Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Center Clinical Laboratory,	)	DATE: February 15, 1996
	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-95-160
	)	Decision No. CR411
Health Care Financing Administration.	)	
	)	

DECISION ON REMAND

Background

The procedural history of this case is contained in my prior decision, CR358 (1995), and in the decision of the appellate panel of the Departmental Appeals Board, DAB 1526 (1995), which reversed my decision and remanded the case to me for further proceedings. In its decision, the appellate panel has set forth the interpretations of the regulations that govern the outcome of this case. The appellate panel concluded that I erred in setting aside the sanctions imposed by the Health Care Financing Administration (HCFA) on procedural grounds. The panel determined instead that HCFA had acted properly in imposing all of the sanctions in question. DAB 1526, at 11 - 20.

In accordance with the appellate panel's directives on remand, I have evaluated the evidence concerning the sole factual issue remaining in this case: whether Petitioner had any condition-level deficiency as determined by the State surveyors and HCFA. As the appellate panel stated in the last paragraph of its decision,

> [I]f the ALJ determines that Petitioner did have any condition-level deficiency as determined by the State surveyors and HCFA, . . . [t]he ALJ merely has to affirm the principal sanctions being imposed by HCFA: suspension,

> revocation, and cancellation of Medicare payments. The regulations provide, as HCFA here clarified, that HCFA's decision to revoke [Petitioner's CLIA Certificate] becomes effective after a hearing decision by the ALJ upholding HCFA's decision is issued. [42 C.F.R.] Section 493.1844(d). Moreover, alternative sanctions, such as a directed plan of correction, are no longer relevant since they are designed to prevent the principal sanctions from going into effect and therefore may themselves continue in effect only until a suspension or revocation becomes effective. Section 493.1810(d)(2).

DAB 1526, at 24.

The appellate panel has determined that HCFA acted properly in imposing all of the sanctions in issue (id. at 11 - 20), that an affirmation of the principal sanctions imposed by HCFA depends solely on the existence of condition-level deficiencies (id. at 24) and the other sanctions also imposed by HCFA are no longer relevant (id.). Accordingly, I have reviewed the record as a whole and now make the following findings material to the issues on remand.

Findings of Fact and Conclusions of Law

1. During February and March of 1993, the New Jersey Department of Health, acting as agent for HCFA, surveyed Petitioner under the Clinical Laboratory Improvement Act (CLIA). HCFA Exhibits (Exs.) 1, 1b, 127, 128.

2. Between May 27 and June 1, 1993, HCFA imposed various sanctions under CLIA pursuant to its determination post survey that Petitioner's deficiencies posed "immediate jeopardy" to patient health and safety. HCFA Exs. 127, 128; see 42 C.F.R. § 493.2 (definition of "immediate jeopardy").

3. HCFA's determination of "immediate jeopardy" is not reviewable in this forum. 42 C.F.R. § 493.1844(c)(6).

4. The principal sanctions HCFA imposed are the suspension and revocation of Petitioner's CLIA certification and the cancellation of Petitioner's approval to receive Medicare payment. HCFA Exs. 127, 128; 42 C.F.R. §§ 493.2, .1806(b), .1807(a).

5. A condition-level deficiency means noncompliance with one or more requirements identified as "conditions"

within subparts G through Q of 42 C.F.R. Part 493. 42 C.F.R. § 493.2.

6. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart H (re participation in proficiency testing). Pages 4 - 6, herein.

7. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart J (re the management of patient tests). Pages 6 - 10, herein.

8. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart K (re quality control of tests). Pages 11 - 13, herein.

9. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart P (re quality assurance). Pages 13 - 14, herein.

10. HCFA proved that, during the time of the February - March 1993 survey, Petitioner had condition-level deficiencies under 42 C.F.R. Part 493, Subpart M, insofar as they pertain to the responsibilities of laboratory directors and supervisors. Pages 13 - 14, herein.

11. HCFA properly imposed principal sanctions against Petitioner. Findings 4 - 10; DAB 1526, at 24.

Discussion

By way of overview, I note that all of the condition-level deficiencies alleged and proven by HCFA are inter-related by facts or logic. See Tr. 347 - 48. I find persuasive HCFA's use of Petitioner's records to prove HCFA's contention that Petitioner had incurred condition-level deficiencies as a laboratory performing tests of moderate or high complexity.[1] Petitioner had made its records available to the surveyors during the February - March 1993 survey, and the records randomly selected for review by the surveyors reflected ongoing chaotic, inconsistent, inadequate, and sometimes aberrant methods

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[1] Petitioner has not disputed that the regulations governing laboratories performing moderate or high complexity tests apply to its operations.

for performing proficiency tests and patient tests, identifying patient test specimens and reporting patient test results, and performing required quality control procedures. In the absence of any substantive or credible rebuttal by Petitioner, the nature and extent of such problems establish that Petitioner had violated the conditions for performing proficiency tests (Subpart H), management of patient tests (Subpart J), and quality control (Subpart K).

