Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Planned Parenthood Choice of Abilene, Texas,
(CLIA No. 45D2019250),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-1229

Decision No. CR2854

Date: July 12, 2013

DECISION

Until recently, Petitioner, Planned Parenthood Choice of Abilene, Texas (Petitioner or lab), was a Texas clinical laboratory, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq*. The parties agree that, before submitting its first-quarter 2011 proficiency testing (PT) report, the lab employee charged with performing the tests called a second lab and compared results. Based on this and other findings, the Centers for Medicare and Medicaid Services (CMS) revoked the lab's CLIA certificate and canceled its approval to receive Medicare payments.

Petitioner now appeals, challenging the sanctions imposed. CMS has moved for summary judgment. Petitioner opposes, but "does not dispute the underlying conduct alleged in the statement of deficiencies." Instead, Petitioner argues that CMS "is not entitled to judgment as a matter of law on its imposition of sanctions." P. Br. at 1-2.

For the reasons set forth below, I grant CMS's motion and sustain the penalties imposed.

I. Background

In order to ensure the accuracy and reliability of laboratory tests, and thus the health and safety of those tested, CLIA creates a federal certification process for laboratories that perform clinical diagnostic tests on human specimens. Public Law No. 100-58, *amending* section 353 of the Public Health Service Act, codified at 42 U.S.C. § 263a *et seq.*; *see* H.R. Rep. No. 100-899, at 8, *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. To be certified, a laboratory must meet the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. Part 493. A condition represents a major division of laboratory services or required environmental protections; each condition is broken down into more detailed standards that laboratories must meet to be compliant with the overall condition. *White Lake Family Medicine, P.C.*, DAB No. 1951 at 2-3 (2004); *RNA Labs.*, DAB No. 1820 at 3 (2002).

The statute gives the Secretary of Health and Human Services broad enforcement authority, which the Secretary has delegated to CMS. CMS or its designee conducts periodic inspections to determine a laboratory's compliance with CLIA requirements. 42 C.F.R. § 493.1777. CMS may suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions and may also impose alternative sanctions (directed plan of correction, state monitoring, civil money penalty). 42 C.F.R. § 493.1806; *White Lake Family Medicine, P.C.*, DAB No. 1951 at 5. Noncompliance with even one standard, if sufficiently serious, may justify a condition-level deficiency. *RNA Labs.*, DAB No. 1820 at 3; *Edison Medical Labs., Inc.*, DAB No. 1713 at 2-3 (1999).

Here, following a certification survey completed October 6, 2011, CMS determined that Petitioner did not meet two conditions of participation: 42 C.F.R. § 493.801, which governs the enrollment and testing of samples; and 42 C.F.R. § 493.1403, which sets forth requirements for the lab director for labs performing moderate complexity testing. CMS Exs. 1, 2. Based on these findings, CMS revoked Petitioner's CLIA certificate and cancelled the laboratory's approval to receive Medicare payments for its services. CMS Ex. 1 at 2.

Petitioner timely appealed. CMS has filed a motion for summary judgment, which Petitioner opposes. With its motion and brief (CMS Br.), CMS submits eight exhibits (CMS Exs. 1-8). With its response brief (P. Br.), Petitioner submits three exhibits (P. Exs. 1-3). CMS also filed a reply (CMS Reply).

II. Issues

I consider whether summary judgment is appropriate.

On the merits, the issues before me are whether Petitioner violated CLIA and its implementing regulations, and, if so, whether CMS properly revoked Petitioner's CLIA certificate and cancelled its approval to receive Medicare payments.

III. Discussion

A. CMS is entitled to summary judgment because the undisputed facts establish that: 1) the lab did not test PT samples in the same manner as patient specimens; 2) prior to submitting its PT testing results, a lab employee compared her test results with those of a second laboratory; and 3) for two testing events, the lab director did not attest that the PT samples were integrated into the regular patient workload. The lab thus violated the statute (42 U.S.C. § 263a(i)(4)) and was not in substantial compliance with two conditions of certification: 42 C.F.R. § 493.801 and 42 C.F.R. § 493.1403.[1]

Summary Judgment. Summary judgment is appropriate where a case presents no disputed issues of material fact and where the only questions presented involve either questions of law or the application of the law to the undisputed facts. *Livingston Care Center*, DAB No. 1871 at 6 (2003), *aff'd*, *Livingston Care Ctr. v. Dep't of Health & Human Servs.*, 388 F.3d 168 (6th Cir. 2004). Where, as here, the parties agree on all material facts, I need not convene an oral hearing. *Sol Teitelbaum*, M.D., DAB No. 1849 at 10 (2002), *citing Glenburn Home*, DAB No. 1806 at 17 (2002) ("[I]n reviewing a case where an ALJ failed to either obtain a written waiver or hold an oral hearing, we may nonetheless uphold the decision if the affected party either had conceded all of the material facts or proffered testimonial evidence only on facts which, even if proved, clearly would not make any substantive difference in the result.").

