Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Williams Bio Medical Laboratory,	)	Date: August 5, 1997
	)	
Petitioner,	)	
	)	
-v.-	)	Docket No. C-96-101
	)	Decision No. CR487
Health Care Financing Administration.	)	
	)	

DECISION

This case arises under the Clinical Laboratory Improvement Amendments of 1988 (referred to as "CLIA" or "the Act"), 42 U.S.C. § 263a and on implementing regulations in 42 C.F.R. Part 493. On November 28, 1995, the Health Care Financing Administration (HCFA) notified Williams Bio Medical Laboratory (WBML or Petitioner) that, based on a survey completed on October 26, 1995, deficiencies had been found in Petitioner's facility which remained uncorrected 12 months after having been identified originally in surveys dated August 4, 1994 and November 2, 1995. HCFA notified Petitioner also that it had failed to comply with an August 24, 1995 Directed Plan of Correction, which had required correction of all deficiencies by September 29, 1995. As a result, HCFA informed Petitioner that it had decided to revoke Petitioner's CLIA certificate and cancel all Medicare payments for services furnished by Petitioner. By letter dated December 2, 1995, Petitioner timely requested a hearing.[1]

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[1] Petitioner's CLIA certificate was subsequently revoked on separate and independent grounds, effective March 21, 1996, as a result of Petitioner's failure to pay required CLIA fees. Petitioner acknowledges that it did not pay the required fees and that it did not appeal

(continued...)

This case was assigned initially to Administrative Law Judge Mimi Hwang Leahy. In a Ruling dated August 20, 1996, Judge Leahy granted partial summary judgment, based on HCFA's motion for summary judgment. Judge Leahy ruled that only two issues remained for hearing: (1) whether Petitioner had deficiencies that remained uncorrected over 12 months following the survey of August 4, 1994; and (2) whether Petitioner had failed to comply with the terms of the Directed Plan of Correction requiring that all deficiencies (whether condition-level or standard-level) be corrected by September 29, 1995. Specifically, Judge Leahy ruled that, under the first issue, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that Petitioner failed to correct all standard-level and condition-level deficiencies from the August 4, 1994 survey. 42 C.F.R. §§ 493.1816(b), 493.1820, 498.1828(b)(2). Judge Leahy further ruled that, under the second issue, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that by September 29, 1995, Petitioner had even one standard-level deficiency that remained uncorrected from either of the two prior surveys. If HCFA prevails on either one of these two issues, then HCFA is entitled to prevail as a matter of law on its imposition of the sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), and 493.1842(a). Finally, Judge Leahy ruled that Petitioner must prevail on both issues for the sanctions imposed by HCFA, in the notice of November 28, 1995, to be set aside. Id.

On September 26, 1996, this case was reassigned to me. I scheduled a hearing to commence on February 11, 1997, solely on the issues remaining after Judge Leahy's ruling of August 20, 1996. However, on February 7, 1997, in a telephone prehearing conference, Petitioner withdrew its request for an in-person hearing, and requested instead that the case be heard based on an exchange of documentary evidence and briefs. After consideration,

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[1](...continued)
its revocation based on this failure to pay required CLIA fees. Unappealed determinations are binding and cannot be set aside in this proceeding. Administrative Law Judge Mimi Hwang Leahy's August 20, 1996 Ruling in this case (ALJ Ruling), Findings of Fact and Conclusions of Law (FFCL) 17-20.

HCFA agreed to submit its case on briefs and documentary evidence, including declarations.[2]

I have considered the relevant evidence, the applicable law and the parties' arguments. Any argument or issue raised by the parties that is not specifically addressed