Since there is no evidence that Petitioner had taken meaningful steps to ascertain and correct the foregoing condition-level deficiencies, it is reasonable to conclude also that Petitioner has failed to meet the condition-level requirements for quality assurance (Subpart P) and for Petitioner's laboratory director and supervisor to perform their duties as specified by the regulations (Subpart M). The quality assurance condition requires the laboratory to ensure the quality of its own work through a continuing self-monitoring process, and the condition pertaining to laboratory directors and supervisors requires that these individuals effectuate their responsibilities so that proficiency testing, patient testing, quality control, and other requisite procedures are implemented in accordance with CLIA requirements. 42 C.F.R. Part 493, Subparts M and P. Therefore, the evidence supports the conclusion that if Petitioner had complied with the conditions for quality assurance and for its laboratory director and supervisor to perform their responsibilities as required by the regulations, Petitioner should not have incurred condition-level deficiencies for performing proficiency tests, patient test management, or quality control.

I discuss below the condition-level deficiencies proven by HCFA on the basis of evidence which I find to be credible and essentially unrebutted by Petitioner.

A. Petitioner was not in compliance with the condition of participation governing proficiency testing of samples.

Subpart H of the regulations sets forth the condition for the performance of proficiency tests by laboratories performing tests of moderate or high complexity. 42 C.F.R. Part 493, Subpart H. Proficiency testing is a system used to check a laboratory's ability to perform certain patient tests. Tr. 900. Four times each year, a proficiency testing organization approved by HCFA sends out a set of five proficiency testing samples of unknown values to the laboratory for testing by that laboratory. Tr. 900 - 02. The regulations are specific in requiring

that the laboratory: 1) test its proficiency samples in the same manner as it tests its patient specimens; 2) test its proficiency samples the same number of times as it routinely tests patient samples; 3) document the handling, preparation, processing, examination, and each step in the testing and reporting of proficiency testing samples; and 4) maintain, for a minimum of two years, the relevant records (including the attestation statement documenting that the proficiency testing samples were tested in the same manner as patient specimens). 42 C.F.R. § 493.801(b).

During the February - March 1993 survey, the surveyors analyzed Petitioner's records concerning its performance of proficiency chemistry tests in 1992. See, e.g., HCFA Ex. 1 at 33; HCFA Ex. 97; Tr. 899 - 908. The surveyors concluded that Petitioner was not performing its proficiency tests in the same manner and with the same frequency that it was routinely performing its patient tests. HCFA Ex. 1 at 33. For example, in 25 out of the 27 proficiency chemistry tests reviewed by one surveyor, Petitioner had tested its proficiency chemistry samples more than once, even though the results from these samples were all within the normal range. Tr. 904 - 12. In contrast, Petitioner did not retest any patient specimen that had attained a normal result, and Petitioner did not consistently retest patient specimens that attained abnormal or odd results. Id. In addition, by comparing the contents of the proficiency test reports and the documents Petitioner generated in preparation of those reports, the surveyors found instances where Petitioner reported proficiency test results which, according to Petitioner's work papers, Petitioner had not attained. Tr. 907 - 08.

There is no logical reason for repeatedly testing proficiency samples having normal results, especially when Petitioner appears to know this from its routine practice of not testing patient specimens more than once after attaining a normal result. Tr. 906. Nor can Petitioner's retesting of numerous proficiency samples having normal results be reconciled with its practice of failing to retest patient samples even when those patient samples have very odd or abnormal results. These disparities in methodologies violate Petitioner's obligation to conduct its proficiency tests 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) and (b)(2). In addition, the conclusion that Petitioner violated the recordkeeping requirements of 42 C.F.R. § 493.801(b)(5) is shown by the absence of correlation between some of the proficiency test results reported by

Petitioner and the documents supplied to the surveyors for review.

