Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Fullerton-Kimball Medical & Surgical Center – Laboratory,
(CLIA ID# 14D1047993),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-326

Decision No. CR4694

Date: August 30, 2016

DECISION

I grant summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS), sustaining its determination to impose remedies against Petitioner, Fullerton-Kimball Medical Surgical Center – Laboratory. The remedies that I sustain are the following:

- Suspension of Petitioner's certificate to perform testing subject to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578 (section 353 of the Public Health Services Act, 42 U.S.C. § 263a);
- Cancellation of Petitioner's approval to receive Medicare payments effective December 22, 2015;
- Civil money penalties of $7,500 for each day of a three-day period beginning December 19, 2015 and running through December 21, 2015; and
- Revocation of Petitioner's CLIA certificate.

I. Background

Petitioner, a clinical laboratory, filed a hearing request in order to challenge CMS's remedy determinations. CMS moved for summary judgment. CMS filed 14 proposed exhibits with its motion, which are identified as CMS Ex. 1-CMS Ex. 14. Petitioner opposed the motion and filed 35 proposed exhibits in opposition, which are identified as P. Ex. 1-P. Ex. 35.

I receive the parties' proposed exhibits into the record for purposes of deciding the motion for summary judgment. I make no findings as to whether any or all of these exhibits would be admissible were I to hold an evidentiary hearing.

II. Issues, Findings of Fact and Conclusions of Law

A. Issues

The issues are whether Petitioner failed to comply with CLIA conditions of participation and whether CMS's remedy determinations are authorized by law and reasonable.

B. Findings of Fact and Conclusions of Law

This case is governed by CLIA and by regulations published at 42 C.F.R. Part 493. I discuss the Act and regulations in more detail below. However, I note preliminarily, that there is no dispute between the parties as to the law applying to this case. Furthermore, Petitioner does not assert that the facts alleged by CMS, if true, would not support the imposition of the remedies that CMS determined to impose. Rather, Petitioner's argument is based strictly on what it contends is a dispute as to the material facts.

CMS premises its case against Petitioner on the assertion that, as of a survey conducted on November 18, 2015, Petitioner was not complying with six distinct CLIA conditions of participation. CMS Ex. 3. Specifically, according to CMS, Petitioner was not complying with conditions stated at: 42 C.F.R. § 493.1213, governing toxicology services and testing; 42 C.F.R. § 493.1250, governing analytic systems; 42 C.F.R. § 493.1441, governing the role and duties of the laboratory director; 42 C.F.R. § 493.1447, governing the role and duties of a technical supervisor; 42 C.F.R. § 493.1459, governing the role and duties of a general supervisor; and 42 C.F.R. § 493.1487, governing the role and duties of testing personnel. CMS asserts additionally that it provided Petitioner with the opportunity to file credible allegations of compliance to address the deficiencies that CMS had identified. According to CMS, Petitioner did so but its evidence of compliance was inadequate and incomplete. CMS Ex. 5.

The facts offered by CMS, if not contested, establish that Petitioner was noncompliant with the six conditions of participation cited in the Statement of Deficiencies from the

November 18, 2015 survey. The allegations of noncompliance, as I shall discuss, involve failures by Petitioner to comply with specific certification standards. Its noncompliance with these standards is sufficient to establish condition-level deficiencies in the way Petitioner operated its laboratory.

Petitioner asserts that it always has been and remains in full compliance with all CLIA requirements and that there is at least a dispute as to material facts that precludes entry of summary judgment. But, on close analysis, Petitioner doesn't actually rebut the facts offered by CMS. As I shall discuss, with the exception of one of the conditions governing the laboratory's technical supervisor, Petitioner for the most part doesn't really challenge the fact findings made by the surveyor on November 18, 2015, nor does it deny the incompleteness and inadequacy of its plan of correction. Rather, Petitioner proffers an alternate universe of facts that, it contends, establishes a true picture of its operations. I have examined these asserted facts, which I assume to be true for purposes of ruling on CMS's motion, and I find them to be irrelevant because they beg the crucial questions of whether Petitioner was out of compliance as of the November 18th survey and whether it demonstrated compliance with its subsequent filing of allegations of compliance.

Based on the undisputed facts, I find that Petitioner failed to comply with five of the six conditions that CMS contends that it violated. The only condition about which I find a genuine dispute as to material facts is the condition governing technical supervisor stated at 42 C.F.R. § 493.1447. As I shall discuss, Petitioner's noncompliance with the other five conditions justifies imposition of all of the remedies CMS determined to impose.