Regulatory requirements. A laboratory that holds a CLIA certificate may perform moderate and high complexity tests but must participate in a PT program, as outlined in 42 C.F.R. Part 493, Subpart H. Part 493 mandates that each laboratory enroll in an approved PT program that meets the specific criteria set out at Subpart I of Part 493. 42 C.F.R. § 493.801. A laboratory performing "nonwaived" testing (which includes the moderate complexity tests that Petitioner performed) "must successfully participate" in an approved PT program for each "specialty, subspecialty, and analyte or test in which [it] is certified under CLIA." 42 C.F.R. § 493.803(a).[2]

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[1] My findings of fact and conclusions of law are set forth, in bold and italics, as captions in the discussion sections of this decision.

[2] To be waived, an examination or procedure must present "an insignificant risk of an erroneous result," and the Food and Drug Administration must approve the waiver. 42 C.F.R. § 493.2; 42 U.S.C. § 263a(d)(3).

A laboratory must treat and analyze PT samples in the same manner as patient samples. 42 C.F.R. § 493.801(b); 42 C.F.R. § 493.61(b)(1); 42 U.S.C. § 263a(d)(1)(E). The PT samples must be integrated with the laboratory's regular patient workload, and the tests must be performed by the same personnel who routinely do the testing, using the laboratory's routine testing method. 42 C.F.R. § 493.801(b)(1). The integration of PT samples must be attested to by the laboratory director and the individual who performs the testing. PT samples must be tested the same number of times as routine patient samples. 42 C.F.R. § 493.801(b)(2). Records documenting each step taken in the testing of PT samples are required. 42 C.F.R. § 493.801(b)(5).

A laboratory may not engage in inter-laboratory communications pertaining to PT results until after the due date by which the laboratory must report its results to the PT program. 42 C.F.R. § 493.801(b)(3). It must not refer PT samples or portions of PT samples to another laboratory for any analysis that it is certified to perform in its own laboratory. 42 U.S.C. § 263a(i); 42 C.F.R. § 493.801(b)(4). Until recently, the statute mandated that CMS revoke for at least one year the license of a laboratory that intentionally referred a PT sample to another laboratory for analysis. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.1840(b); *accord, Wade Pediatrics v. Dep't. of Health and Human Servs.*, 567 F.3d 1202, 1204 (10th Cir. 2009); *Lackawanna Medical Group Lab.*, DAB No. 1870 (2003).[3]

A laboratory must also have a qualified director (*see* 42 C.F.R. § 493.1405) who provides overall management and direction in accordance with 42 C.F.R. § 493.1407. 42 C.F.R. § 493.1403. Among the director's specific responsibilities, he/she must ensure that the laboratory is enrolled in an approved PT program, that the PT samples are tested as required, and that PT results are reviewed in order to identify problems. 42 C.F.R. § 493.1407.

Application of law to undisputed facts. The parties here agree on all material facts. Petitioner operated a clinical laboratory that, until September 2011, tested blood for the Rh factor.[4] Such testing is considered moderate complexity. P. Ex. 1 at 2 (Holeva Decl. ¶ 3). To meet its proficiency testing obligations, the lab enrolled in a testing program offered by the American Proficiency Institute (API). API sponsored periodic testing "events," which involved sending test samples to the lab. The lab was to integrate the

[3] This mandatory provision was in effect at the time CMS imposed sanctions in this case. Since then, Congress has amended CLIA. The statute now authorizes – but does not compel – CMS to revoke a referring laboratory's license. Pub. L. 112-202 (2012); *see* discussion, *infra*.

[4] The Rh (Rhesus) factor is a protein found in blood, and the test checks blood for its presence. The test is important for pregnant women, because serious problems can occur if a woman with Rh-negative blood is pregnant with a fetus that has Rh-positive blood.

samples into its normal testing routine, perform the tests, and send the results back to API. For the first testing event of 2011, API sent testing samples to the lab. A lab employee tested the samples, but, to verify her results, she then engaged in impermissible communications with another laboratory that was taking the same test. A February 3, 2011 entry in the lab's testing records documents this improper communication:

> Called Nanci about unsure results. Nanci said to call [San Angelo] location and compare results. After speaking with Heather Keeling, all of our results are the same. Submitted the results online.

