Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
Central Valley Medical Laboratory,	DATE: September 28, 1994
Petitioner,	
- v. -	Docket No. C-94-062 Decision No. CR335
Health Care Financing Administration.	

DECISION

This case is governed by the Clinical Laboratory Improvement Amendments of 1988 (referred to throughout this decision as "CLIA" or "the Act"), 42 U.S.C. § 263a, and implementing regulations at 42 C.F.R. Part 493. On November 15, 1993, the Health Care Financing Administration (HCFA) notified Central Valley Medical Laboratory (CVML or Petitioner) that HCFA had determined to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare payments for its services. HCFA advised Petitioner that it had based its determination on Petitioner's refusal to comply with a directed plan of correction which HCFA had imposed previously, resulting in immediate jeopardy to individuals served by Petitioner. HCFA stated that its determination was justified also by a pattern of failures by Petitioner to comply with the requirements of regulations published pursuant to CLIA.

By letter dated January 13, 1994, Petitioner requested a hearing. I held a hearing in San Francisco, California, on May 10 and 11, 1994. Subsequently, the parties submitted briefs.[1]

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[1] With its posthearing brief, Petitioner submitted a letter requesting that I admit in evidence four additional exhibits. One of the exhibits, CVML Exhibit (Ex.) 29, had been offered and rejected at the hearing. Also, I am rejecting the other exhibits, CVML Ex. 4, 6, and

(continued...)

I have considered the relevant evidence, the applicable law, and the parties' arguments. I conclude that HCFA's determination in this case is supported by the preponderance of the evidence and the law, and I sustain it.

I. Issues and Conclusions

There are two broad issues in this case which I have resolved in favor of HCFA. In resolving these issues, I make specific conclusions of fact and law. These conclusions are set forth below, beneath the relevant issues. In setting forth these conclusions, I cite to relevant portions of the decision, at which I discuss my conclusions in detail.

A. Was HCFA authorized to revoke Petitioner's CLIA certificate and to cancel Petitioner's approval to receive Medicare reimbursement for its services based on a pattern of noncompliance by Petitioner with conditions for certification under CLIA? With respect to this issue, I conclude that:

> 1. Petitioner consistently has failed to comply with conditions for certification under CLIA. Pages 10 - 14.
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> 2. Petitioner's failure to comply with conditions for certification under CLIA is due to the failure of its owner and operator to exercise effective supervision of Petitioner's operations, to institute meaningful quality controls, and to correct deficiencies that were identified in Petitioner's operations. Pages 10 - 14.
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> 3. The condition level deficiencies in Petitioner's operations comprise a pattern of deficiencies in management and in quality control. Pages 15 - 18.
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> 4. The pattern of failure by Petitioner to comply with conditions for certification under CLIA demonstrates that Petitioner is incapable of

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[1](...continued)
11. Although these three had been listed as proposed exhibits, they were not offered at the hearing. See Transcript, May 11, 1994, at 235 - 38. Their presentation after the hearing is untimely and Petitioner has offered no legitimate reason for their untimely presentation.

providing services to its clients which are consistent with the requirements of CLIA and with implementing regulations. Pages 15 - 18.

5. Petitioner's pattern of failure to comply with conditions for certification under CLIA caused immediate jeopardy to individuals whose tests were performed by Petitioner. Pages 15 - 18.

6. HCFA was authorized by Petitioner's pattern of failure to comply with conditions for certification under CLIA to revoke Petitioner's CLIA certificate and to cancel Petitioner's approval to receive reimbursement from Medicare for its services. Page 21.

B. Was HCFA authorized to revoke Petitioner's CLIA certificate and cancel Petitioner's approval to receive Medicare reimbursement for its services, based on Petitioner's failure to comply with a directed plan of correction? With respect to this issue, I conclude that:

7. Petitioner was required by a directed plan of correction imposed by HCFA to supply HCFA with a list of physicians and clients who had requested that Petitioner perform cytology tests. Page 15.

8. Petitioner did not comply with the directed plan of correction. Pages 18 - 20.

9. Petitioner's failure to comply with the directed plan of correction was due to the failure of its owner and operator to supply HCFA with the list of physicians and clients required by the plan of correction. Pages 18 - 20.

10. Petitioner's failure to comply with the directed plan of correction resulted in immediate jeopardy to patients whose tests had been performed by Petitioner. Pages 18 - 20.

11. HCFA was authorized by Petitioner's failure to comply with the directed plan of correction to revoke Petitioner's CLIA certificate and to cancel Petitioner's authority to receive reimbursement from Medicare for its services. Page 21.

II. Governing law

A. CLIA

Congress enacted CLIA in order to assure that clinical laboratories perform medical tests accurately. CLIA was intended by Congress to establish a single set of standards which govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. H.R. Rep. No. 899, 100th Cong., 2d Sess. 8 (1988), reprinted in 1988 U.S.C.C.A.N. 3828, 3829 - 3836 (House Report).

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).