CMS contends that Petitioner failed as of November 18, 2015 to comply with the Toxicology and Analytic Systems conditions at 42 C.F.R. §§ 493.1213 and 493.1250 for three reasons. First, it asserts that Petitioner was required to have a comprehensive procedures manual that advised laboratory employees about the performance of a range of necessary testing tasks. CMS contends that Petitioner failed to produce that manual when its surveyor demanded it. 42 C.F.R. §§ 493.1251(b) and 493.1242(a); CMS Ex. 1 at 3-6, 10-11; CMS Ex. 9; CMS Ex. 14 at ¶¶ 8-12. Nor did the laboratory, according to CMS, have a comprehensive manual available that addressed when and how an employee should take corrective action, among other things, to address problems, or proceed in the event of imminently life threatening results. 42 C.F.R. § 493.1251(b); CMS Ex. 1 at 11; CMS Ex. 9; CMS Ex. 14 at ¶ 12.

Petitioner concedes that it was unable to produce requested manuals on November 18th. Petitioner's pre-hearing brief at 5. It argues that it was compliant with the requirement that it maintain manuals because those manuals in fact existed even if the staff was unable to find them and offer them to the surveyor. P. Ex. 3.[1] For purposes of deciding

[1] Petitioner asserts that its laboratory director was out of the country on November 18, 2015. It is unclear to me whether Petitioner is suggesting that his absence condones its

CMS's motion I accept Petitioner's assertion as true. It is irrelevant. Those manuals, to be meaningful, had to be available to Petitioner's staff on November 18th so that the staff could refer to them as needed. The fact that the manuals – even if they existed – could not be located on that date rendered them useless to the staff. For compliance purposes, it was as if the manuals did not exist.

Petitioner made allegations of compliance on January 7 and 8, 2016. In responding to Petitioner's allegations, CMS noted that the manual portions that Petitioner provided on January 7 and 8 were substantially incomplete. CMS Ex. 5. Petitioner doesn't deny that what it submitted on January 7 and 8 was incomplete, but it now asserts that its policy and procedures manual is complete and that it addresses all of the concerns raised by CMS. Petitioner's pre-hearing brief at 6-7. For purposes of deciding this case I accept Petitioner's representation that it has corrected all of the inadequacies that CMS identified with the manual portions that Petitioner located and submitted. But, Petitioner did not prove that its manuals were complete as of November 18, 2015 or as of January 7 and 8, 2016. Rather, its proffered facts and arguments address the *current condition* of its manuals.

Petitioner's assertions about its manuals' current condition are irrelevant because the current status of the manuals isn't at issue in this case. What matters is whether Petitioner was in compliance as of the November 18 survey or as of January 7 and 8, 2016. CMS made its remedy determination based on its evaluation of Petitioner's status as of those dates and it is under no obligation to accept Petitioner's subsequent corrective actions. CMS's inspections of clinical laboratories are not open-ended processes in which the laboratories get infinite bites at the apple until they get things right. CMS properly set deadlines and Petitioner failed to establish compliance by those deadlines. That is what matters here and not what may have occurred subsequently.

Second, CMS asserts that Petitioner failed to comply with the Toxicology and Analytic Systems requirements because at the November 18, 2015 survey Petitioner could not demonstrate that it was conducting tests to verify the performance of its equipment. CMS alleges additionally that Petitioner failed to demonstrate that it performed tests of control materials on each day that patient specimens were being tested. 42 C.F.R. §§ 493.1253(b)(2) and 493.1256(d)(3)(i), (g); CMS Ex. 1 at 12-15; CMS Ex. 14 at ¶¶ 12-13. On at least one date, June 16, 2015, according to CMS, Petitioner conducted a patient

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inability to produce laboratory manuals on that date. It does not. Moreover, I note that Petitioner received advanced notice of the November 18 survey by letter dated November 4, 2015. It had nearly two weeks to prepare for that survey and it could easily have made its manuals accessible during that period. *See* CMS Ex. 2.

test but was unable to show that it had conducted quality control testing. CMS Ex. 11 at 2; CMS Ex. 14 at ¶ 13. CMS also asserts that on dates when the laboratory alleged that it had conducted quality control tests the test results were incomplete. CMS Ex. 12; CMS Ex. 14 at ¶ 13.

