Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

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

DECISION

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

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

PROCEDURAL BACKGROUND

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

---

[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).

By letter dated July 19, 1995, Petitioner filed a request for hearing. On October 25, 1995, I held a hearing in San Francisco, California. Subsequently, the parties filed briefs.[3] Based on the evidence and the law, in light of the parties' arguments, I affirm HCFA's determination to revoke Petitioner's CLIA certificate for a one-year minimum mandatory period, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

ISSUES

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

FINDINGS OF FACT AND CONCLUSIONS OF LAW

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

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

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

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

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

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

---

[3] Petitioner's opening brief [Petitioner's "Post-Hearing Brief"] is cited as "P. Br." Petitioner's "Supplemental Brief" is cited as "P. R. Br."

HCFA's opening brief [HCFA's "Posthearing Memorandum"] is cited as "HCFA Br." HCFA's "Posthearing Reply Memorandum" is cited as "HCFA R. Br." I cite to the transcript as "Tr." (page).

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

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

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

10. David Dohi is a licensed medical technologist, who in September 1994 was working part-time at Petitioner [one day a week for two to three hours a day], full-time at the Madera Community Hospital (community hospital), and part-time at the hospital in Chowchilla [on call every other weekend and on call Wednesday nights]. HCFA Ex. 4; Tr. 262-263.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

61. For all types of laboratory testing performed in a day, quality control should be conducted on that day for those tests. Tr. 67, 72.

62. Quality control in the area of hematology is performed for every eight hours of operation. Tr. 67.

63. Petitioner failed to perform quality control daily in hematology. Tr. 68; HCFA Ex. 8. Petitioner failed to perform and document two levels of hematology quality control materials each day of testing. HCFA Ex. 1 at 10.

64. Specifically, Petitioner failed to run hematology quality control on four of 18 days in February 1995, when patients were tested. HCFA Ex. 8 at 1; HCFA Ex. 1 at 10. Petitioner performed quality control only 78 percent of the time in February 1995. Tr. 80.

65. Petitioner conducted gonorrhea screenings. Tr. 61-62, 255.

66. Petitioner did not have in place a tracking system for sending gonorrhea cultures to other labs. Tr. 64-65; HCFA Ex. 1 at 9.

67. Petitioner's procedure manual did not contain written procedures for gonorrhea testing. Tr. 75.

68. The temperature chart on Petitioner's incubator, an instrument used in gonorrhea screenings, indicated that the last time the temperature was documented (checked) was in November 1992. Tr. 63, 76; HCFA Ex. 1 at 11.

69. Mr. Dohi admitted that the incubator was used for gonorrhea incubations and that results were reported on the gonorrhea cultures. Tr. 278.

70. Mr. Dohi admitted that he was unaware that the incubator thermometer was broken until the survey. Tr. 278.

71. Petitioner replaced the broken thermometer in March 1995. Tr. 259, 277; P. Ex. 5 at 48.

72. Mr. Dohi could not recall if he ever saw a positive culture. Tr. 278-279.

73. At the time of the survey, Petitioner did not have any culture media records with respect to gonorrhea screening. Tr. 77; HCFA Ex. 1 at 12.

74. Petitioner failed to meet the Condition for Patient Test Management set forth at 42 C.F.R. § 493.1101.

75. As laboratory director, Dr. Johnstone was responsible for the overall management and direction of Petitioner in accordance with 42 C.F.R. § 493.1445. 42 C.F.R. § 493.1441.

76. Dr. Johnstone failed to ensure that Petitioner's laboratory's testing system in hematology provided quality testing, as evidenced by the records showing that quality control was performed only 78 percent of the required time in February 1995.

77. Dr. Johnstone failed to ensure that Petitioner's laboratory's proficiency testing samples were tested as required under subpart H of 42 C.F.R. Part 493. See Finding 58. This failure is evidenced by the following: proficiency tests on the hematology testing samples were run at two sites with two different instruments, there were two sets of answers for the chemistry isoenzymes proficiency testing samples, and documentation containing chemistry results, as well as other documentation, was not available. Tr. 80; see HCFA Ex. 1 at 14.

78. Dr. Johnstone had the ultimate responsibility for ensuring that Petitioner's laboratory's proficiency testing was performed in accordance with the requirements set forth at 42 C.F.R. § 493.801.

79. Dr. Johnstone failed to ensure that quality control and quality assurance programs were established and maintained in Petitioner's laboratory, and he failed to identify failures in quality as they occurred. 42 C.F.R. § 493.1445(e)(5).

80. Petitioner's laboratory's procedure manuals did not have any documentation for doing quality control. Tr. 81; HCFA Ex. 1 at 15.

81. Dr. Johnstone failed to have in place a system by which to monitor the competency of Petitioner's laboratory employees. Tr. 82-83; HCFA Ex. 1 at 16; see also Finding 85.

82. Dr. Johnstone failed to ensure that Petitioner's laboratory procedure and policy manuals were current, complete and approved, especially regarding gonorrhea cultures and quality control. HCFA Ex. 1 at 17; Tr. 83-84.

83. Dr. Johnstone failed to assign in writing the duties and responsibilities involved in all phases of the patient testing process for Petitioner's laboratory's technical consultant, technical supervisor, and testing personnel. HCFA Ex. 1 at 17-18; Tr. 87-88.

84. Petitioner's laboratory last reviewed charts for completeness of laboratory work documentation on April 3, 1992. Tr. 84-86; HCFA Ex. 1 at 18-19.

85. Petitioner's laboratory did not have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence. Tr. 89; HCFA Ex. 1 at 19; see also Finding 81.