Under CLIA, the Secretary of the United States Department of Health and Human Services (Secretary) is authorized to inspect clinical laboratories and, in effect, license them to perform tests. The Act prohibits a clinical laboratory from soliciting or accepting specimens for testing unless it has first received from the Secretary a certificate authorizing it to perform the specific category of tests which the laboratory intends to perform. 42 U.S.C. § 263a(b). The Act directs the Secretary to establish standards to assure that clinical laboratories certified by the Secretary perform tests that are valid and reliable. 42 U.S.C. § 263a(f)(1).

The Act directs the Secretary to establish standards for cytology testing by clinical laboratories. 42 U.S.C. § 263a(f)(4).[2] The specific requirements for cytology

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[2] The Secretary is directed to establish cytology testing standards that include standards governing: (i) the maximum number of cytology slides that may be screened by an individual in a 24-hour period; (ii) record-keeping of cytology tests; (iii) rescreening of cytological

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testing reflect Congress' concern about the potential adverse consequences to patients of PAP smear readings based on improperly prepared slides, or of PAP smears being read by inadequately trained or overworked laboratory employees. House Report at 3852.

Under CLIA, the Secretary may impose sanctions against clinical laboratories which have been certified, but which no longer meet the requirements for certification. These may consist of intermediate sanctions, including any of the following, either individually or in combination: directed plans of correction, civil money penalties, or payment of costs for outside monitoring of laboratories. 42 U.S.C. § 263a(h).

The Act provides for revocation of a CLIA certificate under specified circumstances. These include, among other things, failure by a laboratory's owner or operator to comply with statutory requirements for certification or with standards issued by the Secretary, failure by the owner or operator to respond to reasonable requests by the Secretary for materials or information, or failure by the owner or operator to abide by an intermediate sanction issued by the Secretary. 42 U.S.C. § 263a(i)(1)(C), (D), (G).

Although not explicitly stated in the Act, it is apparent that Congress intended that the Secretary employ intermediate sanctions as a remedy to bring noncompliant clinical laboratories into compliance with CLIA certification standards. The more serious sanction of revocation is intended to be applied in cases where laboratories are incapable of complying with standards, where they refuse to comply, or where they fail to cooperate with reasonable requests by the Secretary which are intended to monitor their compliance with CLIA or to protect individuals, including Medicare beneficiaries, from the possible adverse consequences of noncompliance.

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[2](...continued)
preparations; (iv) periodic confirmation and evaluation of the proficiency of individuals who perform cytology tests; (v) procedures for detecting inadequately prepared slides and for assuring that no diagnoses are made based on inadequately prepared slides; (vi) requirements that all cytology tests be performed on the premises of a laboratory that is certified to perform such tests; (vii) requirements for retention of cytology slides by clinical laboratories; and (viii) standards requiring periodic inspection of laboratories performing cytology tests. 42 U.S.C. § 263a(f)(4)(B).

B. Regulations

Regulations issued by the Secretary pursuant to CLIA establish standards for certification of clinical laboratories in addition to those contained in the Act. The regulations establish a framework for inspection of clinical laboratories and for certification of laboratories. They provide for the imposition of sanctions in the event that laboratories fail to comply with applicable standards.

The regulations define a CLIA certificate to be a certificate which is issued to a clinical laboratory by HCFA (the agency which has been delegated authority by the Secretary to administer CLIA) after an inspection that finds the laboratory to be in compliance with all condition level requirements. 42 C.F.R. § 493.2.[3] The regulations define condition level requirements to mean those requirements for certification under CLIA established in subparts G through Q of 42 C.F.R. Part 493. Id.

The 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 CLIA requirements. 42 C.F.R. § 493.1804(a)(1) - (3).

The regulations give HCFA two types of administrative remedies which it may employ in appropriate cases. These are alternative sanctions and principal sanctions. The alternative sanctions which HCFA may apply in the appropriate case correlate with the intermediate sanctions described in CLIA. They consist, individually or in combination, of directed plans of correction, onsite monitoring, and civil money penalties. 42 C.F.R. § 493.1806(c)(1) - (3); see 42 U.S.C § 263a(h). The regulations provide also that, for laboratories that participate in Medicare, alternative sanctions may include

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[3] The regulations specify also that a CLIA certificate may consist of a certificate which has been issued where a laboratory has been found to be out of compliance with one or more condition level requirements, and where alternative sanctions have been imposed by HCFA. 42 C.F.R. § 493.2. Alternative sanctions are defined to be synonymous with intermediate sanctions as specified by the Act. Id.

suspension of payments for Medicare services. 42 C.F.R. § 493.1807(b).

The elements of the alternative sanctions which HCFA may impose are explained by the regulations. 42 C.F.R. §§ 493.1832 - .1836. Directed plans of correction are described in 42 C.F.R. § 493.1832. As one element of a plan of correction, HCFA may direct a laboratory to submit, within 10 calendar days of notice to the laboratory of the plan, a list of names and addresses of all physicians, providers, suppliers, and other clients who have used some or all of the services of the laboratory since the last certification inspection or within any other time frame specified by HCFA. 42 C.F.R. § 493.1832(b)(2)(i).

