances. First, the individual may be a laboratory's director if he or she is performing the duties of the laboratory director. Second, the individual may be a laboratory's director if that individual has agreed to perform the duties of the laboratory director whether or not he or she is actually performing them. Under the second test, an individual may meet the definition of "laboratory director" even if he or she is derelict in fulfilling the laboratory director's obligations if he or she has agreed to serve as laboratory director.

The evidence that CMS relies on to establish that Petitioner was Polymedic's laboratory director in May 2000 consists of the three documents that Petitioner executed on September 22, 1999, and which constitute Polymedic's CLIA certificate application. HCFA Ex. 3. These documents unambiguously state that Petitioner was Polymedic's laboratory director as of that date. *Id*. These documents support the conclusion that Petitioner had agreed to be Polymedic's laboratory director as of September 22, 1999 and that he was performing the director's duties on that date.

It is reasonable to infer from these documents, absent evidence to the contrary, that Petitioner continued to be Polymedic's laboratory director after that date. I would conclude that Petitioner had agreed to serve as Polymedic's laboratory director and was, in fact, performing the director's duties, if these documents comprised the only evidence in this case concerning Petitioner's relationship with Polymedic.

However, the inference that Petitioner was the director in May 2000 is rebuttable. I find that Petitioner rebutted that inference persuasively with his credible testimony at the hearing. Tr. 138 - 179.

I conclude, based on Petitioner's credible testimony, that Petitioner was not performing any of the duties of laboratory director in May 2000. The only action that Petitioner ever took as Polymedic's laboratory director was to execute the CLIA certificate application documents in September 1999. Petitioner has established, persuasively, that he did nothing for Polymedic thereafter. Indeed, Petitioner never visited Polymedic's facilities except for one brief visit in late August or early September 1999. I conclude also that Petitioner did not agree to serve as Polymedic's laboratory director after September 1999. He entered into neither an oral nor a written agreement with Polymedic to continue serving as its laboratory director.

Petitioner testified persuasively that his relationship with Polymedic consisted only of the following: a brief visit to the laboratory in late August or early September 1999, which included a meeting with the laboratory's owner; a telephone conversation with Polymedic's owner that took place shortly after Petitioner's visit to the laboratory; a subsequent face-to-face meeting with Polymedic's owner in September 1999, at which he signed the documents that are in evidence as HCFA Ex. 3; and, a telephone conversation with the laboratory's owner in December 1999, in which the laboratory's owner informed him that she would have to cease her effort to operate the laboratory due to the laboratory's inability to receive certification from Medicare and MediCal. Tr. at 145 - 151. Petitioner's credible testimony is that he never spoke again with the laboratory's owner after the December 1999 telephone conversation. *Id.* at 154. I note that the testimony that Petitioner gave at the hearing is consistent with the statement he submitted to CMS at the end of October 2000. HCFA Ex. 2.

The thrust of Petitioner's testimony, which I find to be credible, is that he may have agreed in principle to become Polymedic's laboratory director, but that he never finalized that agreement. Petitioner never entered into a written agreement with Polymedic to become its laboratory director, never agreed orally to continue serving as its director after signing the CLIA certificate application form, never agreed with Polymedic as to his compensation, never visited the laboratory after late August or early September 1999, and never received any compensation from Polymedic. Petitioner performed none of the duties that are performed by a laboratory director aside from executing Polymedic's application for a CLIA certificate and associated documents. He assumed, based on his December 1999 conversation with Polymedic's owner, that whatever relationship he had established with the laboratory had ended. *Id.* at 150 - 154.

Petitioner's execution of a CLIA certificate application on behalf of Polymedic in September 1999 establishes that, for at least a very brief period of time, Petitioner acted in the capacity of Polymedic's laboratory director. He explicitly represented himself to be the laboratory director on the application. HCFA Ex. 3. However, there is no evidence in this case that he engaged in any actions as laboratory director subsequent to his signing the application. Petitioner's testimony satisfies me that, whatever he may have represented himself to be on the CLIA certificate application, he did not come to a meeting of the minds with Polymedic's owner to serve as Polymedic's laboratory director, nor did he perform any of the duties of laboratory director for Polymedic aside from signing the CLIA application form. Furthermore, even if Petitioner could have been considered to be Polymedic's laboratory director in the autumn of 1999, that relationship ceased definitively with Petitioner's December 1999 telephone conversation with

Polymedic's owner. At that time, she told him that the laboratory would be closed and he assumed, naturally, that any discussions concerning assuming the directorship were over.

Petitioner directs several laboratories other than Polymedic. He testified persuasively that his relationship with all of the other laboratories that he directs is memorialized in written contracts and that his normal practice is to request that he be compensated for his services once he begins performing the duties of laboratory director. Tr. at 152. It is fair to conclude that Petitioner never requested a written director's agreement or compensation from Polymedic because he did not consider himself to be Polymedic's director.

CMS produced a record of reimbursement claims submitted by Polymedic which establishes that the laboratory filed claims for services for several months after September 1999. HCFA Ex. 7. But, the fact that Polymedic may have claimed reimbursement for services after Petitioner's late August or September 1999 meeting with Polymedic's owner does not mean that these services were provided or claimed under Petitioner's direction. There is nothing about the claims records produced by CMS which supports a finding that those claims were made at Petitioner's direction. The records document only that claims were made. *See id*.

CMS argues that a laboratory director who fails to notify CMS when he or she ceases serving as director continues to be responsible for the laboratory's compliance with CLIA conditions. Under this theory, Petitioner should be deemed to be Polymedic's laboratory director even though he had not agreed to serve as Polymedic's director after September 1999 and even though he performed none of the director's duties after September 1999. I do not find this argument to be persuasive. There is no language in either CLIA or implementing regulations which provides that a laboratory director retains the legal responsibilities of director after he or she has severed all ties with the laboratory if he or she does not give notice to CMS. Consequently, a failure by Petitioner to apprize LFS that he was not serving as Polymedic's laboratory director did not mean, as a matter of law, that Petitioner continued to serve as the laboratory director.

There is a requirement in the regulations that a *laboratory* must give notice to CMS, within 30 days of the occurrence of events which include a change of the laboratory's director. 42 C.F.R. § 493.51(a)(4). Polymedic failed to comply with this requirement when, after notifying CMS on September 22, 1999 that Petitioner had become its director, it failed to notify CMS that its relationship with Petitioner had been terminated. However, the regulation does not impose a separate duty on a laboratory director to notify CMS when he or she terminates a relationship with a laboratory. Presumably, CMS could revoke a laboratory's CLIA certificate for failing to comply with the requirements of 42 C.F.R. § 493.51(a)(4). But, that revocation would not prevent collaterally the laboratory's former director from owning or operating another laboratory because the former director was not the laboratory's director at the time that the laboratory contravened the regulation's notification requirements.

Moreover, failure to give notice of a change of director was not the basis for CMS's determination to impose sanctions against Polymedic or Petitioner. CMS advised Polymedic and Petitioner, in both its October 20, 2000 and in its November 16, 2000

notices, that the basis for CMS's action was Petitioner's failure to comply with 42 C.F.R. § 493.1777 (now recodified at 42 C.F.R. § 493.1773).

I am not persuaded that it may be inferred by Petitioner's failure to notify CMS timely that he no longer was the director of Polymedic that either he had agreed to be Polymedic's laboratory director or was serving as the laboratory director as of May 2000. That is not a reasonable inference to make given the other facts of this case. It was unwise for Petitioner not to have notified CMS that he would not be serving as Polymedic's laboratory director as soon as it became apparent to him that he would not be serving in that position. This case would never have arisen had he done so. But, the weight of the evidence in this case strongly supports the conclusion that Petitioner was not serving as Polymedic's laboratory director in May 2000, regardless of his failure to give notification that he would not be serving in that position.

4. CMS is without authority to impose sanctions against Petitioner.

The preponderance of the evidence shows that Petitioner was not serving as Polymedic's laboratory director in May 2000. Therefore, no basis exists for CMS to impose sanctions against Petitioner as the laboratory director of a laboratory whose CLIA certificate has been revoked.

JUDGE

Steven T. Kessel
Administrative Law Judge

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

IN THE CASE OF	
SUBJECT: Premium Diagnostic Laboratory, Inc., Petitioner, - v - Centers for Medicare and Medicaid Services	DATE: October 10, 2001 Civil Remedies CR808 Docket No. A-01-112 Decision No. 1790

DECISION

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Premium Diagnostic Laboratory, Inc. (Petitioner), appealed an August 9, 2001 decision by Administrative Law Judge (ALJ) Steven T. Kessel dismissing Petitioner's request for a hearing (ALJ Decision). Petitioner had requested a hearing before the ALJ to contest the decision by the Centers for Medicare and Medicaid Services (CMS) to revoke its certificate issued under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The ALJ found that CMS's subsequent determination to rescind the revocation of Petitioner's CLIA certificate resulted in no appealable determination under the regulations and therefore dismissed Petitioner's request for a hearing.

Petitioner is an independent laboratory operating in California. On March 30, 2001, CMS sent a notice to Petitioner that CMS was proposing to impose sanctions on Petitioner, including the revocation of its CLIA certificate, because Petitioner was owned, operated, or directed by an individual who owned, operated, or directed a laboratory whose CLIA certificate had been revoked within the preceding two years. After Petitioner timely requested a hearing before an ALJ, CMS notified Petitioner on June 29, 2001, that it had determined not to pursue any sanctions against Petitioner and was withdrawing its determination to revoke Petitioner's CLIA certificate and to deny

Petitioner Medicare payments.

The ALJ dismissed Petitioner's request for a hearing, finding that, after CMS's rescission of its sanctions, there was no initial determination from which Petitioner could take an appeal, and that since Petitioner had no right to a hearing, dismissal was appropriate under 42 C.F.R. § 498.70(b). The ALJ stated that the consequence of CMS's rescission of the sanctions was the elimination of the sanctions determination which was the basis for Petitioner's hearing request. The ALJ further noted that, even if CMS had not rescinded the sanctions and the ALJ had overturned CMS's determination, he could not have provided any greater relief to Petitioner than what had occurred as a result of CMS's withdrawal of its initial determination and sanctions. ALJ Decision at 3.

The record here includes the record before the ALJ, the ALJ Decision, and the parties' submissions on appeal. Our standard of review on a disputed conclusion of law is whether the ALJ Decision is erroneous. *See, e.g.*, *Lake Cook Terrace Nursing Center*, DAB No. 1745 (2000). Our standard of review on a disputed finding of fact is whether the ALJ Decision is supported by substantial evidence on the record as a whole. *Id*.

On appeal Petitioner stated that it was entitled to a review by the ALJ of what it labeled an abuse of discretion by CMS in imposing sanctions against Petitioner. Petitioner asserted that CMS, at relevant times, failed to review documentation Petitioner supplied that demonstrated its compliance with CLIA regulations. Petitioner further argued that the ALJ's dismissal was "erroneous" and "not fair" to Petitioner because it deprived Petitioner of the opportunity to receive damages for CMS's inappropriate actions. Petitioner's Reply Brief at 2. Petitioner claimed that CMS, in revoking its CLIA certificate, had damaged Petitioner's reputation and violated its civil rights, as well as caused Petitioner to suffer financial hardship due to the loss of business revenue and costs incurred in contesting CMS's actions.

We find that the ALJ correctly determined that, with the withdrawal by CMS of the sanctions imposed on Petitioner, there was no longer any appealable determination before him. Actions that are appealable initial determinations under the CLIA regulations are set forth at 42 C.F.R § 493.1844(b). That regulation lists "actions" that are "initial determinations" and therefore subject to appeal, including the "revocation of the laboratory's CLIA certificate . . . because of non-compliance with CLIA requirements" and the "cancellation of the laboratory's approval to receive Medicare payments for its services." 42 C.F.R § 493.1844(b)(1) and (4). If those actions are subsequently rescinded in full, as they were here, there is no longer an initial determination in dispute and an ALJ may properly dismiss the request for a hearing. 42 C.F.R. § 498.70(b). The ALJ Decision cited *Lakewood Plaza Nursing Center*, DAB No. 1767 (2001), and *Schowalter Villa*, DAB No. 1688 (1999). Those decisions were based primarily on the language of 42 C.F.R. § 493.3(b)(12), which is not applicable here, but similarly addressed the situation where remedies had been fully rescinded and no relief could be granted as a result of an administrative proceeding.

Petitioner has not provided any legal basis for challenging the ALJ's decision to

dismiss its hearing request, instead focusing on the unfairness of CMS's action and the harm Petitioner suffered as a result. While Petitioner may have experienced difficulties as a result of CMS's initial determination to revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare payments, there is no authority in the regulations for the ALJ or the Board to provide the type of relief Petitioner is seeking. The ALJ found, and Petitioner did not deny, that the certificate was reinstated retroactively and that Medicare payments were paid retroactively for the period between the initial effective date of the cancellation and the date the laboratory closed and ceased operating. Thus, even if the ALJ found in Petitioner's favor on the merits, he could not grant any greater relief than was already given through the rescission. Petitioner received all of the relief that the ALJ had the authority to provide.

Conclusion

For the reasons discussed above, we sustain the ALJ's dismissal of Petitioner's request for a hearing. In doing so, we affirm and adopt all the FFCLs made by the ALJ.

JUDGE	

Judith A. Ballard

M. Terry Johnson

Donald F. Garrett
Presiding Board Member

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

IN THE CASE OF	
SUBJECT: Mark Gary Hertzberg, M.D., P.C., Petitioner, - v - Centers for Medicare & Medicaid Services	DATE: December 14, 2001 Docket No. A-2001-119 Civil Remedies CR805 Decision No. 1805
DECISION	

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Mark Gary Hertzberg, M.D., P.C. (Petitioner), a clinical laboratory, appealed an August 3, 2001 decision by Administrative Law Judge (ALJ) Alfonso J. Montaño granting summary disposition in favor of the Centers for Medicare & Medicaid Services (CMS).[(1)] *Mark Gary Hertzberg, M.D., P.C.*, DAB CR805 (2001) (ALJ Decision). There, the ALJ sustained the following remedies imposed by CMS against Petitioner: the suspension and revocation of Petitioner's certificate under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the cancellation of Petitioner's approval to receive Medicare payments for its services.

The ALJ Decision was based on six findings of fact and conclusions of law (FFCLs). On appeal, Petitioner excepted to each FFCL and asked that we reverse the ALJ Decision. We have reviewed Petitioner's exceptions and conclude that the ALJ Decision should be affirmed and the remedies imposed by CMS should be upheld.[(2)]

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*. CLIA further grants the Secretary of this Department broad enforcement authoritv. including the ability to suspend, limit, or revoke the certificate of a

laboratory that is out of compliance with one or more requirements for a certificate. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829.

A laboratory's CLIA certification is dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*.(3) Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. The regulations also set forth standards, the specific components of the conditions of laboratory certification that a laboratory must meet as part of achieving compliance with applicable conditions.

A key component of the statutory and regulatory program to assure that laboratories holding CLIA certificates are competent to perform tests of moderate and high complexity is the requirement for participation in a proficiency testing (PT) program that is approved by CMS, as outlined in 42 C.F.R. Part 493, Subpart H. Among the requirements of that subpart are the following: a participating laboratory must test PT samples it receives in the same manner as it tests patient samples; must not communicate the results of its tests to other laboratories prior to the deadline for reporting results; must not refer PT samples to another laboratory for analysis; and must document and maintain documentation for the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 C.F.R. § 493.801.

A laboratory's failure to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.(4)

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations at 42 C.F.R. § 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E.

Background

This is the fifth in a series of related CLIA appeals.(5) The undisputed factual background is drawn from the ALJ Decision and the record below.

Petitioner is a physician-owned clinical laboratory engaged in high complexity testing for routine chemistry and endocrinology in Southfield, Michigan. Petitioner is owned

and operated by Mark Gary Hertzberg, M.D., who served as Petitioner's laboratory director. CMS Ex. 5. Petitioner employed Deborah Sabo. Ms. Sabo performed high complexity routine chemistry and endocrinology testing, PT and tests billable to Medicare. CMS Ex. 7.

Some of the metropolitan Detroit laboratories participating in the American Association of Bioanalysts (AAB) PT program were Mark Hertzberg, M.D.; Stanley Boykansky, M.D.; Oakland Medical Group (also known as Moretsky/Trager/Flor); John Dunn, M.D.; Rochester Road Clinic; Nazar Sarafa, M.D. (also known as Garden City Medical Clinic); Liptawat Family, P.C.; Lakeland Medical; and Ecorse Med Center. CMS Exs. 1 and 27; *Oakland*, at 3. The AAB would mail to each participating laboratory an identical group of five specimens three times a year. The laboratories were required to test these specimens for analytes for which they did patient testing and mail their results to the AAB by a date certain. Petitioner was required to test the specimens for cholesterol, glucose, HDL cholesterol, triglycerides, iron, thyroid stimulating hormone, total thyroxine, triiodothyronine, and thyroid uptake.

While working for Petitioner, Ms. Sabo also performed PT for the Dunn, Ecorse, Boykansky and Garden City laboratories and worked for the Rochester Road laboratory as substitute testing personnel. CMS Ex. 26 (Tr.)[(6)] at 42-43.

During this period, Rene Wheatley performed PT for the Rochester Road, Liptawat, Lakeland and Oakland laboratories. *Boykansky* at 3, *citing* HCFA Exs. 1 and 2 in that record.

In early January 1999, Dennis W. Jay, Ph.D., Technical Director of the Proficiency Testing Service of the AAB, sent a letter to the Michigan Department of Consumer and Industry Services (MDCIS), the state survey agency, concerning PT results for a group of Detroit area laboratories that he deemed suspect. Specifically, he suggested that the same PT results were being submitted by nine laboratories including Petitioner. CMS Exs. 24 at 2-4 and 25 at 2-3.

On February 25, 1999, MDCIS surveyors conducted a complaint investigation of Petitioner to determine whether Petitioner was complying with CLIA requirements. The surveyors determined that Petitioner's 1998 PT results were not obtained in compliance with CLIA requirements.[(7)] CMS Ex. 25 at 3-12. Generally, the surveyors found that Petitioner's PT results for numerous tests were identical to PT results at some or all of eight other Detroit area laboratories, identified above, at which Ms. Sabo and Ms. Wheatley worked. The surveyors also found that the underlying calculations ostensibly used to produce those results did not always support them.

The surveyors referred their findings to CMS. On June 23, 1999, CMS notified Petitioner that it had found Petitioner deficient in complying with CLIA requirements. CMS Ex. 4. CMS advised Petitioner that it would impose remedies against Petitioner which included cancellation of Petitioner's approval to receive Medicare payment for its services and revocation of Petitioner's CLIA certificate.

CMS followed its June 23, 1999 notice with a second notice dated August 17, 1999. There, CMS advised Petitioner that its determination to impose remedies was based on its finding that Petitioner had referred PT samples to another laboratory for testing or had improperly collaborated with another laboratory in the administration of PT samples. CMS identified two specific CLIA conditions with which it asserted Petitioner had not complied. These conditions are stated at 42 C.F.R. §§ 493.801 (proficiency testing) and 493.1441 (laboratory director). CMS Ex. 22.

On August 19, 1999, Petitioner requested a hearing before an ALJ.

On September 3, 1999, CMS sent a third notice to Petitioner, supplementing its June 23rd notice "by clarifying, and setting forth in more detail, our basis for imposing the sanctions . . . ." CMS indicated that it had inadvertently failed to include evidence, in addition to survey findings, upon which its determinations were based. The evidence was abstracted in a chart for Petitioner which compared Petitioner's proficiency testing to eight other laboratories in Michigan. CMS asserted that the "identity of the results reported by these nine laboratories, especially for the third quarter of 1998, is strong evidence of improper referral or collaboration, or both." CMS Ex. 23.

On February 22, 2000, CMS filed a Motion for Summary Affirmance. Petitioner opposed CMS's Motion and requested a hearing. The ALJ denied CMS's motion and scheduled an in-person hearing for November 8, 2000. On November 2, 2000, this hearing was canceled at the request of the parties. The parties stipulated that if Ms. Sabo were to testify in this matter, her testimony would be the same as her April 12, 2000 testimony given in the hearing before the ALJ in *Boykansky* and contained in the transcript from that proceeding (submitted in this proceeding as CMS Ex. 26). Petitioner subsequently submitted a supplemental affidavit by Ms. Sabo (P. Ex. 5).[(8)] The ALJ granted summary disposition for CMS on August 3, 2001.

Applicable Legal Standards

The standard of proof employed at a hearing concerning CMS's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. CMS has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance established by CMS. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999), *aff'd Edison Medical Laboratories, Inc., v. Thompson*, 250 F.3d 735 (3rd Cir. 2001); *see also Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd Hillman Rehabilitation Center v. United States*, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

Our standard of review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000).

ANALYSIS

Petitioner took exception to the six FFCLs underlying the ALJ Decision. Petitioner filed, concurrently, both a Request for Review, listing exceptions to the FFCLs, and a Brief in which its discussion of some FFCLs was subsumed within broader arguments. In presenting Petitioner's position, we cite both its Request for Review and its Brief.

We have considered each argument raised by Petitioner as well as the entirety of evidence before the ALJ. Below we address each relevant argument relative to a disputed FFCL. We have concluded that the challenged FFCLs are not erroneous and are supported by substantial evidence on the record as a whole. Thus, any nuance of Petitioner's contentions that we have not addressed specifically is subsumed in our analysis of its position and rejected.

FFCL 1. CMS properly notified Petitioner of condition-level deficiencies.

Petitioner contended that this FFCL was clearly erroneous and not supported by substantial evidence in the record. Petitioner asserted that it did not receive proper notice of the condition-level deficiencies in accordance with 42 U.S.C. § 263a(i) and 42 C.F.R. § 493.1844(g). Petitioner alleged that it had suffered prejudice because its Medicare payments were canceled prior to its receipt of notice of any alleged condition-level deficiencies. Petitioner noted further that, based on the ALJ Decision, it could have its CLIA certificate revoked. Petitioner Request for Review at 1-2; Petitioner Br. at 7.

Petitioner conceded that CMS's June 23, 1999 notice properly alleged standard-level deficiencies. However, Petitioner asserted that it was not until CMS's August 17, 1999 notice that allegations of condition-level deficiencies relative to 42 C.F.R. § 493.801 (testing of samples) arose. Petitioner contended that it received the August 17th notice after the sanctions were either imposed or appealed. Further, Petitioner contended, this notice provided no opportunity for Petitioner to respond to or to appeal previously undisclosed deficiencies. Petitioner alleged that CMS's actions constituted a blatant violation of 42 U.S.C.§ 263a(i), 42 C.F.R. §§ 493.1842, 493.1844, and the Due Process and Equal Protection Clauses of the United States Constitution. Petitioner Br. 7-11.

Petitioner argued that the ALJ misinterpreted both the statute, 42 U.S.C. § 263a(i), and parallel regulations at 42 C.F.R. § 493.1842. Petitioner contended that this legislation provided that neither cancellation nor revocation may occur without proper notice and opportunity to respond. Petitioner recognized that 42 C.F.R. § 493.1842(b) authorized CMS to amend notices. However, Petitioner asserted that CMS was not authorized to impose a principal sanction unless it had properly alleged a condition-level deficiency. Petitioner argued that the ALJ erred in finding that CMS's August 17th notice was an adequate basis for principal sanctions. Petitioner acknowledged this Board's prior consideration of this issue in *Bovkansky*. in which the Board stated that pervasive

noncompliance with standards could constitute a failure to comply with the overall condition. However, Petitioner asserted that the general analysis in *Boykansky* was wrong and that the ALJ here erred in relying on that decision to reach this FFCL. Here, Petitioner asserted, CMS imposed a condition-level remedy, cancellation of payment, then alleged condition-level deficiencies. Additionally, Petitioner asserted, CMS erroneously determined that it could cancel payments and revoke Petitioner's CLIA certificate based on an accumulation of standard-level deficiencies justifying condition-level sanctions. Petitioner Br. at 7-15.

We reject Petitioner's contention that it lacked timely and adequate notice of the basis for CMS's determination. As the ALJ found, the June 23rd notice expressly cited 42 C.F.R. § 493.801(b)(4), the CLIA standard concerning the intentional referral of PT samples. *See* ALJ Decision at 7, citing CMS Ex. 4. That standard specifically mandates the principal sanction of certificate revocation. Thus, the ALJ reasoned, the fact that the other regulatory provisions cited in the Statement of Deficiencies accompanying the June 23rd notice concerned only standard-level deficiencies does not make the notice inadequate as a basis for imposition of principal sanctions. Moreover, contrary to Petitioner's contention that it was not provided an opportunity to address the alleged deficiencies prior to cancellation of approval to receive Medicare payments (as required by 42 C.F.R. §§ 493.1842(b) and 493.1810), the ALJ was correct in holding that the June 23rd letter provided Petitioner its opportunity to respond before the cancellation went into effect. ALJ Decision at 8; *see* CMS Ex. 4. In addition, as we discuss extensively below, this case has parallels to *Boykansky*. Here, too, the egregious undermining of the PT system alleged by the June 23rd notice was sufficient to constitute an allegation of a condition-level deficiency within the meaning of the regulations, even if the notice did not specifically state this.

Petitioner also claimed that CMS's action against it violated the Equal Protection Clause of the Constitution because one of CMS's affiants stated that other laboratories in other states also reported identical PT results, yet CMS failed to prosecute those laboratories. Since Petitioner did not raise this issue before the ALJ, and offered no evidence or legal authority to support its claim, we summarily reject this contention.

We therefore affirm and adopt FFCL 1.

FFCL 2. During 1998, Petitioner colluded with other clinical laboratories in the performance of proficiency testing.

Petitioner asserted that the ALJ's finding of collusion was not supported by "substantial facts presented and is clearly erroneous." Petitioner Request for Review at 2. Petitioner argued that in reaching this FFCL, the ALJ ignored the only credible evidence of record, Ms. Sabo's testimony, and relied instead on the similarity of Petitioner's PT results to the results of other laboratories in the Detroit area. Petitioner contended that the ALJ's findings, that Ms. Sabo and Ms. Wheatley were well-acquainted and that Ms. Sabo had offered no explanation for similar or identical PT results, were not supported by substantial evidence. *Id.* at 2-5.

In addition, Petitioner alleged that CMS had not met its burden regarding allegations of intentional referral. Petitioner also contended that CMS improperly relied on simple rounding errors and inconsequential human errors by Ms. Sabo as evidence of a greater scheme of collusion or collaboration. Petitioner Br.at 16-17.

Petitioner also challenged the qualifications of the two CMS affiants (the Technical Director, Proficiency Testing, AAB; and the Chief, Laboratory Improvement Section, MDCIS). Petitioner asserted that these affiants' credentials did not include expertise or special knowledge in the area of statistical analysis. Thus, Petitioner said, the ALJ's reliance on them was misplaced. Petitioner asserted that the affiants' declarations were suspect because they did not consider the totality of the testing process. Further, Petitioner contended, at least one of the affiants, as well as the ALJ, failed to understand that the reduction of the number of variables in a testing equation reduces the chances for dissimilarity of results. According to Petitioner, since the laboratories participating in the AAB testing had the same samples and many used the same reagents and/or equipment, the chance for similar results was increased. Petitioner Br. at 16-20; CMS Exs. 24 and 25.

Finally, Petitioner asserted that neither CMS nor the ALJ alleged, "expressly or impliedly," that Petitioner did not perform all clinical laboratory testing for its patients. Petitioner asserted that there was no evidence before the ALJ which would constitute a motive for the actions attributed to Ms. Sabo. Moreover, since there had been no showing that Ms. Sabo had acted in conjunction with anyone else, collusion was a "legal impossibility." Petitioner Br. at 24-25.

We have previously considered similar arguments in *Boykansky*. Here, we have reviewed this FFCL in light of Petitioner's contentions and our previous consideration of the issue. We conclude that this FFCL is supported by substantial evidence in the record. As we noted in *Boykansky*, our review of Ms. Sabo's testimony confirmed that Ms. Sabo had testified to the effect that she and Ms. Wheatley were well-acquainted and that Ms. Sabo offered no credible explanation for the similarity of testing results. *Boykansky* at 8; CMS Ex. 26. While Ms. Sabo denied that she colluded, the ALJ reasonably concluded that this denial was not credible in light of the evidence in the record as a whole.

Moreover, while the ALJ did not specifically address Petitioner's argument that Ms. Sabo had no motive to falsify the PT results, because it would not save her any work, that argument does not avail Petitioner here. While motive, if proven, would have buttressed the ALJ's findings concerning Ms. Sabo's credibility, lack of motive does not undercut the evidence supporting the ALJ's finding that the PT results reported by Ms. Sabo simply did not match the records she made of the PT testing at the time that she allegedly performed the tests.

In addition to the lack of explanation from Ms. Sabo as to how all nine laboratories could innocently reach identical PT results in all three PT events for 1998, the ALJ based the FFCL on his analysis of the testimony of two CMS affiants and his

examination of the records Petitioner had produced to support the PT results reported. The ALJ relied on the affiants' opinions concerning the likelihood that identical results could be reached without collusion. Additionally, the ALJ made an independent determination that Petitioner's records contained data that was inconsistent with the results reported. Consequently, the ALJ reasonably concluded that Petitioner did not arrive at these results through human error or coincidence, but by intentional referral, collaboration, and manipulation of the results.

We also reject Petitioner's arguments about CMS's affiants' alleged lack of credentials and the similarity of test methods used by the laboratories which obtained identical testing results. Petitioner mischaracterizes the nature of the ALJ's reliance on the testimony of CMS's experts. He addressed Petitioner's challenge to these individuals' statistical expertise as follows:

> I do not find Petitioner's arguments to be persuasive. These experts did not perform statistical analyses to obtain their conclusions. Rather, their conclusions were based on their training in their respective fields, their experience in those fields, and on the evidence which pertained to the specific proficiency tests that are at issue in this case.

ALJ Decision at 11.

Further, adopting the ALJ's reasoning in *Boykansky*, the ALJ here specifically addressed Petitioner's allegation that the identical PT results for the nine laboratories could be due to the similar testing conditions for the laboratories. He stated:

> Although some of the laboratories had the same model spectrometer--a device that was used to perform proficiency testing--others had different models. Tr. at 77. All of the spectrometers were calibrated separately. *Id.* at 77-78. Each of the nine laboratories had its own supply of controls and reagents. *Id.* at 76-77. Room temperature varied from laboratory to laboratory. *Id.* at 78.

ALJ Decision at 12. Indeed, in making his finding that variability would be expected, the ALJ relied in part on Ms. Sabo's own testimony. *Id.* at 12-13.

We conclude that the ALJ properly weighed the evidence before him in reaching his finding that the results Petitioner reported for PT in 1998 were not its own. As we discuss below, we also conclude that he did not err in determining that this factual finding meant that Petitioner had participated in unlawful communication of PT results in contravention of 42 C.F.R. § 493.801(b).

We reject Petitioner's contentions that the ALJ erred in affirming CMS's finding of

intentional referral here because CMS relied on decisions where the laboratory in question had admitted referral and on documents showing what Petitioner characterized as rounding errors or inadvertent human error. The ALJ thoroughly discussed the evidence supporting his application of the referral and inter-laboratory communication regulations to the circumstances here. *See* ALJ Decision at 8-15. As we have already stated, his analysis of these issues is supported by substantial evidence in the record.

We therefore affirm and adopt FFCL 2.

FFCL 3. Petitioner's conduct in colluding with other laboratories as to the testing of proficiency testing samples during 1998 constitutes a violation of the following standards concerning proficiency testing set forth at 42 C.F.R. § 493.801(b): section 493.801(b)(1) (failing to test proficiency testing samples in the same manner as it tests patients' specimens); section 493.801(b)(3) (engaging in inter-laboratory communications pertaining to the results of proficiency testing samples); and section 493.801(b)(4) (intentionally referring proficiency testing samples to another laboratory for analysis).

In challenging the evidentiary basis for this FFCL, Petitioner relied heavily on what it characterized as Ms. Sabo's "unequivocal testimony." The essence of her testimony was that PT and patient testing were properly performed in 1998. Additionally, Petitioner contended that there was no reliable evidence that PT was not performed on site. Petitioner Br. at 25-26. Petitioner argued that not only was there no evidence before the ALJ that Petitioner had engaged in inter-laboratory communication, but also the relevant CLIA regulation, 42 C.F.R. §§ 493.801(b)(3) and (4), dictated that inter-laboratory communications be treated as a standard-level deficiency, not sanctionable by revocation. Consequently, Petitioner concluded, since this Department and Congress intended that inter-laboratory communications be treated as a standard-level deficiency, neither CMS nor the ALJ had the authority to impose principal sanctions in this case. Petitioner Br. 26-27.

In connection with our review of Petitioner's exceptions to FFCL 2, we have already discussed the substantial evidence in the record supporting the ALJ's finding that Petitioner's 1998 PT results were reached through collusion rather than through testing in accordance with the regulations. Based on that same analysis, we reject Petitioner's reliance on Ms. Sabo's testimony that PT testing was done properly on site.

We also reject Petitioner's regulatory analysis leading to its conclusion that CMS is not authorized to impose a principal sanction for inter-laboratory communication. One of the subsections cited by Petitioner, 42 C.F.R. § 493.801(b)(4), specifically requires imposition of a principal sanction, revocation of a laboratory's CLIA certificate for one year, for any laboratory that CMS determines intentionally referred its PT samples to another laboratory for analysis. This clearly contradicts Petitioner's assertion that the captioning of 42 C.F.R. § 493.801(b) as a standard evidences an intent to limit CMS's authority to impose a principal sanction for violations of this provision. CMS is not limited to alternative sanctions where a laboratory's actions constitute an egregious

violation of its PT responsibilities. *Boykansky*, at 18-19; *see also Oakland*, at 23.

We therefore affirm and adopt FFCL 3.

FFCL 4. Petitioner failed to comply with the standard set forth at 42 C.F.R. § 493.801(b)(5) which requires the clinical laboratory's director to sign proficiency testing attestations.

The ALJ found that, contrary to the standard established at 42 C.F.R. § 493.801(b)(5), Petitioner's owner and laboratory director, Dr. Hertzberg, did not sign the attestation sheets accompanying the three PT events in 1998. This FFCL was based on unrefuted evidence in the record, which shows that only Ms. Sabo signed those sheets. ALJ Decision at 17, citing CMS Exs. 8, 10 and 12. Petitioner did not contend that Dr. Hertzberg had actually delegated to Ms. Sabo the laboratory director's responsibility to sign the attestation form.

Petitioner asserted that this FFCL was not supported by substantial evidence in the record and was clearly erroneous based upon the unambiguous regulatory language. Specifically, Petitioner contended that the ALJ's finding that the laboratory director was required to sign the PT attestation form was unsupported by the regulation because, pursuant to 42 C.F.R.§ 493.1445, a laboratory director's duties may be delegated. Petitioner Request for Review at 6. Other than raising it in its Request for Review, Petitioner did not expand further upon this issue.

Section 493.801(b)(5) requires that the "individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods." Section 493.1445 does not specifically state that this attestation function may be delegated. Section 493.1445(a) refers to delegation of "these responsibilities," referring back specifically to "the duties of the technical supervisor, clinical consultant, general supervisor and testing personnel." Section 493.1445(b) provides that "[i]f the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed." Among other things, the laboratory director must ensure that "proficiency testing samples are tested as required under Subpart H . . ." 42 C.F.R.§ 493.1445(e).

Based on these provisions read as a whole, the ALJ properly concluded that Dr. Hertzberg was required to sign the attestation. Delegating to the individual actually doing the testing the authority to sign the attestation on behalf of the laboratory director could not reasonably be viewed as authorized since it could provide no assurance that the testing was done properly. Indeed, in affirming the ALJ's finding in *Boykansky* that the petitioner failed to comply with the requirement at 42 C.F.R. § 493.1441 that the laboratory director provide overall management and direction, we noted that, by permitting Ms. Sabo to sign the attestation alone, Dr. Boykansky abdicated his responsibilities under that regulation. *Boykansky* at 15, 17.

We therefore affirm and adopt FFCL 4.

FFCL 5. Petitioner's failure to comply with the standards set forth in 42 C.F.R. § 493.801(b) constitutes a failure to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

Citing *Boykansky*, the ALJ noted that if standard-level deficiencies are sufficiently egregious they will constitute a failure by a laboratory to comply with the overall condition of which the standards are subparts. Essentially, the ALJ determined that Petitioner's collusion was so egregious as to make its participation in a PT program meaningless. ALJ Decision at 17-18.

Petitioner asserted that this FFCL was not supported by substantial evidence in the record and was clearly erroneous. Petitioner noted that there was no evidence of a deliberate attempt by Petitioner to "frustrate the purpose of proficiency testing." Petitioner Request for Review at 6 (quoting ALJ Decision at 18).

Petitioner asserted that the alleged deficiencies here were no more than standard-level. Thus, Petitioner said, CMS's enforcement options were limited to those found at 42 C.F.R.§ 493.1816, for situations where deficiencies are not at the condition level. Principally, Petitioner contended that CMS should have permitted it an opportunity to submit a plan of correction. Further, Petitioner cited the ALJ's analysis in *Edison Medical Laboratories*, DAB CR599 at 4 and 18 (1999), where the ALJ examined the difference between CLIA "conditions" and "standards." In addition, Petitioner insisted that CMS and the ALJ neglected to give weight to the findings of CMS's agent, the Commission on Office Laboratory Accreditation (COLA), which had not reported any PT-related deficiencies for Petitioner in 1998. Petitioner Br. at 32-34.

Petitioner's arguments are a restatement of those previously considered in both *Oakland* and *Boykansky*. Here, as in those cases, Petitioner's contentions rest on its assertion that it was given timely notice of standard-level deficiencies only. Petitioner's position is without merit and dependent on an overly technical reading of the regulations as restricting CMS's authority to take action to protect patients from relying on laboratory results produced by laboratories which are found to be noncompliant with CLIA requirements. As we previously stated, "[i]t is indisputable that a laboratory can be so pervasively noncompliant with standards as to have failed to have complied with the overall condition." *Boykansky* at 18-19 (quoting *Oakland* at 23). CMS is not restricted by regulation to the use of a plan of correction, as urged by Petitioner, when "Petitioner's collusion was so egregious as to make its participation in a proficiency testing program meaningless." ALJ Decision at 18. Moreover, Petitioner's reliance on its COLA accreditation in 1998 is misplaced. Petitioner presented no evidence that COLA was aware of the discrepancy between Petitioner's records and what it reported to AAB or of the similarity of the reported results with those of other laboratories.

We therefore affirm and adopt FFCL 5.

FFCL 6. CMS is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions of participation.

The ALJ concluded that CMS was authorized to impose principal sanctions, including revocation of a laboratory's CLIA certificate, as remedies for the laboratory's failure to comply with one or more CLIA conditions. ALJ Decision at 19, citing 42 C.F.R. § 493.1806(a),(b). Further, CMS may impose the additional remedy of cancellation of a laboratory's approval to receive Medicare payment for its services where the laboratory has not complied with one or more CLIA conditions. *Id.*, citing 42 C.F.R. § 493.1807. Based on the regulations and the evidence before him, the ALJ concluded that CMS was authorized to act against Petitioner.

Petitioner asserted that this FFCL was not supported by substantial evidence and was, therefore, clearly erroneous. Petitioner argued that the ALJ failed to address its argument that CMS was not authorized under the CLIA statute and regulation to "independently deem" standard-level or condition-level deficiencies. Further, Petitioner again contended that the ALJ had ignored the 1998 COLA survey, performed by CMS's agent, which found no deficiencies. Petitioner Request for Review at 6-7.

This Panel addressed essentially this same issue in *Boykansky*. The ALJ in that case found that CMS was authorized to make independent determinations about the nature and severity of the petitioner's alleged noncompliance with CLIA requirements. Like the petitioner in that case, Petitioner here argued before the ALJ that CMS could not impose principal sanctions unless it had properly alleged a condition-level deficiency and Petitioner argued that CMS's determinations are invalid inasmuch as they differ from the standard-level deficiencies found by the surveyors. ALJ Decision at 6.

Petitioner contended that this FFCL does not adequately address its arguments about CMS's authority to impose principal sanctions where the state surveyors had cited only standard-level deficiencies. However, the ALJ addressed all aspects of Petitioner's contentions on this topic in FFCL 1, where he found that Petitioner had adequate notice, FFCL 2, where he concluded that Petitioner colluded with other clinical laboratories and FFCL 5, where he concluded that Petitioner failed to comply with a condition of participation stated in 42 C.F.R. § 493.801. We have addressed Petitioner's contentions in the sections of this decision dealing with those FFCLs. Moreover, the ALJ's discussion of CMS's authority to make independent determinations about the nature and severity of Petitioner's noncompliance with CLIA requirements is legally sound, as it is based on the plain language of 42 C.F.R. §§ 493.1806(a) and (b) and 493.1807.

We therefore affirm and adopt FFCL 6 without further discussion.

Conclusion

Based on the preceding analysis, we affirm and adopt each of the FFCLs underlying the ALJ Decision and sustain that decision in its entirety. In doing so, we reject Petitioner's request for an alternative remedy, specifically a hearing on the merits of its case.

JUDGE

Judith A. Ballard

Donald F. Garrett

M. Terry Johnson
Presiding Board Member

FOOTNOTES

1. CMS was previously named the Health Care Financing Administration (HCFA). *See* 66 Fed. Reg. 35,437 (July 5, 2001).

2. Petitioner also included in its appeal an alternative request that, if the Board did not reverse the ALJ Decision, it should order a full hearing on the merits of the case. As indicated below, Petitioner stipulated to the procedures followed by the ALJ which led to the issuance of a decision without an in-person hearing. We therefore deny Petitioner's request.

3. CMS may deem a laboratory to meet all applicable CLIA program requirements if the laboratory obtains a certificate of accreditation, as required in 42 C.F.R. Part 493, Subpart D, and meets the other requirements listed in 42 C.F.R. § 493.551(b).

4. These remedies are also available if a laboratory with a certificate of accreditation fails to meet the requirements of 42 C.F.R. § 493.61, including the requirement that it treat the PT samples in the same manner as patient samples. 42 C.F.R. §§ 493.61(b)(1) and (c).

5. *See Oakland Medical Group, P.C.*, DAB No. 1755 (2000); *Stanley Boykansky, M.D.*, DAB No. 1756 (2000), *Boykansky v. Health Care Financing Administration*, No. 01-3189, 2001 WL 493421 (6th Cir. May 1, 2001) (dismissed as untimely); *Garden City Medical Center*, DAB No. 1763 (2001); and *Evette Elsenety, M.D., et al.*, DAB No. 1796 (2001).