86. Petitioner failed to meet the Condition for Laboratory Director, in violation of 42 C.F.R. § 493.1441.

87. HCFA's Notice, dated May 23, 1995, provided Petitioner with adequate notice that non-compliance with respect to the laboratory director condition, in violation of 42 C.F.R. § 493.1441, would independently support revocation of Petitioner's CLIA certificate.

88. Petitioner's failure to meet the Condition for Laboratory Director forms an independent basis for HCFA's revocation of Petitioner's CLIA certificate under 42 C.F.R. § 493.1814(a)(2).

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

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

91. HCFA is required to cancel a laboratory's approval to receive Medicare payment for its services where the laboratory's CLIA certificate is revoked. 42 C.F.R. § 493.1808(a) and § 493.1842(a)(1).

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

DISCUSSION

The word "intentionally" requires careful analysis in determining whether Petitioner "intentionally referred" its proficiency testing samples to another laboratory for analysis. This is the key issue in this case, and I will

address it first; thereafter I will address the remaining alleged deficiencies.[4]

I. Intentional Referral of Proficiency Testing Samples to Another Laboratory for Analysis

A. Statute and Regulations

CLIA provides both **civil** sanctions and **criminal** sanctions:

Civil Sanctions

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

42 U.S.C. § 263a(i)(4).

Regulations which implement CLIA parallel the Act's requirement that the Secretary revoke[6] a laboratory's CLIA certificate where that laboratory improperly refers a proficiency testing sample to a reference laboratory:

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

42 C.F.R. § 493.801(b)(4).

---

[4] The remaining alleged deficiencies relate to the enrollment and testing of samples condition, 42 C.F.R. § 493.801; patient test management condition, 42 C.F.R. § 493.1101; and laboratory director condition, 42 C.F.R. § 493.1441.

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

[6] Revocation is a civil sanction.

> Adverse action based on improper referrals in proficiency testing. If HCFA determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, HCFA revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty.

42 C.F.R. § 493.1840(b).

Criminal Sanctions

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

42 U.S.C. § 263a(l).

The implementing regulations regarding such criminal violations provide:

> Definitions. Intentional violation means knowing and willful noncompliance with any CLIA condition.

42 C.F.R. § 493.2.

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

42 C.F.R. § 493.1800(a)(3)(i).

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

42 C.F.R. § 493.1806(e).

B. Definitions of "Intentionally" under CLIA

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

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

civil:

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

42 U.S.C. § 263a(i)(4).

criminal:

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

42 U.S.C. § 263a(l).

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

1. Factual background

Petitioner is a physician's office operating a laboratory, located in Madera, California. Theodore Johnstone, M.D., is Petitioner's owner and laboratory director. P. Br. 2, P. R. Br. 4. Petitioner's laboratory did testing in the following areas: general chemistry (i.e., glucose, blood urea, nitrogen, creatinine, total protein, cholesterol); isoenzymes; hematology (complete blood counts and platelet counts); and microbiology (gonorrhea screening only). Tr. 22, 255. The results obtained from Petitioner's laboratory tests were used in the treatment of Dr. Johnstone's patients.

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

proficiency samples the same way it tests patients' specimens.

3rd Quarter 1994 Proficiency Testing Samples

Pursuant to 42 C.F.R. § 493.801, Petitioner is enrolled in an approved proficiency testing program conducted by the American Association of Bioanalysts (AAB). P. Br. 3. On September 22, 1994, Petitioner's laboratory received certain hematology samples for testing. HCFA Ex. 2, P. Br. 3.

David Dohi is a licensed medical technologist who, in September 1994, was working part-time at Petitioner's laboratory [one day a week for two to three hours a day], full-time at the Madera Community Hospital (community hospital), and part-time at the hospital in Chowchilla [on call every other weekend and on call Wednesday nights]. HCFA Ex. 4; Tr. 262-263. Mr. Dohi's duties for Petitioner's laboratory included drawing blood, doing laboratory testing, and reporting the results. HCFA Ex. 5; Tr. 262.

On September 28, 1994, Mr. Dohi tested Petitioner's 3rd quarter 1994 hematology proficiency testing samples within Petitioner's laboratory, using Petitioner's laboratory equipment. [The evidence is unclear whether Mr. Dohi counted platelets at Petitioner. Tr. 92.] HCFA Ex. 2; Tr. 232-238; P. Br. 3.

On September 29, 1994, Mr. Dohi, on his own initiative and without the knowledge of Dr. Johnstone, took Petitioner's 3rd quarter 1994 hematology proficiency testing samples to the laboratory at the community hospital, where Mr. Dohi was also employed. Mr. Dohi retested Petitioner's hematology proficiency testing samples in the community hospital's laboratory, using the community hospital's laboratory equipment. Tr. 239, 246, 316-317; P. Br. 4.

The computer printouts obtained from the community hospital's Cell-Dyn 1600, as well as Mr. Dohi's admission that he ran the proficiency test samples on that instrument, constitute proof that Petitioner's hematology proficiency samples were analyzed at a laboratory other than Petitioner's, on an instrument other than Petitioner's own Cell-Dyn 400.

Mr. Dohi was unaware that his retesting of Petitioner's 3rd quarter 1994 hematology proficiency testing samples, at the community hospital's laboratory, was prohibited by law. Mr. Dohi's motive for retesting Petitioner's hematology proficiency testing samples at the community hospital's laboratory was to check the results he had obtained at Petitioner's laboratory. Tr. 239, 266-267. P. Br. 4.

Dr. Johnstone was unaware that Mr. Dohi had retested Petitioner's 3rd quarter 1994 hematology proficiency testing samples at the community hospital's laboratory until, during a survey of Petitioner's laboratory conducted on February 28, 1995, a CLIA Laboratory Expert employed by HCFA, Dorothy Maurer, told Dr. Johnstone so. Tr. 17, 21; P. Br. 6; P. R. Br. 4.