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[2] Petitioner's exhibits 1-6, 8-25, 25A, 26-28, and 18 attachments (P. Att. 1-18) were accepted into the record by Judge Leahy. Subsequently, Petitioner submitted a copy of its brief in opposition to HCFA's motion for summary judgment, which was labeled exhibit 1 (and which was previously submitted to Judge Leahy); a declaration ("Reference to Franklin R. Barnes Declaration"), which was labeled exhibit 2 and which I have remarked as P. Ex. 29; and a revised response to the October 26, 1995 revisit survey, which was labeled exhibit 3 and which I have remarked as P. Ex. 30. At the same time, Petitioner submitted 23 attachments. I am discarding part of the second set of attachments, attachments 1-18, because these attachments are duplicates of P. Att. 1-18 which were accepted into the record by Judge Leahy. Petitioner submitted five new attachments (P. Att. 19-23). I am re-marking P. Att. 1-23 as P. Ex. 31-53, to conform with Civil Remedies Division practice. I am discarding the brief Petitioner submitted as exhibit 1, as it is of record already.

HCFA had previously submitted HCFA exhibits 1-15 in support of its motion for summary judgment. Judge Leahy accepted those exhibits into the record. Following Judge Leahy's ruling, HCFA submitted a brief in support of the revocation of Petitioner's CLIA certificate, and 17 exhibits (HCFA Ex. 1-8 and 10-18). I am discarding part of the second set of exhibits, HCFA Ex. 1-8 and 10-15, because these exhibits are duplicates of exhibits already in the record. HCFA submitted three new exhibits (HCFA Ex. 16-18). In order to decide the case before me, I am receiving into the record those exhibits that were not previously admitted as exhibits: P. Ex. 29-53 and HCFA Ex. 16-18.

The parties have submitted several briefs, some referred to above. Those submitted to Judge Leahy include the brief accompanying HCFA's motion for summary judgment (HCFA Br.), Petitioner's brief in response to this motion (P. Br.), and HCFA's response brief (HCFA Resp. Br.). Before me, HCFA submitted a brief in support of the revocation of Petitioner's CLIA certificate (HCFA Br. 2) and Petitioner submitted a summary letter in response (P. Let.).

in this decision I have rejected as either lacking in merit or irrelevant. I conclude that Petitioner has failed to prevail on either issue identified above.[3] I conclude further that HCFA's determination to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare reimbursement for its services is authorized by CLIA and implementing regulations.

GOVERNING LAW

Congress enacted CLIA in order to guarantee that clinical laboratories perform medical tests accurately. CLIA was intended by Congress to establish a single set of standards which govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. See H.R. Rep. No.

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[3] Petitioner sought to raise other issues in its brief. Specifically, Petitioner claimed that the deficiencies cited in the November 2, 1994 survey were incorrect. Petitioner alleges that it did not receive the letter dated March 30, 1995, from the California Department of Health Services (State agency) which notified WBML that, as a result of the November 2, 1994 survey, four condition-level deficiencies were still out of compliance. This letter further stated that the State agency would recommend to HCFA that alternative sanctions be imposed. However, even if all Petitioner's claims are true, as Judge Leahy found, Petitioner still received HCFA's notice imposing alternative sanctions, and was aware that all deficiencies had to be corrected by September 29, 1995. ALJ Ruling, FFCL 6. Petitioner did not request a hearing to contest the results of the August and November 1994 surveys, or to contest the imposition of alternative sanctions pursuant to those surveys. ALJ Ruling, FFCL 7. Judge Leahy ruled that Petitioner may not dispute HCFA's findings of deficiencies from the survey of November 2, 1994, because unappealed determinations are binding on Petitioner and cannot be set aside in this proceeding. ALJ Ruling, FFCL 7, 20.

Petitioner also submitted a declaration with reference to the declaration of Franklin R. Barnes, the State agency surveyor (P. Ex. 29). This declaration relates to procedural points that are not relevant to the issues before me. In her August 20, 1996 Ruling, Judge Leahy ruled that the issues raised by WBML, other than the issues referred to above, were beyond the scope of Petitioner's remaining hearing rights, since WBML had failed to appeal any of HCFA's prior sanctions.

899, 100th Cong., 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N. 3828-3836 (House Report).