Principal sanctions consist of remedies which HCFA may impose for any of the reasons set forth in section 263a(i)(1) of the Act. 42 C.F.R. § 493.1840(a). For example, HCFA may impose principal sanctions where a laboratory has not complied with applicable standards, where its owner, operator, or employees have not complied with reasonable requests by HCFA for information or materials, or where the laboratory has not complied with an alternative sanction. 42 C.F.R. § 493.1840(a)(3), (4), (7); see 42 U.S.C. § 263a(i)(1)(C), (D), (G). 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, .1807, .1840(a), .1842.

The regulations permit HCFA to revoke a laboratory's certificate where the laboratory continues to pose immediate jeopardy to individuals. 42 C.F.R § 493.1812(b). The regulations provide that HCFA will always cancel a laboratory's approval to receive Medicare reimbursement where HCFA revokes that laboratory's CLIA certificate. 42 C.F.R. § 493.1842(a)(1). They provide also that HCFA may cancel a laboratory's authority to receive reimbursement from Medicare for its services where the laboratory fails to comply with condition level requirements or correct deficiencies within the time specified by HCFA. 42 C.F.R. § 493.1842(a)(2).

The regulations implement Congress' intent that alternative sanctions be used as a mechanism to remedy deficiencies, but also to encourage laboratories to comply with CLIA. They implement Congress' intent further by reserving principal sanctions for those circumstances where laboratories have demonstrated that they are either incapable of complying with CLIA or where they have failed to comply with alternative sanctions which HCFA has imposed previously. The factors which HCFA considers in

determining to impose a particular sanction are specified by 42 C.F.R. § 493.1804(d). Paraphrased here, they include:

> (1) whether deficiencies identified by HCFA pose immediate jeopardy to individuals whose tests the laboratory performs;[4]
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> (2) the nature, incidence, severity, and duration of the deficiencies or noncompliance identified by HCFA;
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> (3) whether the same condition level deficiencies have been identified repeatedly;
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> (4) the accuracy and extent of laboratory records relevant to noncompliance by a laboratory and their availability to HCFA or to individuals or entities who operate on HCFA's behalf;
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> (5) the relationship of deficiencies to each other;
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> (6) the overall compliance history of a laboratory;
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> (7) the outcome that HCFA intends to achieve through application of a sanction;
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> (8) whether the laboratory has improved its operations after being given a reasonable opportunity to correct deficiencies; and
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> (9) any recommendation by a State agency operating on HCFA's behalf as to which sanction would be appropriate.

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[4] The term "immediate jeopardy" is defined at 42 C.F.R. § 493.2 to mean:

> a situation in which immediate corrective action is necessary because the laboratory's noncompliance with one or more condition level requirements has already caused, is causing, or is likely to cause, at any time, serious injury or harm, or death, to individuals served by the laboratory or to the health or safety of the general public. This term is synonymous with imminent and serious risk to human health and significant hazard to the public health.

III. Relevant facts

Subpart A of this section provides background about Petitioner and its ownership and operation. None of these facts is disputed by the parties. Subpart B of this section concerns surveys of Petitioner which were conducted by the State survey agency on behalf of HCFA, the findings of these surveys, and the alternative sanctions which HCFA imposed on Petitioner in order to remedy deficiencies which the surveys uncovered.[5] Petitioner disputes at least some of the findings of deficiencies which I discuss in subpart B. However, for reasons which I shall explain in subpart B, these findings are administratively final and cannot now be disputed.

As I discuss in more detail below, there are only four questions of fact which are within my authority to decide. The first question is whether condition level deficiencies found by State agency surveyors constitute a pattern of deficiencies in the management of Petitioner's operations, as opposed to separate, unrelated incidents. The second question, assuming such a pattern exists, is whether this pattern proves that Petitioner is incapable of providing laboratory services in compliance with CLIA or poses immediate jeopardy to individuals who rely on Petitioner to perform clinical tests, including PAP smears. I discuss my findings concerning these two questions in subpart C of this section.

The third question is whether Petitioner's director and owner failed to comply with a directed plan of correction. The fourth question is whether failure to comply with a directed plan of correction posed immediate jeopardy to individuals whose tests had been performed by Petitioner. I discuss my findings concerning the third and fourth questions in subpart D of this section.

A. Petitioner

Petitioner is a clinical laboratory in Modesto, California. Petitioner has operated under various names and with different combinations of owners since 1981. Tr. 5/11 at

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[5] Surveys of Petitioner were conducted on HCFA's behalf by the Office of Laboratory Field Services of the California Department of Health Services. This agency is the State agency which HCFA has authorized to conduct surveys for it of clinical laboratories in California.

197 - 99.[6] It has operated under its current name since 1991. Tr. 5/11 at 197. Mahindokht Raiszadeh, M.D., has directed Petitioner since its inception. Tr. 5/11 at 199. Dr. Raiszadeh has been the sole owner of Petitioner since August 1992. Id. Dr. Raiszadeh is a physician who is licensed to practice medicine in the States of Arizona and California. Tr. 5/11 at 195. She specializes in the fields of clinical and anatomical pathology, and has been board certified in these fields since 1975. Tr. 5/11 at 196.