The survey of Petitioner's laboratory conducted by Ms. Maurer on behalf of HCFA on February 28, 1995, was done to determine whether Petitioner was in compliance with requirements imposed under CLIA. Ms. Maurer analyzed Petitioner's records concerning its performance of proficiency testing in the 2nd and 3rd quarters of 1994.

Ms. Maurer testified that, in examining the testing documentation relating to the hematology proficiency samples, she realized that she "had two sets of answers." Tr. 38. Although Petitioner has a Cell-Dyn 400 on the premises, Ms. Maurer stated that she found computer generated printouts from a Cell-Dyn 1600 among the 3rd quarter 1994 proficiency testing documentation in Petitioner's files. Tr. 37-40. Petitioner's Cell-Dyn 400 does not have the ability to count platelets nor can it generate computer printouts.

The computer printouts discovered by Ms. Maurer, each of which is titled "Cell-Dyn 1600 Specimen Data Report," contained various hematologic values, including platelet counts. HCFA Ex. 2 at 2-7. According to Ms. Maurer, it would not have been possible for Petitioner to have obtained these printouts from its own instrument, i.e., the Cell-Dyn 400.

The platelet count was the only Cell-Dyn 1600 result that was reported as if it had been Petitioner's result. With the exception of the platelet count values, Mr. Dohi submitted to the AAB the values obtained from using Petitioner's Cell-Dyn 400. Tr. 235. Mr. Dohi admitted that the platelet count values he reported to the AAB were those obtained from the Cell-Dyn 1600 at the community hospital's lab. Tr. 47, 286-287.

2. Parties' arguments

Petitioner's arguments

Petitioner responds to HCFA's citation of the Long case [see HCFA's arguments, infra]: "Long is simply incorrect insofar as it states that 'intentionally' is not defined in the applicable regulations. 42 C.F.R. Part 493, which contains

the regulations relied upon by HCFA as the basis for revoking Petitioner's CLIA certificate, states:

> As used in this part, unless the context indicates otherwise . . . .
>
> Intentional violation means knowing and willful noncompliance with any CLIA condition.

42 C.F.R. § 493.2.

Petitioner argues that the definition of "intentional violation" found in at 42 C.F.R. § 493.2 is to be applied to the terminology used in 42 C.F.R. §§ 493.801(b)(4) and [493.]1840(b). P. Br. 7; P. R. Br. 3.

Petitioner argues further that revocation of a Petitioner's CLIA certificate pursuant to 42 C.F.R. §§ 493.801(b)(4) and 493.1840 is improper unless Petitioner or its employees knowingly and willfully violated a CLIA condition. Petitioner adds that 42 C.F.R. § 493.2 makes it clear that no intentional violation can occur without the putative offender's knowing and willful noncompliance with a legal duty imposed by the CLIA regulations. P. Br. 7.

Petitioner maintains that neither Petitioner nor any of its employees had a specific intent to violate a CLIA condition at the time Dohi verified the proficiency testing results obtained at Petitioner's laboratory. P. Br. 11. Moreover, Petitioner contends that Dr. Johnstone was unaware of Mr. Dohi's referral of proficiency testing samples until the survey and thus could not have intended to violate the CLIA regulation. P. Br. at 6.

HCFA's arguments

HCFA argues: "[T]he issue at hand is whether petitioner "intentionally referred" its proficiency samples to another facility, not whether there was an "intentional violation" of a CLIA condition. Although the elements necessary for proving whether there was an intentional referral may be similar to those for proving an intentional violation of a Condition, the definition itself is not controlling in making the determination in petitioner's case." HCFA R. Br. 2.

HCFA argues that criminal case standards, including the "'knowing and willful' elements," and "'specific intent' to do something which the law forbids," "should not be controlling on this administrative proceeding." HCFA R. Br. 2-3.

HCFA (HCFA Br. 23) quotes Long Medical Laboratory v. HCFA, DAB CR334 (1994):

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

Long, supra, at 6.

HCFA continues: "With respect to the element of 'intent' that is contained in both the statute and regulation, the Administrative Law Judge [ALJ] in Long noted that while the term is not defined, 'it is apparent, from both the language of CLIA and the regulations, that it was intended that this term be given its common and ordinary meaning.' Long, supra, at 6. The ALJ then notes that in Webster's New Collegiate Dictionary, 1975 ed., at 601, 'Intention' is defined to mean a determination to act in a certain way. 'Intentional' or 'intentionally,' means to act by intention or design. Id. 'Thus, when one acts 'intentionally,' he or she acts deliberately.'" Long, supra, at 6. HCFA Br. 25-26. "[T]he knowledge element...is satisfied by showing that the referring laboratory knew the sample it was referring was a proficiency testing sample as opposed to a patient sample." HCFA R. Br. 3.

3. Purpose of CLIA

The Clinical Laboratory Improvement Amendments of 1988 (CLIA), enacted by Congress, require certification of all laboratories that perform clinical diagnostic tests on human specimens. CLIA was established to address the issue of unacceptably high error rates at unregulated laboratories and the dangers to patients that these high laboratory error rates posed. H.R. Rep. No. 899, 100th Cong., 2d Sess. 14, reprinted in 1988 U.S.C.C.A.N. at 3831; S. Rep. No. 561, 100th Cong., 2d sess. 3-4. Congress intended CLIA to establish a single set of standards to govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. See H.R. Rep.