Petitioner acknowledges that the regulation governing proficiency testing requires the laboratory to process proficiency test samples in the same manner as it does patient specimens. P. Br. at 14. Nevertheless, Petitioner argues that it was in compliance, even though it did not test patient samples and proficiency testing samples the same number of times. Id. Petitioner argues that its practice does not violate the regulation. Petitioner's argument is plainly wrong, however, as 42 C.F.R. § 493.801(b)(2) quite specifically requires that proficiency samples be tested the same number of times as patient specimens.

On the basis of the foregoing evidence and the absence of any credible proof supporting a contrary conclusion, I find that Petitioner violated the condition for performing proficiency tests in the manner required by 42 C.F.R. § 493.801.

B. Petitioner was not in compliance with the condition of participation governing patient test management.

Subpart J of the regulations sets forth the condition for patient test management in laboratories performing moderate or high complexity tests. 42 C.F.R. Part 493, Subpart J. To satisfy this condition, the laboratory must employ and maintain a system that provides for, inter alia, the proper identification, preservation, and processing of patient specimens, and the accurate reporting of results. 42 C.F.R. § 493.1101. It is incumbent upon the laboratory to ensure the reliable identification of patient specimens as they are processed and tested to assure that accurate test results are reported. 42 C.F.R. §§ 493.1101, .1107.

The laboratory also must send test reports promptly to the authorized individual who requested the test. 42 C.F.R. § 493.1109. This means, for example, that the laboratory should have in place an adequate system for reporting patient test results in a timely, accurate, reliable, and confidential manner. 42 C.F.R. § 493.1109(a). The laboratory must make available to the authorized person who requested the test the "reference" or "normal" ranges determined by the laboratory, and the laboratory must develop and follow written procedures for immediately reporting any imminent life-threatening results or "panic values" to the authorized individual who requested the test. 42 C.F.R. § 493.1109(d), (f). The laboratory must also retain copies of test records

and test reports for specified periods of time after the results are sent promptly to the authorized individual who requested the test. 42 C.F.R. §§ 493.1107, .1109. For example, immunohematology test records and reports must be maintained by the laboratory for at least five years, and pathology test reports must be retained for a minimum of 10 years after the date of reporting. Id.

The evidence in this case establishes that Petitioner did not comply with the condition of participation for patient test management, for three reasons. First, Petitioner's practices did not assure the proper identification of patient specimens. Second, Petitioner failed to maintain the records required by regulation. Third, Petitioner did not insure that test results were promptly reported to the individual that requested them.

1. Petitioner failed to insure that patient specimens were properly identified.

During their review of Petitioner's records and practices, the surveyors discovered that Petitioner's identification of culture plates was inadequate. A surveyor testified that the markings on the culture plates indicated only the date the culture was made and the last three digits of the patient identification number. Tr. 503, 505 - 07. This identification was inadequate because, as explained at the hearing, the lab must have a record system that permits the tracking of a patient specimen from entry to final report. Tr. 246 - 48. However, the surveyors found it impossible at times to confirm that patient specimens had been identified correctly because neither the patients' names nor their identification numbers had been entered in Petitioner's work records. HCFA Ex. 1 at 14. Instead, Petitioner entered in its records only the last one or two digits of the patients' identification number, which, in its entirety, should consist of nine digits containing also the year, month, day, and sequence in which Petitioner had logged in the physician's request for testing the specimen. Id. Even though Petitioner routinely entered the testing date and date of specimen collection in its work records, such entries were not adequate for accurately identifying patients from Petitioner's work records. Id. Because in several cases specimens were collected or tested on days that differed from those on which the doctors gave their orders or when Petitioner received the specimens, it was not appropriate to construe the two dates appearing in Petitioner's work records as the missing digits from the patient identification numbers. Id.

The surveyors found also that Petitioner accepted some urine specimens in unlabeled containers, which, even if the patient's name had been written on the lid of the container, presented the risk of having the contents of the container associated with the wrong lid and wrong patient name. Tr. 339 - 43, 351 - 52. Petitioner admitted that it does not keep all information on the specimen containers, but it alleges that it maintains all the necessary information on the request forms, which are logged in with the specimen. P. Ex. 15 at 3. However, the request forms and log information reviewed by the surveyors contradict Petitioner's allegations. Petitioner's records reveal that Petitioner: 1) failed to include in its accession number system the dates on which specimens were collected; 2) assigned duplicate numbers to some specimens; 3) failed to assign consecutive numbers to specimens collected from one collection station; 4) omitted the names and addresses of some physicians who requested tests; and 5) failed to indicate which of two collection stations the specimens came from. Tr. 249 - 89.