6. CMS Exhibit 26 is the Hearing Transcript from the proceeding before the ALJ in *Stanley Boykansky, M.D.*, DAB CR690 (2000). The transcript consists solely of Deborah Sabo's testimony.

7. We do not recount here each of Petitioner's questioned PT results. Those results were before the ALJ and their existence is not in question. Rather, the manner in which the PT results were obtained is at issue.

8. The Sabo affidavit discussed the plan of corrections submitted by Petitioner in response to CMS's findings of deficiencies; it did not pertain to her earlier testimony.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF

SUBJECT:

Sol Teitelbaum, M.D.,

DATE: January 28, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-01-204
Decision No. **CR863**

DECISION

DECISION

Summary judgment is entered affirming the determination of Respondent, the Centers for Medicare & Medicaid Services (CMS)[(1)] revoking the certificate of Physicians Independent Laboratory, the only appealable issue in this case. By operation of law, and therefore not subject to appeal, Sol Teitelbaum, M.D. (Petitioner) is prohibited from owning, operating or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of the certification of the Physician Independent Laboratory (PIL) of which he was the laboratory director. The two-year prohibition runs from the date of the revocation of the laboratory's certificate pursuant to 42 U.S.C. § 263a(i)(3) and not from the date of this decision as CMS indicated in its notices to Petitioner. Summary judgment is appropriate as there are no genuine issues of material fact in dispute and the controlling issues may be resolved as a matter of law.

PROCEDURAL HISTORY AND UNDISPUTED FACTS

Petitioner was the laboratory director of PIL from July 21, 1999 to July 20, 2000. Petitioner's Reply Brief Re: Jurisdiction, p. 5. The California Laboratory Field Services initiated a survey of PIL on August 17, 1999. Affidavit of Edd E. Epstein, MS, Petitioner's Reply Brief Re: Jurisdiction, Ex. R. PIL appealed the CMS notice of deficiencies arising from the survey, but subsequently withdrew its request for hearing, the case was dismissed, and CMS revoked PIL's CLIA[(2)] certificate effective January 23. 2001. CMS Brief on Jurisdictional Issues, p. 2, fn. 1 and Attachment A. CMS

advised Petitioner of the revocation of PIL's CLIA certificate by letter dated April 6, 2001. CMS Brief on Jurisdictional Issues, Attachment B. CMS further advised Petitioner that as laboratory director for PIL he was subject to a two-year bar from owning, operating or directing any laboratory, but, because his November 15, 2000 request for hearing was pending before the Departmental Appeals Board, the bar would not be effective until an Administrative Law Judge upheld the CMS action. *Id*.

Petitioner filed his request for hearing on November 15, 2000. Petitioner alleged that CMS's failure to accept the PIL Plan of Correction was an abuse of discretion; that the Statement of Deficiencies was procedurally and substantively defective; that the noted deficiencies did not occur during his tenure as laboratory director; that he was an employee of PIL as laboratory director and not subject to sanction as an owner or operator; that he is entitled to a hearing; and that CMS's actions were in retaliation for his actions in the *Sentinel* case.[(3)]

The procedure related to and substance of CMS's Statement of Deficiencies for PIL are no longer disputed by Petitioner. "Petitioner *is not* seeking a hearing to contest whether or not [CMS] has the authority to impose sanctions upon an owner of a laboratory who has allegedly violated [CMS] regulations or if there is any truth to the condition level deficiencies which it alleges were present at the laboratory." Petitioner's Reply Brief Re: Jurisdiction, p. 10 (emphasis in original). Therefore it is unnecessary to discuss facts related to the Statement of Deficiencies for PIL that gave rise to the sanction of Petitioner.

GOVERNING LAW

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Pursuant to CLIA, the Secretary of HHS has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to achieve compliance. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose

alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

CLIA provides the following with respect to the owners and operators of non-compliant laboratories in addition to sanctions which may be imposed directly against a laboratory:

> (3) Ineligibility to own or operate laboratories after revocation.
>
> 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.

42 U.S.C. § 263a(i)(3). The Secretary's regulations specify that a "laboratory director" is considered an "operator" of a laboratory:

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory.
>
> The term includes- (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2 (emphasis in original).

This definition of "operator" was part of the final regulations that became effective September 1, 1992. The source of the provision that a "laboratory director" is an operator is reflected at 57 Fed. Reg. 7226 (1992) in the discussion of the public comments related to the proposed regulation:

> Comment: Four commenters voiced the opinion that if a laboratory's CLIA certificate has been revoked within the preceding two-year period, [CMS] should initiate adverse action, not only against its owner or operator, but also against those directors involved in the operation of the laboratory.
>
> Response: We have added a definition of "operator" which clarifies that directors of laboratories who are involved in their overall operation, are knowledgeable about the workings of the entire facility, and who bear primary responsibility for the safety and reliability of laboratory testing, are considered operators for the purpose of this regulation. It is our belief, consistent with the direction given by Congress in section 353(i)(3) of the PHS Act, that any laboratory director who meets the criteria as an operator should not be permitted to operate or own any laboratory within 2 years of operating a laboratory which has had its CLIA certificate revoked, as set forth at § 493.1840(a)(8) of these

> regulations.

The regulations also require that any laboratory conducting moderate or high complexity testing, as was PIL, have a laboratory director who meets specific qualifications and has clear and specific responsibilities. 42 C.F.R. §§ 1403, 1405, 1407. The regulations specify that:

> The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report testresults promptly, accurate, [sic] and proficiently and for assuring compliance with the applicable regulations.

42 C.F.R. § 493.1407.

The director's responsibilities also include ensuring that appropriate test methodologies are used, that verification procedures are followed, that proficiency testing is complied with, that appropriate corrective actions are taken as necessary, that the laboratory follows quality control and quality assurance programs, and that several other specified requirements are met. *Id*. Any laboratory that has as its owner or operator (which includes laboratory director) an individual who owned or operated a laboratory that had its CLIA certificate revoked within the previous two years is subject to adverse action including suspension and/or revocation pursuant to 42 C.F.R. § 493.1840(a)(8).

CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory . . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an ALJ. 42 C.F.R. § 493.1844(a). The hearing procedures found in subpart D of Part 498 are incorporated by reference. 42 C.F.R. § 493.1844. The "suspension, limitation or revocation of the laboratory's CLIA certificate . . . because of noncompliance . . . ." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1).

ISSUES, FINDINGS OF FACT, CONCLUSIONS OF LAW AND ANALYSIS

The threshold issue in this case is:

> Whether Petitioner has a right to appeal the action of CMS?

If Petitioner has a right to appeal, the issues are:

> Whether Petitioner is subject to the two-year ban on owning, operating, or directing another laboratory.
>
> Whether Petitioner was properly subject to sanction by CMS in this case.[4]

1. Petitioner has the right to appeal the initial determination of CMS to sanction PIL by limiting, suspending, or revoking the laboratory's CLIA certification.

It is unnecessary to explore the legal theories Petitioner advances for why he has the right to request a hearing because the Departmental Appeals Board has made clear in prior cases that the right exists in cases such as this. *See Sentinel Medical Laboratories, Inc.*, DAB CR679, DAB No. 1762 (2001), fn. 6. Section 493.1844(a) of 42 C.F.R. only specifically lists laboratories and prospective laboratories as having the right to appeal adverse initial determinations by CMS. However, the regulation may not be construed without reference to CLIA which specifically requires notice to the owners and operators of a laboratory and the right to a hearing prior to suspension, revocation or limitation of a laboratories certification. 42 U.S.C. § 263a(i)(1). Under the Secretary's definition, "laboratory directors" are "operators." 42 C.F.R. § 493.2. Because they are by the Secretary's definition operators, laboratory directors have the right to file an appeal under CLIA.

Given the plain language of the statute and regulations, CMS cannot argue on one hand that Petitioner has no right to appeal as laboratory director, but he is subject to sanction as an operator. Similarly unpersuasive is Petitioner's argument that he has the right to an appeal as laboratory director, but he is not subject to being sanctioned because he is a mere employee and not an operator.

Petitioner, as the former "laboratory director" for PIL and himself subject to sanction, has the right to request a hearing.[(5)] The statute and regulations do not specify that only one request for hearing may be filed on behalf of a laboratory or its owners and operators. The fact that the owners or other operators of PIL also filed requests for hearing, but subsequently withdrew them, does not affect Petitioner's right to maintain this appeal. Therefore, I have jurisdiction to resolve this case.

2. Petitioner is properly subject to the two-year ban on owning, operating or directing a laboratory based upon his status as "laboratory director" for PIL, whether or not he was also an employee.

Petitioner has conceded that he was laboratory director of PIL from July 21, 1999 to July 20, 2000. Petitioner has also waived any alleged errors in the CMS findings of deficiencies at PIL either arising or existing during his tenure as laboratory director. Thus, no material facts are in dispute.

Petitioner argues that he was an "employee" of PIL while he held the position of laboratory director and that as an "employee" he was not an "operator" and, thus, not subject to CMS sanctions.[(6)] The lynch pin for Petitioner's argument[(7)] appears to be the definition of operator found at 42 C.F.R. § 493.2:

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary

> responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes- (1) A director of the laboratory if he or she meets the stated criteria....

Petitioner specifically argues that as an employee laboratory director for PIL, he was not responsible for "all facets" of the laboratory operations and, thus, he was not a director who met the "stated criteria" to be an operator. It is not clear from the language of the quoted section whether the reference to "stated criteria" is to the definition of operator established by that section or to 42 C.F.R. §§ 493.1405 and 493.1407 which establish the qualifications and responsibilities for a laboratory director. However, it is important to note that the definition for operator clearly contemplates that the term may apply to an individual or a group of individuals - indicating that the responsibilities for safety and reliability may be shared and not necessarily "all" vested in a single laboratory director.

It is also significant that in order for PIL to maintain its certification for performing moderate complexity testing it had to have a laboratory director who provided "overall management and direction" of the laboratory in accordance with 42 C.F.R. § 493.1407 and who met the qualification requirements of 42 C.F.R. § 493.1405. These regulations draw no distinctions regarding a laboratory director who has status as an employee as opposed to being a contractor, an owner entitled to an equity share, a volunteer, or one who serves in some other status.

The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence, the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. The Secretary's purpose in treating a laboratory director of a laboratory which has its CLIA certificate revoked as an operator for purposes of the two-year ban on owning or operating another laboratory is consistent with the legislative purpose of CLIA. 57 Fed. Reg. 7226 (1992).

Petitioner's construction of the regulations in a way that would shield him from his responsibilities as a laboratory director and the sanctions contemplated by the statutes and regulations is unreasonable and inconsistent with the purposes of CLIA. My conclusion is that by accepting the title of "laboratory director" of a laboratory that has or is seeking a CLIA certificate, the director accepts all the specified regulatory responsibilities and is subject to the authority of CMS and any sanctions specified by law, regardless of the actual employment status of the director. [(8)]

3. Petitioner is properly banned from owning, operating or directing a laboratory for two years in this case.

Petitioner has conceded that he was laboratory director of PIL from July 21, 1999 to July 20, 2000. Petitioner has also waived any alleged errors in the CMS findings of deficiencies at PIL either arising or existing during his tenure as laboratory director. PIL's CLIA certification was revoked subsequent to dismissal of its request for a hearing. No material facts are in dispute.

The revocation of PIL's certification triggers 42 U.S.C. § 263a(i)(3), which is applicable to Petitioner for the reasons already discussed. Section 263a(i)(3) provides that "(n)o 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." Section 493.1840(a) of 42 C.F.R. is also triggered, which requires CMS to initiate adverse action to suspend, limit or revoke the CLIA certificate of any laboratory if it is found that an owner or operator owned or operated a laboratory that had its CLIA certificate revoked within the last two years. CMS has no discretion and, in fact, takes no action under 42 U.S.C. § 263a(i)(3); the two-year ban on owning and operating is automatic. Similarly, CMS has little discretion under 42 C.F.R. § 493.1840(a)(8) as it must initiate action against the offending laboratory.

4. The two-year ban on owning, operating or directing a laboratory is effective from the date of the revocation of PIL's certificate.

PIL appealed the CMS notice of deficiencies arising from the survey, but subsequently withdrew its request for hearing, the case was dismissed, and CMS revoked PIL's CLIA certificate effective January 23, 2001. CMS Brief on Jurisdictional Issues, p. 2, fn. 1 and Attachment A. CMS advised Petitioner of the revocation of PIL's CLIA certificate by letter dated April 6, 2001. CMS Brief on Jurisdictional Issues, Attachment B. CMS further advised Petitioner that as laboratory director for PIL he was subject to a two-year bar from owning, operating or directing any laboratory, but, because his November 15, 2000 request for hearing was pending before the Departmental Appeals Board, the bar would not be effective until an Administrative Law Judge upheld the CMS action. *Id*.

The CMS advice regarding the effective date of the two-year ban is in error in this case. Unlike the case in *Sentinel*, CMS effected the revocation of PIL's certificate based upon the ALJ's dismissal of the PIL request for hearing and did not await my decision. The language of 42 U.S.C. § 263a(i)(3) is clear: "(n)o 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...." (Emphasis added.) Therefore, the 2-year ban against Petitioner runs from January 23, 2001, the date of revocation of PIL's certificate, and expires, January 22, 2003.

CONCLUSION

For the foregoing reasons, summary judgment is entered affirming the determination of CMS revoking the certificate of PIL, the only appealable issue in this case. By operation of law, and therefore not subject to appeal, Petitioner is prohibited from owning, operating or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of the certification of PIL of which he was the laboratory director. The two-year prohibition runs from January 23, 2001 through January 22, 2003.

JUDGE

Keith W. Sickendick
Administrative Law Judge

FOOTNOTES

1. Effective July 5, 2001, the Health Care Finance Administration was renamed the Centers for Medicare and Medicaid Services (CMS). 66 Fed. Reg. 35437.

2. Clinical Laboratory Improvement Amendments of 1988.

3. The reference is to the case of *Sentinel Medical Laboratories, Inc.*, DAB CR679, *aff'd* DAB No. 1762 (2001) in which Dr. Teitelbaum was also a Petitioner as Laboratory Director. In that case, Dr. Teitelbaum pursued similar issues after Sentinel withdrew its request for hearing. Dr. Teitelbaum was unsuccessful before the ALJ and the Departmental Appeals Board. Petitioner was subject to a two-year ban on owning, operating or directing a laboratory under CLIA, effective June 27, 2000, the date of the ALJ decision in *Sentinel*.

4. Petitioner casts his issues in general terms as challenges to the validity of the regulations. *See* Petitioner's Reply Brief Re: Jurisdiction, p.10. However, Petitioner never clearly specifies grounds for why the Secretary's regulations are unlawfully promulgated. Petitioner has asserted that similar challenges to the regulations are currently pending before the Ninth Circuit Court of Appeals. Indeed, Petitioner requested that this decision be delayed pending a decision by the Ninth Circuit. Delay is not warranted. If the Ninth Circuit rules completely in favor of Petitioner, the ban I am affirming and the ban affirmed by the ALJ in *Sentinel* will be declared invalid anyway. If the Ninth Circuit upholds the regulations, then my presumption that they were validly promulgated and are legally binding will be vindicated. The only issues properly before me relate to the specific facts of this case and whether the regulations have been properly applied to Petitioner. A general discussion of the validity of the regulations would constitute nothing more than dicta. I note however that the presumption I make is not without legal foundation to the extent that it is clear that the Secretary was granted authority to promulgate regulations to implement CLIA, those regulations appear to have been promulgated in accordance with the requirements of the Administrative Procedure Act, and Petitioner has offered no evidence to the contrary.

5. However, a distinction needs to be drawn in this case. The appealable issues in the usual case relate to whether the laboratory is appropriately sanctioned and not whether the owner or operator should be or is properly barred from operating another laboratory. This is true because the clear language of 42 U.S.C. § 263a(3) is that the two-year ban on owning or operating is automatic upon revocation of a laboratories CLIA certificate. The Secretary and CMS are granted no discretion under the statute regarding the two-year ban. There is no procedure for imposing the ban; it is automatic as a matter of law. No administrative appeal rights are provided related to the two-vear

ban as no administrative decision is made to be challenged. The only administrative decision subject to challenge is the limitation, suspension, or revocation of the CLIA certificate. Thus, Petitioner correctly states in the face of his concessions, that the only issue is whether as laboratory director he is subject to the two-year ban.

6. Petitioner appears to have wisely abandoned his "respondeat superior" argument. While application of this common-law tort doctrine might have the effect of extending liability for Petitioner's actions to the other "owners and operators" of PIL, it does nothing to relieve Petitioner of responsibility for his acts or his obligations under the regulations. *See Sentinel*.

7. *See* Petitioner's Initial Jurisdiction Brief, p. 8; Petitioner's Reply Brief Re: Jurisdiction, pp. 4-5.

8. Petitioner's argument that CMS has no authority over him because he is not the "licensee" under CLIA, is not persuasive. Petitioner presumably knew the law to which he was subject when he accepted the position of laboratory director at PIL. Indeed, given Petitioner's involvement in *Sentinel* there can be little doubt he knew of CMS regulation of laboratories under CLIA and voluntarily submitted thereto by accepting the position of laboratory director.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	

SUBJECT:

Millenium Medical Group,

DATE: February 25, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No. C-01-207
through
C-01-217
Decision No. **CR875**

DECISION	

DECISION

This is another in a series of related appeals involving Michigan-based clinical laboratories.(1) Petitioners in these cases are 11 physician office laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).(2) They appeal Centers for Medicare & Medicaid Services' (CMS') decision to revoke their CLIA certificates. For the reasons discussed below, I uphold CMS' decision.

BACKGROUND

Millennium Medical Group (Millennium) is the owner of a physician office laboratory directed by Dr. Stanley Boykansky. CMS proposed revocation of the Boykansky laboratory's CLIA certificate, and Dr. Boykansky appealed. Following a hearing, Administrative Law Judge (ALJ) Steven Kessel issued a decision, dated July 28, 2000, that upheld CMS' revocation. *Stanley Boykansky, M.D.*, DAB CR690 (2000). In a decision dated December 21, 2000, an appellate panel of the Departmental Appeals Board affirmed the ALJ's decision. *Stanley Boykansky, M.D.*, DAB No. 1756 (2000).(3)

Following its receipt of the ALJ's decision in *Boykansky*, CMS revoked the Boykansky laboratorv's CLIA certificate, and, in a letter dated October 17, 2000, advised Dr.

Boykansky of his obligation to provide the names and addresses of any other laboratories he owned or operated. The letter warned that intentional violation of CLIA's provisions could result in criminal penalties, including imprisonment. 42 U.S.C. § 263a(l). CMS Exhibit (Ex.) 2. Dr. Boykansky's counsel subsequently provided CMS with two lists of laboratories owned by the Oakland Medical Group, P.C. and the Millennium Medical Group, P.C. as of February 20, 1998. CMS Ex. 3.[(4)] He also advised CMS that Millennium was a professional corporation with three shareholders, Drs. Trivax, Panush, and Feldman. *Id*.

In letters dated November 16, 2000, CMS advised Petitioners here that, because they were also owned by Millennium, it was initiating action to revoke their CLIA certificates as well. By statute, no person who has owned or operated a laboratory whose CLIA certificate has been revoked may, within two years of the revocation, own or operate a lab. 42 U.S.C. § 263a(i)(3). Federal regulations authorize CMS to initiate an adverse action to suspend, limit, or revoke any CLIA certificate if CMS finds that the laboratory's owner or operator has owned or operated a laboratory that had its CLIA certificate revoked. 42 C.F.R. § 493.1840(a)(8)(e).

Petitioners appealed, asserting that the sanctions set forth in 42 C.F.R. § 493.1840(a)(8) do not extend to clinical laboratories owned by a parent corporation, that were not operated by an owner of the parent corporation, and that did not themselves have any cited deficiencies. The matters were assigned to me for resolution.

In a submission dated February 23, 2001, the parties stipulated that the 11 laboratories have a common owner, Millennium Medical Group, P.C.; that their cases present substantially similar questions of law and fact; and asked that the matters be consolidated. I have therefore consolidated these 11 matters. The parties subsequently filed cross-motions for summary affirmance.[(5)]

In the absence of objection, I admit Petitioners Exs. 1-3 and CMS Exs. 2-3, which were attached to their respective briefs. Petitioners Ex. 1 duplicates CMS Ex. 1, so I decline to admit the same exhibit twice.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Each Petitioner is owned by Millennium Medical Group, P.C.

Petitioners have not specifically denied Millennium's ownership of these laboratories, and, initially, they appeared to have conceded the ownership issue. However, in their brief they argue that CMS "has presented no evidence that [Millennium] owned or operated any of the clinical laboratories." P Brief at 2. For multiple reasons, I reject Petitioners' inference and conclude that Millennium owns these laboratories.

First, the regulations governing these proceedings do not allow a party to be coy about the issues it means to raise. Part 498 Subpart D governs the conduct of these appeals. 42 C.F.R. § 493.1844(a). Under those regulations, the hearing request must identify the specific issues with which the affected party disagrees. 42 C.F.R. § 498.40(b). Here,

Petitioners did not, in their hearing request, challenge CMS' assertion that they were owned by Millennium. They assert only that they (with the possible exception of Petitioner Trivax) "are not owners or operators of the [Boykansky] clinical laboratory." Hearing Request. But CMS has not suggested that they are owners or operators of the Boykansky laboratory. Its sanction is based on Millennium's common ownership of Dr. Boykansky's laboratory and the Petitioners' laboratories.

If anything, the hearing request suggests Millennium's ownership in that it is filed "on behalf of Millennium Medical Group, P.C., its owners, and the above captioned locations (listing Petitioners and their addresses) requesting a hearing before an Administrative Law Judge. . . ."

Second, in their February 23, 2001 submission, the parties stipulated that all eleven laboratories are owned by Millennium. CMS would not be required to present evidence on an issue to which the parties have stipulated.

In any event, evidence in the record demonstrates Millennium's ownership. In a letter dated February 5, 2001, CMS points out that each of the CLIA numbers held by these Petitioners was issued to Millennium. P. Ex. 2 at 1. Petitioners have not challenged this assertion.

In addition, the October 24, 2000[(6)] letter lists Petitioners as laboratories owned by Millennium. Petitioners complain about CMS' reliance on this letter, suggesting that it was sent only for settlement purposes. These arguments were addressed in *Evette Elsenety, M.D.*[(7)] Nothing on the face of the letter suggests that Millennium considered the information proffered as part of any settlement negotiations. On its face, it appears that, faced with the prospect of criminal liability, Millennium provided the requested information promptly. See *Elsenety*, DAB No. 1796 at 6. In any event, the letter's contents are not less probative simply because it was sent as part of settlement discussions. Petitioners have not claimed that they provided CMS with false information in order to settle these cases, and I have no reason to assume that they would do so. *Elsenety*, DAB CR 779 at 3, *aff'd* DAB No. 1796 at 5.

2. Petitioners' CLIA certificates must be revoked.

The plain language of the statute requires revocation of these Petitioners' certificates. CLIA provides that any person whose CLIA certificate has been revoked is prohibited from owning another laboratory within a two-year period from the date of the revocation. 42 U.S.C. § 263(a)(i)(3). Regulations authorize CMS to enforce this section by initiating adverse action to, among other actions, revoke a laboratory's CLIA certificate where that laboratory's owner or operator has owned or operated another laboratory whose CLIA certificate was revoked during the preceding two-year period. 42 C.F.R. § 493.1840(a)(8).

Millennium owned the Boykansky laboratory and its CLIA certificate was revoked. By law, Millennium is prohibited from owning any CLIA-certified laboratories for two years from that date. CMS was thus plainly authorized to revoke Petitioners' CLIA

certificates inasmuch as they are all owned by Millennium. *See Elsenety, M.D., et.al.*, DAB CR779 at 4, *aff'd* DAB No. 1796.

Petitioners' argument that they are unfairly penalized because of their organizational structure, which is mandated by the Stark Amendment, 42 U.S.C. 1395nn(b)(2), was rejected by ALJ Kessel and by the Board in *Elsenety*. As ALJ Kessel wrote:

> The problem with Petitioners' argument is that it does not deal with the express requirements of CLIA. CLIA strictly prohibits a person whose CLIA certificate has been revoked from owning another laboratory during the two-year period after the date of revocation. It does not contain exceptions or permit a case-by-case analysis as Petitioners suggest is appropriate. Consequently, I may not consider essentially equitable arguments made by Petitioners. Furthermore, Petitioners have not offered anything that would suggest that Congress intended to modify CLIA with the enactment of subsequent legislation.

DAB CR779 at 5, *aff'd* DAB No. 1796.

Petitioners also raise some constitutional challenges, which, they concede, I have no authority to adjudicate.

CONCLUSION

For these reasons, I uphold CMS' decision to revoke Petitioners' CLIA certificates.

JUDGE

Carolyn Cozad Hughes

Administrative Law Judge

FOOTNOTES

1. *See Oakland Medical Group, P.C.*, DAB No. 1755 (2000); *Stanley Boykansky, M.D.*, DAB No. 1756 (2000), *Boykansky*, No. 01-3189, 2001 WL 493421 (6th Cir. May 1, 2001) (dismissed as untimely); *Garden City Medical Center*, DAB No. 1763 (2001); *Evette Elsenety, M.D., et. al.*, DAB No. 1796 (2001); *Mark Gary Hertzberg, M.D., P.C.*, DAB No. 1805 (2001).

2. Petitioners are: Geoffrey A. Trivax, M.D. (C-01-207), Barry W. Feldman, M.D. (C-01-208), Mark Hertzberg, M.D. (C-01-209), Raad J. Toma, M.D. (C-01-210), Imad M. George, M.D. (C-01-211), Henry Brystowski, M.D. (C-01-212), David L. Benkoff, M.D. (C-01-213), Arthur M. Powell, M.D. (C-01-214), Jeffrey F. Parker, M.D. (C-01-215), Ronald D. Pelavin, M.D. (C-01-216), and Seth M. Mindell, M.D. (C-01-217).

3. Among other findings sustained by the Board, the ALJ found that Petitioner colluded with other clinical laboratories in the performance of proficiency testing; that it did not test its proficiency test samples in the same manner as it tested patient's specimens; and that it engaged in inter-laboratory communications pertaining to the proficiency test results. *Id*.

4. The Oakland Medical Group was the subject of a separate decision, *Evette Elsenety, M.D., et. al.*, DAB No. 1796 (2001).

5. In the alternative, Petitioners request an in-person hearing. However, summary disposition is appropriate where there are no issues of material fact. A party opposing summary disposition must allege facts which, if true, would refute the facts relied on by the moving party. *Elsenety*, DAB No. 1796 at 4. As there, Petitioners here have offered no facts that would refute those relied on by CMS in moving for summary disposition.

6. The parties agree that the letter was misdated October 24, 1998 instead of October 24, 2000. P. Brief at 3; CMS Brief at 4; *see also Elsenety* at 5.

7. It appears to have been the same letter sent in both cases.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF

SUBJECT:

Caroline D. Zohoury, D.O.,

DATE: March 12, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-00-832
Decision No. **CR879**

DECISION

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to deny Petitioner, Caroline D. Zahoury's, application for a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate of waiver. I do so because I find that Petitioner was an "owner" and/or "operator" of Rochester Road Clinic, P.C. (RRC), whose CLIA certificate was revoked within the last two years prior to Petitioner's application. CMS is, therefore, authorized to prohibit Petitioner's ownership or directorship of any CLIA laboratory for a period of two years from October 14, 1999, the date of RRC's revocation.

I. Procedural Background

This case is before me pursuant to a request for hearing filed by Petitioner on August 23, 2000, in accordance with 42 C.F.R. § 498.40.

On March 31, 2000, CMS (formerly, the Health Care Financing Administration or HCFA) sent Petitioner a notice (Notice) that her application for a CLIA certificate of waiver (Waiver) was denied pursuant to 42 U.S.C. § 263a(i)(3). The Notice informed Petitioner that, based on a review of her request for a Waiver, she met the definition of either an owner or operator, or both, in accordance with the definition of those terms in

42 C.F.R. § 493.2, of RRC. Petitioner's Waiver was denied because RRC's CLIA certificate was revoked on October 14, 1999. Petitioner's Waiver was for a physician's office laboratory at the same address and with the same phone numbers as RRC, the laboratory whose CLIA certificate was revoked.

CMS moved for summary judgment. Both parties submitted briefs. I refer to the briefs as CMS Br. and P. Br., respectively. Both parties submitted reply briefs which I refer to as CMS R. Br. and P. R. Br., respectively. CMS offered 16 proposed exhibits (CMS Exs. 1 - 16) with its brief and one proposed exhibit (CMS Ex. 17) with its reply brief. Petitioner offered three proposed exhibits (P. Exs. 1 - 3) with her brief. As a result of the prehearing conference of April 25, 2000, Petitioner offered some of her tax records for the fiscal tax-years of 1997, 1998, and 1999, which I refer to as P. Ex. 4, collectively. Following proposed findings of fact based upon the prehearing conference, the parties provided additional written comment on the proposed findings of fact. Additionally, CMS filed a motion to re-open the record and proffered proposed CMS Ex. 18, a CLIA Survey Report Form with surveyor notes for RRC dated February 24, 1999 . Petitioner was given an opportunity to respond to proposed CMS Ex. 18. In response to CMS's motion to admit proposed CMS Ex. 18, Petitioner argued that proposed CMS Ex. 18 was unsubstantiated and therefore an in-person hearing was necessary. Petitioner did not proffer any proof, by affidavit or otherwise, tending to put a relevant and material fact contained within proposed CMS Ex. 18 in dispute. Thereafter the record was closed. Neither party objected to the exhibits of the other (except as to proposed CMS Ex. 18). I admit into evidence CMS Exs. 1 - 18 and P. Exs. 1-4. I do not rely on CMS Ex. 18 to solely determine the ultimate question of ownership or directorship of RRC. The previously proposed findings of facts are incorporated into this decision. My decision is based upon the arguments of the parties, the exhibits, and applicable law and regulations.

II. Background

Petitioner is an osteopathic physician having a medical practice located at 115 North Rochester Road, Clawson, Michigan. This appeal arises out of her request for a Waiver for a physician office laboratory which is located at the same address as Petitioner's medical office and at the same address as RRC, whose CLIA certificate was revoked on October 14, 1999.

On February 24, 1999, during the normal hours of business operation, surveyors of the Michigan Department of Consumer and Industry Services (MDCIS) made an unannounced on-site survey at RRC concerning an allegation of an intentional referral of proficiency test (PT) samples to another laboratory for analysis (a prohibited act). *See* 42 C.F.R. § 493.1840(b). Upon reasonable request by MDCIS survey officials to complete their survey of RRC, Petitioner did not permit the survey to be conducted on that occasion as was required to do under 42 C.F.R. § 493.1840(a)(5).

On May 27, 1999, CMS suspended the CLIA certificate of compliance for RRC

because of an allegation of an improper proficiency test referral. CMS Ex. 3, at 7. CMS then revoked RRC's CLIA certification of accreditation. *Id.*, at 11. The revocation was to become effective on July 11, 1999. Because RRC appealed CMS's revocation, the revocation of RRC's certificate of accreditation did not become effective until October 14, 1999, when RRC withdrew its appeal. CMS Exs. 9, 10. CMS notified RRC, specifically Petitioner and her father, Badi Zohoury, that the revocation of its CLIA certificate of accreditation was for two years. CMS Ex. 11. Thus, the revocation remained in effect until October 13, 2001.

In addition, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit Petitioner, as an owner(s) and/or operator(s) (including the laboratory director) of a lab whose CLIA certificate is revoked, from owning or operating a laboratory for two years following the revocation of RRC's CLIA certificate.

On or about March 10, 2000, Petitioner filed an "Initial Application" for a CLIA Waiver pursuant to 42 C.F.R. § 493.15 of the regulations. In that application, Petitioner listed the name of the new laboratory as "Caroline Zohoury" in which she was the sole "Owner/Director." CMS Ex. 12. The listed address and phone number of the new laboratory is the same address and phone numbers as RRC's. Therefore, on March 31, 2000, CMS denied Petitioner's application for a CLIA certificate of waiver on the grounds that Petitioner met the definition of an owner or operator, or both, of a laboratory, RRC, whose CLIA certificate had been revoked. CMS Ex. 14.

III. Applicable Law and Regulations

Congress enacted CLIA (42 U.S.C. § 263a) to ensure that the results of tests performed in clinical laboratories, including those tests performed in physicians' office laboratories, are reliable and accurate. *See* H.R. Rep. No. 899, 100th Cong., 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. The statute provides as follows:

> No person may solicit or accept materials derived from the human body for laboratory[(1)] examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary[(2)] under this section applicable to the category of examinations or procedures which includes such examination or procedure.

42 U.S.C. § 263a(b).

CLIA was intended by Congress to establish one set of standards which would govern all suppliers of laboratory services, including those which supply laboratory services to Medicare beneficiaries. *See* 1988 U.S.C.C.A.N. 3828, 3829, 3843.

The statute directed the Secretary to issue regulations to implement various provisions set out in CLIA, including standards to assure consistent performance of valid and reliable laboratory examinations by laboratories which are issued a certificate under the Act. 42 U.S.C. § 263a(f)(1). The Secretary's regulations implementing CLIA are found in 42 C.F.R. Part 493. A laboratory which is accredited by a private, non-profit

accreditation program is deemed to meet all CLIA program requirements. 42 C.F.R. § 493.551. The Committee of Laboratory Accreditation (COLA) is one of those organizations which may qualify a laboratory for CLIA certification.

In order for a laboratory to perform testing under CLIA, and bill for services provided to Medicare beneficiaries and Medicare recipients under Titles XVIII (Medicare) and XIX (Medicaid) of the Social Security Act (Act), it must comply with all CLIA requirements in 42 C.F.R. Part 493 and have a CLIA certificate.

The regulations confer broad enforcement authority to CMS, in order to assure that laboratories comply with CLIA. 42 C.F.R. § 493.1800. Where CMS determines that a laboratory is not complying with one or more CLIA conditions of participation (Conditions) --

> (a) CMS may impose sanctions against that laboratory which include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a);
>
> (b) CMS 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; and
>
> (c) CMS may prohibit any person who has owned or operated a laboratory which has had its CLIA certificate revoked from owning or operating a laboratory within two years of the revocation. 42 U.S.C. § 263a(i)(3); 42 C.F.R. § 493.1840(a)(8). A laboratory director is included within the definition of an operator. *See* 42 C.F.R. § 493.2.

A laboratory that is not satisfied with the imposition of remedies by CMS may request a hearing before an administrative law judge (ALJ). 42 C.F.R. § 493.1844.

IV. Issue

The issue in this case is whether Petitioner is precluded from owning or operating a laboratory for a period of two years from October 1999 because Petitioner was an "owner" or "operator" of RRC, a laboratory whose CLIA certificate was revoked.

V. CMS's Contentions

CMS contends that Petitioner satisfied the criteria for being an owner or operator, or both, of RRC, a CLIA laboratory, within a two-year period preceding the revocation of RRC's CLIA certificate on October 14, 1999, and, consequently, she is prohibited from owning or operating a CLIA laboratory for a period of two years following the date of revocation.

VI. Petitioner's Contentions

Petitioner contends that her father, Badi Zohoury, was the sole owner/operator and Director of RRC at all times, and that CMS has failed to produce evidence to show that Petitioner meets the definition of an "owner of any interest" or "director" of RRC within the prohibited period. She argues that she did not have the responsibilities that pertained to an operator, nor does she meet the qualifications under 42 C.F.R. § 493.1405 to be a laboratory director.[3] Petitioner further argues that the State of Michigan corporate filing and corporate personal property tax returns for RRC are strong evidence that she is not an "owner of any interest."

VII. Findings and Discussion

I make the findings of fact and conclusions of law (Findings) to support my decision. Each Finding is noted below, in bold face and italics, followed by a discussion of the finding.

1. Summary Judgment is appropriate in this case.

Federal Rule of Civil Procedure 56 empowers a court to enter summary judgment if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56; *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1996). Once the moving party has satisfied this initial burden, the opposing party must establish that a genuine factual issue exists. *See Jersey Central Power & Light Co. v. Township of Lacey*, 772 F.2d 1103, 1109 (3d Cir. 1985), *cert. denied*, 475 U.S. 1013 (1986). Not every issue of fact will be sufficient to defeat a motion for summary judgment. Issues of fact are genuine "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). Further, the opposing party cannot rest upon mere allegations; it must present actual evidence that creates a genuine issue of material fact. *See id.*, at 249 (citing *First Nat'l Bank of Arizona v. Cities Service Co.*, 391 U.S. 253, 290 (1968)). The court must draw all reasonable inferences in the opposing party's favor, and *must* accept the party's evidence when considering the merits of the summary judgment motion. *See Pollock v. American Tel. & Tel. Long Lines*,794 F.2d 860, 864 (3d Cir. 1986).

In its briefs, CMS presented credible documentary evidence strongly suggesting that Petitioner was either an owner or operator/director, or both. Petitioner submitted only self-serving affidavits by herself and her father, Badi Zohoury, that she was not an owner or operator/director of RRC. P. Exs. 2, 3.

2. Petitioner meets the definition of an "owner" of a CLIA laboratory.

CMS made a determination to exclude Petitioner from owning or operating a laboratory. The basis for CMS's determination was that Petitioner was, in fact, an owner or operator, or both, of RRC, a CLIA laboratory, within a two-year period preceding the date that RRC's CLIA Certificate was revoked. The period of revocation for Petitioner is for a period of two-years following the date of revocation of RRC's

CLIA certificate on October 14, 1999.

CMS based its determination on 42 U.S.C. § 263a which provides, in pertinent part, that --

> [n]o 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.

42 U.S.C. § 263(a)(i)(3). Regulations authorize CMS to enforce this section by initiating adverse action to, among other things, revoke a laboratory's CLIA certificate where that laboratory's owner or operator has owned or operated another laboratory whose CLIA certificate was revoked during the preceding two-year period. 42 C.F.R. § 493.1840(a)(8).

Thus, if Petitioner is found to be an owner or operator, or both, of RRC, as those terms are defined in 42 C.F.R § 493.2, then Petitioner is excluded from owning or operating and/or directing any other CLIA laboratory for a two-year period **following** the date RRC's CLIA Certificate was revoked.

The regulations provide in pertinent part --

> *Owner* means any person who owns any interest in a laboratory[.]

42 C.F.R. § 493.2.

CMS has provided prima facie evidence that Petitioner was an owner because, (a) Petitioner **said** she was an owner, and (b) she held herself out as an owner (or partial owner) by taking affirmative steps consistent with a person having ownership rights.

CMS's evidence that Petitioner was an owner is based, in part, on the following:

> [Petitioner is] listed on the Disclosure of Ownership and Control Interest Statement, Form HCFA-1513, as one of two individuals having direct or indirect ownership or a controlling interest in the entity. The other individual is Dr. Badi Zohoury. This document was completed [by Petitioner] during the February 24, 1999 complaint investigation survey conducted by MDCIS.

HCFA Ex. 16, at 1 - 2.

Petitioner argued that her actions, at the time of the unannounced complaint survey by MDCIS on February 24, 1999, were that of a mere employee of RRC. On the day of the unannounced survey, Petitioner unlocked the non-public door to the laboratory at the request of the MDCIS surveyors. Subsequently, she prevented MDCIS from completing their survey. These are more than the actions of a mere employee. Petitioner was ostensibly exercising the rights of a person with authority and/or

ownership.

> ***3. Petitioner meets the definition of "operator" which term includes a director of a laboratory.***

The regulations provide in pertinent part --

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes --
>
> (1) A director of the laboratory if he or she meets the stated criteria[.]

42 C.F.R. § 493.2.

CMS provided prima facie evidence that Petitioner was a director because Petitioner **said** she was a director.

CMS's evidence that Petitioner was a director is based on the following:

- On page one of a CLIA Laboratory Personnel Report, Form HCFA-209, dated February 24, 1999, Petitioner signed as the director of the laboratory. CMS Ex. 1, at 1. On page 3 of Form HCFA-116, Dr B. Zohoury and Dr. C. Zohoury are listed under "Signature of Owner/Authorized Representative of Laboratory." CMS Ex. 1, at 6.
- RRC would not have been allowed to participate in the CLIA program but for its accreditation by COLA. On COLA Form VI-Signature, which confirms that [the RRC] laboratory will comply with "the requirements for accreditation established by COLA. . . ." Petitioner's signature and printed name are noted on the document as "Laboratory Director." This form is date stamped as verified by COLA on May 28, 1996. CMS Ex. 2, at 2.
- By letter to Petitioner from COLA dated July 3, 1995, COLA confirms that RRC directed by Petitioner participates in COLA. CMS Ex. 2, at 4.
- According to COLA officials, Petitioner is the only laboratory director they have conducted laboratory business with since the laboratory became accredited. CMS Ex. 16, at 1 - 2; CMS Ex. 17.
- Again, on December 19, 1998, COLA notified Petitioner that her laboratory, RRC, had successfully completed the on-site survey and "now meets the Commission's requirements for accreditation." CMS Ex. 8.
- Petitioner filled out a "Disclosure of Ownership and Control Interest

> Statement," Form HCFA-1513, on which she indicated she had a direct or indirect ownership or controlling interest in RRC together with her father, Dr. Badi Zohoury. She signed the form as the authorized representative and indicated in her own handwriting,"We passed COLA with flying colors!!" CMS Ex. 4, at 2.

In order for Petitioner to be excluded from owning or operating any CLIA laboratory under 42 C.F.R. § 493.1840(a)(8), CMS must show that she satisfies the definition of an owner or operator of another CLIA laboratory for the preceding two-year period before RRC's CLIA Certificate was revoked.

I do not find Petitioner's self-serving affidavit and Michigan Professional Service Corporation records sufficiently persuasive as to the issue of CLIA laboratory directorship or ownership, nor do they satisfy the criteria for rebuttal evidence in a summary judgment action. P. Ex. 1, at 1 - 11. I take note that at the same time that RRC was filing Michigan corporate records showing ownership and directorship by Badi Zohoury, Petitioner was dealing with COLA officials and MDCIS officials as a person with more than a mere employee's interest. CMS Ex. 4.

The evidence contained in CMS Exs. 2 at 2, 4 at 1, and 17 at 4 - 6, 8 - 9, which was created by Petitioner's own hand, is ample evidence for me to decide that Petitioner had some controlling authority as a director. The beginning of Petitioner's presumptive directorship began as early as July 3, 1995. CMS Ex. 17, at 7. Petitioner's status as director of RRC appears confirmed by both her own actions and passive acceptance to periodic written contact with MDCIS or COLA officials, or both, between July 3, 1995 through December 19, 1998. On the latter date, COLA sent a letter to Petitioner congratulating RRC on its successful on-site survey. CMS Ex. 8. Petitioner offered no evidence that she sought to clarify or correct her "mistaken" status of laboratory director upon having received the December 19, 1998 correspondence from COLA, or during the on-site visits by COLA during the bi-annual renewals. P. Br., at 5.