CLIA authorizes the Secretary of the United States Department of Health and Human Services (Secretary) to inspect clinical laboratories. The Act directs the Secretary to establish standards to assure that clinical laboratories certified by the Secretary perform tests that are valid and accurate. 42 U.S.C. § 263a(f)(1). Before a clinical laboratory can accept or solicit specimens, a clinical laboratory must first receive a certificate from the Secretary authorizing it to perform the specific category of tests which the laboratory intends to perform. 42 U.S.C. § 263a(b).

The Act provides for revocation of a CLIA certificate under specified circumstances. These include, among others things, failure of the laboratory's owner or operator to comply with standards issued by the Secretary, or failure by an owner or operator to abide by an intermediate sanction issued by the Secretary. 42 U.S.C. § 263a.

In addition to standards established by the Act, regulations are issued by the Secretary pursuant to CLIA that establish standards for certification, provide a framework for inspections, and provide for the imposition of sanctions in the event that laboratories fail to comply with the applicable standards.

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

Principal sanctions consist of remedies which HFCA may impose for any of the reasons set forth in section 263a(i)(1) of the Act. 42 C.F.R. § 493.1840(a). HCFA may impose principal sanctions where a laboratory has not complied with applicable standards or where the laboratory has not complied with an alternative sanction. 42 C.F.R. § 493.1840(a)(3), (7). Principal sanctions may include revocation of a laboratory's CLIA certificate and cancellation of its approval to receive Medicare payments for its services. 42 C.F.R. §§ 493.1806, 493.1807, 493.1840(a), 493.1842.

BURDEN OF PROOF

By notice letter of March 26, 1997, I afforded the parties the opportunity to file a supplemental brief addressing what effect, if any, the decision in the case of _____ Center, DAB 1611 (1997) might hav ' availed itself of the opp Hillman, llate panel of the Departmental Appeals Board held that HCFA has an initial obligation to set forth the basis for its determinations with sufficient specificity to allow the petitioner to respond (the obligation to make a prima facie case). To prevail, a petitioner must prove by a preponderance of the evidence on the record as a whole that it is in substantial compliance with relevant statutory and regulatory provisions. Thus, under Hillman, the petitioner, not HCFA, bears the ultimate burden of persuasion. This case is governed by the burden of proof set forth in Hillman.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Judge Leahy's Ruling of August 20, 1996 sets forth 33 Findings of Fact and Conclusions of Law (FFCL). These are set out below. The rest of the FFCL pertain to the October 26, 1995 revisit survey and to the resultant November 28, 1995 notice letter issued by HCFA.

1. Pursuant to a CLIA survey conducted on August 3 and 4, 1994 by the California Department of Health Services (State agency), Petitioner was found to have various standard-level deficiencies as well as the following seven condition-level deficiencies:

a. Enrollment and testing (proficiency testing) samples (42 C.F.R. § 493.801);

b. Bacteriology (42 C.F.R. § 493.1227);

c. Laboratories performing high complexity testing; laboratory director (42 C.F.R. § 493.1441);

d. Laboratories performing moderate complexity testing; laboratory director (42 C.F.R. § 493.1403);

e. Quality assurance; moderate or high complexity testing, or both (42 C.F.R. § 493.1701);

f. Patient test management; moderate or high complexity testing, or both (42 C.F.R. § 493.1101);

g. General quality control; moderate or high complexity testing, or both (42 C.F.R. § 493.1201).

HCFA Br. at 2-3; HCFA Ex. 1.

2. In response to the deficiencies found during the survey which was completed on August 4, 1994, Petitioner submitted a plan of correction which was found acceptable by HCFA's agent (the State agency), and a revisit survey was conducted. HCFA Ex. 3 at 1; HCFA Ex. 4 at 1.

3. The results of the revisit survey conducted on November 2, 1994, showed that Petitioner had five of the same condition-level deficiencies (FFCLs 1a to e) as noted during the August 1994 survey. HCFA Ex. 2, 4.