Petitioner's services have included tests in the areas of chemistry, hematology, serology, cytology, pathology, histopathology, and bacteriology. Tr. 5/10 at 38 - 39, Tr. 5/11 at 199. The services provided by Petitioner have been provided either directly by Dr. Raiszadeh or by employees working under her supervision. Tr. 5/11 at 199 - 203. Dr. Raiszadeh has been responsible for establishing Petitioner's operating procedures and for monitoring the quality of its services. Id.

B. Condition level deficiencies in Petitioner's operations and HCFA's efforts to remedy those deficiencies with alternative sanctions

Petitioner was surveyed by the State survey agency on behalf of HCFA on five separate occasions beginning in December 1992. These surveys produced findings of numerous and repeated condition level deficiencies in Petitioner's operations. HCFA attempted to remedy these deficiencies by imposing alternative sanctions, including a directed plan of correction.

The intent of the regulations governing appeals of HCFA's initial determinations is that such determinations become final where a party fails to appeal, fails to appeal timely, or abandons an appeal. The regulations provide that hearings in cases involving initial determinations made under CLIA are conducted pursuant to the regulations contained in 42 C.F.R. Part 498. 42 C.F.R. § 493.1844(a)(2). A laboratory that is dissatisfied with an initial determination by HCFA under CLIA may request a hearing before an administrative law judge to contest that determination. The Part 498 regulations provide that a party must request a hearing within 60 days of its receipt

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[6] The transcript for May 10, 1994 contains pages numbered 1 - 322. The transcript for May 11, 1994 contains pages numbered 1 - 238. I cite to the May 10 transcript as "Tr. 5/10 at (page)." I cite to the May 11 transcript as "Tr. 5/11 at (page)."

of a notice of an initial determination. 42 C.F.R. § 498.40(a)(2).

The various alternative sanctions imposed by HCFA, including the directed plan of correction, were initial determinations which Petitioner had the right to contest in administrative hearings. However, Petitioner either did not request hearings concerning the determinations to impose these sanctions, or, in the case of one of the determinations, withdrew the hearing request that it had filed.[7] HCFA's initial determinations to impose alternative sanctions against Petitioner thus became the Secretary's final determinations, as did the State agency findings of condition level deficiencies on which HCFA based these initial determinations.

Petitioner seeks now to contest at least some of HCFA's initial determinations that condition level deficiencies existed. Petitioner's posthearing brief. I conclude that Petitioner's objections to the findings are either untimely or were made by it previously in connection with a hearing request which Petitioner withdrew. Therefore, I accept the findings of condition level deficiencies made by the State agency in its five surveys of Petitioner. I conclude also that Petitioner no longer has the opportunity to dispute the authority of HCFA to impose alternative sanctions against it based on the findings of these surveys.

The first of the five surveys was conducted on December 9, 1992. The surveyors found seven condition level deficiencies. HCFA Ex. 1. A condition level deficiency was found in quality control in the performance of moderate and high complexity tests. HCFA Ex. 1 at 11 - 12; 42 C.F.R. § 493.1223. Condition level deficiencies were found in the areas of bacteriology and hematology testing. HCFA Ex. 1 at 12 - 15; 42 C.F.R. §§ 493.1227, 493.1253. Condition level deficiencies were found in the performance of the laboratory director of a laboratory performing both moderate and high complexity testing. HCFA Ex. 1 at 16, 26; 42 C.F.R. §§ 493.1403, 493.1441. A condition level deficiency was found in the performance of the general

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[7] On March 30, 1993, HCFA advised Petitioner that it was imposing alternative sanctions, based on findings of condition level deficiencies at a survey conducted on March 18, 1993. See HCFA Ex. 10. Petitioner requested an administrative hearing regarding this determination. I scheduled a hearing in the case. On September 24, 1993, Petitioner notified me that it was withdrawing its request for a hearing. On October 6, 1993, I dismissed Petitioner's hearing request.

supervisor of a laboratory performing high complexity testing. HCFA Ex. 1 at 31; 42 C.F.R. § 493.1459. Finally, a condition level deficiency was found in quality assurance in the performance of moderate and high complexity tests. HCFA Ex. 1 at 35 - 36; 42 C.F.R. §§ 493.1701.

The surveyors concluded that Petitioner was not following manufacturers' instructions in the performance of tests, was not documenting quality control checks, or, in some cases, was not performing such checks. HCFA Ex. 1 at 8, 13. The surveyors found that Dr. Raiszadeh was permitting unlicensed and unsupervised personnel to make quality control decisions routinely. Id. at 17. The surveyors found also that Dr. Raiszadeh was failing to carry out her overall duties to supervise and exercise oversight over Petitioner's activities. Id. at 31.

HCFA provided Petitioner the opportunity to submit a plan of correction to remedy the deficiencies found in this survey. HCFA Ex. 2, 3. Petitioner did not respond. HCFA gave Petitioner a second opportunity. HCFA Ex. 4. This time, Petitioner responded; however, HCFA determined the response to be inadequate and incomplete. HCFA Ex. 5.