Petitioner's signature on Form HCFA-1513 on or about February 24, 1999 was directly below clear written warnings of its importance.

> WHOEVER KNOWINGLY AND WILFULLY MAKES OR CAUSES TO BE MADE A FALSE STATEMENT OR REPRESENTATION OF THIS STATEMENT, MAY BE PROSECUTED UNDER APPLICABLE FEDERAL OR STATE LAWS IN ADDITION, KNOWINGLY AND WILLFULLY FAILING TO FULLY AND ACCURATELY DISCLOSE THE INFORMATION REQUESTED MAY RESULT IN A DENIAL OF A REQUEST TO PARTICIPATE OR WHERE THE ENTITY ALREADY PARTICIPATES, A TERMINATION OF ITS AGREEMENT OR CONTRACT WITH STATE AGENCY OR THE SECRETARY, AS APPROPRIATE.

CMS Ex. 4, at 2.

If Petitioner's signature on the official Form HCFA-1513 was the "mistake" she now alleges, it is not without its consequences.

On line I(a) of the same HCFA Form 1513, Petitioner reaffirms in her own handwriting that she is a person having direct or indirect ownership in the entity. There is nothing in the "Remarks" section on page 2, below her signature, where she clearly disavows her directorship or ownership roles. *Id*.

On line IV(a), she again misses an opportunity to tell CMS that there has been a change in her relationship with RRC, even if there had been a past relationship with RRC as an owner or director. *Id*.

The burden of proof in this case is governed by the decision of an appellate panel of the Departmental Appeals Board in *Hillman Rehabilitation Center*, DAB No. 1611 (1997). Under *Hillman*, CMS bears the burden of coming forward with evidence sufficient to establish a prima facie case that: (1) RRC's CLIA Certificate was revoked on October 14, 1999; and (2) the collateral sanction against Petitioner is warranted and lawful under the statute and regulations. Petitioner has the burden of proving, by a preponderance of the evidence, that: (1) Petitioner complied substantially with participation requirements; and (2) the collateral sanction against her is unwarranted and unlawful under the statute and regulations.

In determining whether CMS has met its burden of establishing a prima facie case, I may consider rebuttal evidence, if offered by Petitioner, that CMS's evidence is neither credible or relevant to the issue of Petitioner's owner/operator/director relationship with RRC. *Hillman Rehabilitation Center*, DAB CR500, at 3-8 (1997). I have received no such rebuttal evidence from Petitioner.

VIII. Conclusion

I find that the CLIA Certificate for RRC was revoked on October 14, 1999. Based on the applicable law and undisputed facts, I conclude that Petitioner's relationship with RRC meets the definition of owner or operator, or both, under 42 C.F.R. § 493.2.

Accordingly, I find that CMS's decision to deny Petitioner's request for a Waiver is justified.

JUDGE	

José A. Anglada

Administrative Law Judge

FOOTNOTES

1. CLIA defines a "laboratory" or a "clinical laboratory" as a facility for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. *See* 42 U.S.C. § 263a(a).

2. The Secretary means the Secretary of the United States Department of Health and Human Services.

3. Petitioner made only an allegation without any substantiation that she could not be a director of a moderate complexity laboratory because she did not have the necessary qualifications. 42 C.F.R. § 493.1405. The regulations require that a "laboratory director must . . . be a doctor of medicine [or] doctor of osteopathy. . . licensed to practice medicine in the State in which the laboratory is located . . . and have at least one year directing or supervising non-waived testing." 42 C.F.R. § 493.1405(b)(2). Petitioner presents no evidence of her qualifications or her lack thereof under this regulation. Yet she applied to COLA as the laboratory director and never denied that she was qualified to do so. I find this nothing more than a baseless and unsubstantiated assertion on Petitioner's part. Frankly only Petitioner, and not CMS, can demonstrate her qualifications or lack thereof to be a director. It is unreasonable to presume CMS somehow has a duty to show her qualifications, given that Petitioner held herself out as the laboratory director.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

IN THE CASE OF

SUBJECT: RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic,

DATE: March 18, 2002

Petitioners,

- v -

Centers for Medicare & Medicaid Services

Docket No. A-2002-20
Civil Remedies: CR829
Decision No. 1820

DECISION

FINAL DECISION ON REVIEW OF

ADMINISTRATIVE LAW JUDGE DECISION

Petitioners, RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic (RNA and Ter-Zakarian), appealed an October 23, 2001 decision by Administrative Law Judge (ALJ) Steven T. Kessel. *RNA Laboratories, Inc. and Ter-Zakarian Medical Clinic*, DAB CR829 (2001) (ALJ Decision).(1) The ALJ found that the Centers for Medicare & Medicaid Services (CMS)(2) properly imposed the remedies of 1) suspension and revocation of Petitioners' certificates under the Clinical Laboratory Improvement Amendments of 1988 (CLIA); 2) cancellation of Petitioners' approval to receive Medicare payments for their services; and 3) alternative sanctions against Petitioners consisting of civil monetary penalties.

The ALJ Decision was based on six findings of fact and conclusions of law (FFCLs). Petitioner took exception to the four FFCLs (2, 3, 5 and 6) which were adverse to them.(3) We have reviewed Petitioners' exceptions. The ALJ's FFCLs were supported by substantial evidence in the record and were not erroneous.

Thus, we conclude that the ALJ Decision should be affirmed. However, as explained more fully in our analysis below, we modify subsection "d" to FFCL 2 deleting reference to 42 C.F.R.
§ 493.801(a) and substituting in its place 42 C.F.R. § 493.801.

Applicable law and regulations

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Public Law No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*. CLIA further grants the Secretary of this Department broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for a certificate. The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829.

A laboratory's CLIA certification is dependent upon whether the laboratory meets the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Each condition represents a major division of laboratory services to be offered by the laboratory or required environmental protections at the laboratory. The regulations also set forth standards, the specific components of the conditions of laboratory certification that a laboratory must meet as part of achieving compliance with applicable conditions.

A key component of the statutory and regulatory program to assure that laboratories holding CLIA certificates are competent to perform tests of moderate and high complexity is the requirement for participation in a proficiency testing (PT) program that is approved by CMS, as outlined in 42 C.F.R. Part 493, Subpart H. Among the requirements of that subpart are that each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493. 42 C.F.R. § 493.801. The condition at 42 C.F.R. § 493.803(a) specifically requires that a laboratory performing high complexity testing "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which it is certified under CLIA."

Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. The CLIA regulations at 42 C.F.R.§ 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E.

Background

This undisputed factual background is drawn from the ALJ Decision and the record below.

Petitioners are clinical laboratories located in suburban Los Angeles, California. Petitioner RNA's mailing address was North Hollywood and Petitioner Ter-Zakarian's, Santa Monica.

Dr. Hovanes Ter-Zakarian was the medical director and owner of Petitioner Ter-Zakarian. Petitioner RNA was owned by a corporation which, in turn, was owned by Dr. Ter-Zakarian's brother, Vahe. Dr. Ter-Zakarian was also RNA's medical director.[(4)]

Both Petitioners enrolled in an approved PT program operated by the American Association of Bioanalysts Proficiency Testing Service (AAB). The AAB mails to each laboratory participating in its PT program an identical group of five specimens three times a year. The laboratories are required to test these specimens for analytes for which they do patient testing, and mail their results to the AAB by a date certain. *See Oakland Medical Group, P.C.*, DAB No. 1755, at 4 (2000); *Stanley Boykansky, M.D.*, DAB No. 1756, at 3-4 (2000).

Testing PT samples in the same manner as patients' specimens means that the PT samples must be integrated fully into the laboratory's testing regime. The requirement for full integration is found in the standard at 42 C.F.R. § 493.801(b). The laboratory must use the same techniques to test patient specimens and PT samples. 42 C.F.R. § 493.801(b)(1). The laboratory must not test PT samples a greater or fewer number of times than it tests patient specimens. 42 C.F.R. § 493.801(b)(2). The laboratory must not collaborate with any other individual or entity in the performance of proficiency testing. 42 C.F.R. § 493.801(b)(3). The laboratory must maintain complete and accurate documentation of all proficiency testing for a minimum of two years from the date of the PT event. 42 C.F.R. § 493.801(b)(5).

Petitioners received the same PT samples from the AAB at the same time. Petitioners did not dispute that for the third 1999 testing event, they reported identical results for nine analytes in the five samples provided by AAB. CMS alleged that Petitioners failed to comply with the CLIA condition at 42 C.F.R. § 493.801 in that they failed to test PT samples in the same manner as patients' specimens. Specifically, CMS asserted that Petitioners failed to comply with several of the standards that are part of this condition and that their failure to comply was so egregious as to constitute a failure by each Petitioner to comply with the condition itself. ALJ Decision at 6.

The ALJ concluded that CMS made a prima facie case supporting its allegations and that Petitioners did not rebut CMS' case. *Id.* at 2.

Standard of Review

Our standard of review of an ALJ decision on a disputed issue of law is whether the

ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence on the record as a whole. *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000).

The record before us consists of the briefs, exhibits and hearing testimony provided to the ALJ, the briefs on appeal to the Board and a tape of oral argument on the appeal that was held at Petitioners' request.

ANALYSIS

Below we set out the challenged FFCLs followed by our analysis of Petitioners' arguments.

FFCL 2. Petitioners RNA and Ter-Zakarian failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

Petitioners alleged that each of the underlying "four sub-FFCLs" and thus FFCL 2 is not supported by substantial evidence. Petitioners Br. at 3. We have reviewed Petitioners' contentions and conclude below that this FFCL is supported by substantial evidence in the record and is not erroneous.

a. Petitioners RNA and Ter-Zakarian engaged in prohibited inter-laboratory communications about proficiency testing.

The ALJ found that the evidence of identical PT results on so many tests was powerful circumstantial proof that Petitioners engaged in prohibited communications. In so finding, the ALJ cited expert testimony of Dr. Dennis Jay, AAB's Technical Director, Proficiency Testing, that the presence of multiple variables in the two laboratories' testing processes made it extraordinarily unlikely that identical results in so many instances could occur by happenstance. ALJ Decision at 7-8.

Petitioners questioned the statistical validity of the opinions offered by Dr. Jay and the ALJ's conclusions based on the testimony of that witness. Petitioners asserted that Dr. Jay was inexperienced and not qualified to offer a valid statistical analysis regarding the probability of two laboratories producing identical PT results. Further, Petitioners noted that the ALJ ignored Dr. Jay's testimony, on cross-examination, that he had no opinion about whether Petitioners shared PT information or samples. Petitioners argued that the ALJ simply ignored the flaws in Dr. Jay's testimony and substituted, without support, his opinion that Petitioners had engaged in prohibited inter-laboratory communications. Petitioner Br. at 3-8.

Petitioners also asserted that the ALJ's reliance on his decision in *Stanley Boykansky, M.D.*, DAB CR690 (2000), *aff'd*, *Stanley Boykansky, M.D.*, DAB No. 1756 (2000), where he found improper PT referrals, was misplaced because the circumstances of *Bovkanskv* were vastly different from theirs. Petitioners noted that *Bovkanskv* involved

nine facilities which shared some testing personnel and produced a degree of identical results over the course of three PT events. Here, Petitioners maintained, there were no shared testing personnel and the laboratories produced the same values on 9 of 32 analytes during one PT event. Moreover, Petitioners contended that the ALJ focused on only one event in spite of the fact that CMS had offered evidence alleging improper referral over the course of three PT events. Petitioners also alleged that the ALJ ignored a printout offered by Petitioner Ter-Zakarian and related testimony which showed that each Petitioner performed its PT testing independently. Finally, Petitioners asserted that the ALJ erred by "entirely discounting the fact that Petitioner RNA scored successfully for 115 values on chemical analytes that were not reported or tested by Petitioner Ter-Zakarian." Petitioner Br. at 5-8.

There is no merit in Petitioners' challenge to the testimony of CMS witness Dr. Jay. As we have noted in other CLIA cases involving his testimony, the ALJ did not rely on Dr. Jay's testimony, or that of similarly qualified witnesses, for statistical expertise. Rather, the credibility of Dr. Jay's conclusions is based on his training and expertise in the areas of clinical laboratory testing and PT. Specifically, the ALJ relied on Dr. Jay's testimony concerning the manner in which certain chemicals will behave in specific testing conditions, not on any statistical analysis of test results. *See Oakland* at 14-15; *Boykansky* at 10. Consequently, the ALJ did not (and was not required to) discuss Petitioners' expert testimony and arguments attacking the statistical validity of Dr. Jay's observations.

Dr. Jay testified that, in his experience, it would be unlikely for two independently operated laboratories to produce identical results for any sample. Here, there is no dispute that Petitioners reported identical testing results for nine categories of analytes in five specimens during the third 1999 PT event, for a total of 45 identical testing results. The ALJ correctly concluded that the logical inference to be drawn from the evidence before him was that Petitioners had collaborated in obtaining or reporting the results in issue. ALJ Decision at 7-8.[(5)]

Petitioners' attempt to distinguish their circumstances from those in *Boykansky* and related decisions is not convincing. Although there are only two laboratories involved in this case, they share both geographic proximity and their laboratory director. In addition to being the laboratory director for both facilities, Dr. Ter-Zakarian owns Petitioner Ter-Zakarian. Further, Dr. Ter-Zakarian's brother is the owner of the corporation which controls Petitioner RNA. Therefore, the relationship between these Petitioners is at least equally, if not far more, intertwined than that present in *Boykansky* and related decisions.

Moreover, there is no merit in Petitioners' contention that the ALJ erred by focusing only on the results of the third 1999 PT event, even though CMS had offered evidence regarding two other testing events that year. We do not agree with Petitioners' contention that by relying only on the alleged referral for the third testing event, the ALJ was rejecting CMS' allegations of referral in the other two 1999 testing events or was otherwise finding that the Statement of Deficiencies (the HCFA 2567) was

unreliable. There is no indication that the ALJ was making any such findings; in fact the ALJ cited the HCFA 2567 in discussing PT deficiencies other than referral that took place during other testing events. As we discuss more fully in our analysis of Petitioners' exception to FFCL 3, the third event in 1999 was not the sole basis for the sanctions imposed by CMS or the ALJ Decision. Our review of the ALJ Decision indicates that the ALJ's reliance on a single testing event was simply a matter of judicial economy. Regardless of whether there was evidence in the record to demonstrate that Petitioners had been fully compliant in other PT events that year, the violations present in the third 1999 event provide a sufficient basis to sustain the sanctions imposed by CMS. The condition established at 42 C.F.R. § 493.801 requires strict compliance. CLIA does not permit a laboratory to simply offset one bad PT event with one or two good ones. The CLIA statute and regulations are intended to ensure safe, reliable and accurate laboratory testing for all tests, for all patients, at all times.

Similarly unpersuasive is Petitioners' argument that it would be illogical to find referral between the laboratories considering that Petitioner RNA scored successfully for 115 values on other analytes in the third PT event that were not reported or tested by Ter-Zakarian. All referral between laboratories is prohibited. Even assuming Petitioner RNA scored successfully on *other* analytes independent of Petitioner Ter-Zakarian, and that Petitioner Ter-Zakarian's analyzer print-outs confirmed that Petitioner Ter-Zakarian achieved the testing results reported, neither fact overcomes the ALJ's determination that there was no credible evidence that RNA *independently* achieved PT scores identical to those reported by Petitioner Ter-Zakarian for 45 separate tests. By stating that there was no "credible" or "persuasive" evidence that Petitioners independently came up with identical test results, the ALJ was clearly making a credibility determination with respect to Petitioners' witnesses. When the Board reviews an ALJ decision under the substantial evidence standard, it generally accords considerable deference to the ALJ's assessment of witness credibility because the ALJ has the best opportunity to observe the witnesses and weigh the evidence. *St. Anthony Hospital*, DAB No. 1728, at 8 (2000). None of the witnesses offered a plausible explanation for how two laboratories, performing testing using different mechanics, methods and employees, could independently arrive at identical results for 45 tests. The ALJ's rejection of Petitioners' witnesses' testimony as a credible counterweight to the substantial evidence of collusion is reasonable and we will not disturb it. Thus, this aspect of his FFCL was not erroneous.

b. Petitioner RNA failed to comply with documentation and record keeping requirements in its conduct of proficiency testing.

Petitioner RNA conceded that it had not produced the analyzer reports which would show actual PT results either at the time of the survey or at the ALJ hearing. The ALJ relied on this specific lack of documentation in reaching his FFCL. Petitioners, in contrast, asserted that the ALJ erroneously found that there was no way to verify the accuracy of RNA's testing report forms. Petitioner argued that this finding was overcome by the testimony of a witness who averred that she performed PT for RNA.

Petitioners Br. at 9.

Petitioner RNA's contention that the testimony of its witness was sufficient to overcome the absence of analyzer reports is unavailing. The regulation is clear in requiring a clinical laboratory to -

> document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results . . . for a minimum of two years from the proficiency testing event.

45 C.F.R. § 493.801(b)(5).

As the ALJ noted, the regulation does not permit a partial production of records. Rather, it requires a laboratory to produce all records. The analyzer reports contain raw data and test results that a laboratory produces when it conducts a proficiency test; a witness' memory of conducting such tests is not a substitute for this data. Absent this information, there is no way to verify the accuracy of testing report forms. *See* ALJ Decision at 10.

> **c. Petitioner Ter-Zakarian did not test proficiency testing samples the same number of times that it routinely tested patient samples.**

Petitioners asserted that this subsection of the ALJ's FFCL was based on the ALJ's adoption of a witness' inference, the ALJ's refusal to consider testimony by that same witness more favorable to Petitioners' position, and the ALJ's failure to consider other favorable facts established by Petitioners. Petitioners Br. at 9-10.

The program regulations require that a clinical laboratory must test PT samples the same number of times that the laboratory routinely tests patient samples. 45 C.F.R. § 493.801(b)(2). The ALJ determined that CMS had established a prima facie case through documents showing that Petitioner Ter-Zakarian often tested PT samples multiple times while routinely testing patient samples only once. Before the ALJ, Petitioner Ter-Zakarian argued that it had tested PT and patient samples in the same manner because it used the same equipment and testing techniques for both types of tests. The ALJ found that Petitioner Ter-Zakarian did not address the issue. ALJ Decision at 11-12.

Petitioners' assertions that the ALJ's determination was erroneously based on the ALJ's reliance on certain testimony coupled with his unwillingness to consider other testimony are without foundation. CMS provided documentary evidence sufficient to establish a prima facie case that Petitioner Ter-Zakarian did not test PT samples in the

same manner as it tested patient samples. Petitioners did not supply to the ALJ evidence sufficient to overcome CMS' prima facie case since their arguments addressed the method rather than the frequency of testing, and since they offered no documentary evidence to support the suggestion that repeat testing, although only evidently performed on PT samples, was part of its quality control program.

d. The failures by Petitioner RNA and Petitioner Ter-Zakarian to conduct proficiency testing in the same manner as the testing of patients' specimens were so egregious as to be failures by these Petitioners to comply with the condition of participation that is stated at 42 C.F.R. § 493.801(a).

Petitioners asserted that the ALJ's conclusion that Petitioners had failed to comply with the condition of participation at 42 C.F.R. § 493.801(a) was invalid because there was "no condition level violation . . . [in the regulation] which provides the **standard** of enrollment." Petitioners Br. at 11 (emphasis in original).

The regulation at 42 C.F.R. § 493.801 is titled "Condition: Enrollment and testing of samples." As Petitioners noted, 42 C.F.R. § 493.801(a) is a standard, titled "Enrollment." Section 493.801(b) is titled "Standard; Testing of proficiency testing samples." Subsections (b)(1) and (b)(2) require that PT samples be integrated into the laboratory's regular patient workload, by personnel who routinely perform the testing in the laboratory, using the laboratory's routine testing method. Samples must be tested the same number of times the laboratory routinely tests patient samples. Subsection (b)(5) addresses documentation in the PT process.

Clearly, contrary to the heading for this subpart of FFCL 2, the ALJ's analysis was based on the totality of Petitioners' actions measured against the CLIA condition found at 42 C.F.R. § 493.801, not just the standard at 42 C.F.R. § 493.801(a). The evidence supported the ALJ's determinations that 1) both Petitioners violated the standards at 42 C.F.R. § 493.801(b)(1); 2) Petitioner RNA individually violated the standard at 42 C.F.R. § 493.801(b)(5); and 3) Petitioner Ter-Zakarian individually violated the standard at 42 C.F.R. § 493.801(b)(2).

Given the evidence, the ALJ found that Petitioners did not conduct PT testing honestly during the third event of 1999. Their collaboration rendered meaningless the PT results they did submit. Further, based on the absence of any supporting evidence from Petitioner RNA, the ALJ could not reasonably determine that RNA actually performed PT for the tests involving 45 results which were part of that event. Consequently, FFCL 2 is fully supported by the evidence of record and is not erroneous.

We therefore affirm FFCL 2, but modify subsection "d" to delete reference to 42 C.F.R. § 493.801(a) and substitute in its place 42 C.F.R. § 493.801.

FFCL 3. Petitioners RNA and Ter-Zakarian failed to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.1403.

The condition at 42 C.F.R. § 493.1403 is titled "Laboratories performing moderate complexity testing; laboratory director." The ALJ found that CMS introduced evidence which established a prima facie case that both Petitioners failed to comply with the condition governing the performance of the laboratory director.

Again, Petitioners asserted that the "sub-FFCLs" upon which this FFCL is based are not supported by substantial evidence. Thus, according to Petitioners, the FFCL is erroneous. Petitioners Br. at 11-12. We find that this FFCL is supported by substantial evidence in the record and is not erroneous.

a. Petitioner RNA did not comply with the laboratory director condition.

The ALJ determined that Petitioner RNA's deficiencies in PT, including the prohibited communications and the failure to maintain documentation established in FFCL 2, meant that Petitioner RNA was also out of compliance with the laboratory director condition. Petitioners contended that, in reaching this conclusion, the ALJ relied on no "evidence" other than his FFCL 2. Petitioners asserted that this Board's holding in *St. Anthony Hospital* required that an ALJ's "assessments" must be supported by reliable evidence and an ALJ's inferences must be reasonably drawn from the evidence. Here, Petitioners argued, the ALJ's "wholesale incorporation of . . . unsupported, unreasonable determinations fail to show that . . . 3(a) is supported by substantial evidence." Petitioners Br. at 12.

Further, Petitioners noted that Petitioner RNA was "owned by a non-party to these proceedings" and "was not operating at the time records were requested." Thus, Petitioners questioned how the ALJ could reasonably find that the creation and preservation of PT records were within the scope of the RNA laboratory director's duties. Petitioners Br. at 12-13.

As the ALJ noted, the CLIA condition of participation found at 42 C.F.R. § 493.1403 requires a clinical laboratory to have a director who is responsible for the overall management and direction of the laboratory. Specifically, a laboratory director must provide management and direction that comports with the standard set out at 42 C.F.R. § 493.1407. Thus, in part, a laboratory director must assure that PT is conducted in compliance with the requirements of all applicable regulations. *See* ALJ Decision at 13. As noted above, the evidence supports the ALJ's finding at FFCL 2 that Petitioner RNA did not comply with PT conditions. Consequently, Petitioner RNA was also out of compliance with the laboratory director condition since it follows that the laboratory director failed in his duty to assure compliance.

Moreover, in spite of clear regulatory documentation requirements, Petitioner RNA could produce no evidence to show that it performed PT for the 45 testing results questioned by CMS for the third 1999 testing event. Here, RNA's laboratory director bore the responsibility to ensure that RNA produced and maintained proper CLIA documentation for two years after the testing event. Petitioner RNA's laboratory

director's failure to ensure that RNA maintained proper PT documentation for the requisite period of time was not excused by the closing of RNA's facility in 2000. Consequently, Petitioner RNA failed to meet the laboratory director condition at 42 C.F.R. § 493.1403.

The fact that, in reaching an earlier FFCL, the ALJ found that RNA did not have any documentation to support certain PT results, does not preclude the ALJ from relying on that same evidence in finding that Petitioner RNA did not comply with the laboratory director condition. Thus, contrary to Petitioners' assertion, the ALJ's determination was supported by substantial evidence in the record and was not erroneous.

b. Petitioner Ter-Zakarian did not comply with the laboratory director condition.

Generally, the ALJ found that CMS' evidence established "a wholesale failure by Petitioner's [Ter-Zakarian] laboratory director to manage or direct the laboratory in compliance with applicable requirements." Specifically, Petitioner Ter-Zakarian was conducting specimen tests for TSH and its laboratory director had not enrolled in the PT program for that substance. Petitioner Ter-Zakarian received PT results for the third PT event in 1999 showing an unsuccessful test for creatinine, but did not present evidence to show that the laboratory director reviewed and evaluated those reports or had taken corrective action based on those results. Petitioner Ter-Zakarian's staff ran PT tests multiple times, but the laboratory director established no quality controls instructing his staff on how to distinguish correct from erroneous PT results. Further, for the first 1999 PT event, Petitioner Ter-Zakarian reported PT results which differed from the scores contained in its supporting paperwork. ALJ Decision at 15.

Petitioners noted that the ALJ's determination that Petitioner Ter-Zakarian was conducting patient specimen testing for a substance, but was not enrolled in PT for that substance, was based on the HCFA 2567. Petitioners asserted that there was no evidence that the HCFA 2567 was accurate. Additionally, Petitioners questioned the ALJ's reliance on the HCFA 2567 for this finding since he had otherwise "utterly disregarded the primary basis of the 2567, namely, that Petitioners engaged in PT referral over three testing events."[(6)] Petitioners also contended that the ALJ ignored the testimony of Dr. Ter-Zakarian when the ALJ determined that Petitioner Ter-Zakarian's laboratory director (Dr. Ter-Zakarian) failed to take corrective action when faced with sub-standard PT results. Finally, although Petitioners did not dispute the ALJ's finding that Petitioner Ter-Zakarian ran the same PT specimen multiple times, Petitioners argued that such multiple testing was valid so long as patient samples were tested in the same manner. Petitioners Br. at 13-14.

Petitioners' arguments are unavailing. In the main, the ALJ used information contained in the HCFA 2567 relevant to the third PT event in 1999 to reach his findings on the validity of PT in that event. Petitioners have not demonstrated that those determinations by the ALJ were not supported by substantial evidence. *See* ALJ Decision at 14-15. As the ALJ found, CMS' evidence established that Petitioner Ter-Zakarian conducted patient specimen tests for TSH, but had not enrolled in the PT

program with AAB for that substance in violation of 42 C.F.R. §§ 493.1407(e)(4) and 493.801(a). If Petitioner Ter-Zakarian had indeed enrolled, it should have provided evidence of its enrollment to rebut this evidence. Further, Dr. Ter-Zakarian's testimony cited by Petitioners (Tr. at 405) stated only that it was Dr. Ter-Zakarian's general practice to take corrective action when presented with evidence of unsuccessful testing. Petitioners offered no evidence whatsoever to rebut CMS' specific allegation that Petitioner Ter-Zakarian had not taken any corrective action when presented with evidence of unsuccessful testing for creatinine in the third 1999 PT event. *See* ALJ Decision at 15, citing HCFA Ex. 25, at 27. Petitioner Ter-Zakarian's failure constituted a violation of the standards at 42 C.F.R. § 493.1407(e)(4)(iii). Additionally, contrary to Petitioners' arguments, the third 1999 PT event was not the sole basis for the ALJ's finding Petitioner Ter-Zakarian in violation of the CLIA conditions of participation. The ALJ found that Petitioner Ter-Zakarian did not offer evidence or explanation justifying the fact that it allowed its staff to run PT multiple times and reported PT scores at variance with its recorded PT results for the first PT event in 1999. ALJ Decision at 14-15.

We have previously rejected Petitioners' assertion that multiple proficiency testing was valid so long as patient samples were tested in the same manner. Thus, we affirmed the ALJ's determination that Petitioner Ter-Zakarian failed to comply with that specific condition for PT. FFCL 2, the ALJ's finding that Petitioners did not comply with other conditions governing PT, called into question Petitioners' compliance with the standards concerning the laboratory director. FFCL 3 was based, in part, on the fact that "Petitioners offered no meaningful response to CMS' allegations and evidence except to aver that they complied with the condition governing proficiency testing." ALJ Decision at 13. Petitioners have presented no evidence to show that the ALJ's determinations were erroneous or otherwise not supported by substantial evidence.

We therefore affirm and adopt FFCL 3.

FFCL 5. A basis exists to impose remedies against Petitioners RNA and Ter-Zakarian.

Petitioners noted that FFCLs 2 and 3 were the basis for this FFCL. Consequently, Petitioners argued that since they had demonstrated that those FFCLs were unsupported and unreasonable, it followed that FFCL 5 was also unsupported and unreasonable. Petitioners Br. at 15.

We have found above that FFCLs 2 and 3 are supported by substantial evidence and are not erroneous. Consequently, contrary to Petitioners' argument, a basis exists to impose remedies against Petitioners RNA and Ter-Zakarian.

We therefore affirm and adopt FFCL 5.

FFCL 6. I deny Petitioners' Motions.

Petitioners noted that based on FFCL 2, the ALJ had denied three of its motions.[(7)]

Petitioners argued that since they had demonstrated that FFCL 2 was unsupported and unreasonable, it followed that FFCL 6 was also unsupported and unreasonable. *Id*. We have affirmed and adopted FFCL 2. Consequently, to the extent that Petitioners' exception to FFCL 6 is based on an allegation of the invalidity of FFCL 2, we find that Petitioners' exception has no merit.

We therefore affirm and adopt FFCL 6.

JUDGE

Cecilia Sparks Ford

Donald F. Garrett

M. Terry Johnson
Presiding Board Member

FOOTNOTES

1. Each Petitioner requested a hearing before an ALJ and their appeals before him were separately docketed. The ALJ conducted a consolidated hearing in these cases since they involved similar issues and common evidence. The ALJ did not formally consolidate the cases since the parties requesting hearing were not the same entity. ALJ Decision at 3.

2. CMS was previously named the Health Care Financing Administration (HCFA). *See* 66 Fed. Reg. 35,437 (July 5, 2001).

3. Petitioners also alleged that the ALJ erred by not making individual FFCLs for each Petitioner for each alleged regulatory violation. Other than a vague allegation that this violated their due process rights, Petitioners did not state any basis for their objection. Below, we review each of the FFCLs to which Petitioners excepted and conclude that all of them, both joint and individual, are sound, except for one instance where a citation has to be modified.

4. After the parties filed their respective hearing requests, Dr. Ter-Zakarian asserted through counsel that he was the real party in interest in Petitioner Ter-Zakarian's hearing request. Dr. Ter-Zakarian's position was based on a statement in CMS' Notice of Remedies to Petitioner Ter-Zakarian which addressed the impact those remedies would have on Dr. Ter-Zakarian's future in the CLIA program. The ALJ permitted Dr. Ter-Zakarian to participate in Petitioners' hearing and ultimately ruled that Dr. Ter-Zakarian did have a right to a hearing. ALJ Decision at 3-5.

5. Petitioners also maintained that the ALJ erred in relying on Dr. Jay's testimony as evidence of improper referral because Dr. Jay testified that it was not his job to determine whether laboratories were sharing PT results but rather, his job was to report to CMS. However, it is clear from the record that Dr. Jay meant that he was only providing expert testimony about the likelihood of coincidence as the reason two

laboratories independently obtained 45 identical test results. Tr. at 76-77 and 98-107. The ALJ stated at the hearing that he would, and clearly did, make his own decision about whether the circumstances warranted a finding of improper referral under the applicable regulations. Tr. at 4 and 46-47; ALJ Decision at 7-9.

6. Specifically, Petitioners referenced their earlier argument that although the HCFA 2567 questioned results for three PT events, the ALJ Decision focused on only one PT event.

7. Petitioners' motions involved exclusion of evidence, preclusion of testimony, and an examination of due process issues. *See* ALJ Decision at 17.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	

SUBJECT:

Gen Sys, Incorporated,

DATE: April 15, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-00-007
Decision No. **CR889**

DECISION	

DECISION

Summary judgment is entered affirming the determination of Respondent, Centers for Medicare & Medicaid Services (CMS), [(1)] suspending Petitioner's certificate of participation under the Clinical Laboratory Improvement Act (CLIA). Pursuant to 42 C.F.R. § 493.1844(d)(4)(ii), Petitioner's CLIA certificate is revoked effective the date of this decision due to the prior CMS suspension of the certificate based on a finding of immediate jeopardy. By operation of law, the owners and operators of Petitioner are prohibited from owning, operating, or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of Petitioner's certificate. The two-year prohibition runs from the date of the revocation of the laboratory's certificate pursuant to 42 U.S.C. § 263a(i)(3) - the date of this decision. Summary judgment is appropriate as there are no genuine issues of material fact in dispute and the controlling issues may be resolved as a matter of law.

PROCEDURAL HISTORY AND ADMISSION OF EXHIBITS

1. Procedural History:

Petitioner, Gen Sys, Inc., is a clinical laboratory located in Aurora, Illinois. Petitioner sought certification pursuant to CLIA to participate in the Medicare and Medicaid program. On April 16, 1999, CMS and the Illinois Department of Public Health personnel conducted an initial survey of Petitioner's laboratory to determine compliance with applicable CLIA conditions and requirements. The survey team noted

both condition and standard level deficiencies and Petitioner was notified accordingly. Upon the resignation of Petitioner's director, Respondent declared that immediate jeopardy existed for the public by virtue of Petitioner's continued operation and its CLIA certificate was suspended effective August 3, 1999.

Petitioner timely requested a hearing on September 24, 1999. Petitioner disputed all findings of the survey of April 16, 1999 and the propriety of the suspension by Respondent. The request for hearing was received and the case was assigned to Judge Alfonso Montano for hearing. On November 22, 2000, Respondent filed its motion for summary affirmance. Petitioner filed is response to the motion on April 6, 2001, opposing summary judgment. Respondent replied on June 15, 2001. The case was reassigned to me for hearing and decision on October 18, 2001. I have jurisdiction and this case is ripe for decision on the issues set forth hereafter. I have decided that summary judgment is appropriate in this case and no hearing is necessary or required to make a full and complete adjudication.

2. Admission of Exhibits:

Petitioner has submitted 47 numbered exhibits and an affidavit from Stephen R. Wechter executed April 6, 2001, which was attached to Petitioner's response to CMS's motion for summary affirmance and which I marked as Petitioner's exhibit 48 (P. Exs.1 - 48). Respondent made no objection to any of Petitioner's exhibits and they are all admitted.

Respondent submitted 13 exhibits with its motion for summary affirmance and an additional 9 exhibits with its reply brief. The exhibits submitted with the opening brief will be referred to as "R. Ex." and those submitted with Respondent's reply will be referred to as "RR Ex." [(2)]

Although no objection was made by Petitioner, the first two pages of R. Ex. 1 are not admitted. It appears from the face of the first two pages of R. Ex. 1 that they are part of a statement of deficiencies and plan of correction for a survey of Heartland Manor at Carriage Town, Flint, Michigan that was completed February 12, 1999. The provider listed on the first two pages of R. Ex. 1 is not a party in this case. Therefore, those pages are irrelevant and are not admitted. The balance of the pages appear on their face to relate to Petitioner and, absent objection, they are admitted. [(3)]

Petitioner specifically objects to the admission of: (1) R. Ex. 10, which purports to be a "Consultants [sic] Final Report: William Komaiko, M.D. of ProbeLabs to Gen Sys, Inc. 9/20/99; (2) R. Ex. 11, an unsigned, undated document with the first page titled "The Corporation" and the remaining pages bearing questions and answers purportedly related to Gen Sys, Inc.; and, (3) R. Ex. 12, titled "Introduction to the Spirochetes." Petitioner's Response, at 25, ¶ 73 - 76.
In administrative adjudications conducted pursuant to the Administrative Procedures Act, 5 U.S.C. § 556(d) provides that "(a)ny oral or documentary evidence may be received, but the agency as a matter of policy shall provide for the exclusion of irrelevant, immaterial, or unduly repetitious evidence." Pursuant to 42 C.F.R. § 498.61,

I may receive evidence in an administrative adjudication that would not be admissible under the rules of evidence applicable to a court proceeding. Thus, the primary considerations for the admission of evidence in an administrative adjudication are whether the evidence offered is relevant, and in the case of documents, whether they are authentic. Evidence is not excluded simply because it is hearsay, but the fact that evidence is hearsay may impact the weight it is given in deliberation and decision. Petitioner raised hearsay objections to all three documents and those objections are overruled as to all three documents.

Petitioner also objected to R. Ex. 10 arguing that it is not authenticated pursuant to Fed. R. Evid. 901. Although Fed. R. Evid. 901 does not technically apply, we often look to the Federal Rules of Evidence for guidance. Rule 901 provides an excellent but not exhaustive list of methods to establish authenticity. In this instance, I note it significant that Petitioner has chosen not to deny the authenticity of R. Ex. 10 but rather only to note the documents that comprise R. Ex. 10 have not been authenticated. On summary judgment, the absence of denial is as good as an admission, and the exhibit should be considered. However, it is also possible in this case to authenticate the documents based on their context and content. For example, the report is dated September 20, 1999, approximately the ending date of Dr. Komaiko's admitted relationship with Petitioner. [(4)] The documents also contain a significant number of facts related to Petitioner and this case, the accuracy of which are reflected by the evidence and pleadings offered by Petitioner. Based upon the foregoing factors, I am satisfied that the documents submitted as R. Ex. 10 are what they purport to be. Therefore, R. Ex. 10 is admitted. *See generally*, Fed. R. Evid. 901.

R. Ex. 11 is not admitted because I cannot determine its authenticity. Counsel for CMS represent in their reply brief at page 10 that the documents were originally filed in a law suit in the State of Illinois and that they are part of a public record. Although I may accept an assertion by counsel as sufficient to establish authenticity of a document in some cases, counsel's assertion is not sufficient in this case because the fact that counsel retrieved the documents from the records of a civil litigation involving Petitioner does not establish that Petitioner was the source of the documents. CMS counsel have not revealed whether the State court accepted the documents as authentic. Even if I accepted the documents as authentic, I would assign them little weight without more certainty that they originated from Petitioner and were unaltered.

R. Ex. 12 is admitted. Authenticity is established by the website address which appears at the bottom of each page of the document and the attribution found near the middle of the second page. Although the document is admitted as authentic and has some relevance due to its subject matter, it has no bearing on my decision in this case.

Respondent's exhibits that are admitted are R. Ex. 1 (except pages 1 and 2), 2 through 10, 12, 13, and RR. Ex. 1 through 9. R.R. Exs. 6 and 8 are admitted as no objection was filed and they appear to be minimally relevant. However, these documents only indicate the pendency of criminal and civil cases involving some of the principals of

Petitioner and do not indicate any findings of guilt or liability. Therefore R.R. Exs. 6 and 8 are given no weight and have no impact on my decision.

GOVERNING LAW

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Pursuant to CLIA, the Secretary of the Department of Health & Human Services (HHS) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. § 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to achieve compliance. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

The regulations specify "conditions" and "standards" that laboratory's must meet and maintain in order to obtain and retain their CLIA certification and their eligibility to receive Medicare or Medicaid reimbursement. Title 42 C.F.R. §§ 493.1441 through 1445 provide an example. The condition specified at section 493.1441 is that a laboratory performing high-complexity testing, must have a laboratory director who meets the qualifications of section 493.1443 and has the duties specified in section 493.1445. Sections 493.1443 and 1445 are both characterized as "standards" and each respectively lists in detail, required qualifications and required duties for a laboratory director. Pursuant to the enforcement provisions, CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency. 42 C.F.R. § 493.1804(b)(2). Principal sanctions include suspension, limitation, or revocation of a CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions include a directed plan of correction, state on-site monitoring, and civil money penalty. 42 C.F.R. § 493.1806(c). Cancellation and or suspension of Medicare payments are also authorized. 42 C.F.R. § 493.1807.

The phrase "immediate jeopardy" is defined at 42 C.F.R. § 493.2 to

mean:

> (A) situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public.

If, on inspection, a laboratory is found to have condition-level deficiencies that pose immediate jeopardy, CMS must require immediate action to remove the jeopardy and may impose alternative sanctions to assist. If the deficiencies remain on revisit, CMS may suspend or limit and later revoke the laboratory's CLIA certificate. CMS is also delegated authority to bring a civil suit for injunction against a laboratory in specified circumstances where there is immediate jeopardy. 42 C.F.R. § 493.1812. Condition-level deficiencies that do not constitute immediate jeopardy and standard level deficiencies that do not rise to condition level are treated differently and the laboratory is generally accorded 12 months in which to make corrections. 42 C.F.R. §§ 493.1814-1816.

CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory. . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an Administrative Law Judge (ALJ). 42 C.F.R. § 493.1844(a). CMS's decision to suspend, limit, or revoke a laboratory's certificate due to noncompliance with CLIA requirements is an initial determination that is subject to appeal and a hearing by an ALJ. However, the CMS determination that condition-level deficiencies pose immediate jeopardy is not subject to appeal or review. 42 C.F.R. §§ 493.1844(b)(1) and (c)(6). Generally, the suspension, limitation, or revocation of a CLIA certificate is not effective if appealed, until the ALJ makes a decision. However, when CMS declares immediate jeopardy, there is no delay in the suspension, limitation, or revocation of the offending laboratory's CLIA certificate. 42 C.F.R. § 493.1844(d)(2).

CLIA provides the following with respect to the owners and operators of noncompliant laboratories in addition to sanctions which may be imposed directly against a laboratory:

> (3) Ineligibility to own or operate laboratories after revocation.
>
> 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.

42 U.S.C. § 263a(i)(3). This statutory disability arises by operation of law immediately upon revocation of a laboratory's certification. No action by the Secretary is required, no discretion is granted the Secretary, and there is no appeal.

Four condition-level deficiencies are alleged in this case: (1) violation of 42 C.F.R. § 493.1227, (2) violation of 42 C.F.R. § 493.1447, (3) violation of 42 C.F.R. § 493.1701, and (4) violation of 42 C.F.R. § 493.1441. [(5)] Section 1227 sets the conditions for bacteriology for laboratories. Section 1447 establishes conditions to be met by the individual holding the technical supervisor position in a laboratory performing high complexity testing with specific references to qualifications (42 C.F.R. § 493.1449) and technical supervision of laboratory operations and personnel (42 C.F.R. § 1451). Section 1701 provides the condition that a laboratory must "establish and follow written policies and procedures for a comprehensive quality assurance program . . ." that cover all facets of the laboratory's operations. Section 1441 establishes the conditions that must be met by the individual holding the laboratory director position in a laboratory that performs high complexity testing, including qualifications (42 C.F.R. § 1443) and management responsibilities (42 C.F.R. § 493.1445).