No. 899, 100th Cong., 2d Sess. 8, reprinted in 1988 U.S.C.C.A.N. at 3828.[7]

The authority to enforce CLIA requirements is granted to the Secretary of Health and Human Services (Secretary). Under CLIA, the Secretary is authorized to inspect clinical laboratories and, in effect, license them to perform tests. 42 U.S.C. § 263a (esp. §§ 263a(b) and 263a(f)); 42 C.F.R. § 493.1800; See Consumer Federation of America and Public Citizen v. U.S. Dept. of Health and Human Services, 83 F. 3d 1497 (D.C. Cir. 1996).

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

> The Committee's investigation focused particularly on proficiency testing because it is considered one of [the] best measures of laboratory performance. It is arguably the most important measure, since it reviews actual test results rather than merely gauging the potential for good results . . .
>
> Proficiency testing is a method of externally validating the level of a laboratory's performance. Proficiency testing is not currently conducted by HHS, but is conducted by private agencies. . . . The standard testing methodology currently in use involves sample test specimens being sent by mail to a laboratory by the proficiency testing agency. The laboratory then analyzes the samples and returns the results of the test to the proficiency testing organization. The proficiency testing organization typically calculates the mean of the test results, determines an acceptable range variation based on standard deviations from the mean, and reports the results to the lab.

---

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

42 U.S.C. § 263a(a).

> The major problems identified by the Committee were lax Federal oversight and direction, lack of proficiency testing for many analytes, inconsistent criteria for acceptable laboratory performance, and improprieties by laboratories in handling specimen samples.
>
> . . .
>
> A significant deficiency in the current proficiency testing regime is its inability to assure that proficiency testing samples are treated like patient specimens. Samples are mailed to laboratories, and although proficiency testing organizations recommend that tests be treated in the same manner as patient samples, there was evidence that laboratories retest samples repeatedly to ensure satisfactory results and send proficiency testing samples out to other laboratories for analysis. The only way to guarantee that samples are treated by the same personnel, at the same speed, using the same equipment as patient specimens is though [sic] blind or on-site proficiency testing. The committee learned, however, that such testing can be quite expensive and may have to be used with discretion to assure proper processing of specimens.

H.R. Rep. No. 899, 100th Cong., 2d Sess. 8, reprinted in 1988 U.S.C.C.A.N. at 3828, 3836, 3837.

Thus, Congress, in enacting CLIA, was concerned about, among other things, laboratories that were sending their proficiency testing samples to other laboratories for analysis or retesting to ensure a satisfactory result. It is within this context that Congress authored the prohibition on intentional referrals of proficiency testing. The Act mandates revocation of a CLIA certificate for improper referral of proficiency testing samples by a laboratory. It states that:

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

42 U.S.C. § 263a(i)(4).

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

"Intentionally" is not defined in the CLIA statute, but some assistance is found in the regulations. "Intentional violation" is defined in the regulations as "knowing and

willful noncompliance with any CLIA condition." 42 C.F.R. § 493.2 ("Definitions").

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

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

42 C.F.R. § 493.1800(a)(3)(i).

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

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

42 C.F.R. § 493.1806(e).

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

By providing a definition for "intentional violation", the authors of the regulations have explicitly provided guidance on how to interpret 42 C.F.R. § 493.1800(a)(3)(i) and § 493.1806(e). There is little doubt that, with respect to the imposition of criminal sanctions, in determining whether there was an intentional violation, the legal standard of "knowing and willful" is to be applied.
Criminal convictions, particularly for persons who work in health care, trigger extremely serious consequences. It is reasonable to require proof of specific intent before subjecting a person to criminal penalties under CLIA. CLIA has clearly delineated two distinct types of penalties -- the first, directed at a laboratory and involving civil sanctions (regarding the laboratory's CLIA certificate, civil money penalties, costs and the like); -- and the second, directed at a person and involving criminal penalties (imprisonment or a fine or both). [See 42 C.F.R. § 493.1806 for available sanctions.]

Under CLIA, a laboratory is subject to inspection and a variety of civil penalties for failing to comply with CLIA standards. 42 U.S.C. § 263a(g), (h), (i). ["Principal sanctions," such as suspension, revocation, and limitation of the laboratory's CLIA certificate, are provided by 42 U.S.C. § 263a(i). "Intermediate" or "alternative sanctions," such as directed plans of correction, civil money penalties, and onsite monitoring costs, are provided by 42 U.S.C. § 263a(h).]

In sharp contrast are the CLIA penalties that are criminal in nature. 42 U.S.C. § 263a(l). The potential penalties include imprisonment for up to one year and a fine or both. Even more serious, a repeat offender can be imprisoned for up to three years and fined or both.

The regulations go to the effort of defining "intentional violation" to ensure that sufficient scienter is proved before a person can be convicted of a criminal violation under CLIA. The fact that "intentional violation" is specifically defined in the regulations [42 C.F.R. § 493.2] suggests that the definition is different from its common and ordinary meaning, and in fact, it is.

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

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

In current practice, where proficiency testing samples are clearly marked, enabling the technician receiving them to know they are test materials, not patients' specimens, it is difficult to conceive of an inadvertent referral. If proficiency testing samples are referred to another laboratory for analysis, with the knowledge that they were proficiency testing samples, the referral is intentional, that is, deliberate, not inadvertent.[8]

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

Mr. Dohi testified that he was the laboratory technologist who had run the tests on the hematology samples. Tr. 232-233. He admitted that he had tested the hematology proficiency test samples on both the Cell-Dyn 400 at Petitioner and on the Cell-Dyn 1600 at the lab at community hospital. Tr. 234-235, 239, 269-271, 287-288; HCFA Exs. 4, 5. Mr. Dohi stated that the reason he took the hematology test samples to the community hospital's lab and analyzed the samples on the Cell-Dyn 1600 there, was that he wished to verify the results he had obtained using Petitioner's Cell-Dyn 400. HCFA Ex. 5.

