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

[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).

> 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.

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[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.

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.

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[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.

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 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]

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[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.

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

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[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.

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,

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[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.

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

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[10] Given the stipulation concerning Ms. Abernathy's training and classification under CLIA, I will refer to her as the "Testing Personnel" herein.

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]

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[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.

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

[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.

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.

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[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.

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.

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[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.

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.

/s/

Mimi Hwang Leahy

Administrative Law Judge