ISSUES

(1) Whether summary judgement is appropriate.

(2) Whether one or more condition-level deficiencies existed at Petitioner's laboratory during the period April 16, 1999 and August 3, 1999 the date of suspension of Petitioner's CLIA certificate by Respondent.

(3) Whether suspension of Petitioner's CLIA certificate is justified by the condition-level deficiencies that did exist at Petitioner's laboratory during the period April 16, 1999 to August 3, 1999. [(6)]

FINDINGS OF FACT, CONCLUSIONS OF LAW AND ANALYSIS

The findings of fact and conclusions of law noted below are followed by a detailed discussion.

1. Summary judgment is appropriate.

Pursuant to 42 C.F.R. § 1844(f) it is presumed that Petitioner has a right to a hearing in this case. *See Garden City Medical Clinic*, DAB No. 1763 (2001), citing 42 U.S.C. § 263a(i)(1) and 42 C.F.R. § 493.1844(a). However, summary judgment is appropriate and no hearing is required where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. A party opposing summary judgment must allege facts which, if true, would refute the

facts relied upon by the moving party. *See e.g.*, Fed. R. Civ. P. 56(c); *Garden City,* supra, *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1977) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony).

Respondent has moved for summary judgment arguing it is entitled to judgment as a matter of law as there are no material facts in dispute. Petitioner argues that there are material facts in dispute as to every alleged deficiency and that Petitioner was actually in compliance with all CLIA requirements. CMS has alleged numerous deficiencies regarding specific standards in addition to the four condition-level deficiencies. Certainly, it is not unreasonable to assume that there are many disputed facts related to Petitioner's scientific methods and its method of operation that could be the subject of a hearing with voluminous exhibits and multiple experts. However, in opposing Respondent's motion for summary judgment, Petitioner bears the burden of showing that there are material facts that are disputed. *Everett Rehabilitation and Medical Center*, DAB No. 1628 (1977). It is not sufficient for Petitioner to rely upon mere allegations or denials to defeat the motion and proceed to hearing. Petitioner must, by affidavits or other evidence which set forth specific facts, show that there is a genuine issue for trial. If Petitioner cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate. Respondent must prevail as a matter of law. Moreover, in this case the CMS citation of condition-level deficiencies makes Petitioner's task of overcoming summary judgment even more burdensome. CMS imposed the principal sanction of suspension of Petitioner's CLIA certificate which will become a revocation of that certificate if I affirm the CMS action. Any one of the four condition-level deficiencies if proved may be sufficient to sustain the suspension by CMS. Therefore, if there is no disputed, material fact and no genuine issue for trial as to one of the condition-level deficiencies, summary judgment may be entered as to that deficiency. The issue then is whether or not that one deficiency is sufficient to support CMS' decision to impose the remedy, i.e., whether the remedy is warranted given the deficiency.

I have carefully reviewed all the evidence and conclude that there are no material issues of fact regarding the condition-level violations of 42 C.F.R. §§ 1441 and 1447 and judgment should be entered for Respondent on those violations as a matter of law. [(7)] Petitioner has not met its burden of presenting and arguing some credible facts that show there is a genuine issue of material fact as to these condition-level violations. Petitioner requested an evidentiary hearing on the motion for summary judgment proposing to call several witnesses to testify. Petitioner's Response, at 24. The request for hearing is denied. Conducting an evidentiary hearing on a motion for summary judgment would defeat the purpose for summary judgment. Indeed, a finding that an evidentiary hearing was necessary would be tantamount to a denial of summary judgment. I further conclude that the condition-level violations of sections 1441 and 1447 are a sufficient basis for the suspension and revocation of Petitioner's CLIA certificate given the facts and circumstances in this case.

2. Two condition-level deficiencies existed at Petitioner's laboratory

during the period April 16, 1999 and August 3, 1999, the date of suspension of Petitioner's CLIA certificate by Respondent. [8]

a. Petitioner did not have a qualified "technical supervisor" because he did not have a bachelor's or higher level degree from an accredited institution in the appropriate discipline, a violation of 42 C.F.R. § 1447.

There is no dispute that Stephen R. Wechter was the laboratory "technical supervisor" when the April 16, 1999 survey was conducted. Respondent, determined based on the survey of April 16, 1999, that Mr. Wechter did not meet the qualifications for a "technical supervisor as required by 42 C.F.R. § 1447 and listed at 42 C.F.R. § 1449. P. Ex. 1, at 10; Tag 6108. During the survey, Mr. Wechter presented the surveyors with copies of diplomas and his curriculum vitae (CV). P. Ex. 1, at 11. Mr. Wechter has provided copies of two diplomas and his CV for my consideration at P. Ex. 11. Subsequent, to the on-site survey, the surveyors further investigated Mr. Wechter's educational credentials finding that the Eurotechnical Research University was, in 1992 when Mr. Wechter's degree was conferred, operating from a post office box in Hilo, Hawaii, and not accredited. P. Ex. 11 (diploma from Eurotechnical indicates it was "conferred at Hilo, Hawaii" on June 15, 1992); R.R .Ex. 5. Mr. Wechter asserts in the multiple affidavits filed in this matter and his CV, that the Doctor of Philosophy conferred upon him by Eurotechnical was in the area of immunology. P. Ex. 11 (diploma and CV); P. Exs. 14, 17, 23, 24, 29, 38, 45, 48. Respondent could not determine based upon its investigation whether or not the Ph.D. was related to the area of immunology and the diploma makes no mention of "immunology" on its face. Respondent's investigation did disclose that Mr. Wechter's "post baccalaureate" studies at the University of Houston in 1975, 1985, and 1986 were in the area of history and no degree was conferred. P. Ex. 1, at 13. Mr. Wechter's CV indicates he studied at the University of Houston but does not specify the field of study but he asserts in his affidavit that his studies were in the area of microbiology, biochemistry, chemistry, and organic chemistry. Mr. Wechter's CV reflects an undergraduate degree from Columbia University in New York awarded in 1982. His diploma indicates he was awarded a Bachelor of Arts (B.A.) with honors in history (P. Ex. 11), which is consistent with the investigation of Respondent (P. Ex. 1). I will assume for purposes of summary judgment that Mr. Wechter's Ph.D. was conferred in the area of immunology - an inference drawn in Petitioner's favor. However, it is the undisputed evidence in this case that the degree was conferred by an unaccredited institution. Petitioner has presented no evidence, even by way of affidavit, to show that the institution was accredited.

It is undisputed that Mr. Wechter's education at Columbia where he received his B.A. was in the area of history. Mr. Wechter asserts in his affidavit at P. Ex. 11 that his studies at the University of Houston in Texas were in microbiology, biochemistry, chemistry and organic chemistry. Respondent's investigation involved contact with the Registrar at the University of Houston who reviewed University records and reported

that Mr. Wechter's studies were in history. P. Ex. 1, at 12-13. For purposes of ruling on summary judgment, I will assume that Mr. Wechter's studies were in the areas he alleges, even though he has presented no transcripts or other evidence to back his claim, an inference drawn in Petitioner's favor. But, it is undisputed that Petitioner received no degree from the University of Houston.

Viewing the evidence on this point in a light most favorable to Petitioner, I see that Mr. Wechter was issued a Ph.D. in the area of immunology. But there is no dispute that the institution that issued the degree was unaccredited. Mr. Wechter studied at the University of Houston in the areas he alleges. But it is undisputed that he was awarded no degree for his work at the University of Houston. Mr. Wechter received a B.A. degree from Columbia University. But there is no dispute that his B.A. was in the area of history.

The minimum education requirement for a technical supervisor in a laboratory performing high-complexity testing is a bachelor's degree from an accredited institution in one of the specified science disciplines. 42 C.F.R. § 493.1449. Mr. Wechter's only degree from an accredited institution is his B.A. from Columbia University in the area of history. Thus, Mr. Wechter does not meet the minimum education requirements for a technical supervisor.

Petitioner never alleges in its pleadings or offers any evidence to show that Mr. Wechter's Ph.D. was actually issued by an accredited institution. *See e.g.* P. Ex. 2, at 4. Rather, Petitioner argues that "in an effort to appease Respondent" Ellen Katz was hired to serve as technical supervisor. Petitioner's Response, at 16, ¶ 40. On June 30, 1999, Ms. Katz signed a list of technical supervisor duties. She was listed on a CLIA Laboratory Personnel Report (Form HCFA-209) signed by the laboratory director Dr. Janes bearing that same date. P. Ex. 4, Attachment 17 & 18. Nevertheless, Mr. Wechter and not Ms. Katz signed the plan of correction dated July 8, 1999. P. Ex. 4. Although it is not possible to decide from the record the date she left the position of technical supervisor, Petitioner concedes in its brief that Ms. Katz left the position after only a brief period. The fact that it was Mr. Wechter and not Ms. Katz who signed the plan of correction on July 8, 1999, tends to indicate that: Ms. Katz never assumed the responsibilities of the position; or that she was just listed to "appease" CMS as counsel for Petitioner states and Mr. Wechter actually continued to function as technical supervisor; or Ms. Katz resigned before that date. However, viewing the evidence in a light most favorable to Petitioner, I will conclude for purposes of this motion that Ms. Katz actually held the position until around January 2000 when Petitioner prepared a revised plan of correction that provided for the Laboratory Director to assume the responsibilities of technical supervisor. P. Ex. 32. Contrary to the assertions of Respondent, I find no statutory or regulatory requirement for Ms. Katz to sign a HCFA Form 209 in order for her to become technical supervisor for Petitioner. P. Ex. 5; CMS Reply Brief, at 9. [(9)]

Viewing the evidence in a light most favorable for the Petitioner, I conclude that prior to April 16, 1999 and until June 30, 1999, while Stephen Wechter was acting as

technical consultant, Petitioner did not have a technical supervisor who met the qualifications for that position. Thus, there was a condition-level violation during this period. 42 C.F.R. § 1447 - 1449.

After June 30, 1999 and until about January 2000, Ms. Ellen Katz was the technical supervisor for the laboratory. She was qualified for the position. Thus, there was no condition-level violation of 42 C.F.R. § 1447 during this period.

In January 2000, Petitioner provided by policy that in the absence of a qualified technical supervisor, the laboratory director would fulfill that function. P. Ex. 32. This policy is specifically permitted by 42 C.F.R. § 1449, so long as the laboratory director meets the qualifications for a technical supervisor. Petitioner has produced no evidence that a technical supervisor was hired after Ms. Katz and the evidence supports my conclusion, in light of Petitioner's adoption of its new policy, that the laboratory director would thereafter also be the technical supervisor. Thus, the laboratory had no technical supervisor when it had no laboratory director and a condition-level violation of 42 C.F.R. § 1447 occurred.

b. Petitioner did not have a qualified "laboratory director" who fulfilled the duties and responsibilities of laboratory director, a violation of 42 C.F.R. § 1441.

During the April 1999 survey, the laboratory director of Petitioner was William O. Janes, M.D. P. Ex. 1. On June 9, 1999, Dr. Janes, as "Medical Director," signed the plan of correction for deficiencies found on the April 1999 survey. By letter dated June 25, 1999, Respondent advised Dr. Janes that Petitioner's plan of correction was insufficient and that

Petitioner continued with the three condition-level violations identified on the original survey. P. Ex. 3. On July 8, 1999, Dr. Janes signed Petitioner's revised plan of correction. P. Ex. 4. Dr. Janes resigned as the laboratory director of Petitioner effective July 22, 1999. R. Ex. 4.

By letter dated July 26, 1999, Respondent advised Petitioner that its CLIA certificate would be suspended due to continuing condition-level violations and the additional condition-level violation due to the resignation of Dr. Janes as laboratory director. Respondent declared that immediate jeopardy existed. Respondent was advised by letter dated August 3, 1999 from counsel for Petitioner, that Petitioner had a new laboratory director, William Komaiko, M.D. R. Ex. 7; P. Ex. 5. Nevertheless, Respondent persisted in finding condition-level violations in (1) bacteriology (42 C.F.R. § 493.1227); (2) laboratory technical supervisor (42 C.F.R. § 493.1447) [(10)]; and, (3) laboratory director (42 C.F.R. § 493.1441). Respondent noted that Dr. Komaiko's qualifications and his assumption of the position and duties were not properly documented as of August 20, 1999, the date of the letter. By letter dated October 27, 1999, Dr. Komaiko advised Respondent that he did not assume duties as

laboratory director until August 10, 1999. He further advised that he was hired as a consultant and agreed to assume laboratory director duties as part of his consulting contract on an interim basis. He terminated his relationship about September 20, 1999, when he delivered his report to Petitioner. R. Ex. 10. Pravin H. Patel, Ph.D. has submitted a letter that advises that he was never engaged as laboratory director for Petitioner as represented in Petitioner's plan of correction from February 2000 (P. Ex. 32), as his agreement to serve was contingent upon CLIA approval which was not forthcoming. R.R. Ex. 4. By letter dated April 4, 2000, Respondent advised Petitioner that Dr. Patel was not qualified to serve as laboratory director, but that he was qualified to serve as technical supervisor. P. Ex. 6. Stephen Wechter submitted a Form HCFA-209, dated May 24, 2000 and signed by James Bryant, M.D. which reflects Dr. Bryant as laboratory director and technical supervisor. P. Ex. 7. However, by letter dated June 5, 2000, Respondent advised Petitioner that Dr. Bryant was ineligible to serve as Petitioner's laboratory director as he was already listed as laboratory director for five other laboratories pursuant to 42 C.F.R. § 493.1445(d). P.Ex. 8. Dr. Bryant resigned as director for one laboratory on July 25, 2000 and reported himself as laboratory director for Petitioner as of August 7, 2000. P.Ex. 9.

The foregoing facts are undisputed, (*see* Petitioner's Response, at 24) and viewing the undisputed facts in a light most favorable to Petitioner, I make the following factual conclusions. Dr. Janes was laboratory director from on and before April 16, 1999, the date of the survey, to July 22, 1999. From July 23, 1999 until August 10, 1999, Petitioner had no laboratory director. From August 10, 1999 to September 20, 1999, Dr. Komaiko was Petitioner's laboratory director. From September 20, 1999 to August 7, 2000, Petitioner had no laboratory director. Dr. Bryant became Petitioner's laboratory director on August 7, 2000, and absent evidence to the contrary, I presume that he continues in that role. Therefore, during the 16-month period from April 16, 1999 to August 7, 2000, Petitioner had no laboratory director for nearly 12 months. Petitioner has presented no evidence or argument to the contrary. Petitioner was in violation of the condition-level requirement established by 42 C.F.R. § 1441 for each month it did not have a qualified laboratory director. I can conceive of no set of facts Petitioner could prove at trial that would lead to different conclusions more favorable to Petitioner.

3. Suspension of Petitioner's CLIA certificate is justified by the condition-level deficiencies that did exist at Petitioner's laboratory during the period April 16, 1999 to August 3, 1999.

Based on the foregoing discussion, I am satisfied that from April 16, 1999 to June 30, 1999, Petitioner had no qualified technical supervisor. From June 30, 1999 to January 2000, Petitioner had a qualified technical supervisor but after January 2000, Petitioner provided by policy that the technical supervisor responsibilities were to be fulfilled by its laboratory director. From September 20, 1999 to August 7, 2000, Petitioner had no laboratory director. From January 2000 to August 7, 2000, Petitioner had neither a qualified technical supervisor nor a qualified laboratory director. Conversely, the only time during the 16-month period from April 16, 1999 to August 7, 2000, that Petitioner

met the condition-level requirements for laboratory director and technical supervisor, was from August 10, 1999 to September 20, 1999, during which period Ms. Katz was technical supervisor and Dr. Komaiko was laboratory director. During the entire period, August 10, 1999 to September 20, 1999, Petitioner's CLIA certificate was suspended.

The final issue is whether or not suspension and revocation are appropriate in this case given the two condition-level violations I have found. Petitioner makes no arguments regarding the propriety of the imposition of the principal sanction of suspension. My review is *de novo* on this issue.

The existence of either of the two condition-level deficiencies in this case is sufficient to support the principal sanction of suspension and revocation of Petitioner's CLIA certificate. The purpose of the Act is to ensure "the accuracy and reliability of laboratory tests, and hence the public health of all Americans." The absence of a qualified technical supervisor or a laboratory director creates the significant risk of inaccuracy and unreliability detrimental to the health of the American public. I can make this determination without the need to assess the reliability of the many other allegations of irregularities that surround the claims of this laboratory, its methods and operations - allegations that I note were raised by those Petitioner retained as laboratory directors. Petitioner has made no argument nor proffered any evidence that would lead to a different result.

CONCLUSION

For the foregoing reasons, summary judgment is entered affirming the determination of Respondent suspending Petitioner's CLIA certificate. Pursuant to 42 C.F.R. 493.1844(d)(4)(ii), Petitioner's CLIA certificate is revoked effective the date of this decision due to the prior CMS suspension of the certificate based upon a finding of immediate jeopardy. By operation of law, the owners and operators of Petitioner are prohibited from owning, operating, or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of the certification of the Petitioner. The two-year prohibition runs from the date of the revocation of the laboratory's certificate pursuant to 42 U.S.C. § 263a(i)(3) - the date of this decision.

JUDGE

Keith W. Sickendick

Administrative Law Judge

FOOTNOTES

1. Effective July 5, 2001, the Health Care Finance Administration (HCFA) was renamed the Centers for Medicare and Medicaid Services (CMS). 66 Fed. Reg. 35437. Reference to either name applies to the same entity.

2. A much preferred practice is for subsequent exhibits to be numbered consecutively beginning with the number following that used on the last submitted exhibit, to avoid having multiple exhibits bearing the same exhibit number.

3. The complete Statement of Deficiencies has been admitted as part of P. Ex. 1.

4. It is interesting that Petitioner represented to CMS that Dr. Komaiko was hired as the laboratory director, curing one of its condition-level deficiencies. Dr. Komaiko, however, viewed himself only as a consultant retained to assist Petitioner to preserve its CLIA certificate. Of course, if Dr. Komiako was actually the laboratory director, R. Ex. 10 could be considered a vicarious admission of a party-opponent and/or an admission against interest.

5. The first three deficiencies were listed in the survey completed April 16, 1999 and are identified by Tags D4188, D6108, and D7000, respectively. P. Ex. 1. The fourth violation or deficiency arose when Petitioner's laboratory director, Dr. William O. Janes, resigned. CMS provided notice of the deficiency and of suspension of Petitioner's CLIA certificate based on a finding of "immediate jeopardy," by letter dated July 26, 1999. R. Ex. 6.

6. The CMS determination that "immediate jeopardy" existed is not subject to appeal or review. 42 C.F.R. § 493.1844(c)(6).

7. I note here that on further analysis of the other condition level violations I might also have found no genuine issues for trial. However, because the two deficiencies addressed are serious enough to justify the remedy imposed by CMS and the eventual revocation of the Petitioner's CLIA certificate, I see no reason to spend further time or resources upon an analysis of this case.

8. I feel it necessary to repeat that I am not ruling that CMS cannot prove the existence of other condition-level deficiencies in this case. My ruling is that: (1) there is no disputed issue of material fact as to the existence of the condition-level deficiencies discussed; and, (2) the two condition-level deficiencies found are a sufficient basis for suspending and revoking Petitioner's CLIA certificate.

9. I can only wonder why, if CMS doubted that Ms. Katz was actually performing as technical supervisor, it did not further investigate by visiting the laboratory or at least calling Ms. Katz.

10. For the reasons already discussed, I do not accept for purposes of ruling on summary judgment that a condition-level violation continued in the technical supervision area after Ms. Katz was appointed to that position June 30, 1999.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF

SUBJECT:

Dearborn Family Clinic,

DATE: June 19, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-01-293
Decision No. **CR919**

DECISION

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) [(1)] to impose remedies against Petitioner, Dearborn Family Clinic, pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq.*

I. Background

A. Background facts

Petitioner is a clinical laboratory that is located in Dearborn Hills, Michigan. Petitioner's laboratory director is Howard Wright, D.O. In November 1999, the American Association of Bioanalysts Proficiency Testing Service (AAB) notified the Michigan Department of Consumer and Industry Services (Michigan State survey agency) that Petitioner and Emil S. Sitto, M.D., & Associates, P.L.L.C. (Sitto), another Detroit area laboratory, had submitted duplicate proficiency testing (PT) results in 1999. The Michigan State survey agency requested and received authorization from CMS to conduct an unannounced complaint survey. The Michigan State survey agency conducted a complaint investigation of Petitioner to determine whether Petitioner was complying with CLIA requirements on February 8, 2000. Based on the results of the February 8, 2000 survey and a comparative analysis of the PT results submitted by Petitioner and Sitto, the Michigan State survev agency made findings which were referred to CMS. On October 25, 2000,

CMS notified Petitioner that it had been found to be deficient in complying with CLIA requirements in that improper referral and/or collaboration and integration occurred during the first, second, and third PT testing events of 1999. In the October 25, 2000 notice CMS identified specific CLIA conditions and other statutory and regulatory requirements with which it asserted Petitioner had not complied, which are stated at 42 C.F.R.§§ 493.801 (proficiency testing), 493.1441 (laboratory director), and 493.1447 (laboratory technical supervisor). CMS advised Petitioner that it had determined to impose remedies against Petitioner which included cancellation of Petitioner's approval to receive Medicare payment for its services and revocation of Petitioner's CLIA certificate.

Petitioner timely requested a hearing, and the case was assigned to me for a hearing and a decision. CMS moved for summary disposition. CMS's motion was accompanied by ten exhibits marked as CMS Exs. 1 - 10 plus two declarations which I now label as CMS Exs. 11 and 12. Petitioner filed a brief in response. Attached to Petitioner's brief were three exhibits marked as P. Exs. 1 - 3. CMS filed a reply brief. In addition, the parties filed a stipulation of facts (SOF). Attached to the SOF were thirteen exhibits labeled A - 1, A - 2, and B - L which I have renamed Administrative Law Judge Exhibits (ALJ Exs.) 1 - 13. No objections were made to any of the exhibits. I am receiving into evidence CMS Exs. 1 - 12, P. Exs. 1 - 3, and ALJ Exs. 1 - 13

B. Stipulation of facts

The parties filed a stipulation of facts that I relate below.

At all relevant times Howard Wright, D.O. was designated Petitioner's laboratory director. SOF 2. During the first, second, and third PT events of 1999, Petitioner retained Robin L. Mills in the capacity of an independent contractor as a part-time laboratory technician. SOF 3. Ms. Mills was identified on the Laboratory Personnel Report as Petitioner's technical supervisor. SOF 4. Both Petitioner and the Sitto laboratory used AAB as a testing service. SOF 5. In 1999, AAB sent endocrinology and chemistry PT samples to Petitioner on three occasions. On each of these occasions AAB sent five samples of each substance, including samples for cholesterol, HDL cholesterol, Thyroid Stimulation Hormone (TSH), and Free Thyroxine (Free T4). SOF 7. Ms. Mills performed the PT at Petitioner during the first, second, and third PT events for 1999 for TSH and Free T4. SOF 8. Ms. Mills recorded the results of these tests on laboratory log sheets. SOF 9; ALJ Exs. 2 - 4. Susan Rosenberg, a laboratory technologist, performed the PT at Petitioner during the first, second, and third PT events for 1999 for, among other things, cholesterol and HDL cholesterol. SOF 10. Ms. Rosenberg recorded the results of these tests on laboratory log sheets. SOF 11; ALJ Ex. 5. In 1999, Petitioner did not normally test patient samples for TSH and Free T4 twice except in circumstances in which there was a concern regarding a test result. SOF 12. In those cases, Petitioner would normally run such patient samples more than once. Id. It was Petitioner's practice to report results of patient tests as they were recorded in the laboratory log. SOF

13.

Ms. Mills wrote a letter to the Laboratory Improvement Section of the State of Michigan dated February 17, 2000, in which she stated that:

> Regarding Dr. Howard Wright's office Laboratory, CLIA#23DO36720, and Dr. Emil Sitto's office Laboratory, CLIA#23DO363337 I am the Consultant for these offices and have used improper procedures for the proficiency results. I unknowingly [sic] was using an average and realize now the importance of exact documentation. Dr. Sitto and Dr. Wright had no knowledge [sic] of this and will most likely be terminating my employment.

SOF 14; ALJ Ex. 6.

1. TSH results in the first PT event of 1999

On or about March 18, 1999, Ms. Mills tested five PT samples for TSH. SOF 15. Ms. Mills reported the results of the tests of the five samples of TSH in a laboratory log. SOF 16; ALJ Ex. 2. Petitioner reported PT results for the five samples of TSH to AAB. SOF 17; ALJ Ex. 7. Ms. Mills signed the report in the area designated for the technical supervisor. SOF 17. The results (SOF 18) shown on the laboratory log and the results (SOF 18) reported to AAB are as follows:

Vial Number	Laboratory log results	Results reported to AAB
Vial no. 1	3.4	3.7
Vial no. 2	3.2	3.2
Vial no. 3	3.4	2.8
Vial no. 4	6.2	7.0
Vial no. 5	5.5	6.0

The TSH results for vial nos. 1, 3, 4, and 5 that Petitioner reported to AAB were different from the results Ms. Mills reported in her laboratory log at Petitioner. SOF 19.

The results of 21 out of 25 endocrinology and chemistry tests in the *first* PT event of 1999 reported to AAB by Petitioner were identical to the results reported to AAB by Sitto. ALJ Exs. 6 - 8; SOF 20.

2. Cholesterol results in the second PT event of 1999

On or about June 15, 1999, Susan Rosenberg, an employee at Petitioner, tested five PT samples for cholesterol. SOF 21. Ms. Rosenberg reported the

results of the tests for the five samples of cholesterol in a laboratory log. SOF 22; ALJ Ex. 5. Petitioner reported PT results for five samples of cholesterol to AAB. SOF 23; ALJ Ex. 10. Ms. Mills signed the report in the area designated for the technical supervisor. SOF 23. The results (SOF 24) shown on the laboratory log and the results (SOF 24) reported to AAB are as follows:

Vial Number	Laboratory log results	Results reported to AAB
Vial no. 1	99	109
Vial no. 2	212	222
Vial no. 3	145	155
Vial no. 4	193	202
Vial no. 5	109	120

The cholesterol results for vial nos. 1 through 5 that Petitioner reported to AAB were different from the results Ms. Rosenberg reported in her laboratory log at Petitioner. SOF 25.

3. TSH results in the second PT event of 1999

On or about June 17, 1999, Ms. Mills tested five PT samples for TSH. SOF 26. Ms. Mills reported the results of the tests of the five samples of TSH in a laboratory log. SOF 27; ALJ Ex. 3. Petitioner reported PT results for the five samples of TSH to AAB. SOF 28; ALJ Ex. 10. Ms. Mills signed the report in the area designated for the technical supervisor. SOF 28. The results (SOF 29) shown on the laboratory log and the results (SOF 29) reported to AAB are as follows:

Vial Number	Laboratory log results	Results reported to AAB
Vial no. 1	0 and 0.08	0.9
Vial no. 2	7.8 and 8.5	8.0
Vial no. 3	2.8 and 2.8	2.8
Vial no. 4	0.8 and 0.8	1.0
Vial no. 5	1.5 and 1.4	1.4

The TSH results for vial nos. 1, 2, 3, 4, and 5 that Petitioner reported to AAB were different from the results Ms. Mills reported in her laboratory log at Petitioner. [(2)] SOF 30.

4. Free T4 results in the second PT event of 1999

On or about June 17, 1999, Ms. Mills tested five PT samples for Free T4. SOF 31. Ms. Mills reported the results of the tests of the five samples of Free T4 in a laboratory log. SOF 32; ALJ Ex. 3. Petitioner reported PT results for the five samples of Free T4 to AAB. SOF 33; ALJ Ex. 10. Ms. Mills signed the report in the area designated for the technical supervisor. SOF 33. The results (SOF 34) shown on the laboratory log and the results (SOF 34) reported to AAB are as follows:

Vial Number	Laboratory log results	Results reported to AAB
Vial no. 1	0.1 and 0	0.2
Vial no. 2	3.1 and 4.0	3.8
Vial no. 3	1.4 and 1.4	1.8
Vial no. 4	1.4 and 1.5	1.5
Vial no. 5	0.3	0.6

Vial no. 5	3.1	3.1

The TSH results for vial no. 4 that Petitioner reported to AAB was different from the results Ms. Mills reported in her laboratory log at Petitioner. SOF 41.

6. Free T4 results in the third PT event of 1999

On or about October 19, 1999, Ms. Mills tested five PT samples for Free T4. SOF 42. Ms. Mills reported the results of the tests of the five samples of Free T4 in a laboratory log. SOF 43; ALJ Ex. 4. Petitioner reported PT results for the five samples of Free T4 to AAB. SOF 44; ALJ Ex. 12. Ms. Mills signed the report in the area designated for the technical supervisor. SOF 44. The results (SOF 45) shown on the laboratory log and the results (SOF 45) reported to AAB are as follows:

Vial Number	Laboratory log results	Results reported to AAB
Vial no. 1	1.2	1.2
Vial no. 2	0.7	0.8
Vial no. 3	0.7	0.7
Vial no. 4	3.0	3.0
Vial no. 5	1.2	1.2

The Free T4 result for vial no. 2 that Petitioner reported to AAB was different from the result Ms. Mills reported in her laboratory log at Petitioner. SOF 46.

The parties stipulated that in the *first* PT event of 1999 the results of 21 of the 25 endocrinology and chemistry tests reported to AAB by Petitioner were identical to the results reported to AAB by the Sitto laboratory. ALJ Exs. 9, 12, 13; SOF 47. [(4)]

II. Governing law

CLIA requires, among other things, that the Secretary of the United States Department of Health and Human Services (Secretary) establish certification requirements for any laboratory that performs tests on human specimens and certify, through the issuance of a certificate, that a laboratory meets certification requirements. 42 U.S.C. § 263a. The Secretary published regulations designed to implement the requirements of CLIA. These regulations are contained in 42 C.F.R. Part 493. The CLIA regulations set forth the conditions that all laboratories must meet in order to perform clinical testing. The regulations also set forth enforcement procedures and hearings and appeals procedures for those laboratories that are found to be noncompliant with CLIA requirements.

The regulations establish both *conditions* and *standards* for participation under CLIA. Conditions of participation are set forth as broadly stated general requirements which must be met in order for a laboratory to qualify under CLIA. Standards of participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. Standards are subparts of the more broadly stated conditions. A failure by a laboratory to comply with one or more standards may be so serious as to constitute failure to comply with the condition of which the standards are subparts.

The CLIA regulations authorize CMS or its designee (such as the Michigan State survey agency) 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 enforcement authority on CMS in order to assure that laboratories comply with CLIA. 42 C.F.R. § 493.1800. Where CMS determines that a laboratory is not complying with one or more CLIA conditions, CMS may impose as remedies *principal* sanctions against the laboratory which may include suspension and/or revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). CMS may also impose *alternative* sanctions against a noncompliant laboratory in lieu of or in addition to principal sanctions. 42 C.F.R. § 493.1806(c). Additionally, CMS 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).

The regulations provide a noncompliant laboratory with the opportunity to correct its deficiencies so that CMS may remove alternative sanctions that have been imposed against that laboratory. 42 C.F.R. § 493.1810(e). However, the regulations do not afford a laboratory the same opportunity to have principal, as opposed to alternative, sanctions lifted.

The regulation at 42 C.F.R. § 493.801 provides that laboratories cannot engage in inter-laboratory communications pertaining to PT results until after the due date by which a laboratory must report its results to the PT program. 42 C.F.R. § 493.801(b)(3). In addition, a laboratory must not refer PT samples or portions of PT samples to another laboratory for any analysis that it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i). If a laboratory intentionally refers PT samples to another laboratory for analysis, its CLIA certificate must be revoked for at least one year. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i)(4).

Further, 42 C.F.R. § 493.801(b) provides that a laboratory is to analyze PT samples in the same manner as patient samples. Thus, PT samples must be integrated with the laboratory's regular patient workload and the tests must be performed by personnel who routinely do the testing using the laboratory's routine testing method. 42 C.F.R. § 493.801(b)(1). The integration of PT samples must be attested

to by the laboratory director and the individual who performs the testing. PT samples must be tested the same number of times as routine patient samples are tested. 42 C.F.R. § 493.801(b)(2). Records documenting each step taken in the testing of PT samples are required. 42 C.F.R. § 493.801(b)(5).

The regulation at 42 C.F.R. § 493.1447 provides that a laboratory performing high complexity testing have a technical supervisor meeting the qualifications set out in 42 C.F.R. § 493.1449. Specifically, a technical supervisor must have a bachelor of science degree and four years of experience. The regulation at 42 C.F.R. § 493.1441 provides that a laboratory have a laboratory director who provides management and direction in accordance with 42 C.F.R. § 493.1445. One of the responsibilities of a laboratory director is the hiring of staff with appropriate education and experience or training.

A laboratory that is dissatisfied with a determination by CMS to impose sanctions against it may request a hearing before an administrative law judge to contest CMS's determination. 42 C.F.R. § 493.1844. The standard of proof that is employed at a hearing concerning CMS's determination that a laboratory is not in compliance with CLIA conditions is preponderance of the evidence. CMS has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by CMS. *Edison Medical Laboratories, Inc.,* DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

III. Issue, findings of fact and conclusions of law

A. Issue

The issue in this case is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving CMS the authority to impose remedies against Petitioner, including canceling Petitioner's approval to receive Medicare payments and revoking Petitioner's CLIA certificate.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. Summary disposition is appropriate in this case.

A threshold question in this case is whether summary disposition is appropriate. Summary disposition is appropriate where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or the moving party must prevail as a matter of law even if

all disputed facts are resolved in favor of the party against whom the motion is made. A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party. *See e.g.,* Fed. R. Civ. P. 56(c); *Garden City Medical Center,* DAB No. 1763 (2001); *Everett Rehabilitation and Medical Center,* DAB No. 1628, at 3 (1977) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony).

Respondent has moved for summary judgment arguing it is entitled to judgment as a matter of law as there are no material facts in dispute. Petitioner argues that there was no actual referral of PT samples to another laboratory in that the vials containing the proficiency samples were not sent by Petitioner to any other facility. However, CMS does not premise its arguments on a physical transfer of the proficiency samples and never so alleges. Petitioner bears the burden of showing that there are material facts that are disputed. *Id*. It is not sufficient for Petitioner to rely upon mere allegations or denials to defeat the motion and proceed to hearing. Petitioner must, by affidavits or other evidence which set forth specific facts, show that there is a genuine issue for trial. If Petitioner cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate.

I have looked closely at the parties' arguments to decide whether there are disputed issues of material fact. There are no disputed material facts in this case. Essentially, the parties are relying on the same facts and are making legal arguments based on those facts.

2. During 1999, Petitioner colluded with another laboratory in the testing of proficiency samples.

The condition of participation that is stated at 42 C.F.R. § 493.801 requires that a clinical laboratory must enroll in a proficiency testing program that meets defined criteria and which is approved by the United States Department of Health and Human Services. Petitioner enrolled in an approved proficiency testing program that is operated by AAB. Petitioner received a group of proficiency testing samples from the AAB at regular intervals each year. Other clinical laboratories who were enrolled in the AAB proficiency testing program received the same samples at the same time as Petitioner. I take notice of the fact that the AAB refers to each mailing of samples to laboratories for proficiency testing as an "event." Under the AAB program there are three testing events per year.

The object of the proficiency testing exercise is for each participating laboratory to test its samples independently as if they are patient specimens and to report the results of its tests to the AAB Proficiency Testing Service. The AAB scores the results for the tests that are performed for each event and rates each laboratory's testing competency for that event based on the scores that the laboratory obtains.

There was no such thing as a single "correct" score on many of the proficiency tests that Petitioner and other laboratories were asked to perform in 1999. The

AAB accepts as "correct" many test scores that fall within a range of possible scores because of the wide range of variables that are involved in the testing process. Indeed, it is highly unlikely that two laboratories performing proficiency tests would obtain identical test results on multiple samples, given the wide range of variables that are involved in the testing process.

During all three PT events in 1999, Howard Wright, D.O., was laboratory director and Robin L. Mills was the technical supervisor and additional testing was performed by Susan Rosenberg. SOF 2 - 4. In 1999, Petitioner and Sitto both participated in the AAB's testing program. SOF 5. Both Petitioner and Sitto were to test the proficiency samples for total cholesterol, triglycerides, TSH, Free T4, and HDL cholesterol. Both laboratories were to test the five samples for each analyte.

The evidence which supports my conclusion that Petitioner and Sitto colluded with each other to produce nearly identical proficiency testing results in 1999 includes the opinions of two experts whose declarations were supplied as evidence by CMS. CMS Ex. 11; CMS Ex. 12. These experts are Dennis W. Jay, Ph.D., DABCC, Technical Director of the AAB Proficiency Testing Service (CMS Ex. 11) and Richard J. Benson, CLS, MT, who is employed as Chief, Laboratory Improvement Section, Bureau of Health Systems, of the Michigan State survey agency (CMS Ex. 12). I find these experts to be well-qualified and their opinions to be persuasive. Their conclusions were based on their training in their respective fields, their experience in those fields, and on the evidence which pertained to the specific proficiency tests that are at issue in this case.

The likelihood of more than one laboratory arriving at the same value for a proficiency test result is low due to the variables that are involved in the testing process. In this case, for example, both facilities used manual techniques for measuring and diluting both samples and reagents. CMS Ex. 12 at 5. Reagents and samples were introduced into test tubes by hand and timed by the individual performing the test. *Id.* Therefore, test results are rarely reproduced exactly even when one person performs the same test twice on the same sample in the same laboratory with the same equipment. *Id*. Therefore, the acceptable range of results for each sample has a broad range. *Id.*; CMS Ex. 11 at 3. Yet, Petitioner and Sitto reported identical scores for all five samples of four analytes. Petitioner and Sitto submitted identical results for 60 out of 60 tests - four analytes tested five times each, on three different testing events in 1999. [(5)] CMS Ex. 3; SOF 20, 36, 47. This gives rise to the inference that Petitioner and Sitto colluded together to report these results.

Dr. Jay stated in his declaration:

> The lack of variability in results submitted for triglycerides and total cholesterol was particularly unusual since these assays typically show poor reproducibility from laboratory to laboratory when compared to other routinely performed tests. This is particularly the case when tests are performed manually, as was done by Petitioner

> and Sitto, since manually performed methods show poorer reproducibility than automated methods. Based on my education and experience, given the imprecise testing methodology and the range of acceptable results, I would expect to see variation in results on the order of 10 - 20% for these assays. Instead, for cholesterol and triglycerides, the exact same values were reported by both laboratories.

CMS Ex. 11 at 3.

Dr. Jay concluded:

> In my professional opinion, based on my experience in reviewing the results of tests such as are involved here, the chances of both laboratories independently arriving at the same values by happenstance for all five specimens for these two different tests are close to nil. The complete identity of Petitioner's reported results for four analytes, fifteen specimens each, with every result reported by another laboratory in the same geographic area leads to the inescapable conclusion that the results reported to AAB were arrived at through referral, collaboration or both.

CMS Ex. 11 at 3.

Mr. Benson came to the same conclusion in his declaration and emphasized how particularly unlikely such an identity in results would be coming from two different laboratories using manual testing methods. CMS Ex. 12.

The evidence which I have discussed so far, in and of itself, is sufficient to support the conclusion that Petitioner and Sitto colluded in 1999 to produce nearly identical proficiency testing results. However, there exists additional evidence which supports this conclusion.

That additional evidence consists in part of evidence showing that the PT results that Petitioner submitted to AAB were not consistent with Petitioner's own records of its proficiency tests. Such evidence strongly supports a conclusion that Petitioner manipulated its proficiency testing results in order to submit results that conformed to those which were submitted by Sitto. The SOF that the parties submitted to me clearly shows many instances where the PT values shown on Petitioner's laboratory logs and the PT values reported to AAB were different. For example in SOF 24, the difference between Petitioner's laboratory logs and the PT results reported to AAB can be seen in the cholesterol results of the second PT event of 1999. The value for the first vial on the laboratory log was 99 while the result reported to AAB was 109. The value for the second vial on the laboratory log was 212 while the result reported to AAB was 222. The value for the third vial on the laboratory log was 145 while the result reported to AAB was 155. The value for the fourth vial on the laboratory log was 193 while the result reported to AAB

was 202. The value for the fifth vial on the laboratory log was 109 while the result reported to AAB was 120.

Further, the evidence establishes that the opportunity for collusion existed. Both Petitioner and Sitto employed the same individual, Ms. Robin L. Mills. Ms. Mills was identified as Petitioner's technical supervisor. SOF 4. Ms. Mills also worked at Sitto, another laboratory that used the AAB as a PT service during 1999. P. Br. at 6. As the SOF shows, Ms. Mills reported the results of the PT samples in the laboratory logs in most cases. SOF 16, 27, 32, 38, 43. However, in all cases in 1999, Ms. Mills signed the report in the area designated as technical supervisor which was sent to AAB containing the PT values. SOF 17, 23, 28, 33, 39, 44.

Finally, Ms. Mills admitted her wrongdoing in her letter to the State of Michigan dated February 17, 2000 that I mentioned previously as part of the recitation of the SOF the parties submitted to me. SOF 14; ALJ Ex. 6.

Petitioner does not deny any of the facts already discussed, however, it blames the entire situation on Ms. Mills and numerous times calls her a renegade lab technician, a liar and dishonest. Petitioner claims that Dr. Wright was completely unaware of Ms. Mills' actions and characterizes this entire situation as "minor deficiencies related to PT." P. Br. at 4. This argument is unavailing because a laboratory is responsible for the acts of its employees, even when it is unaware of the employees' actions. *Melvin C. Murphy, M.D., P.C.,* DAB CR590 (1999); *Thyroid Specialty Laboratory*, DAB CR501 (1997); *Oakland Medical Group, P.C.,* DAB No. 1755 (2000). In addition, Dr. Wright, as laboratory director, was required to attest to the propriety of the PT. 42 C.F.R. § 493.801(b)(5). It was his responsibility to make sure that the PT was properly done. He failed to do so. Had he simply compared the laboratory logs to the PT values reported out to AAB, he would have been aware of this problem before the results were reported out to the AAB.

Here, Petitioner was guilty of a wholesale failure to comply with PT requirements for all three events of 1999. Identical PT results of 60 out of 60 test results submitted by both Petitioner and Sitto coupled with discrepancies between laboratory worksheets and PT results reported to AAB, the opportunity for collusion and Ms. Mills' letter admitting her wrongdoing, are persuasive evidence of collaboration/collusion between Petitioner and Sitto. Petitioner has offered no evidence at all that rebuts this showing of collusion. Thus, Petitioner was out of compliance with the overall condition for participation in PT set forth in § 493.801. CMS is therefore authorized to impose a principal sanction on the laboratory because it is compliance with one or more CLIA conditions.