Although I agree with HCFA that Mr. Dohi "should have known" that he was circumventing the purpose of proficiency testing by analyzing the samples at another laboratory, on different and more sophisticated instruments [HCFA R. Br. 5 - 6], I am persuaded that he did not know. His actions appear to me to be more the result of scientific curiosity than of any intent to violate the law. I agree with the following statement of Petitioner [P. Br. 11]:

> Neither Petitioner nor any of its employees had a specific intent to violate a CLIA condition at the time Dohi verified the proficiency testing results obtained at Petitioner's laboratory.

I agree with Petitioner that Mr. Dohi did not know that his action of retesting Petitioner's proficiency testing samples at another laboratory was prohibited by law, as his statements to Ms. Maurer, his statements of corrective action, and his testimony demonstrate. P. Br. 4, 12. Mr. Dohi still did not know his action was prohibited by law when, in May 1995, he wrote a Corrective Action Plan that

---

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

included the potential of future retesting of Petitioner's proficiency testing samples at another laboratory! [P. Br. 12 - 14]. Also significant to me is that Mr. Dohi placed the Cell-Dyn 1600 printouts in Petitioner's files and did not purge them. P. Br. 4, 12.

Nevertheless, whether Mr. Dohi "should have known," and whether he had specific intent to violate a CLIA condition, are irrelevant to the issue at hand.

HCFA need only establish a general intent to act, and not, as Petitioner suggests, specific intent, as would be required in a criminal case. It is highly improbable that, within the framework of civil penalties against an entity, where no loss of personal liberty is involved, Congress would require specific intent in order to establish a CLIA violation under the statute's civil penalty provisions. Here, a laboratory is subject to civil administrative sanctions for failure to comply with statutory requirements.

To prove "intention" in the context of 42 U.S.C. § 263a(i)(4), 42 C.F.R. § 493.801(b)(4) and § 493.1840(b), HCFA is not required to prove what Mr. Dohi was thinking when he took the proficiency samples to another laboratory and ran the tests there. The issue is whether Mr. Dohi's actions were intentional, i.e., deliberate (not inadvertent). The uncontroverted evidence in this case is that Mr. Dohi referred proficiency test samples to another laboratory intentionally. Mr. Dohi has admitted doing so.

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

Mr. Dohi obtained platelet count values for Petitioner's proficiency testing samples from the Cell-Dyn 1600 at the community hospital's laboratory. The platelet count was the only item reported to AAB from Petitioner's retesting of its proficiency testing samples on the Cell-Dyn 1600 at the community hospital's laboratory. All of the remainder of Petitioner's hematology proficiency testing was reported as performed at Petitioner, on the Cell-Dyn 400. Whether or not a laboratory reports the information it has obtained from another laboratory's analysis of its proficiency testing samples, it is the obtaining of the analysis itself from the other laboratory which constitutes the intentional referral.

Accordingly, I find that Petitioner intentionally referred its hematology proficiency testing samples to another laboratory for analysis, in violation of 42 C.F.R. § 493.1840(b) and § 493.801(b)(4). Petitioner has not disputed that a referral of proficiency testing samples occurred here. As stated above, Petitioner admits taking the proficiency test samples to the community hospital's laboratory and running the tests there on that hospital's Cell-Dyn 1600.

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

While the actions of Mr. Dohi and Dr. Johnstone may not have been as egregious as that of the petitioner in the Long case, they still contravened the purpose of the CLIA statute and regulations.

Where intentional referral of a laboratory's proficiency testing samples to another laboratory for analysis has occurred, there is no possibility of a less severe sanction than a one-year minimum mandatory revocation. The statute itself specifies the sanction:

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

42 U.S.C. § 263a(i)(4).

II. Enrollment and Testing of Samples -- Condition

The laboratory must test its proficiency testing samples in the same manner as patients' specimens. 42 C.F.R. § 493.801.

The enrollment and testing of samples condition includes the "testing of proficiency testing samples" standard. 42 C.F.R. § 493.801(b). Within that standard is found the prohibition against intentional referral of proficiency testing samples to another laboratory for analysis. 42 C.F.R. § 493.801(b)(4). The intentional referral issue has been discussed above. See pp. 11-24 supra.

Hematology proficiency testing

With respect to the 3rd quarter 1994 hematology proficiency testing results, HCFA alleges that Petitioner did not test the hematology samples using its routine method nor did it test the samples in the same manner or the same number of times as it tested patient samples.

I conclude that Petitioner's testing of the hematology samples on the Cell-Dyn 1600 at the community hospital violated its obligation to conduct its proficiency tests using the routine method, in the same manner and for the same number of times that it routinely performs patient tests. See 42 C.F.R. § 493.801(b), (b)(1) and (b)(2).

Hemacytometer

Although there is no dispute that the reported platelet count values were obtained from the Cell-Dyn 1600 at the community hospital (Tr. 286-287), HCFA disputed Mr. Dohi's claim that he did use an instrument called a hemacytometer to count the platelets and that he ordinarily uses this at Petitioner. Ms. Maurer alleged that Mr. Dohi had informed her that he counted platelets using a "smear" technique, which would give an estimated number.[9] Tr. 141. Ms. Maurer stated that she did not look to see if Petitioner had a hemacytometer because Mr. Dohi never told her he used one. Tr. 115. With respect to the "smear" method, Ms. Maurer expressed her opinion that no one had ever "put down an actual number on the smear method". She stated that "the smear method is simply for an estimate of the platelets. I had never heard of anybody else ever doing that." Tr. 144.

Mr. Dohi denied using the "smear" method, and stated that he used a hemacytometer to do the platelet counts. Tr. 238, 240, 287. He described using the hemacytometer as doing a "manual" platelet count. Tr. 241-242.