CMS Ex. 3 at 3. The lab electronically submitted the test results to API at 4:08 p.m. on February 3, 2011. CMS Ex. 3 at 4.

Interviewed by a surveyor on October 5, 2011, the responsible employee (identified as "Testing Person 1") admitted that she contacted the San Angelo laboratory to compare results before she submitted her test report to API, although she also said that the labs independently arrived at the same results. CMS Ex. 2 at 4. The surveyor later spoke to personnel at the San Angelo lab, who confirmed that conversations occur between the two labs as to proficiency testing results, but that San Angelo personnel were "under the impression that the results were not discussed until after the results were submitted." CMS Ex. 2 at 4.[5]

Petitioner admits these facts. It explains that an employee was testing proficiency samples for the first time since her training, one year earlier. She obtained a result that she was unsure about and "was concerned that she had run the test incorrectly." Not aware of the statutory and regulatory restrictions, she called another lab to compare results and ensure that she had not made a mistake. According to Petitioner, the call to

[5] CMS also points to an obvious and unexplained change on the lab's answer sheet. The answer for sample Rh04 has been changed from positive to negative. CMS Ex. 3 at 3. CMS finds it "notable" and suspicious that the San Angelo lab also reported a negative result for Rh04, implying that Testing Person 1 may have changed her answer to conform with San Angelo's answer. CMS Br. at 10, *citing* CMS Ex. 3 at 3; CMS Ex. 4 at 6. Petitioner insists that the employee had already completed the test when she made her call to San Angelo, and denies that she changed any answers as a result of the unauthorized communication. CMS Ex. 5 at 3. For purposes of summary judgment, I accept Petitioner's representation, but I do not consider this a material fact.

verify the result "was an innocent error done by someone unaware of the prohibition regarding calling other sites." In any event, by the time of the survey, the lab no longer tested blood for the Rh factor. CMS Ex. 5 at 3; P. Br. at 5-6.

The parties also agree that, for the first and second testing events of 2011, the lab director did not sign required statements attesting that the PT samples were tested in the same manner as patient specimens. Her signature is not on the attestation statement submitted February 3, 2011, nor the statement submitted May 31, 2011. All lab director signature lines are left blank on these documents. CMS Ex. 3 at 4, 5, 7, 9. During the survey, the lab's clinic manager confirmed that the lab director had not signed the attestations. CMS Ex. 2 at 2. Again, Petitioner does not challenge these facts.

Thus, the lab violated both sections 493.801and 493.1403. In comparing the test results, Testing Person 1 did not follow the lab's routine testing methods, violating section 493.801(b)(1); the lab director did not attest that these samples or samples from a subsequent testing event were integrated into the lab's regular patient workload, violating section 493.801(b)(2). Most egregious, Testing Person 1 engaged in inter-laboratory communications pertaining to the test results for the first testing event, violating section 493.801(b)(3). Further, the lab director did not provide necessary management and direction; she did not ensure that samples were tested as required by sections 493.1403 and 493.1407.

B. CMS properly determined that the lab was not in compliance with two conditions of certification, and the seriousness of the deficiencies justify the sanctions imposed.

Petitioner admits that the lab "failed to ensure that a testing employee fully understood the process of PT and that its laboratory director completed the required review and paperwork for two events." P. Br. at 8. Petitioner even agrees that the violations "were not insignificant" and that they warranted corrective action. P. Br. at 8. Petitioner argues, however, that the violations were not serious enough to put conditions out and that the sanctions imposed are unjustifiably harsh.

According to Petitioner, nobody intended to violate CLIA regulations; rather, the testing employee was confused about PT procedures and the clinic manager was confused about the chain of command. P. Br. at 9. That Testing Employee 1 acted out of ignorance rather than malice does not alter the fact that she intentionally and willfully compared test results with those from another lab. Indeed, the Departmental Appeals Board has consistently rejected this line of defense where, as here, laboratory staff acted knowingly and voluntarily, without realizing that they violated CLIA requirements. *Victor Valley Cmty. Hospital/Clinical Lab.*, DAB No. 2340 at 7 (2010); *Wade Pediatrics*, DAB No. 2153 (2008), *aff'd Wade Pediatrics v. Dep't of Health and Human Servs., 567 F.3d 1202 (10 Cir. 2009)*; *Lackawanna Medical Group Lab.*, DAB No. 1870.