4. After having provided Petitioner with the opportunity to submit additional information or comments concerning the possible imposition of sanctions (HCFA Ex. 3, 4), HCFA notified Petitioner by letter dated August 24, 1995, that the following alternative sanctions were being imposed and that Petitioner had a right to appeal HCFA's determinations:

a. state on-site monitoring (42 C.F.R. § 493.1836);

b. a directed plan of correction (42 C.F.R. § 493.1832) to correct all designated deficiencies by September 29, 1995; and

c. the suspension of all Medicare and Medicaid (Social Security Act, § 1902(a)(9)(C); 42 C.F.R. § 440.30(c), 440.2(b)) payments for laboratory services (42 C.F.R. § 493.1828) effective September 8, 1995.

HCFA Ex. 5.

5. The directed plan of correction stated: "EXPECTED DATE OF CORRECTION FOR ALL DEFICIENCIES: On, or before September 29, 1995." HCFA Ex. 2 at 3.

6. Petitioner received HCFA's notice imposing the alternative sanctions and was aware that all deficiencies should be corrected by September 29, 1995. P. Br. at 2.

7. Petitioner did not request a hearing to contest the results of the above-mentioned August and November 1994 surveys, or to contest HCFA's imposition of alternative sanctions pursuant to those survey results. P. Br. at 2.

8. Petitioner verified that Medicare and Medicaid payments had stopped on September 8, 1995. P. Br. at 3.

9. Subsequent to the imposition of the alternative sanctions and prior to October of 1995, Petitioner changed its location and telephone number without providing HCFA with advance notice. Declaration of Franklin Barnes (HCFA Ex. 14); Petitioner's declaration "Reference to Franklin R. Barnes Declaration."

10. After ascertaining Petitioner's new address, HCFA conducted a scheduled revisit survey on October 26, 1995, and found that 21 standard-level deficiencies still remained uncorrected from the prior two surveys. HCFA Ex. 7.

11. Petitioner was closed in November and has remained closed since then. P. Br. at 3.

12. Based on the October 26, 1995 survey, HCFA notified Petitioner by letter dated November 28, 1995 that, as a result of the deficiencies which remained uncorrected over the 12 months since the August 4, 1994 survey, as well as Petitioner's failure to comply with the terms of the Directed Plan of Correction requiring the correction of all deficiencies by September 29, 1995, HCFA was imposing the following principal sanctions:

> a. revocation of Petitioner's CLIA certificate, effective 60 days after receipt of the notice letter unless a hearing is requested; and
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> b. cancellation of all Medicare payments for services furnished by the laboratory 15 days from Petitioner's receipt of the notice letter, in accordance with 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), and 493.1842(a).

HCFA Ex. 8.

13. Cancellation of Medicare payments under 42 C.F.R. § 493.1842 may be imposed before a hearing, and it terminates any Medicare payment sanctions, regardless of the original time frames. 42 C.F.R. § 493.1842(b), (c).

14. If a hearing is requested, the revocation of a CLIA certificate does not take effect unless and until there is a decision by an administrative law judge which upholds HCFA's revocation determination. 42 C.F.R. § 493.1840(e).

15. By letter dated December 2, 1995, Petitioner timely requested a hearing to contest the results of the October 26, 1995 survey.

16. By letters dated January 16, 1996 (HCFA Ex. 10) and March 15, 1996 (HCFA Ex. 11), HCFA notified Petitioner that it owed outstanding CLIA fees in the amount of $2549 and that Petitioner had a right to appeal the determination of outstanding fees and the imposition of the following sanctions for the nonpayment of CLIA fees:

> a. revocation of Petitioner's CLIA certificate effective March 21, 1996, if a request for hearing was not received; and
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> b. cancellation of Medicare payments to Petitioner within 15 days of receiving the notice dated January 16, 1996.

HCFA Ex. 10, 11.

17. By letter dated March 28, 1996, HCFA informed Petitioner that, since HCFA had not received the outstanding fee payment or any request for hearing, Petitioner's CLIA certificate was revoked as of March 21, 1996 for the nonpayment of CLIA fees, which is an independent and separate basis from the reasons stated for revoking Petitioner's CLIA certificate in HCFA's notice of November 28, 1995. HCFA Ex. 13, 8.