After reviewing the testimony of Ms. Maurer, Mr. Dohi, and Dr. Johnstone, I conclude that I am not able to make a satisfactory determination on what platelet counting method Petitioner routinely used (except that a Cell-Dyn 1600 was not routinely used).

Chemistry proficiency testing

With respect to the 2nd quarter 1994 chemistry proficiency testing results, HCFA alleges that Petitioner did not test the chemistry isoenzyme samples in the same manner or the same number of times as it tested patient samples. Ms. Maurer testified that the chemistry isoenzyme test samples

---

[9] According to Ms. Maurer, the use of a hemacytometer to perform a platelet count is an appropriate and acceptable method. Tr. 115. Ms. Maurer testified further that platelet counting is very difficult and that using a Cell-Dyn 1600 to count platelets would give a more accurate count than a hemacytometer. Tr. 142-144.

were run twice. As proof of this, she stated that there was a worksheet on which Petitioner reported two sets of answers for each test. Tr. 43-46; HCFA Ex. 7 at 2. Ms. Maurer stated that there should have been only one set of answers. Moreover, although there were two sets of answers, Ms. Maurer could locate only one set of answers in the printout from the chemistry analyzer. Tr. 44, 57.

Mr. Dohi testified that he was not the technician who performed the testing on the chemistry samples. Tr. 245. He stated that he did not know why the tests were run twice. Tr. 245-246. Mr. Dohi was unable to find the documentation showing the other set of numbers. Tr. 123. Petitioner did not introduce any evidence to contradict Ms. Maurer, either at the hearing or in its briefs. I conclude that Petitioner's retesting of the chemistry isoenzyme samples violated its obligation to conduct its proficiency tests in the same manner and for the same number of times that it routinely performs patient tests.

Proficiency testing documentation

Ms. Maurer found also that relevant proficiency testing documentation, as required by 42 C.F.R. § 493.801(b)(5), was either missing or incomplete at the time of the survey. She testified that copies of the attestation statements for the hematology samples for the third event and the chemistry samples for the second event were missing. Tr. 40-41, 52-53. Petitioner failed to document the date it ran the tests on the proficiency testing samples, when it received the samples, and that the tests were done there (at Petitioner's laboratory). Tr. 55, 59-60. See HCFA Ex. 1 at 6. Petitioner failed to maintain specimen logs with respect to the proficiency testing in chemistry and hematology. Tr. 55. Petitioner failed to maintain copies of all proficiency testing records for 1994. HCFA Ex. 1 at 7. With respect to the second event for chemistry proficiency testing, Ms. Maurer testified that she was unable to locate the printout with the chemistry results and could not document that the tests had been performed. Tr. 57, 80, 102.

Mr. Dohi did not dispute that some proficiency test documentation was missing at the time of the survey. Tr. 238. He acknowledged that he could not find the worksheet where he had written the results obtained from Petitioner's Cell-Dyn 400. Tr. 271. Mr. Dohi admitted that he had no proof that he had run the samples on the Cell-Dyn 400. Tr. 271. Mr. Dohi admitted that he could not find the worksheet where he had written the platelet values that he had obtained using the hemacytometer. Tr. 238, 286. I conclude that HCFA has proven that Petitioner was deficient in its recordkeeping with respect to proficiency testing.

III. Patient Test Management -- Condition

The laboratory must employ and maintain a system that provides for proper patient preparation; proper specimen collection, identification, preservation, transportation, and processing; and accurate result reporting. 42 C.F.R. § 493.1101.

With respect to the Patient Test Management Condition, Ms. Maurer alleged that Petitioner was deficient regarding documentation and recordkeeping, quality control, and its gonorrhea screening. In the area of documentation and recordkeeping, Ms. Maurer testified that Petitioner did not have specimen logs and had an inadequate and outdated procedure manual. Under 42 C.F.R. § 493.1103(a), which is cited in HCFA Ex. 1, a "laboratory must have available and follow written policies and procedures for . . . conditions for specimen transportation." Ms. Maurer testified:

> [T]he procedure manual did not include any directives for handling of specimens at all. They did not have any directives at all on taking specimens to another laboratory for confirmation or further testing. There were no log sheets to follow a specimen that was transported elsewhere. I don't know how they kept track of them.

Tr. 61.

Ms. Maurer testified also that Petitioner's "procedure manual is old and outdated." Ms. Maurer stated that "when you change a procedure then you should take your old procedure out." Tr. 84. She discovered that the manual contained procedures that Petitioner was no longer doing. Id. In addition, Ms. Maurer discovered that, although Petitioner was conducting gonorrhea screenings, its procedure manual did not contain any written procedures for this. Tr. 75. (I discuss Petitioner's deficient procedure manual further in my discussion regarding Petitioner's deficient practice in conducting gonorrhea screenings).

HCFA's evidence, including Ms. Maurer's testimony, establishes that Petitioner did not comply with the condition of participation for Patient Test Management set forth at 42 C.F.R. § 493.1101.

Further support for Ms. Maurer's findings regarding Petitioner's deficient documentation is found in Petitioner's Exhibit 5. Petitioner, in this exhibit, attempts to show that it has implemented adequate recordkeeping and documentation systems. Tr. 250-259.

IV. Quality Control -- Standards

In the area of quality control, Ms. Maurer testified that, for all types of laboratory testing performed in a day, quality control should be conducted on that day for those tests. Tr. 67, 72, 74. The regulation requires that the laboratory must perform and document its control procedures using at least two levels of control materials each day of testing. 42 C.F.R. § 493.1202(c)(4); HCFA Ex. 1 at 10. Quality control is conducted on a known sample, of which the testing results would already be known. Tr. 67, 74. By performing quality control, a laboratory is able to check that its equipment is operating properly and, also, that its technologist is using the proper procedures. Tr. 67, 74.

