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.

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[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).

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.

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[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.

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

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[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.

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).

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[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).

> 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

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 [emphasis added] its proficiency testing samples to another laboratory for analysis . . . .

42 U.S.C. § 263a(i)(4).

criminal:

> Any person who intentionally [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. arguments

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:

regulations as written. I cannot disregard the unambiguous limitations imposed by the regulations. I adjudicate these cases under a delegation from the Secretary of Health and Human Services. In this capacity, I am required to follow all substantive rules and regulations duly promulgated by the Secretary. See Dyer v. Secretary of Health and Human Services, 889 F.2d 682, 685 (6th Cir. 1989).

There is no regulation which supports Petitioner's legal arguments. The regulations I have considered are dispositive on the issue of whether Petitioner may challenge in this forum the merits of HCFA's decision to ban nurse aide training and testing by Petitioner. For example, the language of the regulation codified at 42 C.F.R. § 498.3(d)(1) does not leave me with any discretion to grant Petitioner the hearing it requests. The critical fact is that the Secretary of Health and Human Services has declined to define the prohibition against nurse aide training and competency evaluations as a remedy or enforcement action subject to a hearing in this forum. 42 C.F.R. §§ 498.3(c)(11), 488.406; FFCL 41, 43, 44, 45. Since HCFA has rescinded the two enforcement actions imposed under 42 C.F.R. § 88.406, there is no determination by HCFA subject to the hearing rights specified in 42 C.F.R. Part 498. FFCL 40, 41, 45. Therefore, Petitioner also cannot challenge the survey findings which resulted in the ban on nurse aide training and testing, and which resulted in HCFA's earlier (but now rescinded) determination to impose two of the enforcement actions specified in 42 C.F.R. § 488.406. FFCL 46 - 48.

Petitioner complains that, without an on-the-merits hearing on the survey findings, Petitioner is at risk for suffering future harm of greater magnitude should HCFA later find that Petitioner has provided substandard quality of care in a total of three consecutive standard surveys. However, Petitioner herein has other hearing requests pending which challenge the substandard quality of care findings from a later survey, a survey which resulted in HCFA imposing a civil monetary penalty and other appealable remedies against Petitioner. FFCL 36, 37. Also pending before me for hearing is another case filed by Petitioner (DAB Docket No. C-96-273), wherein Petitioner challenges, inter alia, the deficiencies found during an "abbreviated standard survey" conducted on February 12, 1996 and HCFA's imposition of a remedy specified in 42 C.F.R. § 488.406. If Petitioner prevails in its other action (DAB Docket No. C-96-350), there would be no findings of substandard quality of care in consecutive standard surveys; in such an event, Petitioner would not need to fear sanctions resulting from three consecutive surveys finding substandard

> 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.

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[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.]

"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.

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

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 Colleg 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 CLIA Certificate 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.

/s/

Jill S. Clifton

Administrative Law Judge