The State agency resurveyed Petitioner on February 17, 1993. On this occasion, the surveyors found nine condition level deficiencies in Petitioner's operation. HCFA Ex. 6. Essentially, the surveyors' findings were the same as those in the first survey. Id.; Tr. 5/10 at 78. However, at this second survey, the surveyors examined more closely the chemistry testing being performed by Petitioner. The surveyors found additional deficiencies in this area, associated essentially with their findings that Petitioner's employees were making numerous unauthorized adjustments to laboratory equipment which was being used to perform chemical analysis. HCFA Ex 6 at 18; Tr. 5/10 at 79 - 80.

On March 2, 1993, the State agency advised Petitioner that it was recommending that HCFA impose principal sanctions against it, consisting of suspension of Petitioner's CLIA certificate and suspension of Petitioner's receipt of Medicare and Medicaid reimbursement. HCFA Ex. 8. On March 3, 1993, HCFA advised Petitioner that it had determined to suspend its CLIA certificate and to suspend Medicare and Medicaid reimbursement to Petitioner. HCFA Ex. 9.

The State survey agency conducted a third survey of Petitioner on March 18, 1993. Based on this survey, the surveyors concluded that two condition level deficiencies persisted. HCFA Ex. 10. These deficiencies were in the areas of quality assurance and in the performance of the

duties of laboratory director for a laboratory performing moderate complexity testing. Id. at 23 - 24, 31 - 32; 42 C.F.R. §§ 493.1403, 493.1701. Several of the deficiencies which the surveyors found at this survey had been found to exist in previous surveys. For example, the surveyors found that Petitioner's employees continued to make unauthorized adjustments to laboratory equipment used to perform chemical analysis. HCFA Ex. 10 at 20.

On the basis of this survey and the two previous surveys, HCFA imposed alternative sanctions against Petitioner. HCFA Ex. 13. These sanctions, which were communicated to Petitioner in a notice dated March 30, 1993, supersede the principal sanctions which HCFA advised Petitioner it was imposing in its March 3, 1993 notice to Petitioner. Id.; see HCFA Ex. 9. The alternative sanctions consisted of onsite monitoring of Petitioner and suspension of Medicare payments to Petitioner. Petitioner requested a hearing, but then withdrew the request. Supra n.6.

The State survey agency surveyed Petitioner for a fourth time on April 29, 1993. The survey was conducted as part of the onsite monitoring alternative sanction which HCFA had imposed against Petitioner. The surveyors found three condition level deficiencies. HCFA Ex. 38. Once again, the surveyors documented problems in operating the equipment used to conduct chemistry tests. Id. at 10 - 11, 18. They again found that Dr. Raiszadeh, acting in her supervisory capacity, had failed to assure that Petitioner met the quality of service requirements of CLIA regulations. Id. at 23 - 28. They found a continuing failure by Petitioner to maintain a quality assurance plan and a continuing deficiency in assuring that accurate laboratory testing services were being provided. Id. at 31 - 36.

On June 9, 1993, HCFA advised Petitioner that, based on the findings of the April 29, 1993 survey, the alternative sanctions previously imposed by HCFA would remain in effect. HCFA Ex. 39 at 1 - 2. HCFA further advised Petitioner that it had determined to impose an additional alternative sanction consisting of a directed plan of correction. Id. at 2. Petitioner was advised of its right to request a hearing regarding this determination. Id. However, Petitioner did not request a hearing.

Petitioner sent its own proposed plan of correction to HCFA on June 4, 1994. However, after reviewing Petitioner's proposal, HCFA determined that it was inadequate. HCFA provided Petitioner with an explanation for its determination on July 15, 1993. HCFA Ex. 40. In response, Petitioner supplied additional information and explanation

to HCFA. HCFA reviewed the additional material, and on August 23, 1993, advised Petitioner that it failed to resolve HCFA's concerns about ongoing deficiencies in Petitioner's operations. HCFA Ex. 41. HCFA advised Petitioner that the previously determined alternative sanctions would remain in effect. Id.

The State agency conducted a fifth survey of Petitioner from August 23 - 26, 1993. This survey was triggered by Petitioner informing HCFA that it had decided to discontinue testing in several specialties and subspecialties, but that it intended to continue to conduct tests in the areas of cytology and histology. Tr. 5/11 at 47 - 48. The State agency concluded that, given Petitioner's history of deficiencies, it could not be entrusted to perform testing in these areas without an additional survey being conducted. Id.

The August 1993 survey focused on Petitioner's conduct of cytology tests. HCFA Ex. 42. The surveyors concluded that Petitioner manifested four condition level deficiencies. Id. One of these specifically related to the manner in which Petitioner performed cytology tests. Id. at 9 - 16; 42 C.F.R. § 493.1257. The others consisted of repeat findings of deficiencies in the performance of duties by the laboratory director, the technical supervisor, and in quality assurance. HCFA Ex. 42 at 16 - 28; 42 C.F.R. §§ 493.1441, .1447, .1701.