18. The reasons provided by HCFA in its January 16, 1996 letter for imposing the sanctions of revocation of Petitioner's CLIA certificate and cancellation of all Medicare payments to Petitioner are separate and distinct from those HCFA set forth in its November 28, 1995 notice imposing the same sanctions against Petitioner. HCFA Ex. 13, 8.

19. Petitioner acknowledges that it had not paid the CLIA fees and that it has no basis for appealing the revocation of its CLIA certificate for that reason. P. Br. at 2-4.

20. Unappealed determinations are binding upon Petitioner and cannot be set aside in this proceeding. See, e.g., 42 C.F.R. § 498.20(b).

21. Petitioner may not dispute HCFA's findings of deficiencies from the survey which was completed on August 4, 1994. FFCL 7, 20.

22. Petitioner may not dispute HCFA's findings of deficiencies from the survey of November 2, 1994. FFCL 7, 20.

23. Petitioner may not dispute any of the sanctions HCFA imposed by notice dated August 24, 1995, which resulted from the surveys of August 3 and 4, 1994 and November 2, 1994. FFCL 7, 20.

24. The alternative sanction of a directed plan of correction, imposed by notice of August 24, 1995, and containing HCFA's directive for Petitioner to correct all deficiencies by September 29, 1995, did not give specific instructions on how Petitioner must make the corrections. HCFA Ex. 2.

25. Petitioner may not dispute HCFA's determination that it failed to pay its CLIA fees. FFCL 19, 20.

26. Petitioner may not dispute the sanctions HCFA imposed based on Petitioner's nonpayment of CLIA fees. FFCL 19, 20.

27. The only issues for hearing are whether, as determined by HCFA on the basis of the October 26, 1995 revisit survey;

> a. Petitioner had deficiencies which remained uncorrected over the 12 months following the survey which was completed on August 4, 1994, and
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> b. Petitioner failed to comply with the terms of the Directed Plan of Correction requiring the correction of <u>all</u> deficiencies (whether condition-level or standard-level) by September 29, 1995.

FFCL 4, 7, 12, 17.

28. Under the issue identified in FFCL 27a, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that Petitioner had failed to correct all standard-level and condition-level deficiencies from the August 4, 1994 survey. 42 C.F.R. §§ 493.1816(b), 493.1820, 498.1828(b)(2).

29. Under the issue identified in FFCL 27b, HCFA will prevail (and Petitioner will lose) if evidence from the October 26, 1995 survey proves that, by September 29, 1995, Petitioner had even one standard-level deficiency which remained uncorrected from either of the two prior surveys. FFCL 5, 6, 20.

30. If relevant to either party's position on the issue identified in FFCL 27b, either party may submit evidence to prove whether Petitioner was closed for any period of time up to and including September 29, 1995.

31. The effective dates specified by HCFA in its November 28, 1995 notice for the imposition of sanctions are in accord with the requirements of the regulations. 42 C.F.R. §§ 493.1842(b), 493.1844(h)(2), 493.1844(d)(2).

32. If HCFA prevails on either one of the two issues identified above in FFCL 27, HCFA is entitled to prevail also as a matter of law on its imposition of the sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), and 493.1842(a).

33. Petitioner must prevail on both issues identified above in FFCL 27 in order to have me set aside the sanctions imposed by HCFA in the notice letter dated November 28, 1995 (revocation of Petitioner's CLIA certificate and cancellation of Medicare payments to Petitioner). Id.

34. By confirming letter dated October 10, 1995, HCFA notified Petitioner that an onsite CLIA revisit survey would be performed on October 26, 1995. HFCA Ex. 6.

35. On October 26, 1995, a second revisit survey was conducted by the State agency. HCFA Ex. 14, at 5, para. 17.

36. The purpose of this second revisit survey was to verify whether Petitioner had corrected all deficiencies identified in the surveys of August 4, 1994 and November 2, 1994, as required by the August 24, 1995 Directed Plan of Correction. HCFA Ex. 6.

The August 24, 1995 Directed Plan of Correction required that all deficiencies be corrected by September 29, 1995. HCFA Ex. 5.