Petitioner also argues that it is a victim of a flawed PT system because AAB sent out identical samples to each laboratory and did not scramble the method for identifying the PT samples. I am without authority to address Petitioner's argument regarding the established procedures for testing in this forum; however, by Dr. Wright's attestation to the propriety of the PT, required by 42 C.F.R. §

493.801(b)(5), it was his responsibility to make sure that the PT were properly done and reported out.

3. Petitioner's conduct in colluding with another laboratory as to the testing of proficiency testing samples during 1999 constitutes a violation of the following standards concerning proficiency testing set forth at 42 C.F.R. § 493.801(b): § 493.801(b)(1) (failing to test proficiency testing samples in the same manner as it tests patients' specimens); § 493.801(b)(3) (engaging in inter-laboratory communications pertaining to the results of proficiency testing samples); and § 493.801(b)(4) (intentionally referring proficiency testing samples to another laboratory for analysis).

The standards for the CLIA condition of participation regarding testing of proficiency testing samples set forth at 42 C.F.R. § 493.801 require that a clinical laboratory must test proficiency test samples in the same manner as it tests patients' specimens; must not engage in inter-laboratory communications pertaining to the results of proficiency testing; and must not refer proficiency testing samples to other laboratories for analysis. 42 C.F.R. § 493.801(b)(1), (3), and (4). Petitioner did not comply with these standards during 1999.

Documentary evidence establishes that Petitioner did not integrate the testing of the PT samples with its regular workload and did not test the PT samples the same number of times as patient samples. On February 8, 2000, Barbara Alspaugh, a surveyor employed by the Michigan State survey agency, conducted a complaint survey of Petitioner. CMS Ex. 5. Ms. Alspaugh photocopied pertinent laboratory records and determined that Petitioner failed to test the PT samples the same number of times as it tested patient samples. Mr. Benson also agreed with this conclusion. CMS Ex. 12. In 1999, Petitioner did not normally test patient samples for TSH and Free T4 twice except in circumstances in which there was a concern regarding a test result. SOF 12. In those cases, Petitioner would normally run such patient samples more than once. SOF 12. However, the PT samples for both TSH and Free T4 were each run twice. ALJ Ex. 3. Therefore, Petitioner did not test the PT samples the same number of times as it did the patient samples in violation of 42 C.F.R. § 493.801(b)(2).

The manner in which Petitioner performed proficiency testing - by performing TSH and Free T4 tests twice, a practice it did not normally engage in, and by colluding with an other laboratory to obtain a collectively determined result - clearly was a departure from standard procedures for testing patients' specimens and involved communicating with another laboratory about the results of proficiency testing. This behavior was a violation of 42 C.F.R. § 493.801(b)(1) and

(3).

I also find that Petitioner's conduct constitutes a violation of 42 C.F.R. § 493.801(b)(4) which prohibits intentional referral of testing samples to another laboratory. In doing so, I reject Petitioner's argument that § 493.801(b)(4) is limited to cases where physical transfer of the testing sample is established.

The question of physical transport was addressed by an appellate panel in *Oakland,* DAB No. 1755 (2000). It concluded that, while use of the word "send" in the first sentence of 42 C.F.R. § 493.801(b)(4) indicates a physical transfer, that sentence was not presented as a definition of "intentional referral" but could be read as a separate prohibition.

The appellate panel noted that the second sentence of that section states: "[a]ny laboratory that HCFA determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year."

Therefore, the appellate panel concluded as follows:

> HCFA could reasonably read this sentence as applying to constructive referral as well as actual physical transfer, particularly in circumstances where the facts render physical transfer unnecessary for the outside analysis to take place. As noted by the ALJ in *Blanding Urgent Care Center Laboratory*, DAB CR438 (1996), the dictionary definition of 'refer' includes 'to direct the attention or thoughts of,' and 'to direct to a person, place, etc., for information or anything required.' *Id*. at 21 citing Random House College Dictionary, revised ed. 1980, at 1108.
>
> . . . .
>
> When the regulations are considered as a whole, reading § 493.801(b)(4) to encompass a constructive referral such as what occurred here is a better reading. Limiting the concept of a referral to a physical transfer is inconsistent with the underlying purposes of the condition for certification. Adopting the values achieved in another laboratory (either with or without having done the tests in one's own laboratory) clearly undercuts the general concept that the [proficiency testing] sample be tested in the same way as regular patient specimens in the laboratory are tested so that the results truly measure the proficiency of the laboratory reporting the [proficiency testing] results.

Oakland , DAB No. 1755, at 21 - 22.

Consequently, I conclude that Petitioner violated 42 C.F.R. § 493.801(b)(4). That provision codifies a statutory provision, found at 42 U.S.C. § 263(a)(i)(4),

requiring CMS to revoke Petitioner's CLIA certificate for at least one year.

4. Petitioner's failure to comply with the standards set forth in 42 C.F.R. § 493.801(b) constitutes a failure to comply with the CLIA condition of participation that is stated at 42 C.F.R. § 493.801.

If standard level deficiencies are sufficiently egregious, they will constitute a failure by a laboratory to comply with the overall condition of which the standards are subparts. *Boykansky,* DAB No. 1756, at 18 - 19. That is certainly the case here.

I conclude that Petitioner's violation of the standards for testing of samples in a proficiency testing program set forth in 42 C.F.R. § 493.801(b) constitutes failure to comply with the condition of participation stated at 42 C.F.R. § 493.801. Petitioner's collusion in the performance of proficiency testing was a deliberate effort to frustrate the purpose of proficiency testing, which is to assure that a clinical laboratory establishes its competence through an impartial proficiency testing process. Petitioner's collusion was so egregious as to make its participation in a proficiency testing program meaningless. Petitioner's collusion undermined the integrity of the proficiency testing process for other laboratories.[(6)] Furthermore, such collusion by Petitioner meant that Petitioner was not performing its proficiency tests in the manner that it normally tested patients' specimens, was engaging in inter-laboratory communication about proficiency testing samples, and was referring proficiency testing samples to another laboratory. Because of these reasons, I reject as meritless Petitioner argument that CMS should impose a less onerous sanction than revocation of its CLIA certificate.

5. Petitioner did not have a qualified "technical supervisor" because Ms. Mills did not have a bachelor's or higher level degree from an accredited institution in the appropriate discipline, a violation of 42 C.F.R. § 1449.

Section 1447 establishes conditions to be met by the individual holding the technical supervisor position in a laboratory performing high complexity testing with specific references to qualifications (42 C.F.R. § 493.1449) and technical supervision of laboratory operations and personnel (42 C.F.R. § 1451). According to 42 C.F.R. § 493.1449, the minimum qualifications for a technical supervisor performing high complexity testing are a bachelor of science degree and four years of experience. A review of the personnel records showed that Ms. Mills, who was designated as the technical supervisor, had only an associate degree in applied science in violation of 42 C.F.R. § 493.1449. CMS Ex. 6 at 3; CMS Ex. 10.

6. Petitioner failed to comply with the condition of participation stated at 42 C.F.R. § 493.1441.

42 C.F.R. § 493.1441 requires that a laboratory have a laboratory director who provides management and direction in accord with 42 C.F.R. § 493.1445. One of the responsibilities charged to the laboratory director under that section is the hiring of staff with the appropriate education and experience or training. As mentioned at Finding 5, Ms. Mills did not have the minimum educational requirements for being a technical supervisor. Therefore, the laboratory director failed in discharging the responsibility required of him under 42 C.F.R. § 493.1445.

7. CMS is authorized to impose principal sanctions against Petitioner as remedies for Petitioner's noncompliance with CLIA conditions of participation.

CMS is authorized to impose principal sanctions, including revocation of a laboratory's CLIA certificate, as remedies for a laboratory's failure to comply with one or more CLIA conditions. 42 C.F.R. § 493.1806(a), (b). CMS may impose the additional remedy of cancellation of a laboratory's approval to receive Medicare payment for its services where the laboratory has not complied with one or more CLIA conditions. 42 C.F.R. § 493.1807.

JUDGE

Marion T. Silva

Chief Administrative Law Judge

FOOTNOTES

1. The Health Care Financing Administration (HCFA) has been renamed the Centers for Medicare and Medicaid Services. Reference to either name shall apply to both names.

2. Although the parties stipulated that the TSH results reported to AAB in all five vials were different from those results reported on the laboratory log, I note that the TSH result reported to AAB in vial 3 was the same as the results on the laboratory log. In addition, the TSH result in vial 5 reported to AAB was different from the first result reported on the laboratory log but the same as the second result reported on the laboratory log.

3. Although the parties stipulated that the Free T4 results reported to AAB in all five vials were different from those results reported on the laboratory log, I note that the Free T4 result in vial 4 reported to AAB was different from the first result reported on the laboratory log but the same as the second result reported on the

laboratory log.

4. I note that this last stipulation was at the very end of the SOF after the parties related the facts concerning the Free T4 results in the *third* PT event of 1999. Further, although the parties stipulated this, I note that the exhibits 9, 12, and 13 referred to by the parties are in actuality referring to the *third* PT event of 1999 not the first PT event of 1999. In addition, when these exhibits are examined as to the third PT event of 1999, it is obvious that 22 not 21 results out of 25 endocrinology and chemistry tests reported to AAB by Petitioner were identical to the results reported to AAB by Sitto. I, therefore, believe that the parties mistakenly repeated SOF 20 that referred to the first PT event in this portion of the stipulation of facts that should have referred to the third PT event.

5. CMS Ex. 3 shows a comparison of results submitted to the AAB by both Petitioner and Sitto for all three events in 1999. Both laboratories submitted results for each of five samples for cholesterol, triglycerides, TSH, Free T4 and HDL cholesterol for each event. This totals 75 results submitted from each laboratory. Out of the 75 results submitted to AAB, 68 were identical. However, when the results for HDL cholesterol are not included in this calculation, then 60 out of 60 results that were submitted to AAB by Petitioner and Sitto were identical.

6. As Dr. Jay states:

When, as occurred here, multiple laboratories reports [sic] PT results that were not obtained as required, *i.e.,* through independent testing of samples in the same manner as patient samples are tested, the integrity of the entire proficiency testing program is undermined. This is because proficiency testing is graded on a "curve."

To determine what constitutes a "passing grade" for a particular analyte, results from laboratories using the same methodology and equipment are grouped together. The average value reported determines the range of "correct" responses. Because any collaboration among laboratories necessarily skews the calculation of the average, collaboration or referral corrupts the grading range against which all laboratories in the given group are evaluated.

Consequently, referral and collaboration not only helps insure those who engage in this improper activity obtain a passing grade, regardless of the quality of their proficiency testing; but also may so disrupt the average values against which all other similarly situated laboratories are rated. In addition, false information concerning the reproducibility of the method is displayed to the public who might want to use the information to evaluate the laboratory testing materials that were used.

CMS Ex. 11 at 3 - 4.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	

SUBJECT:

Emil S. Sitto, M.D., & Associates, PLLC,

DATE: July 29, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-01-064
Decision No. **CR935**

DECISION	

DECISION

Emil S. Sitto, M.D., & Associates, PLLC (Petitioner), is a Michigan-based, physician-owned clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq*. In this action, Petitioner appeals the Centers for Medicare & Medicaid Services' (CMS) [(1)] decision to impose sanctions against it. Those sanctions include suspending Petitioner's CLIA certificate, canceling its approval to receive Medicare payment for its services, and revoking its CLIA certificate for at least one year. For the reasons discussed below, I sustain CMS's determination.

I. Background

In November 1999, the American Association of Bioanalysts Proficiency Testing Service (AAB) notified the Michigan Department of Consumer and Industry Services (State Agency) that Petitioner and another Detroit area laboratory, the Dearborn Family Clinic (Dearborn), had submitted duplicate proficiency testing (PT) results. [(2)] CMS Ex. 2. In response, the State Agency asked CMS for authorization to conduct an unannounced complaint survey to determine whether improper PT had occurred. CMS Ex. 6. CMS authorized the survey, and on February 8, 2000, the State Agency conducted its onsite survey. CMS Exs. 7, 8.

Based on the survey findings and its comparative analysis of the PT results submitted by Petitioner and Dearborn, the State Agency concluded that Petitioner was not in compliance with CLIA requirements, including the condition-level requirement set forth at 42 C.F.R. § 493.801, which covers PT. CMS Exs. 9, 10. It submitted its findings to CMS, with the recommendation that Petitioner's CLIA certificate be revoked for one year. CMS Ex. 15. CMS agreed, and, by letter dated September 1, 2000, advised Petitioner that it was not in compliance with CLIA

requirements because improper referral, collaboration, and non-integration occurred during the first, second, and third PT events of 1999. [3] Specifically, the letter advised, the laboratory was out of compliance with 42 C.F.R. §§ 493.801 (proficiency testing), 493.1441 (laboratory director), and 493.1447 (laboratory technical supervisor). The letter also cited statutory and regulatory "Requirements for Certificate," 42 U.S.C. § 263a(d)(1)(E), 42 C.F.R. § 493.61(b)(1), and 42 C.F.R. § 493.801(b)(1)(2)(3), under which the laboratory agrees to treat PT samples in the same manner as materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business. The letter advised that because of the laboratory's failure to meet CLIA conditions, and because of its referral of PT samples to another laboratory for analysis, CMS would suspend Petitioner's CLIA certificate, effective September 24, 2000, cancel its approval to receive Medicare payments for its services, and revoke its CLIA certificate for at least one year. CMS Ex. 19.

Petitioner timely requested a hearing, and the case was assigned to me. CMS has moved for summary disposition, which Petitioner opposes. CMS has filed 29 exhibits, marked as CMS Exs. 1 - 29, plus two declarations with attachments (Jay Declaration and Benson Declaration). In addition to its Response to CMS's Motion for Summary Affirmance

(P. Br.), Petitioner has filed seven exhibits marked P. Exs. 1 - 7. CMS filed a reply brief. In the absence of objection, I admit CMS Exs. 1 - 29, CMS's Declarations, and P. Exs. 1 - 7.

II. Issue

The issue in this case is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving CMS the authority to impose remedies, including canceling Petitioner's approval to receive Medicare payments and revoking Petitioner's CLIA certificate.

III. Statutory and Regulatory Background

In order to ensure the accuracy and reliability of laboratory tests, and thus the health and safety of those tested, CLIA creates a federal certification process for laboratories that perform clinical diagnostic tests on human specimens. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq*.;

See H.R. Rep. No. 899, 100th Cong., 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.A.N. 3828, 3829. To be certified, a laboratory must meet the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. The statute gives the Secretary of Health and Human Services (Secretary) broad enforcement authority, including the authority to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more conditions. Each condition represents a major division of laboratory services or required environmental protections. Standards are specific components of the conditions. *RNA Laboratories*, DAB No. 1820, at 3 (2002).

Laboratories holding CLIA certificates must participate in the PT program outlined in 42 C.F.R. Part 493, Subpart H. Under its provisions, each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493. 42 C.F.R. § 493.801. A laboratory performing high

complexity testing "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which it is certified under CLIA." 42 C.F.R. § 493.803(a).

A laboratory must analyze PT samples in the same manner as patient samples. 42 C.F.R. § 493.801(b). The PT samples must be integrated with the laboratory's regular patient workload and the tests must be performed by the same personnel who routinely do the testing using the laboratory's routine testing method. 42 C.F.R. § 493.801(b)(1). The integration of PT samples must be attested to by the laboratory director and the individual who performs the testing. PT samples must be tested the same number of times as routine patient samples. 42 C.F.R. § 493.801(b)(2). Records documenting each step taken in the testing of PT samples are required. 42 C.F.R. § 493.801(b)(5).

A laboratory may not engage in inter-laboratory communications pertaining to PT results until after the due date by which a laboratory must report its results to the PT program. 42 C.F.R. § 493.801(b)(3). It must not refer PT samples or portions of PT samples to another laboratory for any analysis that it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i). If a laboratory intentionally refers PT samples to another laboratory for analysis, its CLIA certificate must be revoked for at least one year. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i)(4).

CMS or its designee (such as the State Agency) conducts validation inspections to determine compliance with CLIA requirements. 42 C.F.R. § 493.1780(a). A laboratory's failure to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of its CLIA certificate. *RNA Laboratories,* at 3; *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the State. 42 C.F.R. § 493.1806.

A laboratory is entitled to a hearing before an administrative law judge (ALJ) to contest the imposition of CLIA remedies. The CLIA regulations incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E. 42 C.F.R. § 493.1844(A)(2) and (3). CMS has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA condition. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any prima facie case of noncompliance that is established by CMS. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611, *aff'd*, Hillman Rehabilitation Center v. HHS, No. 98-3789 (GEV), slip op. At 25 (D.N.J. May 13, 1999) (1997).

IV. Discussion

1. Summary judgment is appropriate where, as here, Petitioner has not demonstrated any dispute over genuine issues of material fact.

Summary disposition is appropriate where there are no disputed issues of material fact and where the only questions that must be decided involve either questions of law or the application of the law to the undisputed facts. *Edison Medical Laboratories, Inc.*, at 19. A party opposing summary disposition must allege facts which, if true, would refute the facts relied upon by the moving party. *See. e.g.*. Fed. R. Civ. P.

56(c); *Garden City Medical Center,* DAB No. 1763 (2001); *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1997) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony). The party may not simply state that it disputes the allegations of fact in order to avoid the entry of summary judgment; it must describe the asserted facts credibly in order to establish a dispute.

CMS argues that it is entitled to judgment as a matter of law because no material facts are in dispute. Although Petitioner alludes generally to the "testimony of the laboratory technician who actually performed the tests," it provides no declarations from any laboratory employees to challenge CMS's evidence, nor offers-of-proof suggesting what that testimony might be. *See Oakland Medical Group, P.C.*, DAB No. 1755 at 9 (2000) (Summary judgment deemed appropriate where Petitioner did not supply documents or affidavits to support its defense). Indeed, Petitioner does not specifically challenge the factual underpinnings of CMS's case, but argues that CMS's evidence (the Jay and Benson Declarations and the Mills letter (CMS Ex. 14)) "does not support the conclusion" that the proficiency testing samples were not integrated into regular patient testing and that patient samples were not tested the same number of times as PT samples. Petitioner Brief (P. Br.) at 2. Petitioner asserts that "it is not altogether unreasonable to determine from [the Mills letter, CMS Ex. 14] that Ms. Mills was indeed properly performing PT at any laboratory at which she worked," [(4)] and, "the reasonable assumption," based on the worksheets, "is that the proficiency testing and patient sampling were done in the same manner." P. Br. at 4. The parties thus look at the same evidence and argue different conclusions. Under those circumstances, summary judgment is appropriate.

2. During 1999, Petitioner colluded with another laboratory in the testing of proficiency samples in violation of 42 CFR § 493.801.

As noted above, clinical laboratories must enroll in PT programs that meet defined criteria. 42 C.F.R. § 493.801. Each participating laboratory must test its samples independently, as if they were patient specimens, and must report the results of its tests to an approved testing service. In 1999, Petitioner and Dearborn participated in the AAB's PT program. CMS Exs. 3 - 6, 27 - 29. AAB mailed samples to participating laboratories three times per year, and the laboratories were required to test the samples for analytes for which they did patient testing. Both Petitioner and Dearborn tested for cholesterol, triglycerides, thyroid stimulating hormone (TSH), and free thyroxine (FT4). CMS Exs. 3 - 5, 27 - 29. They were required to test five samples for each analyte. *Id*. For the three 1999 PT events (March, June, and October), Petitioner and Dearborn reported identical scores for all five samples of four analytes. CMS Ex. 6. The undisputed evidence thus establishes that the two laboratories submitted identical results for 60 out of 60 tests (4 analytes tested 5 times each, on 3 occasions).

During the time of the three 1999 PT events, Emil S. Sitto, M.D., was the laboratory director, Robin L. Mills was the technical supervisor, and Pattye Korbal was employed by Petitioner to perform additional testing. CMS Exs. 1, 3 - 5. Robin Mills was also employed at Dearborn as a technical supervisor (high complexity). The same person was thus responsible for performing or supervising high complexity routine chemistry and endocrinology testing for both laboratories. CMS Exs. 3 - 5, 22, 25, 27 - 29.

Both laboratories used manual techniques to measure and compare the samples. Reagents and samples were diluted, measured, and introduced into test tubes by hand, incubated for periods timed by the individual performing the test, and individually analyzed. According to the unchallenged opinions of CMS's experts, the likelihood of two laboratories using these techniques arriving at the same value for a proficiency test result is very low because of the variables involved in the testing processes. In fact, even if one person twice performed the same test on the same sample in the same laboratory with the same equipment, the test results would not be duplicated. Benson Declaration at 4 - 5. According to Dr. Dennis W. Jay, Ph.D., Technical Director of the AAB Proficiency Testing Service, if the same technician repeated the test, one "would expect to see variation on the order of 10-20%." Jay Declaration, at 3.[(5)]

Petitioner's worksheets more than bear this out. For example, for the first testing event (March 1999), the worksheets show that Petitioner tested each sample twice, and, with one exception, obtained two different test results for each sample:

		Test Results
Sample 1	cholesterol	152 and 150
	HDL	26 and 28
	triglycerides	166 and 178
Sample 2	cholesterol	144 and 141
	HDL	34 and 34
	triglycerides	121 and 122
Sample 3	cholesterol	150 and 154
	HDL	44 and 28
	triglycerides	118 and 116
Sample 4	cholesterol	197 and 208
	HDL	30 and 32
	triglycerides	143 and 132
Sample 5	cholesterol	185 and 191
	HDL	40 and 50
	triglycerides	132 and 133

CMS Ex. 11, at 1. [(6)]

Yet. Petitioner and Dearborn reported identical scores for all five samples of four analytes. CMS's experts,

Dennis W. Jay, Ph.D., and Richard J. Benson, CLS, MT, Chief, Laboratory Improvement Section, Bureau of Health Systems, of the State Agency, are well-versed in the areas of clinical laboratory testing and PT, and the Departmental Appeals Board has repeatedly recognized Dr. Jay's expertise. *See RNA Laboratories,* at 7; *Oakland* at 14-15; *Boykansky,* at 10. [(7)] I find these experts to be well-qualified and their opinions to be persuasive. Their conclusions were based on their training and experience in their respective fields and on the evidence that pertained to the specific proficiency tests at issue in this case. According to Dr. Jay, the chances of two laboratories independently arriving at the same values by happenstance for all five specimens for two tests (triglycerides and total cholesterol) "are close to nil."

> The complete identity of Petitioner's reported results for four analytes, fifteen specimens each, with every result reported by another laboratory in the same geographic area leads to the inescapable conclusion that the results that were reported to AAB were arrived at through referral, collaboration, or both.

Jay Declaration, at 3. Mr. Benson came to the same "inescapable" conclusion - that the results reported to AAB "were arrived at through some sort of collaborative process." Benson Declaration, at 4.

In *RNA Laboratories*, ALJ Kessel characterized as "powerful circumstantial proof that Petitioners engaged in prohibited communications," evidence that for one testing event, the petitioner and another laboratory reported identical results for the nine analytes in five samples provided by AAB. *RNA Laboratories,* at 6. An appellate panel of the Board agreed, ruling "that the logical inference to be drawn from the evidence [of identical results] was that Petitioners had collaborated in obtaining or reporting the results." *RNA Laboratories* at 8. I agree, and, based on this evidence, I conclude that CMS has met its initial burden of establishing a prima facie case that Petitioner and Dearborn colluded.

Other uncontested evidence bolsters CMS's case. That Ms. Mills was the technical supervisor for both laboratories, certainly creates a better-than-ordinary opportunity for collusion. She signed the reports submitted to AAB, containing the alleged PT results. CMS Exs. 3 - 5. Nor does she deny her improper conduct. In a letter dated February 17, 2000, she concedes that, as a consultant for the Sitto and Dearborn laboratories, she "used improper procedures for the proficiency results." CMS Ex. 14.

Further, Petitioner compounded its violation by not even reporting to AAB many of the PT scores it actually obtained, but instead submitting an average of its two scores. In explaining that she "used improper procedures," Ms. Mills admits to "using an average." CMS Ex. 14. The written record supports her statement. For example, the chart below compares the PT results shown in Ms. Mills' March 1999 worksheets (CMS Ex. 11) with the scores submitted to AAB. Only occasionally does the submitted score coincide with any of the test results. By examining the scores recorded in the Dearborn laboratory log (CMS Ex. 26), one can see the pattern of "averaging" the scores.

		Test Results	Submitted to AAB	Dearborn Log
Sample 4	cholesterol	162 and 166	164	144
	HDL	26 and 28	24	22

	triglycerides	166 and 178	166	145
	TSH [8]	3.54 and 3.7	3.7	3.4
Sample 2	cholesterol	144 and 141	132	126
	HDL	34 and 34	31	27
	triglycerides	121 and 122	121	99
	TSH	2.6 and 3.1	3.2	3.2
Sample 3	cholesterol	150 and 154	143	143
	HDL	44 and 28	39	34
	triglycerides	118 and 116	110	92
	TSH	2.2 and 2.1	2.8	3.4
Sample 4	cholesterol	197 and 208	196	187
	HDL	30 and 32	27	23
	triglycerides	143 and 132	141	112
	TSH	5.4 and 5.6	7.0	6.2
Sample 5	cholesterol	185 and 191	185	167
	HDL	40 and 50	35	30
	triglycerides	132 and 133	117	94

Compare CMS Ex. 3 with CMS Ex. 11. Absent any other credible explanation, such evidence leads to the inescapable conclusion that Petitioner and Dearborn colluded to manipulate their PT results.

Petitioner points out, accurately, that CMS has not demonstrated the actual physical transport of the PT samples from one laboratory to another. According to Petitioner, the statute is not violated absent the actual physical transport of a sample from one laboratory to another for analysis. P. Br. at 6-8, citing the ALJ decision in *Southfield Medical Clinic,* DAB CR667 (2000). This argument was fully addressed and rejected in *Oakland* and *Boykansky*, where the Board reasonably inferred that the "intentional referral" language of 42 C.F.R. § 493.801(b)(4) applies to constructive referral as well as an actual physical transfer, particularly where the facts render physical transfer unnecessary for the outside analysis to take place.

> Limiting the concept of a referral to a physical referral is inconsistent with the underlying purposes of the condition for certification. Adopting the values achieved in another laboratory (either with or without having done the tests in

> one's own laboratory) clearly undercuts the general concept that the PT sample be tested in the same way as regular patient specimens in the laboratory are tested so that the results truly measure the proficiency of the laboratory in reporting the PT results.

Boykansky, at 14, *quoting Oakland,* at 17-18.

Thus, the statute does not require evidence of actual physical transport. CMS has met its burden of establishing a prima facie case of collusion, and Petitioner has provided essentially no evidence to refute CMS's compelling case.

3. Petitioner failed to test the PT samples in the same manner as it tested patients' specimens, as required by 42 C.F.R. §§ 493.801 and 493.61.

Petitioner asserts that the worksheets available from Petitioner's laboratory indicate that PT was "done with the regular patient workload and it is impossible to determine whether patient samples were tested the same number of times as proficiency samples." P. Br. at 2. I do not see how the worksheets show that the PT was performed "with the regular patient workload." The PT results are recorded together as a group, and the patient samples are recorded together as a group, separate from the PT results, although sometimes on the same sheet.

Even if I accept that Petitioner performed the PT "with the regular patient workload," that fact does not, by itself, satisfy the regulatory requirement that the samples be tested "in the same manner" as patient specimens. CMS correctly asserts that testing the PT samples twice, but patient specimens only once, violates the "same manner" requirement. Because the regulations require record-keeping, it should not be impossible to determine how many times a sample is tested. 42 C.F.R. § 493.801(b)(5). The worksheets confirm the surveyor finding that Petitioner ran tests of the PT samples more than once. As discussed above, they demonstrate two scores for each. *See, e.g.,* CMS Ex. 11, at 1. I see no evidence that patient samples were tested twice. For each patient sample, the worksheet indicates only one value per type of test. *See* CMS Exs. 9, at 1-3; 11, at 4.

Petitioner seemingly acknowledges that it tested the PT samples twice, but claims that "many laboratories test proficiency samples twice because they generally provide abnormal results," and that "[l]aboratories almost without exception perform a second test on a patient specimen if the result is abnormal." P. Br. at 2-3. I agree with CMS that the regulations simply do not allow a laboratory to test its PT samples twice if it routinely tests its patient samples only once. 42 C.F.R. § 493.801(b)(2). Moreover, comparing the PT sample results with the patient specimen test results belies Petitioner's claim. For example, a PT sample for cholesterol yielded a finding of 152. The test was re-run, yielding a finding of 150. However, when a patient specimen yielded the same cholesterol level of 152, no evidence suggests that the test was repeated. *Compare* CMS Ex. 11, at 1(specimen 1) with CMS Ex. 11, at 4 (patient line 5). Similarly, an HDL PT result of 34 was repeated, again yielding 34. CMS Ex. 11, at 1 (sample 2). But patient specimens yielding the same result (34) were not repeated. *See* CMS Ex. 11, at 4. And when PT specimen 4 yielded an HDL score of 30, the test was repeated, but patient specimen scores of 30 were not repeated. *Compare* CMS Ex. 11, at 1 with CMS Ex. 11, at 4.

Finally, Petitioner did not even submit to AAB any of the PT scores it actually obtained, but instead relied on an average of its and Dearborn's test results (see above). Thus, each proficiency sample was tested multiple times in two different laboratories, and a composite score was arrived at and submitted. Such procedures could not be considered testing "in the same manner" as the patients' specimen testing in the ordinary course of business.

4. Petitioner's deficiencies were condition-level.

Petitioner argues that, under 42 C.F.R. § 493.801(b)(3) and (4), an inter-laboratory communication, as opposed to the physical transfer of samples, is, at most, a standard-level deficiency not sanctionable by revocation. As discussed above, Petitioner's conduct falls within the "intentional referral" language of 42 C.F.R. § 493.801(b)(4). The statute and regulations therefore mandate revocation of its CLIA certificate for at least one year. 42 U.S.C. § 263(a)(i)(4).

Moreover, as the Board ruled in *Oakland* and *Boykansky*, cases involving laboratories which submitted identical PT results, "[i]t is indisputable that a laboratory can be so pervasively noncompliant with standards as to have failed to have complied with the overall condition." Where Petitioner's collusion was "so egregious as to make its participation in proficiency testing meaningless," CMS may appropriately find it out of compliance with conditions of participation, and may impose principal sanctions. *Boykansky,* at 18 - 19, *citing Oakland,* at 23.

Here, in an apparent effort to frustrate the purpose of PT, Petitioner colluded with another laboratory, and submitted essentially fabricated PT results, rendering meaningless its participation in the PT program. CMS therefore appropriately determined the Petitioner failed to comply with the condition of participation stated at 42 C.F.R. § 493.801. [(9)] CMS is authorized to impose principal sanctions, including revocation of a laboratory's CLIA certificate, as remedies for a laboratory's failure to comply with one or more CLIA conditions. 42 C.F.R. § 493.1806(a), (b). CMS may impose the additional remedy of cancellation of a laboratory's approval to receive Medicare payment for its services where the laboratory has not complied with one or more CLIA conditions. 42 C.F.R. § 493.1807.

5. Petitioner did not comply with the requirements of 42 C.F.R. §§ 493.1441 (laboratory director) or 493.1447 (technical supervisor).

Section 493.1441 of 42 C.F.R. requires that a laboratory have a qualified laboratory director who provides management and direction in accordance with 42 C.F.R. § 493.1445. Section 493.1445 sets out the director's specific responsibilities, which encompass the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures and report test results promptly, accurately, and proficiently, and for assuring compliance with regulations. As part of his specific responsibilities, the director must ensure that the laboratory is enrolled in an approved PT program, and that the testing samples are tested as required, and he must attest to the propriety of the PT. 42 C.F.R. §§ 493.801(b)(5), 493.1445(e)(4). Similarly, the regulations require that a qualified laboratory supervisor provide technical supervision in accordance with 42 C.F.R. § 493.1451. The laboratory supervisor is also responsible for the laboratory's participation in an approved PT program. 42

C.F.R. § 493.1451(b)(3).

Inasmuch as neither the laboratory director nor the supervisor ensured that the PT samples were tested in accordance with regulatory requirements, Petitioner did not comply with the regulations governing laboratory director and supervisor, and, given the egregiousness of its conduct, these are also condition-level deficiencies.

Without specifically denying his responsibility, Petitioner nonetheless notes that no evidence suggests Dr. Sitto "had any knowledge whatsoever" of the alleged irregularities, that he terminated his relationship with the responsible parties when he became aware of the irregularities, and that he subsequently sought to change his laboratory's CLIA certificate to a CLIA certificate of waiver, which does not require PT. P. Br. at 5. It is well-settled that the laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of testing personnel. 42 C.F.R. § 493.1445; *Boykansky,* at 17; *Oakland, at* 20-22.

V. Conclusion

For the reasons discussed above, I sustain CMS's determination to suspend Petitioner's CLIA certificate, cancel its approval to receive Medicare payment for its services, and revoke its CLIA certificate for at least one year.

JUDGE	

Carolyn Cozad Hughes

Administrative Law Judge

FOOTNOTES	

1. The Health Care Financing Administration (HCFA) has been renamed the Centers for Medicare & Medicaid Services. Reference to either name shall apply to both names.

2. CMS also imposed sanctions against Dearborn, which appealed, and a decision in that matter, consistent with my decision here, was recently issued. *Dearborn Family Clinic*, DAB CR919 (2002).

3. AAB refers to each mailing of samples to laboratories for PT as an "event." Under the AAB program, there are three testing events per year. *See Discussion, Infra*.

4. As discussed *infra*, Ms. Mills served as technical supervisor for both Petitioner and Dearborn. In stark contrast to Petitioner's assertion here, Dearborn characterized Ms. Mills as "a renegade laboratory technician, a liar, and dishonest." *Dearborn* at 13.

5. For this reason, AAB accepts results for each sample from within a broad range. Benson Declaration at 5; Jay Declaration, at 3. The acceptable range is determined by applying a formula that includes averaging the results reported by all participating laboratories that use the same type of equipment and the same methodology. Jay Declaration, at 4. As a result, any collusion among participating laboratories that involves reporting similar or identical values would tend to narrow the overall range of acceptable results for that testing event. *Id*.

6. Further, as discussed below, these specific test results were not the numbers reported to AAB. *See* CMS Ex. 3.

7. Dr. Jay is a Board-certified clinical chemist. He has a Ph.D. in clinical chemistry, and completed a two-year postdoctoral fellowship in clinical chemistry at the Medical College of Virginia. He has held his current position since 1998. Prior to that, he was a clinical chemist with the Central Texas Veterans Health Care System, and held various academic posts, including assistant professor with the Department of Pathology and Laboratory Medicine at Texas A&M University College of Medicine. Jay Declaration. Mr. Benson has a B.S. degree, with a major in medical technology, and is a certified medical technologist and certified clinical laboratory scientist. He is a former president of the Michigan Society for Clinical Laboratory Science. Benson Declaration.

8. CMS Ex. 11 at 2

9. I note that Petitioner's collusion also undermines the integrity of the PT process for other laboratories. As Dr. Jay noted, PT is "graded on a 'curve.'" Results from laboratories using the same methodology and equipment are grouped together, and the average value reported determines the range of "correct" responses. Collaboration among laboratories necessarily skews the calculation of the average. So, when multiple laboratories report erroneous results, the integrity of the entire PT program is undermined. Jay Declaration, at 3-4.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	

SUBJECT:

Medical Service Laboratories,

DATE: July 30, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-00-796
Decision No. **CR936**

DECISION	

DECISION

Summary judgment is entered affirming the determination of Respondent, the Centers for Medicare & Medicaid Services (CMS) [(1)] suspending the CLIA[(2)] certificate of Petitioner, Medical Service Laboratories, due to a finding of immediate jeopardy. Petitioner's certificate is revoked pursuant to 42 C.F.R. § 493.1844(d)(4)(ii) as I have affirmed the suspension.

By operation of law, Robert L. Gillett, the owner/operator of Petitioner, and Adolfo Boye, M.D., the laboratory director of Petitioner, are prohibited from owning, operating, or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) due to the revocation of Petitioner's CLIA certificate. The two-year prohibition runs from the date of the revocation of the laboratory's certificate pursuant to 42 U.S.C. § 263a(i)(3).

The effective date of revocation is the date of my decision affirming the CMS suspension action in this case. 42 C.F.R. § 493.1844(d)(2) and (4)(ii). Summary judgment is appropriate as there are no genuine issues of material fact in dispute and the controlling issues may be resolved as a matter of law.

PROCEDURAL HISTORY

This case is before me pursuant to a request for hearing filed by Petitioner on July 31, 2000, in accordance with 42 C.F.R. § 498.40.

On May 2, 2000, the Texas Department of Health (TDH) initiated a complaint investigation of Petitioner which concluded with its report or statement of deficiencies (SOD) dated May 17, 2000. CMS Exs. 2, 7. [(3)] TDH reported that eight condition-level deficiencies were found at Petitioner. Based upon the TDH report and Petitioner's compliance history, CMS determined that Petitioner did not meet the requirements to perform testing under CLIA. CMS further declared that the deficiencies found on the May 2000-survey constituted immediate jeopardy to patients served by Petitioner. CMS elected to impose principal sanctions including cancellation of approval to receive Medicare payments effective June 9, 2000; suspension of Petitioner's CLIA certificate effective June 9, 2000; and revocation of Petitioner's CLIA certificate if approved by an ALJ in the event of a timely appeal. Petitioner's laboratory director, Adolfo Boye, M.D., and owner, Robert L. Gillett, were notified of the CMS actions by letter dated June 2, 2000. CMS Ex. 1.

Petitioner filed a request for hearing on July 31, 2000. The case was assigned to Chief Judge Silva on August 30, 2000, for hearing and decision. On November 5, 2001, the case was reassigned to me. Respondent filed its motion for summary judgment and supporting brief on October 25, 2001 (R. Brief). Petitioner filed its response to the Respondent's motion on November 19, 2001 (P. Response). Respondent filed a reply brief on November 28, 2001.

FINDINGS OF FACT

1. On May 2, 2000, Petitioner was certified under CLIA to do a limited range of moderate and high complexity human testing. [(4)] CMS Exs. 2, 7.

2. On May 2 and 3, 2000, the TDH conducted a complaint survey of Petitioner and cited Petitioner for eight condition-level deficiencies. CMS Exs. 2, 7.

3. Robert Gillett was the sole owner and operator of Petitioner before and after the survey of May 2000. CMS Exs. 25, 26.

4. Adolfo Boye, M.D. was the laboratory director of Petitioner before and after the survey of May 2000. CMS Ex. 1.

5. On about April 26, 2000, Petitioner began moderate complexity and high complexity testing of human samples. CMS Ex. 2; Affidavit of Robert Gillett, para. 5.

6. In April 2000, Petitioner made inquiry and completed forms to enroll in proficiency testing to begin in May 2000 for hematology and June 2000 for chemistry. Affidavit of Robert Gillett, ¶ 4.

7. Petitioner never enrolled in proficiency testing. Affidavit of Robert Gillett, ¶ 7.

CONCLUSIONS OF LAW

1. Summary judgment is appropriate as the material facts are not in dispute and this case can be decided as a matter of law.

2. Title 42 C.F.R. § 493.801 establishes the condition-level requirement that a laboratory conducting moderate and high complexity testing must enroll in a proficiency testing program approved by the Secretary.

3. Petitioner began conducting human testing at a moderate and high level of complexity on April 26, 2000, without enrolling in an approved proficiency testing program in violation of 42 C.F.R. § 493.801.

4. The CMS declaration that the condition level violation by Petitioner constituted immediate jeopardy for its patients is not subject to review. 42 C.F.R. § 493.1844(c)(6).

5. Cancellation of approval to receive Medicare payments is mandatory upon suspension of the Petitioner's CLIA certificate. 42 C.F.R. § 493.1842(a)(1).

6. Suspension and revocation of Petitioner's CLIA certificate is supported by the finding of a condition-level deficiency. 42 C.F.R. § 493.1806(a) and (b).

7. The owner and operator of Petitioner is barred from owning, operating, or directing another CLIA certified laboratory for a period of two years by operation of law. 42 U.S.C. § 263a(i)(3).

8. The laboratory director of Petitioner is barred from owning, operating, or directing another CLIA certified laboratory for a period of two years by operation of law. 42 U.S.C. § 263a(i)(3).

9. It is not necessary to review the other alleged deficiencies as the revocation of Petitioner's CLIA certificate is fully supported by the one condition-level deficiency, the existence of which is resolved as a matter of law.

ISSUES PRESENTED

1.a. Whether 42 C.F.R. §

493.801 establishes the condition-level requirement that a laboratory conducting moderate and high complexity testing must enroll in a proficiency testing program approved by the Secretary.

b. Whether Petitioner was in violation of a condition-level requirement for a CLIA certified laboratory.

2. Whether Petitioner's CLIA certificate must be revoked.

3.a. Whether Petitioner's owner/operator is barred from owning, operating or directing another CLIA certified laboratory for two years.

b. Whether Petitioner's laboratory director is barred from owning, operating or directing another CLIA certified laboratory for two years.

GOVERNING LAW

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1); 42 C.F.R. § 493.1 *et seq*. Pursuant to CLIA the Secretary of Health and Human Services (Secretary) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. § 263a(f)

and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to achieve compliance. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

The regulations specify "conditions" and "standards" that laboratories must meet and maintain in order to obtain and retain their CLIA certification and their eligibility to receive Medicare or Medicaid reimbursement. Title 42 C.F.R. § 493.801, the regulatory provisions that is key to this decision provides an example of the regulatory scheme. Section 493.801 includes the condition-level requirement that a laboratory must enroll in a proficiency testing (PT) program and test the PT program specimens in the same manner as it tests patient specimens. Section 493.801 also includes two standard-level requirements that impose additional and more detailed requirements regarding enrollment and testing.

Pursuant to the enforcement provisions, CMS may impose principal or alternative sanctions when it finds that a laboratory has a "condition-level" deficiency. 42 C.F.R. § 493.1804(b)(2). Principal sanctions include suspension, limitation, or revocation of a CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions include a directed plan of correction, state on-site monitoring, and civil money penalty. 42 C.F.R. § 493.1806(c). Cancellation and or suspension of Medicare payments are also authorized. 42 C.F.R. § 493.1807.

The phrase "immediate jeopardy" is defined at 42 C.F.R. § 493.2 to mean:

> (A) situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public.