The surveyors concluded that the cytology testing performed by Petitioner manifested serious deficiencies, which resulted in a failure by Petitioner to assure accurate and reliable testing. HCFA Ex. 42 at 10. The surveyors reviewed 421 PAP smear slides and found them to be unreadable due to inadequate preparation or poor staining. Id. at 11. They found that Petitioner had nevertheless issued patient test reports for all 421 of these PAP smears. Id.

The surveyors found additional deficiencies involving the manner in which Petitioner performed cytology tests. They found that Petitioner had not maintained accurate records of the number of PAP smear slides that were being read during a 24-hour period. HCFA Ex. 42 at 10. They found that Petitioner was not comparing malignant and premalignant gynecology reports with previous test results. Id. They found several cases in which Petitioner had rendered negative reports on PAP smear slides which demonstrated apparent abnormalities. Id. at 23 - 24.

On September 15, 1993, HCFA informed Petitioner that, based on the results of the August survey, it had determined to

impose additional sanctions. HCFA Ex. 45 at 1 - 2. HCFA advised Petitioner that it was proposing to revoke Petitioner's certificate in cytology because there existed immediate jeopardy to patients being served by Petitioner. Id. HCFA advised Petitioner that, pending revocation, additional sanctions would apply. These additional sanctions included limitation of Petitioner's CLIA certificate in cytology and limitation of Medicare and Medicaid payments in cytology. Id. Petitioner was advised that, effective September 29, 1993, it could conduct no additional tests in cytology. Id. HCFA told Petitioner that these sanctions would not be rescinded unless HCFA could verify that the deficiencies had been corrected.

On September 20, 1993, Petitioner replied by advising HCFA that, effective September 27, 1993, it would discontinue testing in cytology. HCFA replied to Petitioner by letter dated October 1, 1993. HCFA Ex. 46. HCFA advised Petitioner that it was imposing alternative sanctions consisting of limitation of Petitioner's certificate in cytology and suspension of Petitioner's Medicare and Medicaid payments in cytology. HCFA advised Petitioner further that it was imposing a directed plan of correction. Id. at 2. Petitioner was directed to:

> submit to the State Survey Agency within 10 calendar days, a list of the names and addresses of the physicians, and other clients who have used the laboratory's services in Cytology during the period January 20, 1993 to the present.

Id. HCFA advised Petitioner that it was entitled to request a hearing regarding this determination. Id. Petitioner did not request a hearing.

C. Petitioner's pattern of condition level deficiencies and the potential for harm resulting from those deficiencies

It is evident from the foregoing that, despite repeated surveys by HCFA and the imposition of alternative sanctions aimed at remediation, Petitioner has persisted in manifesting condition level deficiencies in its operations. There is a definite pattern to these deficiencies, and I conclude from this pattern that Petitioner either is incapable of, or unwilling to, correct them. I conclude, furthermore, that the nature of these deficiencies is such as to pose a risk of serious harm to individuals whose tests were performed by Petitioner. This constitutes immediate jeopardy within the meaning of relevant regulations. 42 C.F.R. § 493.2.

A central finding in each of the survey reports is the failure of Dr. Raiszadeh, acting as Petitioner's director, to assert meaningful control over the quality of the tests which Petitioner performed. These tests included bacteriology tests, chemistry tests, and preparation of slides of PAP smears, as well as the reading of those slides. Numerous errors were identified in the performance of these tests. They included failure to perform the tests in accordance with the directions issued by the suppliers of testing materials and the manufacturers of equipment utilized by Petitioner. They included failure to produce slides of PAP smears which were readable.

Another central finding in each of the survey reports is the failure of Dr. Raiszadeh, in her capacity of director and supervisor, to establish procedures which addressed the performance deficiencies identified by the surveyors or to supervise employees effectively. Thus, the surveyors repeatedly identified the same errors in the management of equipment to perform chemistry tests. The surveyors also repeatedly identified failures by Petitioner to document its procedures adequately and to establish meaningful quality control protocols.

The deficiencies in operations identified by the State agency surveyors must be attributed largely to Dr. Raiszadeh's failure to supervise adequately Petitioner's operations or to implement meaningful quality control. It is apparent also that Dr. Raiszadeh did not institute meaningful changes in Petitioner's operations despite repeated surveys and findings of deficiencies, coupled with the imposition of alternative sanctions by HCFA.

These repeated deficiencies establish a pattern of deficiencies, both in the performance of tests by Petitioner and in the management of Petitioner's operations. This pattern of deficiencies placed individuals whose tests were performed by Petitioner at a risk of serious harm and, thus, in immediate jeopardy. The deficiencies identified by the surveyors relate directly to the quality and reliability of tests performed by Petitioner. For example, the surveyors found that Petitioner's staff repeatedly was making unauthorized adjustments to chemistry testing equipment, thereby jeopardizing the accuracy of the tests. These tests had been referred to Petitioner by physicians in order to assist them in diagnosing their patients' medical conditions. Both the referring physicians and their patients were at the mercy of Petitioner's testing procedures. Petitioner's quality deficiencies called into question the accuracy of the test results which it reported

to physicians, and the diagnoses that these physicians may have made based on those reported test results.