37. The State agency found that numerous standard-level deficiencies identified during the prior surveys remained uncorrected, contrary to the terms of the August 24, 1995 Directed Plan of Correction. HFCA Ex. 14, at 5-6, para. 17.

38. As a result of the second revisit survey of October 26, 1995, HCFA now alleges that eight standard-level deficiencies remained uncorrected over 12 months following the August 4, 1994 survey. HCFA Ex. 7, 14, 15, 16, 17.

39. The 13 remaining deficiencies identified during the October 26, 1995 revisit survey, were later determined to be corrected, because HCFA subsequently verified that the laboratory was enrolled in a proficiency testing program at the time of the survey. HCFA Ex. 15, at 5-6, para. 10; HCFA Br. 2, at 13.

40. Petitioner failed to comply with 42 C.F.R. § 493.1103(a), which governs specimen submission and handling, by the second revisit survey on October 26, 1995.

41. Petitioner failed to comply with 42 C.F.R. § 493.1407(e)(5), which governs the responsibilities of the laboratory director to ensure that quality control and assurance programs are established and maintained to assure the quality of laboratory services provided, and to identify failures in quality as they occur, by the second revisit survey on October 26, 1995.

42. Petitioner failed to comply with 42 C.F.R. § 493.1711, which governs quality assurance for moderate or high complexity testing for quality assurance and requires the laboratory to have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria, such as the relationship with other test parameters, when available within the laboratory, by the second revisit survey on October 26, 1995.

43. At the time of the revisit survey of October 26, 1995, eight standard-level deficiencies remained uncorrected over 12 months following the survey of August 4, 1994, as cited under D tags 3013, 6022, 6094, 7009, 7010, 7054, 7057, 7066. HCFA Ex. 7, 14, 15, 16, 17.

44. At the time of the revisit survey of October 26, 1995, the following eight standard-level deficiencies remained uncorrected in violation of the Directed Plan of Correction requiring the correction of all deficiencies (whether condition-level or standard-level) by September 29, 1995:

a. D tag 3013 concerning specimen submission, transportation and handling (42 C.F.R. §§ 493.1103(a) and 493.1445(e)(5));

b. D tag 6022 concerning the responsibilities of the laboratory director (42 C.F.R. § 493.1407(e)(5));

c. D tag 6094 also concerning the responsibilities of the laboratory director (42 C.F.R. § 493.1445(e)(5));

d. D tag 7009 concerning patient test management assessment (42 C.F.R. §§ 493.1103(a), 493.1445(e)(5), and 493.1703);

e. D tag 7010 also concerning patient test management assessment (42 C.F.R. §§ 493.1103(a) and 493.1703);

f. D tag 7054 concerning patient information and test results (42 C.F.R. §§ 493.1445(e)(5) and 493.1711(e));

g. D tag 7057 concerning communications (42 C.F.R. §§ 493.1445(e)(5) and 493.1715);

h. D tag 7066 concerning quality assurance records (42 C.F.R. §§ 493.1407(e)(5), 493.1445 (e)(5), and 493.1721);

HCFA Ex. 7, 14-17.

45. HCFA prevails, since it met its obligation to provide notice of its determinations regarding the October 26, 1995 survey, and since Petitioner failed to prove by a preponderance of the evidence that it had corrected all the deficiencies identified during the August 4, 1994 survey. The period of time between these two surveys is over 12 months. HCFA Ex. 7, 17; 42 C.F.R. §§ 493.1816(b), 493.1820, 493.1828(c)(2).

46. HCFA prevails, since it met its obligation to provide notice of its determinations, and since Petitioner failed to prove by a preponderance of the evidence that, by September 29, 1995, no condition or standard-level deficiencies remained uncorrected, a violation of the terms of the Directed Plan of Correction.

47. As a matter of law, HCFA prevails on its imposition of the sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. FFCL 1-46; 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), 493.1842(a).

DISCUSSION

The evidence and argument presented by Petitioner do not persuade me that, based on the results of the October 26, 1995 survey, Petitioner has proved that all the deficiencies identified by HCFA had been corrected. Petitioner, not HFCA, bears the ultimate burden of persuasion. Petitioner has not met this burden.