If, on inspection, a laboratory is found to have condition-level deficiencies that pose immediate jeopardy, CMS must require

immediate action to remove the jeopardy and may impose alternative sanctions to assist. If the deficiencies remain on revisit, CMS may suspend or limit and later revoke the laboratory's CLIA certificate. CMS is also delegated authority to bring a civil suit for injunction against a laboratory in specified circumstances where there is immediate jeopardy. 42 C.F.R. § 493.1812. Condition-level deficiencies that do not constitute immediate jeopardy and standard-level deficiencies that do not rise to condition level are treated differently and the laboratory is generally accorded 12 months in which to make corrections. 42 C.F.R. §§ 493.1814 - 1816.

Eight condition-level deficiencies are alleged in this case. However, as CMS argues, if on review the existence of even one condition-level deficiency is found, then the CMS suspension of Petitioner's certificate must be upheld. CMS asserts there are no disputed facts as to a violation of 42 C.F.R. § 493.801 and the existence of the violation may be resolved as a matter of law. Title 42 C.F.R. § 493.801 establishes the condition-level requirement that:

> Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients'specimens.

If a condition-level violation is found and the laboratories CLIA certificate is revoked, the laboratories owner, operator, and laboratory director are subject to a two-year statutory ban on owning, operating, or directing a laboratory. CLIA provides the following with respect to the owners and operators of non-compliant laboratories in addition to sanctions which may be imposed directly against a laboratory:

> (3) Ineligibility to own or operate laboratories after revocation.
>
> 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.

42 U.S.C. § 263a(i)(3). This statutory disability arises by operation of

law immediately upon revocation of a laboratory's certification. No action by the Secretary is required, no discretion is granted the Secretary, and there is no appeal. The Secretary's regulations specify that a "laboratory director" is considered an "operator" of a laboratory:

> *Operator* means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes- (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2 (emphasis in original). This definition of "operator" was part of the final regulations that became effective September 1, 1992. The source of the provision that a "laboratory director" is an operator is reflected at 57 Fed. Reg. 7226 (1992) in the discussion of the public comments related to the proposed regulation:

> Comment: Four commenters voiced the opinion that if a laboratory's CLIA certificate has been revoked within the preceding two-year period, [CMS] should initiate adverse action, not only against its owner or operator, but also against those directors involved in the operation of the laboratory.
> Response: We have added a definition of "operator" which clarifies that directors of laboratories who are involved in their overall operation, are knowledgeable about the workings of the entire facility, and who bear primary responsibility for the safety and reliability of laboratory testing, are considered operators for the purpose of this regulation. It is our belief, consistent with the direction given by Congress in section 353(i)(3) of the PHS Act, that any laboratory director who meets the criteria as an operator should not be permitted to operate or own any laboratory within 2 years of operating a laboratory which has had its CLIA certificate revoked, as set forth at § 493.1840(a)(8) of these regulations.

CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate

may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory. . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an Administrative Law Judge (ALJ). 42 C.F.R. § 493.1844(a). CMS's decision to suspend, limit, or revoke a laboratory's certificate due to noncompliance with CLIA requirements is an initial determination that is subject to appeal and a hearing by an ALJ. 42 C.F.R. § 494.1844(c)(6). However, the CMS determination that condition-level deficiencies poses immediate jeopardy is not subject to appeal or review. 42 C.F.R. § 493.1844(b)(1). Generally, the suspension, limitation, or revocation of a CLIA certificate is not effective if appealed, until the ALJ makes a decision. However, when CMS declares immediate jeopardy, there is no delay in the suspension or limitation of the offending laboratory's CLIA certificate. 42 C.F.R. § 493.1844(d)(2). If an ALJ upholds a suspension imposed due to immediate jeopardy, that suspension becomes a revocation. 42 C.F.R. § 493.1844(d)(4)(ii).

On ALJ review, CMS bears the burden of producing evidence sufficient to establish a prima facie case. CMS must set forth the basis for its determination with sufficient specificity for a petitioner to respond and come forward with evidence related to the disputed findings. The evidence set forth by CMS must be sufficient to establish a prima facie case that CMS had a legally sufficient basis to impose a remedy. In order for a petitioner to prevail, the petitioner must then prove by a preponderance of the evidence on the record as a whole that it was in substantial compliance with the relevant statutory and regulatory provisions. *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999); *Edison Medical Laboratories, Inc.,* DAB No. 1713 (1999).

Summary judgment is appropriate and no hearing is required where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party. *See e.g.*, Fed. R. Civ. P. 56(c); *Garden City Medical Clinic*, DAB No. 1763 (2001); *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 2 (1997) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony); *see also, New Millennium CMHC*, DAB CR672 (2000); *New Life Plus Center*, DAB

CR700 (2000).

DISCUSSION

> 1. a. 42 C.F.R. § 493.801 establishes the condition-level requirement that a laboratory conducting moderate and high complexity testing must enroll in a proficiency testing program approved by the Secretary.

CMS alleges that eight condition-level deficiencies were found at Petitioner during the May 2000-survey. However, CMS argues that if the existence of even one condition-level deficiency is found on review, then the CMS suspension of Petitioner's certificate must be upheld. CMS asserts there are no disputed facts as to a violation of 42 C.F.R. § 493.801 and the existence of the violation may be resolved as a matter of law.

Title 42 C.F.R. § 493.801 establishes the condition-level requirement that:

> Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens.
>
> b. Petitioner was in violation of a condition-level requirement for a CLIA certified laboratory.

Petitioner's owner/operator has admitted in this case that the Petitioner began testing human samples on April 26, 2000. Affidavit of Robert Gillett, ¶ 5. He further admits that Petitioner made inquires and completed forms for PT programs in hematology and chemistry, but Petitioner did not "fully enroll." Affidavit of Robert Gillett, ¶ 7. Construing Mr. Gillett's statement that Petitioner did not "fully enroll" in a light most favorable to Petitioner, I find that there is only one possible meaning and that is that Petitioner did not complete the enrollment process and as a result it was not enrolled in a PT program at the time of the May 2000-survey. Furthermore, Petitioner makes no allegation and offers no evidence that it remedied the deficiency by enrolling sometime after the May 2000-survey. Petitioner does argue that it made arrangements to

participate in PT, but it does not specify what those arrangements were. Petitioner indicates that schedules for PT "were to be consummated by Petitioner during the week beginning May 2, 2000," but it "did not fully enroll" based on the inspection on May 2, 2000. P.

Response, at 3. I take Petitioner's point to be that it planned to enroll in PT, had completed the forms and only needed to send the check, but did not do so because it became apparent that the surveyors were going to shut down the Petitioner. While this may be a reasonable explanation for Petitioner's failure to enroll, I do not find that it satisfies the requirements of the regulation.

Petitioner argues that 42 C.F.R. § 493.801 does not specify that testing can only be performed after enrolling in a PT program. I agree with Petitioner that the regulation does not state the requirement in Petitioner's terms. However, the plan language of the regulation is that "(e)ach laboratory must enroll," which is clearly mandatory language. Further, the second sentence of the regulation requires enrollment in an approved program for each specialty and subspecialty for which the laboratory "seeks certification," which clearly implies that enrollment must be accomplished prior to or at the time of issuance of the CLIA certificate.

Further, it is accepted that the Congressional purpose was to ensure the public health by regulating laboratories to ensure quality. If laboratories are allowed to test and report, without being enrolled and participating in an approved PT program, the Congressional intent would be frustrated as there would be no way to ensure test quality. The Secretary's regulations must be construed consistent with Congressional intent and consistent with fulfilling the Congressional purpose. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 n.9 (1984); *Sullivan v. Stoop*, 496 U.S. 478, 493 (1990). There is also a history of strict enforcement to achieve the Congressional purpose. Failure by a laboratory to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of a laboratory's CLIA certificate. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997).

Hence, consistent with the plain language of the regulation and Congressional intent, I conclude that the only reasonable interpretation of the regulation is that a laboratory must enroll in the appropriate PT program at certification and before beginning human testing. (5)

2. Whether Petitioner's CLIA certificate must be revoked.

Petitioner's owner/operator has admitted that Petitioner was not actually

enrolled in a PT program when human testing began on April 26, 2002. Petitioner was not enrolled in an approved PT program during the May 2000-survey. Petitioner has made no allegation that it enrolled in an approved PT program at anytime after the survey. I have resolved as a matter of law, that 42 C.F.R. § 493.801 requires a Petitioner to enroll in an approved PT program prior to commencing human testing. Therefore, Petitioner has violated 42 C.F.R. § 493.801 by failing to be enrolled - a condition-level violation. CMS is authorized to suspend or limit a CLIA certificate based upon a condition-level violation.

In this case CMS declared that Petitioner's deficiencies posed immediate jeopardy to its patients. I may not look behind the declaration of immediate jeopardy. However, as there is a basis for suspension in this case and a declaration of immediate jeopardy has been made, suspension with revocation upon issuance of this decision is clearly supported in this case.

> 3. a. Whether Petitioner's owner/operator is barred from owning, operating or directing another CLIA certified laboratory for two years.

CLIA provides that "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." 42 U.S.C. § 263a(i)(3). This statutory disability arises by operation of law immediately upon revocation of a laboratory's certification. The statute requires no action by the Secretary, no discretion is granted the Secretary, and there is no appeal.

> b. Whether Petitioner's laboratory director is barred from owning, operating or directing another CLIA certified laboratory for two years.

Title 42 U.S.C. § 263a(i)(3) applies equally to Petitioner's laboratory director.

Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes - (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2 (emphasis in original).

Accordingly, both Petitioner's owner/operator, Robert Gillett, and its laboratory director, Adolfo Boye, M.D., are barred from owning, operating or directing a CLIA certified laboratory for a period of two years from the date of this decision.

4. Petitioner's other arguments have no merit.

Petitioner raises several arguments that have no bearing upon the controlling issue and are of no merit. They are mentioned only in the interest of completeness. Petitioner argues that the complaint investigation was invalid. P. Response, at 2. Petitioner's rational is not clear. However, I will not accept an argument in this case challenging the legitimacy of a complaint investigation of a laboratory that has not applied for a certificate, that has not been issued a certificate, that is reportedly testing without a valid certificate, and that is otherwise testing in violation of the law, given the broad enforcement authority Congress granted the Secretary to fulfill the purpose of CLIA.

Petitioner's argument that the survey was unwarranted and unfair and conducted in a harassing and intimidating manner is also without merit. CMS is tasked with conducting enforcement through facility surveys. Whether or not a complaint against a facility has merit may only be determined after a survey is done. A condition of operating is that a laboratory subjects itself to CLIA regulations and enforcement by CMS. Hence, when a complaint is made, a laboratory should expect that a survey will occur and the laboratory has, at least by implication, consented to the survey. I have no doubt that a survey team is intimidating and that laboratory staff may well feel harassed by the mere presence of the team, but the issue is whether either the intimidation or harassment were undue, improper or excessive - allegations which are not present in this case.

Petitioner indicates that the material fact in dispute that prevents entry of summary judgment is that Petitioner "had not been performing patient testing after December 2, 1999, when it was issued a new CLIA certificate." P. Response, at 3. However, I have already discussed that the controlling material facts are that Petitioner admitted beginning testing on April 26, 2000, before enrolling in an approved PT program, and these facts are not in dispute.

Petitioner also argues that CMS violated the settlement agreement it entered into with Petitioner in November 1999, specifically paragraph 8, by conducting a survey without prior arrangement with Petitioner. I have reviewed the settlement agreement at CMS Ex. 27. Paragraph 8 of the agreement states that Petitioner agreed to a compliance survey that

would be conducted by CMS no sooner than 60 days after the date of the settlement agreement. Paragraph 8 does not require prior notice by CMS or require further agreement by Petitioner as to the date and time of the compliance survey. Most importantly, paragraph 8 says nothing about complaint surveys and in no way limits CMS's ability to perform its regulatory duty in that regard. Petitioner further argues that CMS violated paragraph 9 of the agreement by not conducting inspections to assist

Petitioner in its compliance with CLIA. Petitioner concludes by stating that "HCFA cannot enforce an agreement that they themselves have broken." Petitioner's argument misses the point that enforcement in this case is not pursuant to any settlement agreement, but is pursuant to the statutory and regulatory enforcement scheme. [(6)]

CONCLUSION

For the foregoing reasons, the CMS suspension of Petitioner's CLIA certificate due to a finding of immediate jeopardy is upheld, and the suspension becomes a revocation pursuant to 42 C.F.R. § 493.1844(d)(4)(ii).

JUDGE

Keith W. Sickendick

Administrative Law Judge

FOOTNOTES

1. Effective July 5, 2001, the Health Care Finance Administration was renamed the Centers for Medicare and Medicaid Services (CMS). 66 Fed. Reg. 35437 (2001).

2. Clinical Laboratory Improvement Amendments of 1988, codified at 42 U.S.C. § 263a.

3. The parties completed their final document exchanges on March 15, 2001. Respondent, CMS, submitted 28 proposed exhibits marked "HCFA Ex." Respondent subsequently submitted an amended exhibit list which refers to the exhibits as "CMS." Respondent submitted nine documents with its motion for summary judgment which were originally numbered HCFA Ex. 3; HCFA Ex. 5; HCFA Ex. 6, at 8; HCFA Ex. 6, at 7; HCFA Ex. 4; Exhibit 20 (from Petitioner's final exchanges); HCFA Ex. 27, at 4, 5; Exhibit 19 (from Petitioners' final exchanges); and Exhibit 5 (from Petitioner's final exchanges). Respondent's counsel renumbered all the exhibits attached to the motion for summary judgment designating them in order as Exhibits 1 through 9 with the

result that those exhibits now have two exhibit numbers. Renumbering was unnecessary and confusing. Reference to exhibits in this decision is to the exhibit number from Respondent's amended exhibit list filed September 4, 2001 or to Petitioner's list of 26 exhibits filed as part of its final exchanges. CMS exhibits are referred to as "CMS Ex." rather than "HCFA Ex." and Petitioner's exhibits are referred to as "P. Ex.". Petitioner submitted the affidavit of Robert Gillett in support of its brief in opposition to the motion for summary judgment designated as Exhibit A, but it will be referred to as the Affidavit of Robert Gillett.

4. Pursuant to a settlement agreement between Respondent and Petitioner related to an earlier enforcement proceeding, Petitioner was not to do testing involving any atomic absorption procedures, microbiology, or blood banking except ABO typing and RH typing only, for a period of two years. CMS Ex. 27, ¶ 6.

5. The only issues before me relate to whether enrollment in a PT program is required before testing and whether failure to be enrolled violates the regulation. I do not reach the issue that arises when a laboratory is enrolled but participation has not begun.

6. I also note that CMS cannot contract in violation of its regulatory and statutory duties and estoppel will not lie against the government. *Office of Personnel Management v. Richmond*, 496 U.S. 414 (1990); *Heckler v. Community Health Services of Crawford County, Inc*, 467 U.S. 51 (1984). While the Supreme Court has not ruled that estoppel will never lie against the government, the decisions in *Richmond* and *Heckler*, make clear that estoppel will not lie against the government in cases involving benefits to be paid from the Treasury, particularly in the complicated area of Medicare.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	

SUBJECT:

Carlos A. Cervera, M.D.,

DATE: August 1, 2002

Petitioner,

- v -

Centers for Medicare & Medicaid Services

Docket No.C-99-797
Decision No. CR939

DECISION	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to prohibit Carlos A. Cervera, M.D. (Petitioner) from owning or operating a laboratory for at least two years. I find that Petitioner was a "laboratory director" of the San Fernando Diagnostic Laboratory, Inc. (San Fernando), whose Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate was revoked. CMS is therefore authorized to prohibit Petitioner's ownership or directorship of any CLIA laboratory for a period of two years from the issuance date of this decision.

I. Background

This case emanates from sanction determinations that CMS (formerly known as the Health Care Financing Administration or "HCFA") made against San Fernando. The sanctions that CMS imposed against San Fernando include revocation of San Fernando's CLIA certificate. San Fernando has not requested a hearing to contest those sanctions. Petitioner requested a hearing in order to challenge CMS's determination that, as a consequence of being San Fernando's laboratory director, he was precluded from owning, operating, or directing a clinical laboratory for at least two years.

San Fernando was a clinical laboratory seeking certification to perform clinical testing under CLIA. On January 8, 1999, San Fernando filed with the Laboratory Field Services, State of California Department of Health Services (LFS): 1) an application for a clinical laboratory license; 2) a laboratory testing declaration; 3) a laboratory personnel report form; and 4) a clinical laboratory application (CLIA application). HCFA Exs. 1, 2, 3, 4. The Application for Clinical Laboratory License and Laboratory Testing Declaration (HCFA Exs. 1, 2) were signed by Petitioner as "Laboratory Director." Furthermore, the Laboratory Personnel Report Form and the Clinical Laboratory Application both list Petitioner as San Fernando's "laboratory directory." HCFA Exs. 3, 4. San Fernando's CLIA application was approved and became effective as of April 23, 1999. The CLIA certificate was issued to Petitioner on May 18, 1999. HCFA Ex. 13; Hearing Transcript (Tr.) at 56-57.

In the latter part of May 1999, upon review of Petitioner's State license and CLIA applications by LFS, CMS was informed of a discrepancy between the total annual test volume in San Fernando's State licensing application and that provided in the CLIA application. *Id.*, at 52-53. By letter dated June 17, 1999, CMS advised Petitioner of inconsistencies. Specifically, Petitioner was advised that the CLIA application contained the testing volume total (45,000) which was lower than the State application total (485,000), and that it was the lower estimation which established the fee assessment amount to be charged and paid by San Fernando. CMS informed Petitioner that sanctions would be imposed, which included revocation of San Fernando's CLIA certificate for one year, cancellation of San Fernando's approval to receive Medicare and Medicaid payments, and prohibition of the owner and operator (laboratory director) from owning, operating, or directing a laboratory for at least two years from the date of revocation. HCFA Ex. 5.

Petitioner requested a hearing to contest CMS's findings and remedy determinations. This matter was assigned to me for a hearing and decision. I held an in-person hearing in Los Angeles, California on August 28, 2000. The parties each called witnesses to testify. CMS offered, and I accepted, into evidence exhibits identified as HCFA Exhibits (HCFA Exs.) 1-13. [(1)] Petitioner offered, and I accepted, into evidence exhibits identified as Petitioner's Exhibits (P. Exs.) 1-15.

II. Applicable Law

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, amending Section 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a et seq. The purpose of CLIA

is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 et seq. Pursuant to CLIA, the Secretary of Health and Human Services (Secretary) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. § 263a(f) and issued regulations implementing CLIA. *See* 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to achieve compliance. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

CLIA provides the following with respect to the owners and operators of non-compliant laboratories in addition to sanctions which may be imposed directly against a laboratory:

> (3) Ineligibility to own or operate laboratories after revocation.
>
> 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.

42 U.S.C. § 263a(i)(3). The Secretary's regulations specify that a "laboratory director" is considered an "operator" of a laboratory:

> Operator means the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes-(1) A director of the laboratory if he or she meets the stated criteria . .

42 C.F.R. § 493.2.

The regulations also require that any laboratory conducting moderate or high complexity testing have a laboratory director who meets specific qualifications

and has clear and specific responsibilities. 42 C.F.R. §§ 1403, 1405, 1407. The regulations specify that:

> The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate [sic], and proficiently and for assuring compliance with the applicable regulations.

42 C.F.R. § 493.1407.

The applicable law and regulations provide that adverse actions may be taken against a laboratory's owner, operator, or one of its employees where such individual is guilty of misrepresentations in obtaining a CLIA certificate. *See* 42 U.S.C. § 263a(i)(1); 42 C.F.R. § 493.1840(a)(1). Such adverse actions include suspension, limitation, or revocation of the party's CLIA certificate. *Id*.

Any laboratory that has, as its owner or operator (which includes laboratory director), an individual who owned or operated a laboratory that had its CLIA certificate revoked within the previous two years is subject to adverse action, including suspension and/or revocation pursuant to 42 C.F.R. § 493.1840(a)(8).

CLIA further provides, at 42 U.S.C. § 263a(i)(1), that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination, as delineated at 42 C.F.R. § 493.1844(b), is entitled to a hearing before an administrative law judge (ALJ). 42 C.F.R. § 493.1844(a). The hearing procedures found in subpart D of Part 498 are incorporated by reference. 42 C.F.R. § 493.1844. The "suspension, limitation or revocation of the laboratory's CLIA certificate . . . because of noncompliance . . . ." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1).

Where a party requests a hearing, before an ALJ, of CMS's initial determination, the two-year prohibition will not commence until the issuance of a decision by the ALJ. 42 C.F.R. § 493.1844(d)(2) (. . . suspension, limitation, or revocation of a CLIA certificate is not effective until after a hearing decision by an ALJ is issued.).

III. Issues

The threshold issue in this matter is whether Petitioner has an appeal right as to CMS's actions. Prior Departmental Appeals Board (DAB) case law has determined that laboratory directors in such cases as this one do have a right to appeal. *See RNA Laboratories, Inc., and Ter-Zakarian Medical Clinic*. DAB

CR829 (2001); *Eugene R. Pocock, M.D.*, DAB CR527 (1998); *Sentinal Medical Laboratories, Inc.*, DAB No. 1762 (2001). Since the threshold issue is answered in the affirmative, then the subsequent issues are:

- Whether Petitioner was in fact the laboratory's director at the time of the alleged misrepresentation contained in the application forms; and

- Whether Petitioner was properly subject to sanction by CMS.

IV. Findings, Conclusions and Analysis

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

A. *The information contained in the State licensure and CLIA application forms was a misrepresentation of information and, therefore, subject to sanctions by CMS.*

The basis for the actions taken by CMS against San Fernando, and collaterally against Petitioner, was the discrepancy in the test volume estimates contained in both the California State licensing application (State application) and the CLIA application. HCFA Ex. 5, at 1. The estimations are essential for the assessment of fees to be paid by the applicant prior to the issuance of a CLIA registration certificate. *See* 42 C.F.R. § 493.643(c). The estimates in the CLIA application were substantially lower than those reported in the State application. Tr. at 52-53; HCFA Exs. 2, 4. Had the higher estimation been provided in the CLIA application, San Fernando would have fallen into a different capacity category, which would have resulted in a higher fee assessment. Tr. at 68-69.

Petitioner argues that, since the regulations do not specifically define the term "misrepresentation," CMS has applied an inaccurate definition to the term and, therefore, has applied an incorrect interpretation to 42 C.F.R. Part 493. Petitioner's Post-Hearing Brief (P. Br.) at 6. Petitioner further asserts that CMS has failed to meet "the legal requirements and conditions necessary to support a charge of "misrepresentation . . . " *Id.*, at 10. Petitioner argues that the regulation's omission in providing a definition for "misrepresentation" leaves the term subject to interpretation. On this point, I am in agreement with Petitioner. However, I do not agree with Petitioner's particular interpretation on this subject. Petitioner's elucidation suggests that the appropriate definition in this instance would result in "misrepresentation" being synonymous with the term "fraud." Petitioner suggests that Black's Law Dictionary, as published by the Lawbook Exchange, provides the appropriate definition. In essence, Petitioner's reference source states the following:

> False and fraudulent misrepresentation is by representation contrary to the fact made by a person with knowledge of its falsehood and being the cause of the other party's entering into a contract.

Id., at 6.

However viable a definition this may be, it is not one I would use in this case. Upon review of another Black's Law Dictionary, Centennial Edition, I find a somewhat broader definition of "misrepresentation." The Centennial Black's defines "misrepresentation" as:

> Any manifestation by words or other conduct by one person to another that, under the circumstances, amounts to an assertion not in accordance with the facts. An untrue statement of fact. An incorrect or false representation. That which, if accepted, leads the mind to an apprehension of a condition other and different from that which exists . . .

Black's Law Dictionary, Abridged Sixth Edition, 692 (1991).

I agree with CMS's argument that neither the statute nor the regulations require ***specific*** intent for the misrepresentation. Clearly, 42 U.S.C. § 263a(i)(1)(A) prescribes:

> (1) In general
>
> Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory -
>
> (A) has been guilty of misrepresentation in obtaining the certificate.

Nowhere in this provision does it indicate that the misrepresentation must be **deliberate** or **intentional**. If I were to follow Petitioner's particular line of thinking, I would be forced to conclude that by "misrepresentation," the regulations are applicable only to intentional efforts to provide misinformation. I do not comprehend the regulations to be so narrow. In that the term "misrepresentation" is extremely broad and subject to numerous interpretation, I believe that it was Congress' intent to be broad and to mean any inaccurate information contained in an application for certification which, if relied upon by a state or federal agency, would result in certification issuance. Clearly, the misrepresentation could be unintentional or intentionally fraudulent. Based

upon the evidence before me, it is clear that CMS has not argued nor attempted to prove that Petitioner intentionally provided misinformation on the State and CLIA applications. However, CMS has more than substantiated that there was a misrepresentation of information provided in both applications, albeit arguably unintentional.

B. *Petitioner was the laboratory director for San Fernando at the time of the submission of the State and CLIA applications.*

Once the question as to whether there has been a misrepresentation has been answered in the affirmative, the next issue to be addressed is whether Petitioner is one of the individuals delineated in the statute and regulations. Specifically, was Petitioner an owner, operator, or an employee of the laboratory when the misrepresentation occurred.

Petitioner challenges CMS's allegation that he was the laboratory director of San Fernando at the time of execution of the State and CLIA applications. Petitioner also accuses CMS of violating "the well-established legal principle of form over substance" in the alleged attempt to make 'laboratory director' and 'owner/operator,' as delineated at 42 U.S.C. § 263a synonymous. P. Br. at 22. The regulations at 42 C.F.R. § 493.2 define "operator" as:

> . . . . the individual or group of individuals who oversee all facets of the operation of a laboratory and who bears primary responsibility for the safety and reliability for the results of all specimen testing performed in that laboratory. The term includes --
>
> (1) A director of the laboratory if he or she meets the stated criteria . . .

It is clear on its face that at the signing of the State application form, Petitioner held himself out to be the laboratory director for San Fernando. Without Petitioner's affirmation that he was serving in such a capacity, San Fernando's application would not have been processed by the State agency. Tr. at 82. Furthermore, this was not Petitioner's first encounter with clinical laboratories or with the functions associated with being a laboratory director. According to evidence and testimony, Petitioner had been a director of, at least, two known laboratory facilities prior to his involvement with San Fernando. *See* HCFA Ex. 4, at 4. Therefore logic would dictate that Petitioner would have some knowledge of the intricacies of being a laboratory director.

However, Petitioner contends that at the time of the signing and submission of the State application forms, he was not qualified to act as a laboratory director.

P. Br. at 19. The regulations prescribe the standard by which an individual is qualified to serve as a laboratory director. The regulations delineate, among other things:

> The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and(b) The laboratory director must --(1)(i) Be a doctor of medicine or doctor . . . . licensed to practice medicine . . . . in the State in which the laboratory is located; and (ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (ii) Have had laboratory training or experience consisting of: (A) At least one year directing or supervising non-waived laboratory testing, ...

42 C.F.R. § 493.1405(a), (b)(1), (b)(2)(i), (b)(2)(ii)(A).

Neither party has argued nor presented evidence which would question whether Petitioner did or did not meet the educational/professional qualifications stipulated in section 493.1405. However, the testimony of Alyce Brydon, Section Chief, LFS, substantiates Petitioner's eligibility to serve as a laboratory director pursuant to 42 C.F.R. § 493.1405. Tr. at 203-204. It is not the initial qualifications that Petitioner disputes. But rather, he argues that his

disqualification to serve as a laboratory director is the result of an internal investigation by LFS of Petitioner's prior involvement with two other laboratories. Petitioner particularly asserts that:

> Petitioner made no "misrepresentation" to HCFA as the Laboratory Director . . . . at the time the application was made because . . . . Petitioner was not be [sic] qualified to be a laboratory director under California State regulations.

P. Br. at 19.

Petitioner contends that, because of an ongoing investigation by Ms. Bryden's office six months prior to the submission of the State and CLIA applications, it was known well in advance that Petitioner was not eligible to serve as the laboratory director of San Fernando. Petitioner's argument would have merit had there been an ultimate determination made during the six months prior as to Petitioner's ineligibility to serve as San Fernando's laboratory director. On cross examination, Ms. Bryden testified that the investigation in essence was the result of her office's repeated attempts to acquire records from Petitioner relating to the two other facilities in which he was the laboratory director. Ms. Bryden stated:

> . . . . because we were beginning to investigate these laboratories, we needed records from the laboratories. These were requested from [Petitioner] in December of 1998. He did not respond. We requested them again in January of '99. He did not respond. We requested them again in February of '99. He did not respond. Then we wrote him a letter of intent to impose sanctions upon him for not responding.
>
> His answer to that was, "I wasn't laboratory director at that time and I never saw any of the letters." So after some discussion on this he produced letters of his - his letters of resignation for these two laboratories. We sent the issue to our legal department for a decision since we did not have copies of those letters, although he had said

> he had sent them to us. And at that time, our legal department finally in about November [1999] said, "Well, we'll give him the benefit of the doubt that these are legitimate letters and we won't impose sanctions . . . .

Tr. at 225-226.

It is clear from the testimony of Ms. Bryden that no adverse determination against Petitioner resulted from the investigation. And even if I were to find that LFS's determination did in fact result in a determination that Petitioner was ineligible to be a laboratory director, such information was never conveyed to CMS for consideration. As Ms. Bryden testified, the matter under investigation dealt was a state licensure issue and such information would have never been relayed to CMS. Tr. at 227. Therefore,

Petitioner's argument that an individual under investigation for "any alleged or actual wrong doing" is unacceptable as a laboratory director is without merit. Therefore, I find that as of January 8, 1999, the date of the signing of the applications, Petitioner was the laboratory director of San Fernando.

Even if I concluded that Petitioner was not the laboratory director subsequent to January 8, 1999, he was the laboratory director at the time of execution of the four application documents and submission to LFS. *See Edward Ming-Che Lai, M.D.*, DAB CR848 at 7 (2001). In *Ming-Che Lai*, there was a question of whether the petitioner was a laboratory director eight months after submission of the initial application documentation, which included the CLIA application. The ALJ in that case concluded that it was clear from the executed documents that the petitioner was functioning as the laboratory director as of the date of the documents; However, rebuttal evidence supported the argument that petitioner was not serving as the laboratory director as of May 2000, eight months after the execution date. Such an analogy is applicable to the facts of the present case. Petitioner has not presented any compelling evidence to support his contention that he was not serving, nor had he agreed to serve, as the laboratory director as of January 8, 1999 when the application forms were executed and filed with LFS.

C. *Petitioner's arguments relating to his alleged status as an "employee" laboratory director are without merit.*

Petitioner next asserts that, even though he may have been considered a laboratory director for San Fernando, he was an "employee of the organization and as such cannot be held liable for the actions of the employer." P. Br. at 24. Petitioner also suggests that he would have been an employee of San Fernando only if the facility had opened for business. *Id*. Petitioner sums up his argument by concluding that, since 42 C.F.R. § 1840(A)(8) "singles out one

employee to be punished" and is not applicable to all employees, then the regulatory provision is unconstitutional. *Id*.

It is significant that, in order for San Fernando to acquire and maintain certification for performing moderate complexity testing, it had to have a laboratory director who provided "overall management and direction" of the laboratory, in accordance with 42 C.F.R. § 493.1407, and who met the qualification requirements of 42 C.F.R. § 493.1405. These regulations draw no distinctions regarding a laboratory director who has status as an employee, as opposed to being a contractor, an owner entitled to an equity share, a volunteer, or one who serves in some other status.

The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and thus, the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3829. The Secretary's purpose in treating a laboratory director of a laboratory which has its CLIA certificate revoked as an operator for purposes of the two-year ban on owning or operating another laboratory is consistent with the legislative intent of CLIA. 57 Fed. Reg. 7226 (1992).

Petitioner's unique interpretation of the regulations, whereby he is shielded from his responsibilities as a laboratory director and the sanctions contemplated by the statutes and regulations, is unreasonable and inconsistent with the purposes of CLIA. I have concluded that, by accepting the title of "laboratory director" of a laboratory having or seeking a CLIA certificate, the director accepts all of the specified regulatory responsibilities and is subject to the authority of CMS and any sanctions specified by law, regardless of the actual employment status of the director.

D. *Petitioner is properly subject to the two-year prohibition on owning, operating or directing a laboratory.*

San Fernando did not contest the sanctions imposed by CMS and, therefore, its certification was revoked effective August 16, 1999. The revocation of San Fernando's certification triggers 42 U.S.C. § 263a(i)(3), which is applicable to Petitioner for the reasons previously discussed. Section 263a(i)(3) provides that "[n]o person who has owned or operated a laboratory which has had its certificate revoked may, within two years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this under this section. Section 493.1840(a) of 42 C.F.R. is also triggered, which requires CMS to initiate adverse actions to suspend, limit or revoke the CLIA certificate of any laboratory if it is found that an owner or operator owned or operated a laboratory that had its CLIA certificate revoked within the last two years. CMS has no discretion and, in fact, takes no action under 42 U.S.C. § 263a(i)(3); the two-year ban on owning and operating is automatic. Similarly, CMS has little discretion under 42 C.F.R. § 493.1840(a)(8) as it must initiate

action against the offending laboratory.

> E. *I do not have the authority to address Petitioner's assertion that the regulations at issue are unconstitutional.*

Even if I had entertained Petitioner's constitutional arguments as they relate to 42 C.F.R. § 1840(a)(8), I would be unable to utilize them in my deliberations on this matter. I do not have the authority to decide these issues. Administrative law judges have no statutory or regulatory authority to find invalid or refuse to follow federal statutes or regulations. *Wayne E. Imber, M.D.*, DAB CR661, *aff'd*, DAB No. 1740 (2000); *Richard A. Fishman, D.O.*, DAB CR100 (1990) (administrative law judges do not have authority to declare federal statutes unconstitutional); *Sentinel Medical Laboratories, Inc.*, DAB No. 1762 (2001) ([i]t is well established that administrative forums, such as this Board and the Department's ALJs, do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional).

As a result of these explicit jurisdictional prohibitions, Departmental Appeals Board ALJs lack authority to review the constitutionality of statutes. Petitioner may not use this administrative appeals process to obtain redress for both his alleged constitutional harms. *See Serban I. Cocioba, M.D.*, DAB CR654 (2000) (finding no jurisdiction to rule on constitutional claims); *Morton Markoff, D.O.*, DAB CR538 (1998) (administrative law judges lack authority to decide constitutional claims).

V. Conclusion

Based upon the foregoing, I affirm CMS's determination and conclude that Petitioner is prohibited from owning, operating or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3), due to the revocation of San Fernando's CLIA certification of which he served as laboratory director during the relevant period of time. The two-year prohibition will commence to run from the issuance date of this decision.

JUDGE

Alfonso J. Montano

Administrative Law Judge

FOOTNOTES

1. CMS's exhibits were identified with the acronym "HCFA" and, therefore, I will refer to them by that acronym in order to avoid confusion.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	

SUBJECT:

Alaa Ahmed, M.Sc., Ph.D., (Global Esoteric Reference Labs, Inc.),

DATE: August 30, 2002

Petitioner,

- v -

Center for Medicare & Medicaid Services

Docket No.C-01-455
Decision No. **CR946**

DECISION	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) [(1)] to impose remedies against Petitioner under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a. I find further that CMS was required to revoke Petitioner's CLIA certificate for a period of at least one year and to cancel Petitioner's approval to receive Medicare and Medicaid payments for its services on or after December 23, 2000.

I. Background

Alaa Ahmed, M.Sc., Ph.D., is the owner and operator of Global Esoteric Reference Labs, Inc. (GERL or the laboratory), and both GERL and Dr. Ahmed constitute the Petitioner in this case. Transcript (Tr.) at 549. CMS issued Petitioner a "CLIA Certificate of Registration for a Certificate of Accreditation". CMS exhibit (CMS Ex.) 2. By letter dated December 5, 2000, CMS served Petitioner with notice that it was proposing to impose sanctions due to improper proficiency testing referral. CMS noted that in the course of a survey conducted by the California Department of Health Services, Laboratory Field Services (State agency), which concluded on September 13, 2000, CMS found (based upon the State agency

examiner's Statement of Deficiencies detailing the results of the survey which CMS adopted) that GERL was not in compliance with CLIA conditions of participation. Specifically, the laboratory did not meet the following conditions:

- D2000: 42 C.F.R. § 493.801 Enrollment and testing of [proficiency testing] samples; and,
- D6076: 42 C.F.R. § 493.1441 Laboratory director, high complexity testing.

The notice further stated that the condition regarding proficiency testing (PT) was specifically supported by deficiency D2013 at 42 C.F.R. § 493.801(b)(4), which alleged that Petitioner engaged in improper PT referral by reporting PT results obtained from another laboratory. Other standard-level requirements were also found not to be met.

CMS concurred with the State agency findings and recommendations and determined to impose the following sanctions:

> •Revocation of the laboratory's CLIA certificate, effective February 8, 2001,in the absence of a request for hearing by the laboratory.
>
> •Cancellation of the laboratory's approval to receive Medicare payments for its services performed on or after December 23, 2000.
>
> •Cancellation of payments under the Medicaid program for services performed on or after December 23, 2000.

CMS Ex. 2.

By letter dated February 5, 2001, Petitioner requested a hearing. The case was assigned to me for hearing and decision. I held a hearing in Pasadena, California, on February 28 and March 1, 2002. CMS offered 24 exhibits, after withdrawing its proposed exhibits 4 and 6. I admitted CMS Exs. 1 - 3, 5, and 7 - 26 into evidence. [(2)] Petitioner offered nine exhibits (P. Exs. 1 - 9), which I admitted into evidence without objection. Both parties submitted post-hearing briefs (CMS Br. and P. Br.) and responses (CMS R. Br. and P. R. Br.). [(3)]. Based on the testimony offered at the hearing, the documentary evidence, the arguments of the parties, and the applicable law and regulations, I find that Petitioner was not in compliance with one condition under CLIA involving the improper referral of PT samples, as well as with one other condition-level and standard-level CLIA requirements. The consequence of Petitioner's

noncompliance is that Petitioner's CLIA certificate must be revoked for at least one year. Therefore, CMS was authorized to revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare and Medicaid payment for its services.

II. Applicable Law and Regulations

CLIA was designed to promote accurate medical tests by clinical laboratories. Congress' goal was to establish a single set of standards applicable to all laboratory services, including those provided to Medicare beneficiaries. *See* H.R. Rep. 899, 100th Cong., 2nd Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828.

Under CLIA, the Secretary of Health and Human Services (Secretary) is authorized to inspect clinical laboratories and, in effect, license them to perform tests. The Act 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). The Act 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).

The standards for operation of clinical laboratories promulgated by the Secretary pursuant to the enabling legislation are found at 42 C.F.R. Part 493. Regulations governing the performance of proficiency tests by clinical laboratories are found at 42 C.F.R. § 493.801 *et seq*. A clinical laboratory must enroll in an approved PT program. It must notify the Department of Health and Human Services of each program or programs in which it chooses to participate to meet PT standards. CMS approves certain companies to administer PT under CLIA. The regulation at 42 C.F.R. § 493.911 requires that these approved testing companies send out, three times each year at approximately equal intervals, proficiency test samples to be analyzed by each laboratory for microbiology (in this case involving the subspecialty of microbiology, bacteriology). The participating laboratories then perform the tests and submit their results on forms provided by the testing services. The testing services grade the results and report them to CMS. 42 C.F.R. § 493.903. A laboratory is required to examine or test each PT sample that it receives in the same manner that it tests patient specimens. 42 C.F.R. § 493.801(b). The regulation emphatically prohibits sending PT samples to another laboratory for analysis which it is certified to perform itself. 42 C.F.R. § 493.801(b)(4). The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 C.F.R. § 493.801(b)(5).

Any laboratory that the Secretary determines intentionally refers its PT samples to another laboratory for analysis shall have its CLIA certificate revoked for at least one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.801(b)(4). The regulations further provide that when CMS revokes a laboratory's CLIA certificate, it will also cancel that laboratory's approval to receive Medicare and Medicaid reimbursement for services rendered. 42 C.F.R. § 493.1842(a); Social Security Act (Act) section 1902(a)(9)(C); 42 C.F.R. § § 440.2(b), 440.30(c); 42 C.F.R. § 493.1809.

Additionally, a participating laboratory is required to have a director who provides overall management and direction in accordance with 42 C.F.R. §§ 493.801 *et seq.*; 42 C.F.R. § § 493.1441, 1443, 1445. A technical supervisor must conform to 42 C.F.R. §§ 493.1449, 1451. A laboratory that does not treat PT testing samples in the same manner as patient samples may have its certificate of accreditation revoked. 42 C.F.R. §§ 493.61(b)(1), (c)(3).

III. Issues

The issues in this case involve whether CMS's determination to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare and Medicaid payment for its services was authorized under the applicable law at 42 U.S.C. § 263a and 42 C.F.R. § 493. Whether such determinations were authorized is dependent upon whether or not, based on deficiencies identified during the September 2000 survey, Petitioner improperly referred PT samples to another laboratory and on whether Petitioner failed to comply with the CLIA condition-level deficiencies for PT and for laboratory director.

IV. CMS's contentions

CMS contends that Petitioner failed to comply with the CLIA condition at 42 C.F.R. § 493.801 due to improper referral of PT samples. Based on State agency interviews and review of PT records for the second CAP PT [(4)] event of 2000, CMS determined that the medical technologist employed by Petitioner to do bacteriology testing tested samples in PT module D4 at another laboratory where she was employed in order to compare results, a violation of 42 C.F.R. § 493.801(b)(4). CMS also contends that Petitioner's laboratory director failed to attest to the routine integration of PT samples into patient workload using the laboratory's routine methods, and did not follow the manufacturer's instructions for test system operation and/or test performance. The latter violation of the standard for moderate and/or high complexity testing refers to the storing of reagents at improper temperature levels and storing testing materials that had exceeded their expiration date.

Accordingly, CMS asks that I: (1) sustain the revocation of Petitioner's CLIA certificate for one year, due to the intentional referral of PT by Petitioner to another laboratory; (2) find Petitioner out of compliance with the conditions for enrollment and testing of PT samples and laboratory director, separately authorizing revocation of Petitioner's CLIA certificate under 42 C.F.R. § 493.1840; and (3) prohibit Dr. Ahmed, Petitioner's owner and operator, from owning, operating, or directing any laboratory for at least two years pursuant to 42 U.S.C. § 263(a)(i)(3).