2. Petitioner failed to keep adequate records of its test results.

In addition to its inadequate identification of patient specimens, Petitioner also was not in substantial compliance with the regulation's recordkeeping requirements under the patient test management condition. For example, Petitioner's supervisors were unable to produce any work records to support the parasitology results it reported for 1992. Tr. 415 - 17; HCFA Ex. 1 at 12 - 13. The regulations require such records to be kept for a minimum of two years. 42 C.F.R. § 493.1107. Moreover, even though Petitioner produced its 1993 work records for parasitology, its recordkeeping systems or techniques were so defective that the surveyor was not able to track various specimens from their accession report to the actual work records. Tr. 415 - 17. Another surveyor described similar unsuccessful attempts to establish a correlation between Petitioner's immunohematology reports and actual work records. Tr. 915 - 17. Petitioner is required to maintain immunohematology records for a minimum of five years. 42 C.F.R. §§ 493.1107, .1109. During the February - March 1993 survey, the surveyor randomly selected for review the records and reports for 10 patients tested during a three-month period during 1992. Tr. 915 - 17. She could not find the actual work records for five of the these 10 patients. Id.

Even though Petitioner later submitted a "quality control book" (P. Ex. 6), purporting to substantiate the performance of the tests for all 10 patients, the surveyor noted several reasons for doubting the truth of the information contained in the book. First, the book was submitted only after Petitioner had received notice of the deficiencies. Tr. 918. Moreover, the tests in issue were done manually and not on machines. Tr. 926. Even if a quality control test should have been run on these types of tests, a laboratory should not do a quality control test on actual patient specimens, because a quality control test involves working with samples of known values, whereas actual patient specimens have unknown values. Tr. 918 - 22, 926, 928. The surveyor noted also that the contents of the "book" later produced by Petitioner is highly suspect in that it coincides in all respects with the information the surveyor examined in the laboratory, except that it also has information pertaining to the other five patients (and only the five other patients) in issue for the same time period. Tr. 918 - 22. The surveyor's observations are well-reasoned and persuasive. By contrast, the testimony introduced by Petitioner in defense of the existence of the "book" and its contents appears contrived and conveniently self-serving. See Tr. 937 - 42; P. Ex. 15 at p. 4.

3. Petitioner failed to report test results in a timely and accurate manner.

I found persuasive also HCFA's conclusion that Petitioner failed to meet the timely test reporting requirements of Subpart J. One surveyor testified from the review of Petitioner's records that some tests were completed within 48 hours, but Petitioner took four days to report those results. Tr. 530 - 35. With respect to the requirement for reporting "panic values" or results having life-threatening implications, HCFA showed that Petitioner's records do not contain notations of what action, if any, was taken on the reporting of "panic values." Tr. 314. Even if Petitioner had written policies in place for providing prompt notice of "panic values" to doctors or other authorized individuals who requested the tests, Petitioner's agents and employees did not appear to follow any consistent procedures when they were obligated to report life-threatening results. Tr. 311 - 12. The surveyors found also many instances where Petitioner failed to report abnormal or spurious tests and inaccurately reported patient results. Tr. 318 - 39; HCFA Ex. 1 at 32.

Through the testimony of at least one of its witnesses, HCFA acknowledged the various possibilities that may have

accounted for the grossly abnormal patient test results reviewed during the survey: a bad test system, bad specimens, or patients who were truly very ill. Tr. 889 - 90, 893. However, as also discussed below, if the abnormal results were due to a bad test system or bad specimens, Petitioner took none of the remedial actions required by the regulations. Similarly, if the abnormal test results accurately reflected the serious illness of patients, Petitioner failed to contact the doctors in the manner required by Subpart J. Tr. 890 - 91. In fact, the records reviewed by the surveyors show that, in several instances, abnormal results appear to have been deliberately deleted from patient reports. Tr. 892 - 95.

HCFA's evidence shows also that Petitioner was reporting incorrect and incomplete normal ranges, in contravention of the regulatory requirement that pertinent "reference" or normal ranges, as determined by the laboratory performing the tests, be made available to those who order or will utilize the tests. 42 C.F.R. § 493.1109(d); HCFA Ex. 1 at 20 - 23. At the hearing, one of HCFA's witnesses testified that Petitioner reported incorrect normal ranges for potassium in its chemistry test results. Tr. 876 - 78. Petitioner's failure to report the normal range of tests correctly or completely is seen also in its reporting of only the normal ranges for males in certain tests where the normal ranges are gender-dependent. HCFA Ex. 1 at 22. I agree with HCFA's interpretation that the regulation, in requiring that the pertinent normal or "reference" ranges be made available, means that the correct ones be made available. See 42 C.F.R. § 493.1109(d).[2] Petitioner did not prove its assertions that it reported "accepted medical ranges" and used a "medically accepted formula" in calculating the patient test results. See P. Ex. 15 at 5.