Ms. Maurer stated that quality control in the area of hematology is to be performed for every eight hours of operation. Tr. 67. She alleged that Petitioner failed to perform quality control daily in hematology. Tr. 68; HCFA Ex. 8. Specifically, I find that Petitioner failed to run hematology quality control on four of 18 days in February 1995, when patients were tested. HCFA Ex. 8 at 1; HCFA Ex. 1 at 10.

Gonorrhea screenings

Other deficiencies identified by Ms. Maurer related to the gonorrhea screenings conducted by Petitioner. Under the regulations, a laboratory must have available a written procedure manual for all of the tests it performs. 42 C.F.R. § 493.1211(a). Ms. Maurer testified that, initially, she was unaware that Petitioner was even doing gonorrhea screening because there was no indication in the procedure manual that these tests were being done. Tr. 61-63.[10] Ms. Maurer testified:

> You're to have written procedures for all testing that you do. . . . The technologist should use the procedures. The procedure should be available so people know what you are doing in the laboratory, and how you are doing it, and the correct way, and the equipment that you're using.

Tr. 75.

---

[10] Ms. Maurer stated further that, because Petitioner was conducting gonorrhea screenings, it was required to undergo proficiency testing in this area. Tr. 62, 64, 79-80. I will not discuss whether or not Petitioner was required to undergo proficiency testing with respect to gonorrhea screening since HCFA did not cite this as a deficiency in the HCFA 2567.

The lack of written procedures meant that Petitioner had no way of ensuring that gonorrhea screenings would be subject to proper and uniform protocols. By failing to document the gonorrhea screening procedures in its procedure manual, Petitioner violated the regulatory requirement stated above.

In addition, the lack of culture media records indicated to the surveyor that Petitioner had failed to follow proper control procedures for the culture media used for gonorrhea screening, resulting in a deficiency under 42 C.F.R. § 493.1218(f)(1). Petitioner also was found deficient in the area of specimen transportation, as evidenced by the absence of a tracking system for when Petitioner sent gonorrhea cultures to other labs.

Ms. Maurer discovered also that the temperature chart on Petitioner's incubator indicated that the last time the temperature was checked and recorded was in 1992. Tr. 63, 76. See HCFA Ex. 1 at 11. In addition, the thermometer on the incubator was broken, a fact that was not discovered by anyone until the time of the survey. Tr. 278.

The regulations mandate that a laboratory "perform equipment maintenance and function checks . . . necessary for the proper test performance and test result reporting of equipment, instruments and test systems". 42 C.F.R. § 493.1215. Petitioner's failure to notice the broken thermometer on the incubator, coupled with its failure to keep the temperature chart up-to-date, could have jeopardized the accuracy and reliability of the gonorrhea screening results.[11] Petitioner admitted that the incubator was in use despite having a broken thermometer and that results were reported on cultures. Such inadequate maintenance and poor oversight of crucial laboratory instrumentation serves to underscore Petitioner's laxness in management.[12]

I find that Petitioner's deficiencies with respect to its gonorrhea screenings cannot be considered to be minor. It is apparent from Petitioner's violations that the manner in which it conducted its gonorrhea screenings was grossly inadequate and a cause for alarm. A likelihood existed that

---

[11] Mr. Dohi testified that he could not recall if he ever saw a positive culture. However, he conceded that "it is a possibility" that the reason he may not have seen a positive culture might be due to the fact that organisms were being killed due to incorrect incubator temperature. Tr. 278-279.

[12] Petitioner pointed out at the hearing that it replaced the broken incubator thermometer following the survey.

these violations could have adversely impacted the quality and reliability of the tests performed by Petitioner.

V. Quality Assurance -- Standards

The laboratory must monitor, evaluate, and revise, if necessary, based on the results of its evaluations, the accuracy and reliability of test reporting systems, appropriate storage of records and retrieval of test results. 42 C.F.R. § 493.1703(f). Petitioner last reviewed charts for completeness of laboratory work documentation on April 3, 1992. Tr. 84-86; HCFA Ex. 1 at 18-19.

The evidence establishes that Petitioner did not have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence. 42 C.F.R. § 493.1713; Tr. 89; HCFA Ex. 1 at 19.

VI. Laboratory Director -- Condition

Notice

Before I discuss Petitioner's non-compliance with the condition of participation for Laboratory Director set forth at 42 C.F.R. § 493.1441, I will address the preliminary issue of whether HCFA gave Petitioner adequate notice that this deficiency constitutes an independent basis for revocation of its CLIA certificate.

Petitioner argues that HCFA's Notice was deficient in that it did not state that HCFA had imposed the sanction of revocation in connection with a violation of the Laboratory Director condition. P. R. Br. 6. Petitioner contends that "HCFA asserted for the first time at the hearing . . . that Petitioner failed to meet . . . 42 C.F.R. § 493.1441 and that this failure was the basis for revocation of Petitioner's CLIA Certificate." Id. at 7.

I am not persuaded by Petitioner's assertion that it did not receive adequate notice that its violation of the Laboratory Director condition was a basis for revocation. HCFA's Notice, dated May 23, 1995, states:

> . . .[T]he supplemental information you submitted by letters dated May 16 and May 17, 1995, not only reconfirm that your laboratory (see 42 C.F.R. 493.2) did in fact intentionally refer its proficiency testing samples to another laboratory for analysis, but your admissions therein regarding your failure to meet your overall management responsibilities as the director also further evidence your contravention of the CLIA condition at 42 C.F.R. 493.1441 - a violation which independently supports the revocation of your CLIA

> certificate under the terms of 42 C.F.R. 493.1814(a)(2).