Moreover, Testing Employee 1 does not bear all responsibility for the improper consultation. Plainly, she was inadequately trained.[6] And where was the lab director in all of this? The individual who runs the test is not the only lab employee responsible for maintaining the integrity of the PT process. By regulation, the lab director must also attest to the "routine integration of the samples into the patient workload using the laboratory's routine methods." 42 C.F.R. § 493.801(b)(1). The lab director was thus at least equally responsible for protecting the integrity of the PT samples and the test, which she did not do. Further, the evidence establishes that she did not attest to the integrity of the process for at least two testing events, conducted four months apart. CMS Ex. 3 at 4, 5, 7, 9.

Similarly, that the lab did not ultimately change its answers following the improper communication does not excuse its conduct or make its actions less serious. *Victor Valley Cmty. Hospital/Clinical Lab.*, DAB No. 2340 at 11-13, *Wade Pediatrics*, DAB No. 2153 at 21.

As noted above, at the time of these events, CMS was required to revoke a laboratory's license if it intentionally referred a PT sample to another laboratory. For other types of deficiencies, CMS had (and still has) broad discretion to determine an appropriate sanction. 42 C.F.R. § 493.1800(a)(2)(iii); *Victor Valley Cmty. Hospital/Clinical Lab.*, DAB No. 2340 at 4; *see* 42 C.F.R. § 493.1804(d)(2) (directing CMS to consider, among other factors, the "nature, incidence, severity, and duration" of the noncompliance). CMS acted well within its discretion when it revoked the lab's CLIA certificate and canceled its approval to receive Medicare payments. In terms of the threat posed to the integrity of the PT process, the lab's collusion is comparable to sending its samples to another lab. Its actions fit within the analogy described by the Tenth Circuit in *Wade*:

> Wade is like the student who protests that he did not cheat on his exam because he did not hand in someone else's work but merely checked his answers against those of another student. But peering over the shoulder of another student in the middle of an exam to check one's answers is as much cheating as handing in someone else's work.

[6] The record shows that, unsure of her testing results, she consulted "Nanci," who gave her very bad advice. CMS Ex. 3 at 3. The record does not identify "Nanci's" relationship to the lab, nor does it explain why she gave such advice. Nor has the lab explained why Testing Employee 1 did not consult the lab director, who would have been the logical choice in a properly-supervised lab.

Wade Pediatrics, 567 F.3d at 1204-5; *Victor Valley Cmty. Hospital/Clinical Lab.*, DAB No. 2340 at 13. Here, the lab literally "checked [its] answers" against those of another. *See also Stanley Boykansky, M.D.*, DAB No. 1756 at 13 (2000) (where multiple labs reached identical results, the Board upheld the ALJ's finding unlawful communication that justified revoking a participating lab's CLIA certificate).

Petitioner complains that, in determining the sanction, CMS failed to consider all of the regulatory factors listed in 42 C.F.R. § 493.1804(d). That section lists factors that CMS may consider in determining the sanction. However, the regulation is explicit: CMS considers "*one or more*" of the listed factors, and CMS is not limited to the factors listed in the regulation. Thus, CMS could reasonably determine that the nature of the deficiencies and their relationship to each other justified the sanction, without regard to the other listed factors.

Finally, Petitioner argues that, because of a December 2012 amendment to CLIA, CMS may "no longer impose a sanction of suspension and revocation by simply citing to the mandatory revocation provision. . . ." P. Br. at 17. That legislation, referred to as the TEST Act, changed "shall" to "may" in section 263a(i)(4) of the statute, so that that section now reads:

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

(emphasis added) Pub. L. No. 112-202. Petitioner's argument fails for three reasons: 1) the survey took place more than two years prior to the statutory change and the sanctions were imposed about a year-and-a-half before the change; the amendment is not to be applied retroactively; 2) CLIA's mandatory provision did not apply in this case, which involves collusion, but not referral; and 3) the statutory change increases CMS's discretion, but does not preclude it from revoking a lab's CLIA certificate if it finds that the deficiencies cited warrant that sanction.

IV. Conclusion

Accepting as true all of Petitioner's factual assertions, I find that Petitioner violated two CLIA conditions: 42 C.F.R. §§ 493.801 and 493.1403. I therefore grant CMS's motion for summary judgment, and uphold the revocation of Petitioner's CLIA certificate.

/s/
Carolyn Cozad Hughes
Administrative Law Judge