I conclude, furthermore, that Petitioner's failure to prepare properly PAP smear slides in 421 cases, coupled with its sending of reports based on those slides, is not only a part of this pattern, but in and of itself demonstrates deficiencies which pose a serious risk of harm and immediate jeopardy to patients. These slides were prepared from tests which were made to detect the possible presence of malignancies. Physicians relied on Petitioner's interpretation of the tests to decide whether additional procedures were necessary. Tr. 5/10 at 250 - 51.

Petitioner asserts that the deficiencies identified by the surveyors do not establish a pattern of deficiencies in Petitioner's operations. Petitioner's posthearing brief at 4. Petitioner argues that it may be inferred that these deficiencies showed no jeopardy to patient care because HCFA allegedly "removed" its suspension of Petitioner's CLIA certificate on March 30, 1993.

The record does not support this assertion. The notice which HCFA sent to Petitioner on March 30, 1993 does not reflect a determination by HCFA that the deficiencies identified to Petitioner posed no jeopardy to patient care. To the contrary, that notice states:

> Failure to meet these . . . [CLIA] requirements and standards therein seriously limits the facility's capacity to furnish an adequate level of quality of care or services.

HCFA Ex. 13 at 1. HCFA's determination to impose alternative sanctions in lieu of principal sanctions may indicate that, as of March 30, 1993, HCFA had not given up hope that Petitioner might cure its deficiencies. However, it does not by any stretch suggest that HCFA had concluded that the existing deficiencies were less than serious, or that they did not threaten patients with serious harm. Furthermore, my conclusion that the pattern of deficiencies at Petitioner poses immediate jeopardy to individuals is based on the entire record of the inspections of Petitioner, and not on the record as it stood on March 30, 1993.

Petitioner argues also that the survey which was performed on April 29, 1993 showed that the deficiencies identified by the surveyors did not pose immediate jeopardy to patients. Petitioner's posthearing brief at 4; see HCFA Ex. 38. I do not agree with Petitioner's characterization

of the results of this survey. As I find above, the surveyors who conducted the April 29, 1993 survey identified three condition level deficiencies. HCFA Ex. 38. Although the surveyors did not state explicitly that these deficiencies constituted immediate jeopardy, it is apparent from the deficiencies that they addressed the central issue of the reliability and quality of Petitioner's services. Moreover, my conclusion that Petitioner's deficiencies pose immediate jeopardy to individuals is based on the cumulative record of deficiencies and not solely on the April 29, 1993 survey.

Finally, Petitioner asserts that the reports of surveys contain inaccuracies and unjustified conclusions. As I find above, Petitioner had the opportunity to challenge the findings of these surveys and HCFA's determinations which were based on these surveys, and either failed to avail itself of the opportunity or withdrew its hearing request. It would not be appropriate now for me to permit Petitioner to bootstrap into this case arguments that it had the opportunity to make previously, but which it did not make.

I conclude from the pattern of deficiencies manifested by Petitioner that it is incapable of complying with the requirements of CLIA. The record of this case establishes repeated identification of serious deficiencies by State agency surveyors. These deficiencies, as I have found, did not vary substantially from survey to survey. They were so serious as to call into question the capacity of Petitioner to conduct tests that were reliable and accurate. HCFA attempted repeatedly to encourage Petitioner to ameliorate these deficiencies, to no avail.

D. Petitioner's failure to comply with the directed plan of correction and the potential for harm arising from Petitioner's failure to comply

On October 1, 1993, HCFA imposed a directed plan of correction on Petitioner which required Petitioner, within 10 days, to supply HCFA with a list of the names and addresses of physicians and other clients who had requested that Petitioner perform cytology services after January 20, 1993. HCFA Ex. 46 at 2. HCFA contends that Petitioner refused to comply with this directive. Petitioner denies that it refused to comply. Petitioner's posthearing brief at 5 - 6.

Dr. Raiszadeh and Petitioner failed to comply with the directed plan of correction. I conclude that this failure placed in immediate jeopardy those individuals whose PAP smears had been processed and interpreted by Petitioner.

HCFA premised the plan of correction on its conclusion that, in 421 instances, although Petitioner prepared PAP smear slides which could not be read meaningfully, Petitioner had, nonetheless, sent reports to physicians in those cases. HCFA concluded that it was urgent that these physicians be notified so that they could make informed judgments as to whether their patients could be retested for the presence of abnormalities or malignancies. As one of the surveyors testified, based on her findings:

> [T]hese 421 patients think that they have a negative PAP smear when, in essence, they may not because you can't tell what was on these slides.

Tr. 5/10 at 250.

The directed plan of correction was unequivocal. Petitioner could have complied simply by furnishing HCFA with the names and addresses of physicians and other clients who requested that Petitioner perform tests beginning on January 20, 1993.