Based on the language contained in the May 23, 1995 letter from HCFA to Petitioner, I find that HCFA did allege that Petitioner's non-compliance with respect to the Laboratory Director condition would be a basis for revocation. The contents of the letters establish to my satisfaction that HCFA provided Petitioner with adequate notice concerning this issue. I conclude that HCFA's Notice, dated May 23, 1995, provided Petitioner with adequate notice that violation of 42 C.F.R. § 493.1441 would independently support revocation of Petitioner's CLIA certificate under 42 C.F.R. § 493.1814(a)(2). HCFA Br. 21-22; HCFA R. Br. 8. While it appears that HCFA's Notice, dated May 23, 1995, focused on Petitioner's alleged intentional referral of its proficiency testing samples as a basis for the imposition of sanctions, it is apparent that HCFA also was premising the sanction of revocation on the alleged violation of the laboratory director condition. (See passage quoted above.)

The Notice sufficiently informed Petitioner that the alleged intentional referral of proficiency samples and the alleged violation of the laboratory director condition were each independent grounds for the sanction of revocation.

Deficiencies

The laboratory must have a director who . . . provides overall management and direction in accordance with § 493.1445 of this subpart. 42 C.F.R. § 493.1441.

I find that Petitioner's deficiencies in proficiency testing, quality control, and documentation (including procedure manual) establish that Petitioner failed to comply with the condition of participation for Laboratory Director set forth at 42 C.F.R. § 493.1441. With respect to these alleged deficiencies, Ms. Maurer testified:

> When you find that the conditions have not been met in such things as proficiency testing, for example, or quality control, and it has not been done properly, then you have to cite your laboratory director for failure to perform, and failure to see that it is being performed. It's up to him to look at the laboratory and to check those things.

Tr. 79.

In addition, Ms. Maurer testified that there was no evidence of any documentation showing that Dr. Johnstone was monitoring the competency of the laboratory employees. Tr. 82-83. Ms. Maurer stated also that Dr. Johnstone failed to ensure that the laboratory procedure and policy manuals were

up-to-date and complete. Tr. 83-84; HCFA Ex. 1 at 17. Another deficiency identified by Ms. Maurer was Dr. Johnstone's failure to assign in writing the duties and responsibilities involved in all phases of the patient testing process for the testing personnel. Tr. 87-88; HCFA Ex. 1 at 18. Ms. Maurer discovered also that Petitioner last reviewed charts for completeness of laboratory work documentation on April 3, 1992. Tr. 84-86.

It is evident from the foregoing deficiencies, many of which were previously described by Ms. Maurer in conjunction with her testimony concerning Petitioner's non-compliance with the conditions listed at 42 C.F.R. § 493.801 and § 493.1101, that Dr. Johnstone failed to supervise adequately Petitioner's operations and employees. As laboratory director, Dr. Johnstone was responsible for the overall operation and administration of Petitioner in accordance with 42 C.F.R. § 493.1445. Part of that responsibility is to ensure that quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 42 C.F.R. § 493.1445(e)(5). See sections IV. and V. above. Dr. Johnstone had a duty to keep apprised of the day-to-day operation of his laboratory and to exercise proper supervision over his employees. He was obligated also to familiarize himself with the applicable CLIA regulations. With respect to proficiency testing, Dr. Johnstone had the ultimate responsibility for ensuring that proficiency testing was performed in accordance with the requirements set forth at 42 C.F.R. § 493.801. HCFA Br. 30; HCFA R. Br. 9-11.

A primary objective of the CLIA requirements is to provide the public with safe and reliable laboratory services. Congress, in enacting CLIA, intended to assure that clinical laboratories perform medical tests accurately and reliably.

I conclude from the deficiencies that Dr. Johnstone failed to carry out his duties as Laboratory Director, in violation of the Condition for Laboratory Director set forth at 42 C.F.R. § 493.1441. Dr. Johnstone's failure to ensure that the proficiency testing samples were tested as required, and his failure to have adequate quality control and patient test management programs, demonstrate his neglect of his responsibilities as a laboratory director.

Petitioner's failure to meet the Condition for Laboratory Director forms an independent basis for HCFA's revocation of Petitioner's CLIA certificate under 42 C.F.R. § 493.1814(a)(2).

VII. HCFA Required to Revoke Petitioner's CLIA Certificate for a One-Year Period

Enforcement of CLIA is intended to protect individuals served by laboratories against substandard testing, to safeguard the public against health and safety hazards which might result from noncompliance, and to motivate laboratories to comply with CLIA requirements. 42 C.F.R. § 493.1804(a)(1) - (3).

The evidence establishes that Petitioner was out of compliance with the Conditions of Participation set forth at 42 C.F.R. § 493.801 [Enrollment and Testing of Samples], § 493.1101 [Patient Test Management], and § 493.1441 [Laboratory Director].

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

Neither I nor HCFA has the discretion to revoke Petitioner's CLIA certificate for less than the mandatory minimum period of one year, or to substitute any lesser sanction. HCFA is required to cancel a laboratory's approval to receive Medicare payment for its services where the laboratory's CLIA certificate is revoked. 42 C.F.R. § 493.1808(a) and § 493.1842(a)(1).

CONCLUSION

Petitioner intentionally referred its proficiency testing samples to another laboratory for analysis during 3rd quarter 1994. Accordingly, Petitioner's CLIA certificate must be revoked for a one-year minimum mandatory period, with concomitant cancellation of Petitioner's Medicare payments for laboratory services.

Further, Petitioner's failure to meet the Condition for Laboratory Director forms an independent basis for HCFA's revocation of Petitioner's CLIA certificate.

/s/

Jill S. Clifton

Administrative Law Judge