Specifically, Petitioner failed to comply with the standard governing Specimen Submission and Handling (42 C.F.R. § 493.1103(a)). This resulted in a deficiency cited as D tag 3013. This standard requires that a laboratory must have available and follow written policies and procedures for conditions for specimen transportation. Such policies and procedures must assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until testing has been completed and the results reported. HCFA determined that Petitioner failed to comply with this standard, based upon interviews conducted by the State agency with Petitioner's staff and upon the review of available procedure manuals. This failure was corroborated by Petitioner's general supervisor. HCFA Ex. 7, at 6; HCFA Ex. 17, at 1, para. 3. Petitioner attempts to refute this evidence by referring to P. Ex. 36, a document entitled "Quality Assurance Program-Phlebotomy-Specimen Collecting Procedure for Williams Bio Medical Laboratory." However, Petitioner cannot rely on this exhibit to show its compliance with the regulation, since P. Ex. 36 pertains only to specimen collection, and not to specimen transportation. In addition, P. Ex. 36 has no date or signature on it to show that it was in place at WBML at the time of the October 26, 1995 revisit survey. Obviously, the best evidence to demonstrate that the procedures were in place would be documentation showing they were in use. Petitioner, who would be in the best

position to have such documentation, assuming such documentation was in use, did not offer such proof. Consequently, I must conclude that no such documents exist and that the procedures were never in place. Petitioner claims also that this standard does not apply to it, since it does not transport specimens and all testing is done in house. However, 42 C.F.R. § 493.1103(a) is intended to "assure positive identification and optimum integrity of the patient specimens from the time the specimen(s) are collected until the testing has been completed and the results reported." Clearly, section 493.1103(a) is referring to "in house" specimen transportation. Therefore, this regulation does apply to WBML, and WBML has failed to comply with it.

Petitioner failed also to comply with 42 C.F.R. § 493.1407(e)(5), which requires that a laboratory director of moderate complexity testing must ensure that quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. HCFA found deficiencies (D tags 6022 and 7066) under this standard based, in part, on the State agency's interviews with staff and review of quality control/quality assurance records, and based, in part, on a lack of documentation showing that quality assurance activities, including the identification of problems and corrective actions taken, had, in fact, occurred. HFCA Ex. 7 at 12-13 (D tag 6022) and 28-29 (D tag 7066); HCFA Ex. 15, 17. Petitioner relies on its P. Ex. 39-43 to show that it had quality control and assurance programs in place at the time of the October 26, 1995 survey. However, these exhibits consist of forms and checklists which are blank. There are no dates, signatures, or any other information to show that the required quality control/quality assurance programs were in place at the time of the survey. HFCA Ex. 16. The evidence offered by Petitioner thus does not prove that such a program was in place at the time of the October 26, 1995 survey.

The regulation at 42 C.F.R. § 493.1711(e) requires that for internal quality assurance, a laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria, such as its relationship with other test parameters when available. HCFA determined that, at the time of the surveys, WBML did not have such a mechanism. HCFA Ex. 7, at 24-25; HCFA Ex. 17. This resulted in a deficiency cited as D tag 7054.

Petitioner attempts to refute this by relying on P. Ex. 45, 46, 49, and 51. P. Ex. 45 is a form on which tests are ordered. There is no place on this form to record results. P. Ex. 46 appears to be a form on which results are reported. This form does provide a normal range for each test, but it does not provide a mechanism to identify and evaluate patient test results that are inconsistent with relevant criteria such as patient age, sex, diagnosis, distribution of test results, or relationship with other test parameters, when available. Therefore, these two exhibits do not demonstrate compliance with this regulation.

P. Ex. 49 is a communication log between the laboratory director or clinical consultant and clients or facilities. This form shows blanks to be filled in with the date, time, who was spoken to, patient name, subject of communication, and resolution. There are also blanks to be filled in to identify the individual initiating the communication and the individual who reviews the completed form. A note at the bottom of the form says that the form should be turned in to the Quality Assurance Committee. However, this form does not indicate how or when it should be used. There is no indication what the triggering circumstance would be to initiate communication. Further, the form does not provide a mechanism to identify and evaluate patient test results that are inconsistent with relevant criteria.

