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

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[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

(continued...)

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

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[2](...continued)
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.

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).

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[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).

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

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[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.

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

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[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.

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.

/s/

Steven T. Kessel
Administrative Law Judge