V. Petitioner's contentions

Petitioner contends that the Statement of Deficiencies is inaccurate and fraught with discrepancies. Pertinent to this is Petitioner's claim that CMS made an incorrect inference that there was a referral of PT samples to an outside laboratory. Petitioner goes on to allege that all PT testing was done utilizing the laboratory's own equipment and that no intentional referral of PT samples occurred. The methods and results of the PT samples reported to CAP, says Petitioner, were obtained from its own methods and results. Furthermore, Petitioner argues that any samples tested at another laboratory by its PT technician would not be in violation of CLIA, because they were tested at the other laboratory after the report to CAP from Petitioner's testing was mailed. Petitioner either generally denies the other allegations raised in the Statement of Deficiencies or offers argument in support of its contentions.

VI. Findings of Fact and Conclusions of Law

1. At all relevant times, Petitioner was an independent clinical laboratory, located in Woodland Hills, California, engaged in testing for, among other things, bacteriology, mycobacteriology, mycology, parasitology, virology, serology, general immunology, toxicology, and hematology. CMS Exs. 10 - 12.

2. Alaa Ahmed, M.Sc., Ph.D., was at all relevant times the owner and operator of GERL. *See* CMS Ex. 10, at 1.

3. Rudolph Ulirsch, M.D., was GERL's laboratory director and clinical consultant. Tr. at 490, 506; CMS Exs. 10, at 2; 13, at 1. As laboratory director, he was responsible for Petitioner's overall operation and administration. His responsibilities included employing personnel who were competent to perform test procedures, ensuring that test results were promptly, accurately, and proficiently recorded and reported, and assuring Petitioner's compliance with applicable regulations. 42 C.F.R. § § 493.1443, 1445.

4. Helen Flores was a licensed clinical laboratory scientist and medical technologist (Tr. at 437) employed by Petitioner at all relevant times as a

technical supervisor and as one of Petitioner's testing personnel. CMS Ex. 13, at 1.

5. At all relevant times, Ms. Flores was employed to perform testing by both Petitioner and Dynamic Medical Laboratories. *See* Tr. at 417 - 419, 437, 440 - 441.

6. The CAP generally mails to laboratories participating in its PT program a group of five specimens three times per year. The laboratories are required to test these specimens as they would specimens for which they did patient testing and to mail their results to the CAP. Tr. at 32 - 34.

7. Testing samples sent to Petitioner by the CAP included samples for bacteriology and antibiotic sensitivity. Tr. at 38.

8. The testimonial and documentary evidence submitted by CMS shows that Petitioner reported PT results to the CAP for the second testing event of 2000 for bacteriology that were obtained through referral of PT specimens by Ms. Flores to another laboratory (Dynamic Medical Laboratories, the other laboratory where Ms. Flores was employed) for corroboration, in violation of the condition-level requirement set forth at 42 C.F.R. § 493.801.

9. Petitioner's PT samples, for the second testing event of 2000, thus were not examined with the laboratory's regular patient workload, in violation of the condition-level requirement set forth at 42 C.F.R. § 493.801.

10. The laboratory director failed to ensure that PT samples were tested in the same manner as patient samples, in violation of the condition-level requirement set forth at 42 C.F.R. § 493.1441. *See* 42 C.F.R. § 493.1445.

11. Petitioner did not meet the standard at 42 C.F.R. § 493.1205(e)(1) for test methods.

12. Petitioner did not meet the standard at 42 C.F.R. § 493.1202(c)(1) for moderate and/or high complexity testing.

13. Petitioner did not meet the standard at 42 C.F.R. § 493.1407(e)(14) for laboratory director responsibilities.

14. Petitioner was in violation of the condition at 42 C.F.R. § 493.1441 for laboratory director in failing to provide proper overall management and direction to the facility.

15. Pursuant to 42 U.S.C. § 263a(f), the Secretary is directed to ensure that certified clinical laboratories perform tests that are valid and reliable.

16. Petitioner's intentional referral of PT samples constitutes a violation of CLIA conditions requiring a mandatory revocation of its CLIA certificate for at least one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.801(b)(4).

17. Petitioner's violations of CLIA conditions and standards authorize CMS to revoke its CLIA certificate and cancel its approval to receive Medicare and Medicaid reimbursement for its laboratory services. 42 C.F.R. § § 493.1806 - 1809.

18. The revocation of Petitioner's CLIA certificate for a period of at least one year is both required by law and not unreasonable in light of Petitioner's failure to satisfy the condition-level requirements found above.

VII. Discussion

A. Petitioner was subject to CLIA requirements in September 2000.

Petitioner implies that it was not subject to CLIA requirements at the time of the survey in September 2000. P. R. Br. at 2. Petitioner reasons that since it only possessed a CLIA Certificate of Registration and no California Department of Health Services' license was ever issued to the facility, it was not qualified to engage in any patient testing. Petitioner's reasoning is without merit and inaccurate. GERL was certified to perform testing pursuant to a CLIA Certificate of Registration for a Certificate of Accreditation. That certificate was issued based on Petitioner's pending accreditation with CAP. Consequently, Petitioner was subject to compliance requirements under CLIA, as mandated by 42 C.F.R. Part 493, Subpart E. CMS Ex. 2. Moreover, Mr. Yamamoto, who is employed by CMS as a laboratory consultant with the CLIA program (Tr. at 308), testified that Petitioner was not only certified under CLIA to perform tests, but was also licensed by the State of California. Tr. at 329. Thus, as CMS notes, the fact that Petitioner might have been performing little or no actual patient testing at the time of the survey has no bearing on its burden to meet CLIA requirements. *Id.*; CMS R. Br. at 9.

B. Petitioner sent PT samples to another laboratory for analysis which it was certified to perform in its own laboratory.

Petitioner presents several arguments in its defense against the charge that it improperly referred PT samples to another laboratory. Some of those arguments are redundant while others warrant no discussion. Though none have merit, I will discuss the more substantive ones. [(5)] These are the following:

- CMS did not introduce any evidence that the testing performed by Petitioner's medical technologist at her other place of employment occurred during the 10 working days allotted to the facility to test the PT specimens and return the results to CAP. P. Br. at 4, § 5.
- The PT results reported to CAP were obtained by Petitioner using its own methods and equipment. P. Br. at 5, § 10.
- CMS's position regarding specimens D4-07 and D4-08 is not supported by the medical technologist's indication that the specimen was being referred for ID and that identification was performed using a bacitracin disk. P. Br. at 5, § 11.

Donald Newbold testified that at the time of the complaint survey giving rise to this action, he was acting (at State agency request) as an examiner for the State agency. (6) Tr. at 25 - 26. As an examiner, Mr. Newbold's duties included the inspection of clinical laboratories to assure their compliance with CLIA and State law. Tr. at 26. In this case, Mr. Newbold testified that the State agency asked him to lead an investigation of Petitioner based on a complaint it had received alleging that Petitioner had taken data from other labs to validate instruments. Tr. at 27. Mr. Newbold made an initial visit to Petitioner's location on September 11, 2000, in the company of Victor Escovedo, who is also a State agency examiner. Tr. at 27 - 28, 198. They did not enter the facility, but examined the trash bin behind the laboratory in order to determine if there might be information that could be helpful in their investigation. (7) Tr. at 28 - 29.

Mr. Newbold testified that in their search of the laboratory's trash bin, they found a microbiology worksheet with the name "Dynamic Medical Laboratories" on the heading. *See* CMS Ex. 15; Tr. at 29. He stated that the document is the type that laboratories are required to maintain to substantiate how they arrive at testing results for bacteriology and sensitivities. (8) Tr. at 30. The document Mr. Newbold found was labeled "D409" in the upper left hand corner, and, under the name, it was identified as "CAP." He added that D409 is a typical designation throughout the laboratory industry to identify PT for a specific specimen. In this particular case, it referred to *proteus mirabilis*, a bacteria. CAP referred to College of American Pathologists, which is one of the PT agencies approved by CMS. (9) Tr. at 30 - 36. With respect to this particular specimen, Petitioner was required to test for bacteria as well as sensitivity. Tr. at 38.

On September 12, 2000, Mr. Newbold and Mr. Escovedo entered the laboratory and observed that patient testing was being performed at the time. After they were introduced to Dr. Ahmed by one of the several employees present, the

examiners were given a tour of the facility. Tr. at 44 - 45.

Following the tour, Mr. Newbold and Mr. Escovedo went to the bacteriology testing room and reviewed PT documents until the bacteriologist, Ms. Flores, arrived. Tr. at 45. Mr. Newbold testified that upon her arrival he asked Ms. Flores if she had been performing PT at any other place, and she said no. However, when confronted with CMS Ex. 15, the document which they found in the trash bin, she responded that she had tested the specimen at her other place of employment because she did not trust the MicroScan Walk Away. [(10)] Tr. at 46 - 47. Pertinent to this is the fact that Ms. Flores had no prior testing experience on the MicroScan Walk Away, the equipment in use at GERL to do the testing in question. Tr. at 445 - 446. The worksheet that the examiners found in the trash bin indicated that the specimen was tested using an Enterotube, which Petitioner did not have at its facility. Tr. at 47.

With respect to specimen D4-07, Ms. Flores reported that she was unable to identify the specimen (hemolytic strep) with the MicroScan Walk Away. CMS Ex. 20, at 3. Instead, she made use of a bacitracin disk. However, Petitioner did not use such disks at its facility. Mr. Escovedo testified that when he inquired regarding this specimen, Ms. Flores admitted having performed the test at "Dynamic." Tr. at 210, 244.

On September 14, 2000, Ms. Flores was disciplined by her supervisor because she: (1) performed parallel testing of the microbiology samples of the CAP 2000 survey for the second testing event at Petitioner's facility using the MicroScan Walk Away as well as the testing instruments at her other place of employment; and (2) reported to CAP a mix of GERL's results and those obtained at another laboratory. CMS Ex. 16. Ms. Flores accepted the disciplinary action, stating that she was unaware of the regulations. *Id.*

In her testimony, Ms. Flores stated that she took the D4-09 sample to test at her other place of employment, and that she did it only after the CAP report was submitted. Tr. at 418 - 419. However, she admitted that the worksheet (CMS Ex. 15) contained no date to support her claim that she performed the test at Dynamic only after sending the proficiency test results to CAP. Tr. at 455. Ms. Flores was also inconsistent in her explanation as to why she tested specimen D4-09 at her other place of employment. Whereas she told the examiners that she repeated the proficiency test at Dynamic Laboratories because she did not trust the MicroScan Walk Away, she testified at the hearing that she did it out of mere curiosity. Tr. at 51, 418. I am persuaded that Ms. Flores' first explanation to the examiners is the more logical of the two versions. I find that inasmuch as she did not trust the MicroScan Walk Away, Ms. Flores sought corroboration in order to ascertain that the results being reported to CAP were correct. [(11)]

Additionally, if Ms. Flores was aware that she had done nothing wrong, she would not have accepted responsibility for improper referral to another laboratory or for reporting results obtained through such referral to CAP. I am not persuaded that Ms. Flores accepted a two week suspension from her employment, and did not dispute the serious allegations leveled against her, without giving the matter much thought. Tr. at 483 - 484. Ms. Flores' testimony that she told Dr. Ahmed that she only tested PT samples at Dynamic after the results were sent to CAP is not credible. If that were so, Petitioner would have raised that defense earlier in this proceeding and would not have waited until the hearing. Petitioner has introduced no evidence to show that it corrected the disciplinary action reflected at CMS Ex. 16. If Dr. Ahmed believed Ms. Flores' account to be true, I would expect to see a record of the action taken by the facility to correct the disciplinary action, at least in regard to the allegation of improper referral. [(12)] Finally, Ms. Flores offered no explanation as to why she would accept responsibility for the actions noted in CMS Ex. 16, only to later tell Dr. Ahmed that she had incurred no violation by testing PT samples at Dynamic after the results were sent to CAP.

Although Petitioner argues that Ms. Flores did testing of GERL PT samples at her other place of employment after the results were sent to CAP, I am not persuaded as to her veracity. The manner in which Ms. Flores kept matters shrouded in secrecy raises doubt as to her testimony regarding when the GERL PT samples were sent to CAP, and leads to a conclusion that they were referred to Dynamic prior to the results being sent to CAP. This is because, if Ms. Flores had in fact removed the samples for testing at Dynamic merely to satisfy her curiosity as to the accuracy of the MicroScan Walk Away, she would have freely shared the results with her co-workers so all might benefit from her findings. In the absence of the intent to hide her actions, she would not have been so secretive. In fact, when first approached by the examiners regarding CMS Ex.15, she would not have tried to conceal her actions. Petitioner itself contends that "Miss. Flores was a dishonest technician who kept her actions to her self," and that she is the one who should be held responsible for all the deficiencies. P. R. Br. at 7.

Regarding specimen D4-07, and CMS's contention that D4-07 testing was performed at Dynamic because no bacitracin disks were available at GERL (CMS Ex. 1, at 5 - 6), Petitioner argues that it is normal terminology in bacteriology to refer a specimen for identification by more advanced methodology, such as the bacitracin disk or bacitracin methodology. P. Br. at 5. [(13)] Petitioner appears to suggest that Ms. Flores identified the specimen using bacitracin methodology. I infer from Petitioner's argument that this method did not require the use of bacitracin disks and could have been performed at GERL.

Petitioner has not, however, produced any evidence to rebut CMS's prima facie case that Ms. Flores tested the sample at Dynamic. I note that Ms. Flores had no confidence in her ability to operate the MicroScan Walk Away, and that she specifically stated at CMS Ex. 20, at 3, that she used a "bacitracin disc" for identification. *See also* CMS Ex. 1, at 5 - 6. Furthermore, the worksheet for D4-07 states that the organism was "not identified by Walk-away" and that it was identified as "hemolytic strep," "Bacitracin disc - Resistant." CMS Ex. 20, at 3. I therefore agree with CMS that the evidence shows that Ms. Flores tested samples other than D4-09 or, at least, "confirmed results" at another laboratory. CMS R. Br. at 3, n.1.

In view of the foregoing, it is my finding that CMS established a prima facie case that Petitioner engaged in improper referral of its PT to another laboratory for testing in violation of 42 C.F.R. § 493.801. Petitioner has presented no persuasive evidence to rebut CMS's showing.

Petitioner requests that I not hold it responsible for the actions of Ms. Flores, because she acted secretly and on her own, and the facility had no way of preventing the referral. However, the regulations allow no such avenue of escape. Dr. Ahmed, as owner and operator of GERL, bears the primary responsibility for the reliability of the results of all specimen testing performed in the laboratory. *See* 42 C.F.R. § 493.2.

C. Petitioner failed to examine PT samples with its regular patient workload.

Deviation from the standard practice of routine testing, handling, and reporting of PT samples is a violation of the requirements at 42 C.F.R. § 493.801(b)(1) and (5). Ms. Flores admitted that she tested PT samples at her other place of employment. In the written disciplinary action, Petitioner charged her with reporting to CAP a mix of Petitioner's PT results and those of a second laboratory. Ms. Flores accepted the disciplinary action, asserting that she was unaware of the regulations. CMS Ex. 16. As stated earlier, I do not find credible her testimony that she accepted the discipline unthinkingly, and that she did testing of PT samples at her other place of employment after sending the PT results to CAP. Consequently, the results of PT samples reported to CAP were not obtained through testing performed in the manner in which the laboratory would handle its regular workload.

D. The laboratory director failed to ensure that PT samples were tested in the same manner as patient samples.

The laboratory director, Dr. Rudolf Ulirsch, failed to ensure that PT samples were handled in the same manner as patient samples. The record is devoid of

any supervision exercised by Dr. Ulirsch in the processing of PT samples for the second testing event of 2000. In fact, Dr. Ulirsch admitted that he had no recollection of ever signing, as required by 42 C.F.R. § 493.801(b)(5), the attestation statement provided by the PT program documenting that the PT samples were tested in the same manner as patient specimens. Tr. at 524. Additionally, Dr. Ahmed testified that Dr. Ulirsch was not involved at all in PT activities for the second testing event of 2000. Tr. at 577.

Although Dr. Ahmed stated that he signed the microbiology PT attestation statement for GERL, the examiners found no formal delegation of authority by the laboratory director allowing him to do so. Tr. at 582. Aside from the fact that the attestation form sent to CAP had no laboratory director or designee signature on it, Dr. Ahmed was not permitted to sign the forms by delegation from the director because he lacked the required California clinical laboratory scientist license. Tr. at 205 - 206, 574; CMS. Ex. 20, at 2. I find, therefore, that there was no responsible individual at GERL permitted by the regulations to ensure compliance with PT requirements.

E. Petitioner did not meet the standard at 42 C.F.R. § 493.1205(e)(1) for test methods.

42 C.F.R. § 493.1205(e)(1) requires that reagents, solutions, culture media, control materials, calibration materials and other supplies must be stored and handled in a manner to ensure that they are not used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. Based on the State agency examiner's observation of the stored supplies and materials and the statements of testing personnel interviewed on September 13, 2000, CMS determined that the laboratory had, available for use, reagents and culture media that had exceeded their expiration date. CMS Ex. 1, at 10; Tr. at 224. Mr. Escovedo testified that the majority of the culture media in the refrigerator had expired months before the inspection visit. He added that even if the laboratory was not performing patient testing on the date of the survey, it was required to replace the expired reagents with new unexpired ones, since the facility was licensed and certified to conduct patient testing. [(14)] Tr. at 224 - 225. Additionally, Mr. Newbold testified that an antigen suspension used in testing for syphilis had expired. He added that the testing of samples with expired reagents poses a risk for patient harm. Tr. at 91 - 93. Here, CMS has made a prima facie case that Petitioner did not meet the standard pursuant to 42 C.F.R. § 493.1205(e)(1) for test methods. Petitioner presented no evidence to refute this charge.

F. Petitioner did not meet the standard at 42 C.F.R. § 493.1202(c)(1) for moderate and/or high complexity testing.

Based on the State agency examiner's observation on September 13, 2000, of the stored supplies and materials in a refrigerator located in the bacteriology laboratory, it was determined that the laboratory failed to follow the manufacturer's instructions for test systems operation and/or test performance. The State agency examiner specifically found that the refrigerator labeled F-1, which was located in the bacteriology laboratory, contained several reagents stored at 2 - 8 degrees C when the manufacturer specified on the reagent label to store at 15 - 30 degrees C. CMS Ex. 1, at 7 - 8. Mr. Newbold testified that he personally observed that the various reagents listed on CMS Ex. 1, at 8, were stored at incorrect temperatures. [(15)] The manufacturer had instructed that they should be stored at room temperature, but the laboratory placed them in the refrigerator. Tr. at 90. Mr. Newbold pointed out that improperly stored reagents could deteriorate and adversely affect patient testing by leading to incorrect patient testing results. Tr. at 91. Here, CMS has presented sufficient evidence to establish a prima facie case regarding this deficiency. Petitioner offered no evidence to rebut CMS's showing.

G. Petitioner did not meet the standard at 42 C.F.R. § 493.1407(e)(14) for laboratory director responsibilities.

The laboratory director must specify, in writing, the responsibilities and duties of each person engaged in the performance of preanalytic, analytic, and postanalytic phases of testing that identifies which examinations and procedures each individual is authorized to perform. CMS found that the laboratory director failed to specify, in writing, the duties and responsibilities for each person engaged in the performance of the analytic phases of testing. Specifically, a non-licensed individual was observed in the performance of patient HIV1/HIV2 testing. CMS Ex.1, at 12 - 13. Mr. Escovedo testified that the individual performing HIV testing was not listed on the laboratory's personnel form as someone authorized to perform such testing. Mr. Escovedo stated that he found nothing in writing by the laboratory director specifying the duties and responsibilities of every person working in the facility. Tr. at 227 - 228. This finding, or lack of it, was significant, because HIV1/HIV2 testing is high complexity testing, yet no licensing credentials were made available for the person performing such tests. In the absence of evidence to the contrary, I infer that the individual observed performing HIV testing was not licensed to do so. Petitioner presented no evidence to rebut CMS's prima facie case regarding this deficiency.

H. Petitioner did not meet the condition at 42 C.F.R. § 493.1441 for laboratory director.

A participating laboratory must have a director who provides overall direction

and proper management for a laboratory pursuant to 42 C.F.R. §§ 493.1441 and 1445. The evidence of record, and the admissions of Petitioner's own agents, confirm that proficiency samples were not processed using the laboratory's regular testing procedures. In this regard, it is noted that the PT results reported to CAP were not obtained solely through onsite testing following the facility's routine methods. Dr. Ulirsch's failure to ensure that the PT scores reported to CAP were solely the result of onsite testing, and not those obtained through referral and corroboration at other participating laboratories, are a clear indication that he was out of touch with the day to day operations of his laboratory. Pertinent to this is his testimony to the effect that he made only sporadic visits to the laboratory. Tr. at 526. It is obvious that Dr. Ulirsch did not fulfill his ultimate responsibility to ascertain that proficiency testing and reporting was carried out in accordance with the requirements set forth at 42 C.F.R. § 493.801. It should be noted that Dr. Ulirsch failed to sign the attestation sheets for the second testing event of 2000, documenting that the PT samples were tested in the same manner as patient specimens. This is a clear violation of 42 C.F.R. § 493.801(b)(5).

It is also the laboratory director's duty to ensure that controls and reagents do not exceed their expiration dates, and are stored in keeping with the manufacturer's instructions. Dr. Ulirsch failed to do this. The preceding discussion establishes that Petitioner stored reagents and control materials beyond their expiration dates, and also kept reagents at improper temperatures.

The laboratory director failed to specify, in writing, the duties and responsibilities for each person engaged in the performance of the analytic phases of testing. Specifically, a non-licensed individual was permitted to perform patient HIV1/HIV2 testing.

The regulations promulgated by the Secretary make the laboratory director responsible for assuring that a laboratory satisfies CLIA requirements. Here, Petitioner's failure to meet these requirements points to the laboratory director's failure to properly discharge his duties. Moreover, Petitioner's laboratory director failed to meet his obligations under the standard at 42 C.F.R. § 493.1445 to such an extent that it constitutes a failure on the part of Petitioner to comply with the condition for laboratory director.

I. Petitioner's actions justify revocation of its CLIA certificate and cancellation of its approval to receive Medicare and Medicaid reimbursement.

The regulation at 42 C.F.R. § 493.801 unequivocally establishes that a laboratory must not intentionally send PT samples or portions of samples to

another laboratory for any analysis for which it is certified to perform in its own laboratory. This includes a prohibition against engaging in any inter-laboratory communications or corroboration pertaining to the results of PT samples until after the date by which the laboratory must report PT results to the program for the testing event in which the samples were sent. 42 C.F.R. § 493.801(b)(4). Intentional here means not inadvertent or not through mere oversight. *Long Medical Laboratory*, DAB CR334, at 6 - 9 (1994).

When PT results are not obtained through independent testing of samples in the same manner as patient samples are tested, the integrity of the entire proficiency testing program is undermined.

The legislative history of CLIA not only reflects the significance attached by the legislators to the accuracy and reliability of laboratory testing, but also their concern that laboratories would seek questionable ways to undercut the intent of Congress.

As stated by the Administrative Law Judge in *Long Medical Laboratory*, DAB CR334, at 4:

> It is apparent, both from the Act itself and its legislative history, that Congress considers proficiency testing conducted pursuant to standards developed by the Secretary to be an important factor in assuring that clinical laboratories conduct tests accurately and reliably. The Act directs the Secretary to develop standards for proficiency testing. 42 U.S.C. § 263a(f)(3). The House of Representatives committee report which supported the Act provides that:
>
> > To maintain its certification under the bill, a laboratory would have to participate successfully in a proficiency testing program that met standards established by the Secretary. The Committee believes that proficiency testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes.

1988 U.S.C.C.A.N. 3849.

Petitioner raises several contentions in defense of the revocation and cancellation actions undertaken by CMS. These are all inconsequential, ranging from the inadequacy of the evidence adduced by CMS to its claim that its facility was not actively engaged in the performance of patient testing. Thus, none of Petitioner's arguments suffice to create any doubt that Petitioner failed to comply with the conditions for participation noticed by CMS.

VIII. Conclusion

In September 2000, for the second CAP testing event in 2000, Petitioner had condition-level deficiencies regarding its treatment of PT samples and also its laboratory director's improper direction and management of laboratory operations. Accordingly, CMS had a basis to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare and Medicaid payment for its services. Moreover, CMS was required to take this action with regard to Petitioner's referral of proficiency testing samples.

JUDGE

Jose A. Anglada

Administrative Law Judge

FOOTNOTES

1. The Health Care Financing Administration (HCFA) has been renamed the Centers for Medicare & Medicaid Services (CMS). Reference to either shall apply to both names.

2. I admitted CMS Ex. 24 over Petitioner's objection. *See* Tr. at 8 - 17.

3. Petitioner referred to its response brief as its "Closing - Post Hearing Brief".

4. Petitioner was enrolled in the College of American Pathologists (CAP) PT program at all relevant times. CMS Ex. 2, at 1; P. R. Br. at 1; *see* Tr. at 31 - 36.

5. I note, however, Petitioner's argument that the statement of deficiencies is inaccurate and fraught with discrepancies. One of the "mistaken statements" in the Statement of Deficiencies alluded to by Petitioner refers to an erroneous identification of PT sample D4-09. Tr. at 23. However, Donald Newbold, a State agency examiner and CMS witness, clarified that after drafting the Statement of Deficiencies, he discovered a typographical error in the citation to the proficiency sample which Ms. Flores admitted testing at the other laboratory where she was employed. On page 5 of CMS Ex. 1, §§ "b" and "c" should refer

to CAP PT sample D4-09, rather than D4-07. CMS corrected the error in a letter to Petitioner dated February 22, 2002, which I admitted over Petitioner's objection as CMS Ex. 24. Thus, Petitioner was timely made aware of the error and its correction. Additionally, Petitioner has not shown that it was prejudiced in any way by the error and its correction. The other discrepancies noted by Petitioner are inconsequential. P. Br. at 2, § 1.

6. Mr. Newbold is currently an attorney with the State of California, Department of Health Services, and was so employed at the time of the survey in question. Tr. at 25. He is also a licensed clinical laboratory scientist. Tr. at 26. Prior to his employment as an attorney, Mr. Newbold was employed as a State agency examiner. *Id.*

7. During the time he worked as an examiner, Mr. Newbold operated a special investigation section within the State agency. The section instituted the practice of inspecting trash bins seeking data and records that had been thrown out by laboratories it was investigating. Tr. at 28 - 29.

8. Sensitivity testing is the procedure by which a laboratory determines the antibiotics to which the bacteria being tested is sensitive. Tr. at 37 - 38.

9. One indicator that the testing did not pertain to Dynamic Medical Laboratories was that Dynamic was enrolled in a PT program with the American Association of Bioanalysts (AAB) and not with CAP. Tr. at 41.

10. The MicroScan Walk Away System (CMS Ex. 1, at 5) is variously referred to in the record before me as the Microscan, Microscan Walkaway, or Walk Away. In this decision, I use the term "MicroScan Walk Away" to refer to the equipment in question.

11. From the tenor of Ms. Flores' testimony, it appears that her distrust of the MicroScan Walk Away was in reality a distrust of her own ability and lack of experience in the operation of the MicroScan Walk Away. Tr. at 446 - 448. This is evident from her belief that the MicroScan Walk Away was a superior testing instrument. Tr. at 431 - 432. However, although the MicroScan Walk Away is a computer based, sophisticated testing instrument, Ms. Flores did not appear to be computer literate. Tr. at 576.

12. I defer for later discussion the matter of the other deficiencies for which Ms. Flores admitted responsibility.

13. Petitioner also references specimen D4-08. However, I make no findings regarding specimen D4-08.

14. Mr. Escovedo testified that the laboratory was actively engaged in patient

specimen testing during his survey visit. Tr. at 225.

15. The reagents Mr. Newbold asserts were stored at incorrect temperatures include: 0.8% sulfanilic acid, (NITI), Kovac's reagent, (IND), 40% KOH (VPI), 0.5% N, N-dimenthylalphanaphtylamine (NIT2), and 10% ferric chloride, (TDA). CMS Ex. 1, at 8.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	
SUBJECT: Lackawanna Medical Group Laboratory, Petitioner, - v - Centers for Medicare & Medicaid Services	DATE: Sepetmber 27, 2002 Docket No.**C-01-191** Decision No. **CR957**
DECISION	

DECISION

Lackawanna Medical Group Laboratory's (Petitioner's) certificate to operate as a clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[1] is revoked for a period of one year effective the date of this decision. The Centers for Medicare & Medicaid Services (CMS) [2] motion for summary judgment is granted as there are no material issues of fact in dispute and the only issues may be resolved by application of the law to the undisputed facts.

I. Procedural History

Petitioner was surveyed by the Pennsylvania Department of Health (the State agency) on July 18 and August 7, 2000. By letter dated November 13, 2000, Respondent advised Petitioner that it proposed to revoke Petitioner's CLIA certificate and to cancel Petitioner's authorization to receive Medicare payment for its services pursuant to 42 U.S.C. § 263a. CMS cites as grounds for the proposed action, the survey by the State agency on July 18, 2000, which allegedly showed that Petitioner intentionally referred its proficiency test samples to another laboratory and proficiency test samples were not treated the same as regular patient workload. Petitioner filed a request for hearing by letter dated November 21, 2000.

On December 13, 2000, this case was assigned to Judge Carolyn Hughes for hearing and decision. The case was subsequently reassigned to me for hearing and decision on October 11, 2001.

On February 26, 2001, CMS notified Petitioner that it "reopened" the proposed

revocation of Petitioner's CLIA certificate based on receipt of a revised statement of deficiencies. CMS advised Petitioner that it proposed to revoke Petitioner's CLIA certificate and the authority to receive payment by Medicare, based on both the July 18 and August 7, 2000 surveys and the allegations that: (1) Petitioner intentionally referred its proficiency test samples to another laboratory for analysis; (2) Petitioner did not treat its proficiency test samples the same as regular patient workload and the samples were taken to another laboratory for testing prior to reporting results to the proficiency test program; and (3) Petitioner failed to maintain all required records. Petitioner amended its request for hearing by "Consented Motion for Leave to File Additional Responses and/or to Consolidate Matters, and Responses to February 26, 2001 Re-Opening of Proposed Revocation." filed on April 30, 2001.

On August 2, 2001, CMS filed its motion for summary judgment with two exhibits, CMS Exhibit (CMS Ex.) 1 and 2. Petitioner filed its brief in opposition on September 4, 2001 with five exhibits, Petitioner's Exhibit (P. Ex.) 1 through 5. All exhibits submitted with the motion and opposition are admitted for purposes of this decision.

II. Findings of fact and conclusions of law

A. Findings of fact

The following findings of fact are based upon the pleadings and exhibits submitted related to the motion for summary judgment, considering the facts and all inferences drawn therefrom in a light most favorable to the nonmovant, the Petitioner. [(3)]

1. Petitioner possessed a valid CLIA certificate and was authorized to receive Medicare payments at all relevant times.

2. Petitioner's laboratory was surveyed by the State agency on July 18 and August 7, 2000.

3. CMS proposed to revoke Petitioner's CLIA certificate and authorization to receive Medicare payments based on deficiencies allegedly found during the surveys of July 18 and August 7, 2000.

4. Petitioner had a quality control program.

5. Petitioner's quality control policy states that when it sends its samples for parallel testing at another laboratory, it includes proficiency test samples with its regular patient workload.

6. Petitioner tested proficiency test samples with its regular patient workload, using its regular staff and the regular protocol within its laboratory.

7. Petitioner only reported the results of its own testing of proficiency test samples to the proficiency program and not the results of parallel testing by another laboratory.

8. By sending proficiency test samples with regular patient test samples for parallel testing, Petitioner intended to comply with the requirement of 42 C.F.R. § 493.801(b)(1) which requires that proficiency test samples be treated the same as those of regular patient workload.

9. Petitioner's practice of sending out proficiency test samples with its regular patient workload was reviewed in the past but no deficiency was cited

10. Petitioner intended to send proficiency test samples to another laboratory.

11. Petitioner sent proficiency test samples to another laboratory.

B. Conclusions of Law

1. A laboratory must not send proficiency test samples or portions of samples to another laboratory, intentionally or unintentionally, for analysis which it is certified to perform in its own laboratory, or for any other reason. 42 C.F.R. § 493.801(b)(4).

2. The motives of the laboratory that sends proficiency test samples to another laboratory for analysis that the sending laboratory is certified to perform, are irrelevant and not a defense to violation of 42 C.F.R. § 493.801(b)(4).

3. The fact that the laboratory that sends proficiency test samples to another laboratory for analysis that the sending laboratory is certified to perform, never reports the analysis of the proficiency samples to the proficiency program is irrelevant and not a defense to a violation of 42 C.F.R. § 493.801(b)(4).

4. There is no conflict between 42 C.F.R. § 493.801(b)(1) which requires that proficiency test samples be tested in the laboratory, with regular patient workload, using regular laboratory personnel and procedures, and 42 C.F.R. § 493.801(b)(4) which establishes an absolute ban on sending out proficiency test samples to another laboratory.

5. CMS is not bound or estopped by prior agency action when that action was based on an erroneous interpretation and application of the statute and regulations.

6. There are no material facts in dispute and issues that require resolution are questions of law, therefore summary judgment is appropriate.

7. Petitioner violated 42 C.F.R. § 493.801(b)(4) by admittedly sending proficiency test samples to another laboratory.

8. CMS is required to revoke Petitioner's CLIA certificate for a period of not less than one year for sending proficiency test samples to another laboratory. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b).

9. CMS must cancel Petitioner's approval to receive Medicare payments when its CLIA certificate is revoked. 42 C.F.R. § 493.1842(a).

10. The violation of 42 C.F.R. § 493.801(b)(4) triggers a mandatory one-year revocation of Petitioner's CLIA certificate which requires cessation of entitlement to Medicare payments, therefore it is unnecessary to consider other alleged violations.

11. Revocation of Petitioner's CLIA certificate is effective the date of this decision. 42 C.F.R. §493.1844(d)(2).

III. Discussion

A. Issue

Whether there is a basis for CMS's revocation of Petitioner's CLIA certificate.

B. Applicable law

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Pursuant to CLIA, the Secretary of Health and Human Services (the Secretary) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. 263a(f) and issued regulations implementing CLIA. See 42 C.F.R. Part 493. The regulations specify standards and the specific conditions of certification that a laboratory must meet to

achieve compliance. The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

The regulations provide as a condition for participation that a laboratory conducting moderate or high complexity testing, as was Petitioner, must enroll in an approved proficiency testing program or programs that cover all the specialties and sub-specialties for which the laboratory seeks certification. The laboratory is required to test proficiency test samples in the same manner as its regular patients' specimens. 42 C.F.R. § 493.801. Standards established to satisfy this condition level requirement are set forth at 42 C.F.R. § 493.801(b)(1) through (6). The standards pertinent to this case are:

> 1. Proficiency test samples must be examined or tested with the regular client workload, by the same laboratory personnel, and with the laboratory's regular or routine method;
>
> 2. Proficiency test samples must be tested the same number of times as regular patient samples.
>
> 3. Inter-laboratory communications about the results of testing proficiency test samples is prohibited until after the date for reporting test results to the proficiency testing program.
>
> 4. A laboratory must not send proficiency test samples or portions thereof to another laboratory for any analysis that it is certified to perform and if it intentionally does so, CMS must revoke its CLIA certificate for a year.

CMS must revoke a laboratory's CLIA certificate for one year if CMS determines that the laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b). CMS must also cancel a laboratory's approval to receive Medicare payments when CMS suspends or revokes the laboratory's CLIA certificate. 42 C.F.R. § 493.1842(a). CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory. . . ." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an administrative law judge (ALJ). 42 C.F.R. § 493.1844(a). The hearing procedures found in subpart D of Part 498 are incorporated by reference. 42 C.F.R. § 493.1844.

The "suspension, limitation or revocation of the laboratory's CLIA certificate ... because of noncompliance. . . ." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1). Generally when a hearing is requested, suspension or revocation of a CLIA certificate is not effective until after a hearing decision is issued by the administrative law judge. 42 C.F.R. § 493.1844(d)(2). Pursuant to 42 C.F.R. § 1844(f) it is presumed that Petitioner has a right to a hearing in this case. *See Garden City Medical Clinic*, DAB No. 1763 (2001), citing 42 U.S.C. § 263a(i)(1) and 42 C.F.R. § 493.1844(a). However, summary judgment is appropriate and no hearing is required where either: there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party. *See e.g.*, Fed. R. Civ. P. 56(c); *Garden City,* supra, *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1977) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony). In opposing Respondent's motion for summary judgment, Petitioner bears the burden of showing that there are material facts that are disputed. *Everett Rehabilitation*. It is not sufficient for Petitioner to rely upon mere allegations or denials to defeat the motion and proceed to hearing. Petitioner must, by affidavits or other evidence which set forth specific facts, show that there is a genuine issue for trial. If Petitioner cannot show by some credible evidence that there exists some genuine issue for trial, then summary judgment is appropriate and Respondent must prevail as a matter of law. Furthermore, if CMS establishes a prima facie case that Petitioner violated 42 C.F.R. § 801(b)(4) by intentionally referring proficiency test samples to another laboratory and Petitioner raises no defense, a one-year revocation of Petitioner's CLIA certificate is mandatory with the attendant termination of Medicare payments, and there is no issue related to the reasonableness of these remedies.

IV. Conclusion

For the foregoing reasons, CMS's motion for summary judgment is granted. Petitioner's CLIA certificate is revoked for a period of one year effective the date of this decision and Petitioner's approval to receive Medicare payments is cancelled.

ANALYSIS

CMS alleges three regulatory violations in this case, intentional referral of proficiency test samples to another laboratory, failure to treat proficiency samples the same as regular patient workload and failure to maintain required records, violations of 42 C.F.R. §§ 493.801(1), (2) and (4). Petitioner correctly notes that CMS also alleged in both its November 13, 2000-notice and its February 26, 2001-notice that Petitioner sent the proficiency test program the results of testing of proficiency test samples from another laboratory. Whether or not Petitioner submitted the results of testing by

another laboratory as its own, kept all required records, or failed to treat proficiency test samples the same as its regular patient workload, are fact issues that would require further evidentiary development through a hearing. However, Petitioner admits that it did send proficiency test samples to another laboratory for testing. Because I find that the act of sending proficiency test samples to another laboratory constitutes a violation that triggers a mandatory one-year revocation of Petitioner's CLIA certificate, there is no need to consider further the unresolved questions of fact and no need for a hearing. This case can be fully resolved by application of the law to the undisputed facts.

It is undisputed that Petitioner sent proficiency test samples to another laboratory for testing. Petitioner's director, Frank A. Milani, M.D., provided an affidavit in which he states that Petitioner always intended to comply with 42 C.F.R. § 493.801(b)(1) which requires that proficiency test samples be treated the same as regular patient test samples. Therefore, in accordance with its written policy, Petitioner periodically sent proficiency samples to another laboratory for "parallel testing" with its regular patient workload. P. Ex. 1. Petitioner's employee, Cathy Pratt, also provided an affidavit in which she confirmed the testimony of Dr. Milani, that proficiency test samples were sent to another laboratory for testing with regular patient workload as required by Petitioner's policy. Consistent with Dr. Milani's affidavit, Ms. Pratt states that she actually conducted the testing at both Petitioner and the other laboratory. Ms. Pratt further states that she did not report results from the other laboratory to the proficiency test program. P. Ex. 2.

In its letter dated November 21, 2000, Petitioner responds to the CMS allegation of a violation or 42 C.F.R. § 493.801(b)(4). Petitioner's Director, Dr. Milani, wrote:

> *PT (proficiency test) samples WERE tested in the POL with the laboratories (sic) regular patient workload using the laboratories (sic) routine methods and none other.*
>
> *Our in-house QC (quality control) Program clearly states . . . that the physician's office lab (POL) will submit patient samples to Med Science at regular intervals for parallel studies. Therefore, since this is how we handle our routine patients by adding an extra QC step, it is also necessary (by regulation) to run PT samples for parallel checks for our internal use even though we only report PT samples from our in-house (POL) runs. This practice has been reviewed on previous inspections and no citations were made.*

P. Ex. 3 (emphasis in original).

For purposes of the motion for summary judgment, I accept the affidavit of Dr. Milani, Ms. Pratt, and Dr. Milani's statements in the letter of November 21, 2000 as true.

Therefore, I accept as undisputed fact that:

> 1. Petitioner had a quality control program.
>
> 2. Petitioner's quality control program required that when it sent samples for parallel testing at another laboratory, it included proficiency test samples with its regular patient workload.
>
> 3. Petitioner tested proficiency test samples with its regular patient workload, using its regular staff and regular protocol within its laboratory.
>
> 4. Petitioner only reported the results of its own testing of proficiency test samples to the proficiency program and not the results of parallel testing in another laboratory.
>
> 5. By sending proficiency test samples with regular patient test samples for parallel testing, Petitioner intended to comply with the requirement of 42 C.F.R. § 493.801(b)(1) which requires that proficiency test samples be treated the same as those of regular patient workload.

The question then is whether, in light of these undisputed facts, Petitioner violated 42 C.F.R. § 493.801(b)(4) by sending proficiency test samples to another laboratory. I conclude, as a matter of law, that the admitted conduct constitutes a violation and that CMS is required to revoke Petitioner's CLIA certificate for a period of not less than one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b). CMS must also cancel the laboratory's approval to receive Medicare payments. 42 C.F.R. § 493.1842(a).

The language of 42 C.F.R. § 493.801(b)(4) is clear that a "laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory." The plain language is that a proficiency test sample may not be sent to another laboratory, either intentionally or unintentionally. The regulation further provides that if a sample is "intentionally" sent, then the laboratory's CLIA certificate must be revoked for at least a year. The regulation establishes an absolute bar to sending proficiency test samples to another laboratory for testing if the sending laboratory is certified to do the same testing. The language of the statute is equally clear: "(a)ny laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year. . ." 42 U.S.C. § 263a(i)(4). *See also* 42 C.F.R. § 493.1840(b) which implements the statute. The statute and regulations allow for no exceptions to the prohibition. Thus, the motives of the laboratory that sends proficiency test samples to another laboratory for analysis that the sending laboratory is certified to perform, are irrelevant. The fact that the sending laboratory never reports the analysis of the proficiency samples to the proficiency program is not mentioned by the statutes or regulations as an exception or defense to the prohibition, and is also irrelevant. The act prohibited is the sending of proficiency test samples to another laboratory for

analysis when the sending laboratory is certified to do the analysis. Other judges who have considered this issue have reached the same strict construction. *See Primary Care Medical Group*, DAB CR439 (1996) (includes a lengthy discussion of Congressional intent related to the prohibition that I will not restate here); *Long Medical Laboratory*, DAB CR334 (1994).