Petitioner replies to CMS's assertions by stating flatly that it "is, and always has been, compliant with all . . . [quality control] requirements and performs . . . [quality control] testing as required." Petitioner's pre-hearing brief at 9. It then offers evidence purporting to prove that its quality control testing is compliant as of now. But, that begs the question as to its compliance on November 18. Petitioner does not deny that it was unable to show that it had conducted quality control testing on June 16, 2015 or that the test results that it showed to the surveyor on November 18th were incomplete.

Petitioner seems to argue that its quality control testing was compliant as of November 18, 2015 even if it failed to provide proof of that to the surveyor on that date. According to Petitioner:

> It can be established and verified that performance characteristics of all assays in the subspecialty of toxicology testing were completed, reviewed and signed in a timely manner. *See* P. Ex. 22. All required . . . [quality control testing] was performed before any toxicology testing was completed. The . . . [quality control] records prove compliance. *See e.g.* P. Ex. 19; *see also* P. Ex. 20 and P. Ex. 23 . . . .

Petitioner's pre-hearing brief at 11. However, and notwithstanding Petitioner's representations, it has offered no evidence to show that on November 18th it had performed the tests that CMS alleges Petitioner failed to perform.

Specifically, Petitioner did not rebut CMS's assertion that it had failed on at least one occasion, June 16, 2015, to conduct quality control testing as support of a patient test. Nor did it rebut the assertion that there were dates where quality control test results were incomplete. Petitioner produced exhibits – P. Ex. 19 and P. Ex. 20 – that Petitioner apparently purports to show quality control test results. But, these results, if that's what they are, are for just two dates, October 9 and 12, 2015.[2] Petitioner has made no showing by producing test results that it did quality control testing on June 16, 2015. Nor did

[2] Throughout its argument Petitioner repeatedly offers to provide more evidence in the event that what it has provided is inadequate. Evidently, it labors under the misperception that the hearing in this case is open ended and that it has infinite opportunity and time to amend its submission. That is absolutely contrary to what I ordered the parties to do by way of pre-hearing exchanges. Petitioner was obligated to produce *all* of the evidence on which it intended to rely by a date certain. It cannot hold back evidence and offer vaguely, to provide more if requested to do so.

Petitioner produce evidence showing that it did quality control testing on the several dates requested by the surveyor during the November 18, 2015 survey. CMS Ex. 14 at ¶ 13.

Petitioner relies on two other exhibits, P. Ex. 19 and P. Ex. 20, as ostensible rebuttal of CMS's assertions. But, these exhibits do not show that Petitioner was doing requisite testing on the dates at issue.

Third, CMS alleges that Petitioner erred in the way that it documented and reported toxicology test results. Specifically, CMS contends that, with respect to three patients, Petitioner failed to document the dates and times that it received specimens to be tested. 42 C.F.R. § 493.1242(b); CMS Ex. 1 at 6; CMS Ex. 11; CMS Ex. 14 at ¶ 11. CMS contends additionally that Petitioner failed to include in its test results a disclaimer that the manner in which the toxicology tests were conducted was not FDA-approved. 42 C.F.R. § 493.1291(c); CMS Ex. 1 at 15-16.

Petitioner did not rebut these allegations. It has offered no evidence rebutting CMS's contention that it failed to document the dates and times it received specimens for three individuals, nor did it provide evidence showing that it put the requisite disclaimer on test results. Rather, Petitioner merely states that it has performed tests timely and that it now puts the requisite disclaimer on test results. These assertions again simply beg the question of whether Petitioner was compliant when it was surveyed on November 18, 2015.

CMS makes the following assertions concerning Petitioner's noncompliance with the management and staffing conditions at 42 C.F.R. §§ 493.1441, 493.1447, 493.1459 and 493.1487. First, it contends that Petitioner was not in compliance with the laboratory director condition at 42 C.F.R. § 493.1441 because Petitioner's laboratory director, Dr. Arana, failed to provide specifications of the responsibilities of laboratory personnel. CMS Ex. 1 at 17-24; CMS Ex. 14 at ¶ 14. Second, it contends that Petitioner failed to comply with the technical supervisor and general supervisor requirements of 42 C.F.R. §§ 493.1447 and 493.1459 because the laboratory had neither a technical supervisor nor a qualified general supervisor on its staff. CMS Ex. 1 at 21-24; CMS Ex. 7; CMS Ex. 14 at ¶ 15. Finally, CMS asserts that Petitioner failed to comply with the testing personnel requirements of 42 C.F.R. § 493.1487 because testing personnel at Petitioner's laboratory were not qualified to conduct high complexity tests. CMS Ex. 1 at 21-28; CMS Ex. 14 at ¶ 15.