For the foregoing reasons, I conclude that HCFA has proven that Petitioner had condition-level deficiencies in the management of patient tests.

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[2] The reporting of incorrect and incomplete normal ranges shows also that Petitioner violated the conditions of quality control and quality assurance, discussed below.

C. Petitioner was out of compliance with the condition of participation governing quality control for labs performing moderate or high complexity tests.

Subpart K of the regulations contains the requirements that must be satisfied by laboratories performing tests of moderate or high complexity in order to meet the condition of quality control. 42 C.F.R. Part 493, Subpart K. Quality control refers to techniques for measuring the accuracy of tests by performing the tests on materials for which the correct values are known. Tr. 353 - 54. Under the regulations, a laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of patient tests and results. 42 C.F.R. § 493.1201(b). As especially relevant to this case, the regulation is specific 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). In addition, the laboratory must take remedial actions when appropriate and document such remedial actions. 42 C.F.R. §§ 493.1219, .1221.

In order to ascertain the validity of Petitioner's quality control data, the surveyors chose to review the control records for Petitioner's platelet testing system, automated complete blood count (CBC) system, and chemistry profiling system. HCFA Ex. 1 at 24. At the very basic level, the surveyors found that many of Petitioner's control results were illegible, and no control results were recorded on some days. Tr. 366 - 68; HCFA Ex. 1 at 24. These facts support the conclusion that Petitioner was not performing the required control tests on each day of testing.

At the hearing, one of HCFA's witnesses detailed the various problems found in the review of Petitioner's control data for platelet testing system. Tr. 362 - 92. She explained the significance of the information contained in control product inserts provided by the manufacturer, which list the true or target values for the control material of a particular batch within a particular lot. Tr. 357 - 58, 368 - 72. Petitioner's control records for platelet testing were aberrant in the following respects: 1) the recurrence of a few specific values; 2) the appearance of the same two Low Level control values in 12 out of 15 instances; 3) the recurrence of consecutive identical sets of Normal Level and High Level control results within a short period of time; and 4) the absence of corresponding changes in the

High Level control values reported by Petitioner when the lot number and target levels of the platelet controls changed. HCFA Ex. 1 at 24 - 26; Tr. 372 - 92. Based on these and like problems in Petitioner's control records, I agree with the surveyors' conclusion that Petitioner's quality control system for platelet testing was unsatisfactory. HCFA Ex. 1 at 24 - 26.

The surveyors concluded also that Petitioner's quality control of its CBC test system was unsatisfactory because the accuracy of Petitioner's control data in this area could not be verified, for several reasons. HCFA Ex. 1 at 26. At the hearing, one of the surveyors explained the workings of a Coulter Counter analyzer, which performs the CBC tests for Petitioner and should automatically print out dates and sequence numbers. Tr. 395 - 98. However, the analyzer printouts provided by Petitioner did not have the dates or proper sequence numbers, and Petitioner had discarded the carbon copies of its original analyzer printouts. Tr. 398 - 401; HCFA Ex. 1 at 26. In addition, the information on the originals was very difficult to read. Id. Without sequencing numbers, there was no way for the surveyors to know when the control data were generated: whether they were generated on certain days and used for other days, or generated on each day of patient testing as required by the regulations. Tr. 399 - 400. Even though the surveyor could not be certain whether Petitioner had falsified its CBC control data, she testified that laboratories have been known to generate multiple copies of control results on a day when their analyzer is operating properly, so that these control results could be used on other days when their equipment is not operating properly or when they do not care to run control tests. Tr. 402 - 04. This testimony underscores the importance of having verifiable control data in order to satisfy the condition for quality control.

In the area of patient chemistry testing, the surveyors discovered that Petitioner was calculating certain results incorrectly, and was not investigating or correcting problems that produced spurious test values. See HCFA Ex. 1 at 20 - 23. Petitioner was using the wrong formula to calculate low density lipoprotein (LDL), which caused the wrong results to be reported. HCFA Ex. 1 at 22 - 23; Tr. 567 - 77. Petitioner could not identify a reference source for the single normal LDL range it was reporting for both sexes. Petitioner claimed to have been relying on the same range reported by the previous laboratory owner for the LDL tests. HCFA Ex. 1 at 22; Tr. 565 - 68.