However, notwithstanding Petitioner's assertions to the contrary, the record demonstrates that Dr. Raiszadeh and Petitioner did not comply with the plan. In the weeks subsequent to the imposition of the plan, there were several conversations between a HCFA representative and Dr. Raiszadeh about the plan. In those conversations, Dr. Raiszadeh made it plain that she would not comply with the plan. On October 15, 1993, in a telephone conversation, Dr. Raiszadeh advised the HCFA representative that Petitioner was ceasing its operations and that, therefore, it did not need to provide HCFA with a client list. Tr. 5/11 at 100 - 01. In a followup conversation on October 18, 1993, Dr. Raiszadeh stated that she had decided to notify clients herself and would not be providing HCFA with a client list. Id. at 101.

Petitioner did not send a list of physicians and clients to HCFA in compliance with the directed plan of correction. On November 20, 1993, nearly two months after HCFA had imposed the plan, Petitioner sent HCFA a letter which listed the names of five physicians. CVML Ex. 20. That letter did not purport to contain a complete list of the names of the physicians or clients who had referred samples to Petitioner, it did not provide any information which would enable HCFA to ascertain whether these physicians had referred samples to Petitioner after January 20, 1993, and it did not provide HCFA with the addresses of the physicians who were listed. Id.

Petitioner sent letters also to various physicians informing them that their patients had abnormal cytology tests. CVML Ex. 15, 17. These letters do not comply with the directed plan of correction. First, they do not purport to constitute complete notification of physicians or clients who patronized Petitioner after January 20, 1993. More important, the directed plan of correction did not offer Petitioner the option of notifying physicians and clients in lieu of providing HCFA with a list of those individuals. One obvious purpose of the plan was to give HCFA the opportunity to provide these individuals with notification in order to assure that they were properly notified of Petitioner's deficiencies. Implicitly, HCFA had determined that Petitioner could not be trusted with that responsibility.

On November 30, 1993, HCFA told Dr. Raiszadeh that her submission of November 19, 1993 did not constitute compliance with the directed plan of correction. HCFA Ex. 49; see CVML Ex. 20. It provided Dr. Raiszadeh and Petitioner with an additional opportunity to comply with the plan. HCFA Ex. 49. HCFA received no response.

As I find above, Petitioner's failure to produce readable PAP smears in 421 cases, coupled with its preparation and transmission of reports to physicians in those cases, placed the individuals whose PAP smears were involved in immediate jeopardy. These individuals were placed in additional jeopardy by the failure of Dr. Raiszadeh and Petitioner to comply with the directed plan of correction. It was urgent that HCFA be able to notify the physicians whose patients' PAP smears were involved that the results might be inaccurate. Potentially, any of these individuals could have had a malignancy which had not been detected. The failure of Dr. Raiszadeh and Petitioner to respond to the directed plan of correction by providing HCFA with the list of physicians and clients mandated by the plan resulted in a delay in notification of the physicians.

HCFA was able eventually to construct a list of physicians who had referred PAP smears to Petitioner. HCFA sent a letter of notification to these physicians in December 1993. HCFA Ex. 50. This was more than two months after HCFA had imposed the directed plan of correction and after fruitless efforts to obtain a list of referring physicians and clients from Dr. Raiszadeh and Petitioner.

IV. HCFA's authority to impose principal sanctions

Petitioner engaged in a pattern of deficiencies which posed immediate jeopardy to individuals and which established Petitioner to be incapable of meeting the requirements of CLIA. Petitioner failed to comply with a directed plan of correction, placing individuals in immediate jeopardy. I conclude that HCFA was justified in imposing the principal sanctions which it imposed in this case either by Petitioner's pattern of deficiencies or by its failure to comply with the directed plan of correction.

To briefly restate my analysis of the basis for the imposition of principal sanctions, such sanctions may be imposed under CLIA and relevant regulations where a laboratory fails to comply with CLIA requirements, where it fails to comply with an alternative sanction, or where it fails to respond to HCFA's reasonable requests for information. 42 U.S.C. § 263a(i)(1); 42 C.F.R. § 493.1840(a).[8]

The relevant law and the evidence in this case give HCFA ample grounds to revoke Petitioner's CLIA certificate and to cancel its approval to receive Medicare reimbursement for its services. It is evident that alternative sanctions have failed to induce Petitioner to comply with CLIA. Petitioner consistently has failed to comply with CLIA certification requirements and in doing so has posed immediate jeopardy to individuals. Petitioner has failed to comply with an alternative sanction, the directed plan of correction. This failure also has placed individuals in immediate jeopardy. These failures are the direct consequence of the failures of Petitioner's owner and director, Dr. Raiszadeh, to comply with the requirements of CLIA or with the alternative sanctions which HCFA imposed against Petitioner.

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[8] Both the Act and regulations provide that principal sanctions should be imposed based on a failure by a laboratory's owner or operator to comply with CLIA requirements or to fulfill obligations established by the Act and regulations. That test is met here. Dr. Raiszadeh is the owner and operator of Petitioner. There is no question in this case that actions of Petitioner or failures of Petitioner to act were the consequence of decisions made by Dr. Raiszadeh.

This concludes my analysis of the law and evidence in this case.

/s/

Steven T. Kessel
Administrative Law Judge