I reject Petitioner's argument based on *Oakland Medical Group, P.C.*, DAB No. 1755 (2000) and *Primary Care Medical Group*, DAB CR439 (1996) that sending proficiency test samples to another laboratory for testing is not a violation unless it is also shown that Petitioner submitted the test results to the proficiency test program or that Petitioner failed to treat proficiency test samples like its regular workload. In both *Oakland* and *Primary Care*, the facts required consideration of additional violations, but neither case holds that the act of referring proficiency test samples to another laboratory is not a violation.

Petitioner argues that a strict construction of 42 C.F.R. § 493.801(b)(4) creates a conflict between that regulation and the requirement of 42 C.F.R. § 493.801(b)(1) that proficiency test samples be treated the same as regular patient workload. Petitioner asserts as its defense that it was complying with the requirements of 42 C.F.R. § 493.801(b)(1) and that 42 C.F.R. § 493.801(b)(4) ought to be construed consistently. My review of the two regulatory provisions reveals no challenge of regulatory construction. Section 493.801(b)(1) is clear: "(t)he samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods (emphasis added)." The subsection goes on to require that the laboratory director must certify that the proficiency test samples were integrated into the regular patient workload and tested using the laboratory's routine methods. Subsection 493.801(b)(1) mentions testing within the laboratory using the laboratory's routine methods, there is no mention of the possibility of sending out samples for analysis. The silence of section 493.801(b)(1) regarding sending out samples for analysis is consistent with the absolute ban on sending out samples provided by section 493.801(b)(4). Petitioner cites no legal authority that has recognized any conflict between the two subsections. In its November 21, 2000-letter (P. Ex. 4), Petitioner mentions that its practice of sending out proficiency test samples with its regular patient workload had been reviewed in the past but no deficiency was cited. Again, for purposes of summary judgment, I accept this assertion as true. Petitioner implies that either the State agency or CMS previously surveyed Petitioner's laboratory, considered the practice of sending out proficiency test samples and did not cite Petitioner for any deficiency. Petitioner seeks to have the inference drawn that because no deficiency was cited, the practice was approved by either the State agency or CMS. Even if I accept the inference, I cannot find CMS bound or estopped by the prior agency action as that action would have been based on an erroneous interpretation and application of the statute and regulations as discussed above. Furthermore, the decisions of the United States Supreme Court in *Office of Personnel Management v. Richmond*, 496 U.S. 414, 110 S.Ct. 2465, 110 L.Ed.2d 387 (1990) and *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 104 S.Ct. 2218, 81 L.Ed.2d 42, 5 Soc.Sec.Rep.Ser. 29 (1984) make clear that

estoppel will generally not lie against the government in cases involving benefits to be paid from the Treasury, particularly in the complicated area of Medicare. [4]

In this case, Petitioner has not attempted to show material facts in dispute regarding sending proficiency test samples to another laboratory, which is consistent with my conclusion that there are no material issues of fact in dispute related to the practice. [5] Rather, Petitioner sets forth its legal defenses in its responsive brief. I do not find Petitioner's defenses persuasive. Furthermore, the absence of material fact and the presence of only questions of law, allows for resolution of this case as a matter of law and summary judgment is appropriate. The violation triggers a mandatory one-year revocation of Petitioner's CLIA certificate. Hence, it is unnecessary to consider other alleged violations.

JUDGE

Keith W. Sickendick

Administrative Law Judge

FOOTNOTES

1. Pub. L. 100-578, codified at 42 U.S.C. § 263a.

2. The Centers for Medicare & Medicaid Services was known as the Health Care Financing Administration until July 5, 2001.

3. In findings 6 through 9, I accept as true Petitioner's allegations of fact only for purposes of deciding this motion for summary judgment.

4. It has been consistently held that administrative law judges do not have the authority to hear and decide claims of estoppel against CMS or the Secretary related to alleged dilatory processing of applications. GranCare Home Health Service & Hospice, DAB CR464 (1997); The Rivers Health Care Resources, Inc., DAB CR446 (1996); SRA, Inc. D/B/A St. Mary Parish Dialysis Center, DAB CR341 (1994); T.L.C. Mental Health Center, DAB CR636 (1999); Therapeutic Rehabilitation Centers, Inc., DAB CR531 (1998). However, I find no similar limit to my jurisdiction where Petitioner asserts estoppel as a defense in an enforcement action. Accord Stacy Ann Battle, D.D.S., DAB No. 1843 (2002).

5. This case is readily distinguished from *Garden City Medical Clinic*, DAB No. 1763 and *Southfield Medical Clinic*, DAB CR677, as those cases did not involve an admission by the Petitioner that proficiency test samples were sent to another laboratory for testing.

Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

IN THE CASE OF	
SUBJECT: Preferred Family Clinic, Petitioner, - v - Centers for Medicare & Medicaid Services	DATE: November 18, 2002 Docket No.**C-01-254** Decision No. **CR975**
DECISION	

DECISION

Preferred Family Clinic (Petitioner) is a Michigan-based clinical laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq*. Petitioner appeals the decision of the Centers for Medicare & Medicaid Services (CMS) [(1)] to impose sanctions against it. Those sanctions include revoking Petitioner's CLIA certificate for at least one year and cancelling its approval to receive Medicare payments. For the reasons discussed below, I sustain CMS's determinations.

I. Background

In a letter dated March 3, 2000, the Commission on Office Laboratory Accreditation (COLA) advised CMS that it had denied Petitioner accreditation because Petitioner had knowingly compared the results of proficiency tests (PT) with another laboratory. CMS exhibit (CMS Ex.) 3. In response, CMS directed the Michigan Department of Consumer and Industry Services (State Agency) to conduct an unannounced investigation survey at Petitioner's facility to determine whether the improper PT referral had occurred and to identify the laboratory with which Petitioner purportedly compared results. CMS Ex. 10.

On April 17, 2000, the State Agency conducted its survey and reported its findings to CMS. CMS Ex. 2, at 7 *et seq*. Based on the survey results, CMS

found COLA's allegations credible; improper referral, collaboration, and non-integration of PT samples occurred during 1998 and 1999 testing events. In a notice dated October 27, 2000, CMS advised Petitioner that it was out of compliance with two condition-level CLIA requirements: 42 C.F.R. § 493.801 (Enrollment and Testing of Samples) and 42 C.F.R. § 493.1441 (Laboratory Director). Specifically: 1) Petitioner did not routinely integrate PT samples into its regular workload, in violation of the standard at 42 C.F.R. § 493.801(b)(1); 2) Petitioner referred some PT samples to another laboratory for analysis, in violation of the standard at 42 C.F.R. § 493.801(b)(4); 3) Petitioner collaborated in the administration of the PT samples for specific test events of 1998 and 1999, a violation of the standard at 42 C.F.R. § 493.801(b)(3); 4) Petitioner did not maintain a copy of all PT documentation for 1998 and 1999 PT results, as required by the standard at 42 C.F.R. § 493.801(b)(5); 5) no documentation confirmed that PT was performed after 1998, as required by the standard at 42 C.F.R. § 493.801(b)(5); and 6) Petitioner was not enrolled in a PT program for the first testing event of 1999, in violation of 42 C.F.R. § 493.801. CMS Ex. 2, at 1 - 2.

CMS also determined that Petitioner's laboratory director had not fulfilled his responsibility for assuring that PT samples were tested as required under 42 C.F.R. § 493, subpart H. The laboratory's deficiencies demonstrated that the director had failed to fulfill his responsibility for its overall operation and administration. Thus, CMS found Petitioner out of compliance on the condition-level requirement for laboratory director. 42 C.F.R. § 493.1441. CMS Ex. 2. CMS concluded that Petitioner's noncompliance substantially limited Petitioner's capacity to render accurate and reliable services and to protect the health and safety of Petitioner's laboratory patients. Based on the state survey findings, CMS proposed to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare payment for its laboratory services. CMS Ex. 2, at 3.

Petitioner timely requested a hearing. CMS seeks summary affirmance (CMS Br.), which Petitioner opposes (P. Br.). With its motion for summary affirmance, CMS filed 14 exhibits (CMS Exs. 1 - 14). With its brief, Petitioner filed five exhibits (P. Exs. 1 - 5) and a copy of CMS Ex. 8 and a copy of page 1 of CMS Ex. 4. In the absence of objection, I admit CMS Exs. 1 - 14 and P. Exs. 1 - 5 into evidence. I am not marking Petitioner's copies of CMS Ex. 8 and page 1 of CMS Ex. 4 as separate exhibits, as they are already in the record.

II. Issue

The issue in this case is whether Petitioner failed to comply with one or more CLIA conditions of participation, thereby giving CMS the authority to impose

remedies, including the revocation of Petitioner's CLIA certificate and the cancellation of Petitioner's approval to receive Medicare payments.

III. Statutory and Regulatory Background

In order to ensure the accuracy and reliability of laboratory tests, and thus the health and safety of those tested, CLIA creates a federal certification process for laboratories that perform clinical diagnostic tests on human specimens. Public Law No. 100-578, *amending* section 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq.*; *see* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. To be certified, a laboratory must meet the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263(a)(f)(1)(E); 42 C.F.R. § 493.1 *et seq.* The statute gives the Secretary of Health and Human Services (Secretary) broad enforcement authority, including the authority to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more conditions. Each condition represents a major division of laboratory services or required environmental protections. Standards are specific components of the conditions. *RNA Laboratories, Inc.*, DAB No. 1820, at 3 (2002).

A laboratory that holds a CLIA certificate of accreditation is permitted to perform moderate and high complexity tests and must participate in the PT program outlined in 42 C.F.R. Part 493, Subpart H. Under its provisions, each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493. 42 C.F.R. § 493.801. A laboratory performing moderate or high complexity testing "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which [it] is certified under CLIA." 42 C.F.R. § 493.803(a).

A laboratory must treat and analyze PT samples in the same manner as patient samples. 42 C.F.R. § 493.801(b); 42 C.F.R. § 493.61(b)(1); 42 U.S.C. § 263a(d)(1)(E). The PT samples must be integrated with the laboratory's regular patient workload and the tests must be performed by the same personnel who routinely do the testing, using the laboratory's routine testing method. 42 C.F.R. § 493.801(b)(1). The integration of PT samples must be attested to by the laboratory director and the individual who performs the testing. PT samples must be tested the same number of times as routine patient samples. 42 C.F.R. § 493.801(b)(2). Records documenting each step taken in the testing of PT samples are required. 42 C.F.R. § 493.801(b)(5).

A laboratory may not engage in inter-laboratory communications pertaining to PT results until after the due date by which a laboratory must report its results to the PT program. 42 C.F.R. § 493.801(b)(3). It must not refer PT samples or

portions of PT samples to another laboratory for any analysis that it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i). If a laboratory intentionally refers PT samples to another laboratory for analysis, its CLIA certificate must be revoked for at least one year. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i)(4).

CMS or its designee (such as the State Agency here) conducts validation inspections to determine a laboratory's compliance with CLIA requirements. 42 C.F.R. § 493.1780(a). A laboratory's failure to comply with even a single condition in an area of testing offered by that laboratory may be grounds for suspension or revocation of its CLIA certificate. *RNA Laboratories,* at 3; *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or state monitoring. 42 C.F.R. § 493.1806.

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies. The CLIA regulations incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, Subparts D and E. 42 C.F.R. § 493.1844(a)(2) and (3). CMS has the burden of coming forward with sufficient evidence to prove a prima facie case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, CMS's prima facie case. *Emil S. Sitto, M.D.,* DAB CR935, at 4 (2002), *citing Edison Medical Laboratories, Inc.,* DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd. Hillman Rehabilitation Center v. HHS,* No. 98-3789 (GEV), slip op. at 25 (D.N.J. May 13, 1999).

IV. Discussion

I make findings of fact and conclusions of law (Findings) to support my decision. I set forth each finding, below, in bold and italics, as a separately numbered heading.

1. Summary disposition is appropriate where, as here, Petitioner has not demonstrated any dispute regarding genuine issues of material fact.

Summary disposition is appropriate where there are no disputed issues of material fact and where the only questions that must be decided involve either questions of law or the application of the law to the undisputed facts. A party opposing summary disposition must allege facts which, if true, would refute the facts relied upon by the moving party. *See, e.g.*, Fed. R. Civ. P. 56(c); *Garden City Medical Clinic*, DAB No. 1763, at 12 (2001), *citing Everett Rehabilitation*

and Medical Center, DAB No. 1628, at 3 (1997) (in-person hearing required where non-movant shows there are material facts in dispute that require testimony). A party may not simply state that it disputes allegations of fact in order to avoid the entry of summary disposition; it must describe the asserted facts credibly in order to establish a dispute.

CMS is requesting summary affirmance here as a matter of law because it asserts that no material facts are in dispute. Petitioner argues generally from the undisputed material facts that CMS's evidence does not prove its allegations (P. Br. at 6), but it offers no affidavit, declaration, or other documentary evidence to rebut CMS's case. Instead, the parties look at the same evidence and argue different conclusions. Under these circumstances, summary judgment is appropriate. *Sitto,* at 4 - 5.

2. During 1998 and 1999, Petitioner violated 42 C.F.R. § 493.801 by colluding with other laboratories in the testing of proficiency samples, and by failing to test the samples in the same manner as it tested patient specimens.

As noted above, clinical laboratories must enroll in a PT program that meets defined criteria. 42 C.F.R. § 493.801. Each participating laboratory must test its samples independently, as if they were patient specimens, and must report the results of its tests to an approved testing service. During 1998 and 1999, Petitioner participated in a PT program offered by the American College of Physicians-American Society of Internal Medicine, known as Medical Laboratory Evaluation (MLE). CMS Ex. 5, at 4. MLE mailed samples to its participating laboratories three times per year (each such transmission is known as a testing event). The participating laboratories were required to test those samples and send the results to MLE. *See Id.* at 2. To determine whether the laboratory had properly analyzed its samples, MLE compared the results it received from all the laboratories that had, using the same equipment and reagent combination, analyzed samples from the same specimen pool. MLE then provided each laboratory with a PT evaluation report which included graded results and details of the laboratory's performance in that testing event. The laboratory could use the report to review its own performance, and make any necessary corrections. The accrediting organization, such as COLA, would also consider the report in evaluating the laboratory's performance. *Id*.

COLA's June 1999 Inspection

COLA performs a biannual onsite inspection for each laboratory enrolled in its accreditation program, and on June 29, 1999, COLA inspected Petitioner's facility. *Id.* at 3. The inspector found significant irregularities in MLE test result

forms. For two of the three 1998 testing events - testing event B-1 (form MLE 98-1) and B-2 (form MLE 98-2) - the forms reflected test results for Endocrinology: Triodothyronine Uptake (T3UP). Yet, Petitioner did not perform that test. *Id.* at 4. [(2)]

The inspector found other irregularities. Petitioner's form MLE 98-1 contained an attestation statement, signed by Marilyn Nichols, MT, and another individual whose signature is illegible, certifying that the analyses of the PT specimens were performed, as closely as possible, in the same manner as regular patient samples. Id. at 4 - 5, 19. On the form is a preprinted identification number that MLE assigned to Petitioner, MLE ID 008180. Id. at 5, 19. The laboratory is required to enter manually the last four digits of that number in boxes at the top of each page of the MLE test result form. On two of the pages it appeared that Petitioner's MLE number was written over the top of other numbers. Id. at 5, 20, 21.

In the identification number box of Petitioner's form MLE 98-2, the digits "8045" are discernable. But this was not Petitioner's number. Id. at 5, 25, 28. COLA and MLE had assigned this number to another laboratory - Lab A - also enrolled in their accreditation program. The inspector visited Lab A on August 18, 1999. Marilyn Nichols, MT, was one of Lab A's employees. On August 11, 1999, the inspector visited a third laboratory enrolled in COLA - Lab B. Its PT records contained Lab A's MLE number, rather than the number it had been assigned. Marilyn Nichols was also employed at Lab B. Id. at 5. [(3)]

COLA staff then reviewed PT reports for 1998 testing events for the three laboratories. Id. at 5 - 6, 29. They found that the three laboratories all performed tests in Endocrinology (four separate tests) and Routine Chemistry (four separate tests) after each laboratory received samples from the same MLE specimen pool. The three laboratories, in total, performed 106 analyses in common. Each laboratory reported to MLE exactly the same PT results for all eight tests performed by each of them in 1998 (see Id. at 29). Id. at 6 - 7, 29. According to the unchallenged opinion of CMS's expert, Ms. Betty Kathryn Connolly, BS, MT, three laboratories independently obtaining identical results on eight different tests strongly suggests collusion. Even if a laboratory ran the same test multiple times, the results would be expected to vary at least slightly [(4)]. Id. at 7; accord RNA Laboratories, at 6; Sitto, at 8.

Petitioner had no records or procedures showing how it prepared, processed, and reported PT samples. It had no testing logs or instrument tapes to substantiate that it performed the 1998 tests on the premises. It had no copies of the attestation forms sent to MLE for the second and third events of 1998. Id. at 7 - 8. The laboratory had no records or other evidence showing that it tested T3UP,

even though its MLE test result forms for testing events 98-1 and 98-2 contained results for this test. Id. at 4, 8, 23, 27. In reviewing findings from the COLA survey, Ms. Connolly reasonably inferred that the test result forms did not reflect testing actually performed by Petitioner, but reflected testing performed by some other laboratory. Id. at 8.

Following the June 1999 inspection, COLA's staff accreditation (STAT) team [(5)] reviewed the inspector's findings and determined that Petitioner had either compared PT results or submitted PT samples to another laboratory prior to the PT program end-date for reporting results, a violation of COLA standards. The team recommended denial of accreditation. COLA notified Petitioner by letter dated October 19, 1999, that it had been denied accreditation and could seek reconsideration. Petitioner instead notified COLA that it no longer was performing moderate or high complexity testing and asked to withdraw from the program - an action permitted by COLA policy - which COLA allowed "with notice." When a laboratory withdraws "with notice," COLA informs CMS that the laboratory has withdrawn subject to denial proceedings and apprises CMS as to the reason for the denial and withdrawal. Id. at 8 - 9.

The State Agency Surveys

COLA notified CMS that it had initially denied Petitioner's accreditation because Petitioner had either knowingly compared PT results or had referred its PT samples to another laboratory. In response, CMS asked the State Agency to conduct an unannounced CLIA complaint investigation survey. The State Agency conducted its survey on April 17, 2000. The state surveyor reviewed Petitioner's documentation (CMS Ex. 11) and concluded that Petitioner had not kept PT records required to substantiate that it performed its 1998 and 1999 testing on the premises in the same manner as patient testing. CMS Ex. 6, at 3 - 4.

Moreover, although sparse, the records Petitioner produced suggest multiple testing of the PT samples, but only single tests for the patient specimens. A work sheet for MLE 98-1, for example, shows multiple test results for several of the tests (chol, HDL, Trig, and LDL) of samples 1, 2, 3, 4, and 5. CMS Ex. 11, at 4. Records of the tests on patient specimens, on the other hand, contain only one result per specimen. See, e.g., Id. at 13.

The records suggest other significant irregularities. For the 1998-2 testing event, the test score indicated on the work sheet (Id. at 3) was not the score recorded on the MLE 98-2 (Id. at 2):

		Work Sheet	Report (MLE98-2)
Sample 7	T3	140	2.4

Sample 7	T3	140	2.4
	T4	8.9	9.4
	FT4	1.8	1.7
	TSH	4.1	4.6
Sample 8	T3	280	3.8
	T4	14.0	17.6
	FT4	3.0	3.9
	TSH	7.0	7.8
Sample 9	T3	300	3.5
	T4	13.8	15.5
	FT4	3.1	3.0
	TSH	6.2	7.0
Sample 10	T3	190	1.5
	T4	7.5	6.8
	FT4	1.6	1.2
	TSH	2.1	2.6

The documents confirm that Marilyn Nichols was responsible for Petitioner's PT in 1998 and 1999. Id. at 1; CMS Ex. 4, at 3, 9; CMS Exs. 7, 8. The State Agency was aware that Ms. Nichols also performed PT for Oakland Family Practice (Oakland) (which COLA referred to as Lab A), and on May 10, 2000, conducted an unannounced survey of the Oakland lab. There, the surveyor found a chart prepared by COLA's STAT team comparing test results from Petitioner, Oakland, and Preferred Family Medicine (which COLA referred to as Lab B). CMS Ex. 9; CMS Ex. 6, at 5. Inasmuch as COLA's data showed identical results on eight different tests, State Agency staff undertook their own comparison of the three laboratories' PT results.

Mr. Richard J. Benson, CLS, MT, is the State Agency's Chief of Hospital, Laboratory & Medical Facilities Section, Bureau of Health Systems. He compared the 1998 and 1999 MLE PT data for Petitioner and Oakland. CMS Ex. 12; CMS Ex. 6, at 6. Both laboratories tested for the following seven analytes: Total Cholesterol, Triglycerides, Thyroid Stimulating Hormone (TSH), Thyroxine (T4), Free T4, High Density Lipoprotein (HDL) and Triiodothyronine (T3). The laboratory was given five samples to test for each of the analytes, so each laboratory recorded 35 test results for each testing event. In 1998, there were 3 testing events so each lab performed a total of 105 tests that year. [(7)] Petitioner and Oakland reported identical results for all 105 tests.

Petitioner participated in only one testing event in 1999, and reported results identical to Oakland's in 33 of the 35 tests performed. CMS Ex. 6, at 6 - 7.

Both laboratories used manual techniques to measure and compare the samples. Reagents and samples were measured and introduced into test tubes by hand, incubated, then individually analyzed. In an unchallenged opinion, Mr. Benson explained that such manual procedures are difficult to reproduce exactly; therefore, results are rarely duplicated exactly, even when one person performs the same test twice on the same sample in the same laboratory. For this reason, laboratory monitoring agencies accept a broad range of "correct results" for manual tests for Cholesterol, HDL Cholesterol, Triglycerides, T4, and TSH. According to Mr. Benson,

Exact reproduction of results of all five samples of an analyte series would be astounding. Exact reproduction of results for seven analytes (with five samples per analyte) would defy belief . . . Based on my professional training and experience such identity of reported results is absurd unless explained by some sort of collaborative process between the two laboratories.

CMS Ex. 6, at 7. Accord, RNA Laboratories, at 6; Sitto, at 7 - 8.

Petitioner does not challenge the factual evidence, but asserts, incorrectly, that CMS has the burden of proof and has failed to satisfy that burden because its evidence creates only "strong inferences" that its PT samples were tested elsewhere. P. Br. at 6 [(8)]. As noted above, CMS's burden is to establish a prima facie case of the laboratory's noncompliance. The laboratory has the ultimate burden of rebutting, by a preponderance of evidence, the prima facie case of noncompliance. CMS's showing of identical test results certainly satisfies its prima facie burden. Indeed, in RNA Laboratories, Judge Kessel characterized as "powerful circumstantial proof that Petitioners engaged in prohibited communications," evidence that for one testing event the petitioner and another laboratory reported identical results for the nine analytes in five samples. RNA Laboratories, Inc., DAB CR829, at 7 - 8 (2001). An appellate panel of the Board agreed, ruling "that the logical inference to be drawn from the evidence [of identical results] was that Petitioners had collaborated in obtaining or reporting the results." RNA Laboratories, DAB No. 1820, at 7.

Other uncontested evidence bolsters CMS's case. First, that Ms. Nichols performed the testing for all three laboratories certainly creates a better-than-ordinary opportunity for collusion. Petitioner concedes that she engaged in a "waive of misconducts (sic)" while in Petitioner's employ and that she "may have compared proficiency testing results" with Oakland or other laboratories. CMS Ex. 7. Second, Petitioner has not explained how test results for T3UP appeared on Petitioner's MLE test result forms, even though Petitioner does not test for T3UP. Third, Petitioner has offered no satisfactory explanation as to why its MLE identification number was entered over the last four

digits of Oakland's MLE identification number on Petitioner's 1998-1 MLE test form. And, finally, Petitioner failed to produce records establishing that it integrated the PT samples with its regular patient samples, and actually tested the PT samples in its own laboratory. In the absence of any other credible explanation, I can reasonably infer that Petitioner and Oakland colluded to manipulate their PT results.

Nor does the unfortunate death in February 2000, of Petitioner's then laboratory director relieve Petitioner of its responsibility to demonstrate compliance with CLIA requirements. I note first that Petitioner's serious irregularities were pointed out as early as the June 1999 COLA inspection. I find it incredible that Petitioner's owner and operator, Mr. Ndubisi G. Igwe, would not then have been aware of the allegations against its testing practices. Moreover, the regulations specifically require that laboratories maintain careful PT records. Petitioner's inability to respond to CMS's findings must be attributed to its own sloppy record-keeping practices, not the death of its medical director.

3. During 1998 and 1999, Petitioner did not comply with the requirements of 42 C.F.R. § 493.1441 (laboratory director) .

42 C.F.R. § 493.1441 requires that a laboratory have a qualified laboratory director who provides overall management and direction to the laboratory in accordance with 42 C.F.R. § 493.1445. Section 493.1445 sets out the director's specific responsibilities, which encompass the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures and report test results promptly, accurately, and proficiently, and for assuring compliance with the regulations. Among the director's specific responsibilities, he/she must ensure that the laboratory is enrolled in an approved PT program, that the PT samples are tested as required, and that PT results are reviewed in order to identify problems. See Oakland Medical Group, P.C., DAB No. 1755, at 21 - 22 (2000) ("Adopting procedures to assure that required documentation is produced, maintained, and checked for accuracy is certainly within the responsibilities of a laboratory director.").

Inasmuch as the laboratory director did not insure that PT samples were tested in accordance with regulatory requirements, Petitioner did not comply with the regulation governing laboratory director. Given the egregiousness of its conduct, these are condition-level deficiencies.

Petitioner argues that neither the laboratory owner nor the director knew about the irregularities in testing the PT samples, attributing the problems to a rogue employee. Under the statute and the regulations, the laboratory's owners and operators are responsible for the actions of "all individuals it authorizes to perform chemistry testing at its facility on its behalf." Oakland Medical Group, P.C., at 10, 20 - 22; Stanley Boykansky, M.D., DAB No. 1756, at 17 (2000). 42 C.F.R. § 493.1445 establishes the director's responsibility for the overall operation and administration of the laboratory, including the employment of competent testing personnel. The regulation specifically provides that delegation of those duties does not relieve the director of responsibility. 42 C.F.R. § 493.1445(b). See also Melvin C. Murphy, M.D., DAB CR590, at 7 (1999);

42 C.F.R. § § 493.2, 493.801, 493.1840(b).

4. CMS is authorized to revoke Petitioner's CLIA certificate and cancel its approval to receive Medicare payments.

Petitioner contends that it should be allowed to participate in and be reimbursed by the Medicare program because it withdrew from the COLA accreditation program, is limiting its testing to waived testing, and has a new laboratory director. Petitioner cites no authority for its contention and I must reject it. Having determined that Petitioner failed to comply with conditions of participation, CMS is authorized to impose principal sanctions, including revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a),(b). CMS may also cancel the laboratory's approval to receive Medicare payment for its services. 42 C.F.R. § 493.1807. Where - as here - a laboratory intentionally refers its PT samples to another laboratory, the regulations require that its CLIA certificate be revoked for at least one year. 42 C.F.R. § 493.801(b)(4); 42 U.S.C. § 263(a)(i)(4). Petitioner may not avoid a sanction for deficiencies that affect the overall safety of its testing program by withdrawing its certification for some of its testing. See Ward General Practice Clinic, DAB CR451 (1996), aff'd. DAB No. 1624 (1997).

V. Conclusion

For all of these reasons, I sustain CMS's determination to revoke Petitioner's CLIA certificate for at least one year and to cancel its approval to receive Medicare payment for its services.

JUDGE

Carolyn Cozad Hughes

Administrative Law Judge

FOOTNOTES

1. The Health Care Financing Administration (HCFA) has been renamed the Centers for Medicare & Medicaid Services. Reference to either name shall apply to both names.

2. Petitioner performed the following tests: Endocrinology: Triodothyronine (T3), Thyroxine (T4), Free Thyroxine (FT4), and Thyroid Stimulating Hormone (TSH); Routine Chemistry: Cholesterol (Chol), Low Density Lipoprotein (LDL), High

Density Lipoprotein (HDL), Triglycerides (TRIG). Id.

3. Lab A's MLE identification number is 8045 and Lab B's identification number

is 9015. *Id.* at 6. Lab A is Oakland Family Practice and Lab B is Preferred Family Medicine. CMS Ex. 6, at 4 - 5.

4. Ms Connolly is the Surveys Division Assistant Manager at COLA. In that capacity, she supervises COLA's onsite inspection process, and trains COLA surveyors and team leaders. She has 17 years experience as a clinical laboratory technologist and laboratory manager. CMS Ex. 5, at 1.

5. The STAT team is a technical review team, composed of COLA's senior staff, which reviews laboratory inspection findings for issues affecting accreditation.

6. The work sheet's T3 figures, at roughly one hundred times greater, seem totally out of line with the expected (and reported) range for Triodothyronine testing. Neither party ventured any explanation for the extreme discrepency.

7. COLA's count of the total number of test results differs from Mr. Benson's because the scope of their comparisons differed slightly. As CMS explains, Mr. Benson compared only two, rather than three laboratory results, and did not compare results for all of the analytes tested. CMS Br. at 3 - 4, n.2.

8. I note also that the statute does not require evidence of actual physical transport of samples. The intentional referral language of 42 C.F.R. § 493.801(b)(4) applies to constructive referral as well as physical transfer. *Sitto,* at 9 - 10.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Appeals Board

Civil Remedies Division

In the Case of:	)	
	)	
Alani Medical Management	)	Date: JUN 16 200
Corp., d.b.a. Advanced	)	
Diagnostic Services Laboratory,	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-03-203
	)	
Centers for Medicare &	)	
Medicaid Services.	)	
	)	

RULING DENYING MOTION TO DISMISS AND MOTION FOR SUMMARY DISPOSITION

I deny the motion of the Centers for Medicare & Medicaid Services (CMS) to dismiss the hearing request of Alani Medical Management Corp., d.b.a. Advanced Diagnostic Services Laboratory. I also deny Petitioner's motion for summary disposition.

I. Background and facts

The parties do not dispute the facts on which their respective motions are based. Petitioner offered five exhibits (P. Exs. 1 - 5) in support of its motion which describe all of these facts.

Petitioner operated a clinical laboratory at 5012 Sunset Boulevard, Los Angeles, California. Petitioner was certified to perform clinical testing pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a. Its continued certification was subject to the requirements of CLIA and the Public Health Services Act, 42 U.S.C. § 1395w-2. Additionally, Petitioner's CLIA certification was governed by regulations at 42 C.F.R. Part 493.

On September 25,2002, an inspection was performed of Petitioner's laboratory to determine whether it remained in compliance with CLIA. The inspectors determined that Petitioner was not complying with CLIA conditions, The inspectors' findings are contained in a report that was provided to Petitioner. P. Ex. 2. The inspectors determined that Petitioner's noncompliance with CLIA conditions was so serious as to constitute immediate jeopardy to patients. The term "immediate jeopardy" is defined at 42 C.F.R. § 493.2 to mean noncompliance with a CLIA condition that has caused, is causing, or is likely to cause, at any time, serious injury, harm, or death to individuals served by a laboratory or to the health or safety of the public.

On October 24,2002, CMS sent a notice to Petitioner (October 24 notice). P. Ex. 1. The notice advised Petitioner of *the* noncompliance findings. Among other things, CMS advised Petitioner that the inspectors had found that Petitioner failed to meet requirements for enrollment and testing *of* proficiency testing samples, including engaging in improper proficiency testing referral. activities. *Id.* at 1.

In its October 24 notice, CMS also advised Petitioner that it might impose sanctions against Petitioner based on its allegedly having violated or aiding and abetting the violation of CLIA requirements, "as evidenced by its improper proficiency testing referral activities." P. Ex. 1, at 2, These possible remedies included "principal sanctions" consisting of suspension of Petitioner's CLIA certificate and, ultimately, revocation of that certificate. They also included the ''alternative sanction" of civil money penalties of $10,000 per occurrence ''for each instance in which your laboratory engaged in improper proficiency testing activities." *Id.* at 3. In proposing this alternative sanction, CMS referred to a deficiency citation at Tag D2011 of the inspection report. *Id.*; P. Ex. 2, at 30 - 37. The tag in question cites as a deficiency the laboratory's failure to comply with the requirements of 42 C.F.R. § 498.801(b)(3). This section of the CLIA regulations prohibits a laboratory from engaging:

> any inter-laboratory communications pertaining *to* the results of proficiency testing samples(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

This paragraph of the October 24 notice did not refer explicitly to another tag that was cited in the CLIA inspection report, Tag D2013. P. Ex. 2, at 37 - 40. At this tag the inspectors found that the laboratory had not complied with *the* requirements of 42 C.F.R. § 493.801(b)(4). This section explicitly prohibits a laboratory from sending proficiency

testing samples or portions of samples to another laboratory for any analysis which the sending laboratory is certified to perform. It provides further that any laboratory which intentionally refers proficiency testing samples to another laboratory will have its certification revoked for at least one year.

CMS sent a second notice to Petitioner on November 29,2002 (November 29 notice). P. Ex. 3. The November 29 notice referred to the October 24 notice and to Petitioner's response to the survey findings that are the basis for the October 24 notice. *Id.* at 1. CMS advised Petitioner that it had reviewed Petitioner's response and found that it failed to demonstrate that Petitioner had corrected its deficiencies. Id. CMS further advised Petitioner that it intended to impose sanctions against it including civil money penalties for each day of Petitioner's noncompliance with CLIA requirements from November 29 through December 1, 2002. *Id.* at 2. CMS told Petitioner that the proposed civil money penalties totaled $30,000. *Id.*

On December 4,2002, CMS sent a third notice to Petitioner (December 4 notice). P. Ex. 4. CMS advised Petitioner that it had corrected an error relating to the amount of civil money penalties that was stated in the November 29 notice. *Id.* at 1. In the December 4 notice CMS told Petitioner that it was imposing:

> A Civil Money Penalty in the amount of $10,000 for each of the nine improper proficiency testing referrals that occurred, for a total of $90,000.

Id. at 2.

Petitioner filed a hearing request on December 16,2002. P. Ex. 5. The case was assigned to me for a hearing and a decision. CMS then moved to dismiss Petitioner's hearing request on the ground that Petitioner did not have "standing)) to request a hearing. Petitioner opposed CMS's motion and cross-moved for *summary* disposition. CMS opposed Petitioner's cross-motion.

II. Issues and rulings on the parties' motions

A. Issues

CMS's motion to dismiss raises the issue of whether Petitioner may challenge CMS's imposition of civil money penalties against it. Petitioner's motion for summary disposition raises two issues, consisting of whether: CMS may, as a matter of law, impose

civil money penalties against Petitioner as an "alternative sanction"; and, CMS is barred from imposing civil money penalties against Petitioner because its notices to Petitioner allegedly failed to state legally permissible grounds for imposing civil money penalties as alternative sanctions.

B. Rulings

1. Petitioner has a right to a hearing because Petitioner's hearing request is not bared on a challenge to CMS's discretion to impose civil money penalties.

CMS asserts in its motion that *the only* basis for Petitioner's hearing request is that CMS should not have imposed civil money penalties against Petitioner. It contends that Petitioner concedes the presence of the deficiencies that are the basis for CMS's sanction determinations. It argues that Petitioner's hearing request is, in effect, a challenge to CMS's choice of remedy in this case. It contends that CMS's choice of remedy is an exercise of discretion by CMS which Petitioner has no right to challenge. CMS contends that, under regulations governing hearings in cases involving CLIA determinations, Petitioner may not challenge CMS's exercise of discretion as to which alternative sanctions to impose.

I find these arguments not to be persuasive. Petitioner is not challenging the discretionary determination by CMS to impose penalties. Rather, it is challenging the legal authority and conclusions of fact on which CMS's determination rests.

The hearing request in this case was filed on behalf of Petitioner and an individual, Jamal Taha. The addressees of CMS's notice letters included Mr. Taha as "owner" of Petitioner. The request for hearing states six reasons which allegedly support a conclusion that CMS's determination to impose civil money penalties is unlawful. These consist of the following:

1. The civil money penalties are alternative sanctions which may, by law, be imposed only in lieu *of* principal sanctions. Here, CMS has imposed principal and intermediate sanctions (civil money penalties) without statutory authority for such action.

2. The notice of imposition of civil money penalties is deficient and, therefore, CMS is without authority to impose the penalties.

3. CMS allegedly stated erroneously in its October 24 notice that there were nine proficiency testing violations by Petitioner. If, in fact, there were any violations, there was only one.

4. No civil money penalties could have accrued after October 28,2002, because Petitioner ceased doing business on that date.

5. Civil money penalties may not be imposed against on an individual owner, operator, or director of a laboratory- Arguably, the three notices imposed civil money penalties against Petitioner and against an individual who is a principal in Petitioner.

6. The allegations which are the basis for civil money penalties are not accurate and do not justify imposition of the penalties.

P. Ex, 5, at 1 - 3. After the case was assigned to me I concluded, based on CMS's representation that it had not imposed civil money penalties against Mr. Taha, that Mr. Taha had no right to a hearing. I dismissed the hearing request as it pertained to him. That ended the proceedings insofar as they concerned reason 5 in Petitioner's hearing request.

The remaining reasons advocated by Petitioner for challenging CMS's civil money penalty determination (reasons 1 - 4, and 6) address issues that are clearly within my authority to hear and decide. These remaining reasons fall into two categories of arguments consisting of arguments that: even if the facts of this case are as CMS asserts them to be, CMS is without authority to impose civil money penalties because there is no legal basis for imposition of penalties (reasons 1 and 2); and, there is no basis *in fact* to support CMS's penalty determination (reasons 3, 4, and 6).

Although I find below, at Rulings 2 and 3, that Petitioner's arguments 1 and 2 are without merit, they are certainly legal arguments which I have authority to hear and decide. None of Petitioner's challenges to CMS's legal authority attack CMS's exercise of discretion to impose civil money penalties.

As for reasons 3, 4, and 6, Petitioner is asserting that penalties may not be imposed against it because it was not contravening CLIA conditions as is alleged by CMS. In reason 3 Petitioner contends that CMS's penalty determinations are erroneous because there were arguably fewer proficiency testing violations than CMS asserts to have

occurred. In reason 5 Petitioner asserts that it was not violating CLIA conditions on the dates for which penalties were imposed and, therefore, CMS has no authority to impose penalties for those dates. In reason 6 Petitioner asserts that the deficiency findings that are the basis for CMS's penalty determinations are erroneous.

All of these arguments are traditional fact-driven arguments. Reasons 3, 4, and 6 are not challenges of CMS's exercise of discretion. They challenge the basis for CMS's determination to impose remedies.

2. CMS would have authority to impose civil money penalties against Petitioner if Petitioner is found to have referred proficiency testing samples to another laboratory.

Petitioner grounds its motion for summary disposition on two arguments. First, Petitioner contends that, as a matter of law, CMS lacks authority to impose civil money penalties against Petitioner. That is so, according to Petitioner, because the determination to impose civil money penalties is based on a deficiency for which CMS may impose either principal sanctions (suspension and revocation of Petitioner's CLIA certificate), or alternative sanctions (civil money penalties), but not both remedies. Petitioner asserts that there is no authority in this case to impose civil money penalties because CMS opted to impose principal sanctions against Petitioner.

Petitioner argues that, in most instances, CLIA and the Public Health Services Act arguably only permit CMS to impose civil money penalties "in lieu of' and not "in addition to" principal sanctions such as revocation of a laboratory's CLIA certificate. Petitioner contends that these "in lieu" provisions apply here because the allegedly stated reason for imposing civil money penalties – prohibited inter-laboratory communications between Petitioner's laboratory and another laboratory – are grounds for remedies which fall within the "in lieu of' provisions of the statutes.

Petitioner concedes that there is an exception to the asserted "in lieu of' requirement. The exception exists in the case where a laboratory refers proficiency testing samples to another laboratory. Petitioner acknowledges that, in such circumstance, CMS may impose both principal and alternative sanctions, including civil money penalties, against the laboratory. Petitioner also concedes that the inspection report cites proficiency test referrals as a deficiency. P. Ex. 2, at 30 - 37. But, according to Petitioner, CMS did not rely on this alleged deficiency as a basis for its determination to impose principal and alternative sanctions against Petitioner. Therefore, according to Petitioner, there is no basis in this case to impose both principal and alternative sanctions against Petitioner.

It is unnecessary that I address at this time the statutory distinctions that Petitioner raises because I find it to be clear that CMS determined to impose principal and alternative sanctions against Petitioner based on proficiency test referrals and on prohibited inter-laboratory referrals.[1] That determination is evident from the language of the notices that Petitioner received from CMS, which refer repeatedly to all of the allegations of the inspection report and not just to findings about prohibited inter-laboratory communications. Allegations of unlawful referrals are made specifically at Tag D2013 of the inspection report and in the three notices that CMS sent to Petitioner.

It is true that the October 24 notice explicitly references Tag D2011 (unlawful exchange of information) as a basis for imposing civil money penalties against Petitioner and does not explicitly reference Tag D2013 (proficiency test referrals) as a basis for imposing that remedy. But, the failure to refer explicitly to Tag D2013 does not support a conclusion that CMS excluded proficiency test referrals as a basis for its determination to impose civil money penalties. All three of the notices – and in particular, the October 24 notice – state explicitly in various places that remedies were being based on Petitioner's proficiency test referrals. Indeed, the segment of the October 24 notice in which CMS told Petitioner that it was imposing civil money penalties states that if civil money penalties were imposed against Petitioner, they would:

> be in the amount of $10,000 per occurrence for each instance in which your laboratory *engaged in improper proficiency testing referral activities*.

P. Ex. 1, at 3 (emphasis added).

> ***3. Petitioner received adequate notice of the basis of CMS's determination to impose civil money penalties against Petitioner.***

CMS gave Petitioner adequate notice of its intent to impose civil money penalties against Petitioner based on proficiency test referrals. As I have discussed above, the alleged

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[1] The alleged statutory distinction that Petitioner advocates between proficiency test referrals and prohibited communications would arguably become relevant only if I were to find ultimately that Petitioner engaged in prohibited communications but did not make proficiency test referrals. In that event, I might revisit Petitioner's arguments concerning CMS's authority to impose alternative sanctions. It is unnecessary that I resolve the issue at this time because, as I discuss in these rulings, CMS based its remedy determinations, including the determination to impose civil money penalties, on both findings of prohibited communications and proficiency test referrals.

proficiency test referrals are unambiguously described in the CLIA inspection report, and the three notices cite such referrals as the basis for imposition of remedies, including civil money penalties. The reference to Tag D2011 and not to Tag D2013 in the October 24 notice does create some uncertainty. But, I find that the uncertainty is dispelled when that reference is read in context with the remainder of the notice and with the inspection report.

Steven T. Kessel
Administrative Law Judge