Petitioner denies CMS's allegations as "wholly inaccurate." Petitioner's pre-hearing brief at 13. It contends that it:

> has sufficient and qualified laboratory personnel present at the laboratory during all testing, including high complexity testing. All laboratory

> personnel's roles are properly defined, and each laboratory personnel is qualified to complete assigned tasks.

Id. at 13-14. Significantly, Petitioner makes its assertions in the present tense. I will accept these assertions as true for purposes of ruling on CMS's motion, but they are irrelevant to the extent that they do not address Petitioner's compliance as of the November 18th survey and in January 2016. Asserting that Petitioner is presently compliant does not establish that it was compliant on earlier dates.

Petitioner relies on two exhibits, P. Exs. 25 and 26, to support its assertion that laboratory personnel's roles are properly defined. These two documents spell out the duties of Petitioner's staff. But, they are undated and Petitioner does not allege that they existed as of November 2015 or January 2016. For that reason they do not rebut CMS's assertions that, as of the date of the survey, Petitioner's laboratory director had failed to specify the duties of laboratory staff.

Petitioner discusses at length its decision to hire a new laboratory director to replace Dr. Arana and it asserts that its new director is fully qualified to perform in that capacity. It also argues that Dr. Arana was qualified, by virtue of his education and work experience, to perform the duties of laboratory director. Petitioner's pre-hearing brief at 14-15. Petitioner concedes that Dr. Arana sometimes erred in failing to sign documents timely. However, it asserts that these conceded errors are "moot" because it has replaced Dr. Arana. *Id.* at 15-16.

I find these assertions – assuming their truth – to be irrelevant. The fact that Petitioner replaced its director after the survey was complete does not derogate from CMS's assertions that the director *as of the date of the survey* – Dr. Arana – was not performing his duties consistent with conditions of participation. It is essentially the same argument that Petitioner makes repeatedly, that it corrected whatever was wrong subsequently. This argument is irrelevant for the reasons I have stated.

Petitioner asserts that it did have a technical supervisor as of the November 18th survey and as proof of that contention it has offered the curriculum vitae of Mohammed A. Elmannan, M.D., and a consulting contract with that individual dated December 2013. P. Ex. 32; *Id.* at 11-15. On its face this document appears to show that Petitioner complied with the Technical Supervisor condition of participation and I find a dispute of material fact as to that issue. I do not grant summary judgment in favor of CMS on the issue of whether Petitioner complied with the technical supervisor condition.

However, I find that Petitioner failed to rebut CMS's allegations concerning its failure, as of the November 18th survey, to have a general supervisor as is required by 42 C.F.R. § 493.1459. In order to serve as a general supervisor, an employee of the laboratory must either qualify as a technical supervisor pursuant to the requirements of 42 C.F.R.

§ 493.1449, or meet the laboratory director requirements of 42 C.F.R. § 493.1443. 42 C.F.R. § 493.1461(b). Among other things, the requirements for both technical supervisor and general supervisor include requirements that such individuals have degrees as doctors of medicine or equivalent educational attainment in other specialties.

As of November 18, 2015, Susan DeVries, the individual purporting to be Petitioner's general supervisor, held an associate's degree as a laboratory technician. CMS Ex. 14 at ¶ 15. That is plainly inadequate to qualify her as Petitioner's general supervisor and for that reason Petitioner failed to comply with the condition governing general supervisor.

Petitioner argues that Ms. DeVries is "qualified under § 493.1461 of this subpart to provide general supervision in accordance with § 493.1463 of this subpart." However, Petitioner did not offer anything to rebut CMS's assertion that she lacked the requirements for general supervisor mandated by the applicable regulations.

CMS asserts that Petitioner failed to comply with the regulatory requirements governing testing personnel because two of the three individuals who were performing high complexity testing had only high school degrees. CMS Ex. 14 at § 15. The regulatory requirements governing personnel performing high complexity testing require these individuals to have advanced training. 42 C.F.R. § 493.1487. Having a high school degree without such training plainly disqualifies an individual from performing high complexity testing and a laboratory's utilization of such individuals to perform high complexity tests would be a condition-level violation of requirements.