P. Ex. 51 is part of a document entitled "Quality Assurance" (P. Ex. 50), and it states:

> (f) Standard. The laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with clinically relevant criteria such as--
>
> 1) Patient's age;
> 2) Sex;
> 3) Diagnosis of pertinent clinical data;
> 4) Relationship with other test parameters.

This document simply repeats the wording of the regulation. It states that the laboratory "must have" a mechanism to identify and evaluate patient test results that appear to be inconsistent with relevant criteria. It does not state that the laboratory has identified such a mechanism, nor does it show that such a mechanism was being used by WBML.

P. Ex. 49 and 51 contain no dates, signatures, or other identifying information indicting that any of the procedures reflected there had been adopted by the laboratory, or were in place, at the time of the October 26, 1995 survey. Nor had these exhibits been provided to HCFA previously, either in response to the deficiencies identified during any of the three surveys or at the time Petitioner requested a hearing. HFCA Ex. 16. Further, even assuming that these documents were present in the laboratory at the time of the October 26, 1995 survey, they fail to identify any mechanism in place at that time to assure that the regulation was being carried out.

The remaining uncorrected deficiencies, for which Petitioner has submitted no acceptable documentation to refute the evidence introduced by HCFA, include: deficiencies based on the failure of the laboratory director to establish and maintain quality control and quality assurance programs in order to assure the quality of laboratory services provided and to identify failures as they occur (42 C.F.R. § 493.1445(e)(5), D tags 6094, 7009, 3013, 7054, 7057, 7066); deficiencies based on the failure to have an ongoing mechanism for monitoring and evaluating the systems required under subpart J of 42 C.F.R. Part 493, Patient Test Management (42 C.F.R. §§ 493.1103 and 1703, D tags 7009, 7010); a deficiency based on a failure to have in place a system to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations (42 C.F.R. § 493.1715, D tag 7057); and a deficiency based on the failure to maintain documentation of all quality assurance activities, including problems identified and corrective actions taken (42 C.F.R. § 493.1721, D tag 7066). HCFA determined that these deficiencies existed based on interviews conducted by the State agency with WBML's staff, including WBML's general supervisor, a review of the quality assurance records, and the finding of a lack of documentation where required. HCFA Ex. 7, 15, 17. In addition, HCFA provided declarations from the surveyor, Franklin R. Barnes, and from a laboratory consultant employed by HCFA, Esther-Marie Carmichael. HCFA Ex. 14-17. These declarations support the existence of the deficiencies at WBML.

Petitioner relies on its exhibits to show that it had overcome these remaining deficiencies prior to the revisit survey of October 26, 1995 (P. Ex. 39-43 and 49). These exhibits consist of forms and checklists that are blank. None of these exhibits show that Petitioner had the required quality assurance or other systems in place

at the time of the October 26, 1995 survey. This showing does not meet the burden of persuasion required by Hillman.

CONCLUSION

Petitioner had deficiencies which remained uncorrected over 12 months following the August 4, 1994 survey. Further, Petitioner failed to comply with the terms of the August 24, 1995 Directed Plan of Correction requiring that all deficiencies, whether condition-level or standard-level, be corrected by September 29, 1995.

HCFA may impose principal sanctions where a laboratory fails to correct deficiencies within 12 months of the day of the inspection or where it fails to comply with an alternative sanction, such as a Directed Plan of Correction. 42 C.F.R. §§ 493.1816(b), 493.1840(a)(7). Thus, as a matter of law, HCFA prevails on its imposition of sanctions revoking Petitioner's CLIA certificate and canceling all Medicare payments to Petitioner. 42 C.F.R. §§ 493.1808(a), 493.1816(b), 493.1832(c), 493.1840(a)(7), 493.1842(a).

/s/

Edward D. Steinman
Administrative Law Judge