In addition, the surveyors found frequent instances of biased results in the small sample of Petitioner's records randomly selected for review. HCFA Ex. 1 at 21; Tr. 542 - 62. That is to say, instead of finding patient values equally distributed around the mean of the normal range for a particular test (i.e., 50 percent above and 50 percent below), the surveyors found higher percentages of results at either above the mean to create a positive bias, or at below the mean to create a negative bias. Thus, due to such biases, Petitioner was obtaining an unusually high percentage of abnormal values. HCFA Ex. 1 at 21.

Even though Petitioner's records provided repeated indications of possible malfunctioning of its test systems or equipment (e.g., Tr. 389 - 92, 893), Petitioner undertook no remedial action as required by the regulations. Instead, Petitioner likely deleted information from its test reports by manually overriding certain machine generated data that reflected the existence of its systemic or equipment problems. Tr. 893 - 95.

This and like evidence of record prove that Petitioner failed to satisfy the condition of quality control.

D. Petitioner's deficiencies in proficiency testing, patient test management, and quality control demonstrate that Petitioner failed also to comply with the conditions of participation governing quality assurance and those governing laboratory directors and supervisors.

Subpart P of the regulations contains the requirements for the condition of quality assurance. 42 C.F.R. Part 493, Subpart P. For quality assurance, the laboratory must have ongoing monitoring and evaluation of its test management system and quality control system. 42 C.F.R. §§ 493.1703, .1705. For example, the regulations require that the laboratory assess its quality control system to determine whether its corrective actions have effectively responded to the following: 1) problems identified during the evaluation of calibration and control data for each test method; 2) problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and 3) errors detected in reported results. 42 C.F.R. § 1705. In addition, the laboratory must document all quality assurance activities and make such records available to the Department of Health and Human Services. 42 C.F.R. § 493.1721.

Subpart M of the regulations contains the requirements for laboratory directors and supervisors to perform

certain specified responsibilities. In a laboratory performing moderate and highly complex tests, a laboratory director must provide overall management and direction in accordance with the regulations, and his responsibilities include ensuring that proficiency test samples are tested as required under Subpart H, ensuring that quality control and quality assurance programs are established and maintained, and ensuring that all necessary remedial actions are taken and documented. 42 C.F.R. §§ 493.1403, 493.1407, 493.1445. In a laboratory performing highly complex tests, there must be a general supervisor whose responsibilities include being accessible to testing personnel, providing day-to-day supervision of high complexity testing, and ensuring that acceptable levels of analytic performance are maintained. 42 C.F.R. §§ 493.1459, 493.1463. In addition, the general supervisor may be delegated the laboratory director's responsibility for assuring that all remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications and ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning. 42 C.F.R. § 493.1463(b)(1), (2).

The problems discussed in the earlier sections of this decision and substantiated in the record support the conclusion that Petitioner failed to comply with the conditions for quality assurance and that its laboratory director and general supervisor failed to perform their responsibilities in accordance with the regulations. Because of Petitioner's deficiencies in the areas of proficiency testing, patient test management, and quality control, Petitioner's integrity depended upon its supervisor and director performing their duties properly and undertaking meaningful quality assurance. Only by complying with the regulatory requirements for quality assurance and laboratory directors and supervisors found in Subparts P and M could Petitioner have begun to eliminate on its own the continuing systemic problems found by the surveyors. However, whether it was Petitioner's noncompliance with Subparts P and M that caused the condition-level deficiencies under Subparts H, J, and K, or vice versa, the results were the same: Petitioner did not conduct the required self-evaluation, was not ascertaining its own mistakes and problems, and did not implement any of the necessary remedial actions through its director or supervisor.

For these reasons, I conclude that Petitioner had failed to comply with the conditions at 42 C.F.R. Part 493, Subparts P and M.

Conclusion

For the reasons discussed above, I find that Petitioner was out of compliance with a number of Medicare Conditions of Participation. I conclude, therefore, that HCFA was authorized to impose the principal sanctions of revocation of Petitioner's CLIA certificate and cancellation of Medicare payments to Petitioner.

/s/

Mimi Hwang Leahy

Administrative Law Judge