Petitioner did not rebut CMS's assertions. It asserts that, as of the time of the survey, Ms. DeVries was "testing personnel," avoiding answering CMS's charge that other individuals who were manifestly unqualified as of the survey were performing high complexity tests. Petitioner's pre-hearing brief at 16. Petitioner also argues that its *current* staff includes several individuals who are qualified to perform high complexity tests. *Id.* That begs the question of whether Petitioner was using unqualified personnel as of the survey date or in January 2016 to perform high complexity tests.

I have found that Petitioner was noncompliant with five of the six conditions that CMS alleges Petitioner violated as of the November 18th survey and in January 2016. I find that the remedies that CMS determined to impose, including civil money penalties, are justified by the degree of Petitioner's noncompliance. It is unnecessary that CMS establish that Petitioner failed to comply with all six conditions, as alleged originally, in order to justify the remedies at issue.

In discussing these remedies, I note that Petitioner made no arguments concerning any of them. It effectively concedes that all of these remedies would be appropriate were it to

be found noncompliant as alleged originally by CMS. I would not address the issue of remedy at all but for the fact that I find that summary judgment is appropriate as to five of the six conditions about which CMS alleges noncompliance.

Regulations governing imposition of remedies against noncompliant laboratories are set forth at 42 C.F.R. Part 493, Subpart R. CMS may impose principal and alternative sanctions against a laboratory where noncompliance consists of failure to comply with even just one condition of participation. 42 C.F.R. § 493.1804(b)(2), incorporating 42 C.F.R. §§ 493.1806 and 493.1807. CMS has discretion to determine what remedies to impose where there is condition-level noncompliance. *Edison Med. Labs.*, DAB No. 1713, at 2 (1999), *aff'd*, *Edison Med. Labs., Inc. v. Thompson*, 250 F.3d 735 (3rd Cir. 2001). When CMS revokes a laboratory's CLIA certificate, it must cancel the laboratory's approval to receive Medicare reimbursement for its services. 42 C.F.R. §§ 493.1808(a), 493.1842(a).

Thus, all of the remedies that CMS determined to impose, with the exception of the imposition of civil money penalties, are justified as a matter of law by Petitioner's failure comply with just one CLIA condition of participation. Petitioner's noncompliance with five conditions of participation is more than enough to sustain CMS's remedy determinations.

That leaves the issue of the civil money penalties of $7500 per day for each day of a three-day period. CMS based these penalties on Petitioner's failure to comply with six conditions of participation. Does failure to comply with five of the six conditions also support the imposition of penalties in these amounts? I conclude that it does.

Civil money penalties are authorized where a laboratory manifests condition-level noncompliance, whether or not that deficiency poses immediate jeopardy for patients whose specimens are being tested by that laboratory. 42 C.F.R. §§ 493.1806(c)(3), 493.1834. Penalties in a range of from $3050 to $10,000 per day may be imposed where immediate jeopardy exists. 42 C.F.R. § 493.1834(d)(2). There are regulatory factors governing the determination of penalty amount and these include the nature, scope, severity, and duration of a laboratory's noncompliance. 42 C.F.R. § 493.1834(d)(1).

In this case, CMS found immediate jeopardy level noncompliance because it found that the noncompliance was likely to cause serious injury, harm or death to individuals served by the laboratory. There is ample basis for that determination even if Petitioner was noncompliant with five, and not all six, of the conditions alleged by CMS. Among other things, Petitioner was using personnel to perform high complexity tests who were manifestly unqualified to perform those tests. On the day of the survey, manuals that addressed issues or problems that might come up during the performance of high complexity tests were unavailable to Petitioner's staff. So, untrained staff were

potentially left in the dark as to how to address problems that might arise with tests whose outcomes could be life-altering for the individuals whose specimens were being tested. That level of noncompliance is certainly immediate jeopardy.

The penalty amounts of $7500 per day that CMS determined to impose had the remedial intent of inducing Petitioner to come back into compliance. I find that they were commensurate with the degree of seriousness of that noncompliance and appropriate based on the five conditions with which Petitioner failed to comply.

_____/s/_____
Steven T. Kessel
Administrative Law Judge