Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Saint Elizabeth's Medical Center,
(CLIA: 24D0404612)

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-399

Decision No. CR2159

Date: June 17, 2010

DECISION

In this case, we revisit the question of what constitutes an "intentional referral" of proficiency testing (PT) samples to another laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a *et seq*.

Petitioner, St. Elizabeth's Medical Center (Petitioner or lab), is a CLIA-certified laboratory located in Wabasha, Minnesota. Petitioner appeals the decision of the Centers for Medicare and Medicaid Services (CMS) to revoke its CLIA certificate and cancel its approval to receive Medicare payments. CMS moves for summary judgment, which Petitioner opposes.

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 L. No. 100-578 (codified

as amended at 42 U.S.C. § 263a *et seq.* (1988)); *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. § 263(a)(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 Med., P.C.*, DAB No. 1951, at 2-3 (2004); *RNA Laboratories*, DAB No. 1820, at 3 (2002).

A laboratory that holds a CLIA certificate may perform moderate and high complexity tests but must participate in the PT program outlined in 42 C.F.R. Part 493, Subpart H. Under its provisions, each laboratory must enroll in an approved PT program that meets specific criteria set out at Subpart I of Part 493. 42 C.F.R. § 493.801. A laboratory performing high complexity testing "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).

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 same personnel who routinely do the testing must perform the tests, using the laboratory's routine testing method. 42 C.F.R. § 493.801(b)(1). The laboratory director and the individual who performs the testing must attest to the integration of PT samples. 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. § 263(a)(i); 42 C.F.R. § 493.801(b)(4). If a laboratory intentionally refers a PT sample to another laboratory for analysis, CMS must revoke its license for at least one year. 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 Med. Group Lab.*, DAB No. 1870 (2003).

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.

Here, CMS has determined that Petitioner improperly referred proficiency testing samples to another laboratory for testing and was therefore not in substantial compliance with three CLIA conditions: 42 C.F.R. §§ 493.801 (enrollment and testing of samples), 493.1201 (bacteriology), 493.1441 (laboratories performing high complexity testing; laboratory director). For this reason, CMS has revoked Petitioner's CLIA certificate and cancelled the laboratory's approval to receive Medicare payments for its services. CMS Ex. 4.

Petitioner appeals. CMS has filed a motion for summary judgment, which Petitioner opposes. With its motion and brief (CMS Br.), CMS submits five exhibits (CMS Exs. 1-5). With its response brief (P. Br.), Petitioner submits eight exhibits (P. Exs. 1-8). In an order dated December 18, 2009, I directed CMS to reply to Petitioner's response. CMS thereafter filed its reply (CMS Reply), and Petitioner has filed a sur-reply (P. Sur-reply).

II. Issues

I consider whether summary judgment is appropriate.

On the merits, the issue before me is whether Petitioner violated CLIA and its implementing regulations by "intentionally referring" PT samples to another laboratory.

III. Discussion

Summary Judgment. Summary judgment is appropriate if a case presents no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Illinois Knights Templar Home*, DAB No. 2274, at 3-4 (2009) (including cases cited therein); *White Lake Family Med., P.C.*, DAB No. 1951, at 10-12 (2004). The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr. v. Dep't of Health & Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing and Rehab. Ctr.*, DAB No. 1918 (2004).

> To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in

> its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact . . . .

Illinois Knights Templar, DAB No. 2274, at 4; *Livingston Care Ctr.*, DAB No. 1871, at 5 (2003).

In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Ctr.*, DAB 2132, at 2, 9 (2007); *Livingston Care Ctr.*, 388 F.3d at 172; *Guardian Health Care Ctr.*, DAB No. 1943, at 8 (2004); *but see Brightview*, DAB 2132, at 10 (holding entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). Moreover, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cf. Guardian Health Care Ctr.*, DAB No. 1943, at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts."); *Wade Pediatrics*, DAB No. 2153, at 18 (2008), *aff'd*, *Wade Pediatrics v. Dep't of Health and Human Servs.*, 567 F.3d at 1204; *White Lake Family Med., P.C.*, DAB No 1951, at 14 ("[A] dispute between the parties as to the correct conclusion to draw from undisputed facts is not an impediment to the entry of summary judgment.").

A. CMS is entitled to summary judgment, because the undisputed facts establish that, prior to submitting its PT testing results, the lab's medical technologist also tested the samples at a second laboratory and thus violated the statute (42 U.S.C. § 263a(i)(4)) and regulations (42 C.F.R. § 493.801(b)(4)).

For purposes of resolving this motion for summary judgment, I accept as true Petitioner's version of the facts. The lab received its PT samples from the College of American Pathologists (CAP) in February 2007. P. Ex. 8 at 1 (Hagstrom Decl. ¶ 2). The lab's employee, Medical Technologist Brenda Hagstrom, tested them. Ms. Hagstrom had never before participated in a PT event. After she ran the samples on her lab's analyzer, she took them to the near-by Wabasha Clinic and ran the samples on that laboratory's analyzer. P. Br. at 5; P. Ex. 8 at 1-2 (Hagstrom Decl. ¶¶ 1, 2, 3). She did this "for the sole purpose of validating the functionality of the Wabasha Clinic's analyzer. . . ." P. Ex. 8, at 2 (Hagstrom Decl. ¶ 7). According to Ms. Hagstrom, "on rare occasions," Petitioner used the Wabasha analyzer as a back-up when its own analyzer was not working. P. Ex. 8, at 1 (Hagstrom Decl. ¶ 3). Ms. Hagstrom did not compare or otherwise check the results of her lab's analyzer with the results from the Wabasha Clinic's analyzer. In fact, for some of the samples, the Wabasha analyzer failed to report any results. She did not re-run any of the samples on her own lab's analyzer based on the Wabasha results. She provided no information to anyone at the Wabasha Clinic. Finally, she did not know that

she was violating any statute or regulation and did not intend to cheat on the testing process. P. Ex. 8 at 2 (Hagstrom Decl. ¶¶ 5, 7, 8).

Thus, Petitioner concedes that, before returning the lab's testing results to CAP, its technologist intentionally and willfully took the PT samples to the Wabasha lab, and using that lab's equipment, she performed the analyses that she had performed at her own lab. Notwithstanding her motivation, these deliberate actions, by themselves, establish that she "intentionally referred" the PT samples to a second laboratory. In doing so, she violated the statute (42 U.S.C. § 263a(i)(4)) and regulations (42 C.F.R. § 493.801(b)(4)). Petitioner's license must therefore be revoked for at least one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.1840(b). *Wade Pediatrics*, DAB No. 2153; *Lackawanna Med. Group Lab.*, DAB No. 1870.

Petitioner nevertheless complains that CMS's position is overly harsh. Petitioner argues that the intent requirement of the statute and regulation is not met by what it characterizes as an inexperienced employee's innocent error, "wholly separate from the PT process." P. Sur-reply at 4.

I do not agree that an inexperienced employee bears all responsibility for the improper referral. Ms. Hagstrom was not the only lab employee responsible for maintaining the integrity of PT testing. 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 equally responsible for protecting the integrity of the PT samples and the test. Nor do I agree that Ms. Hagstrom's actions were "wholly separate from the PT process," since she used the same PT samples, re-testing them prior to the end of the testing period and before she returned her own lab's test results to CAP.

I recognize that the intent requirement is not met by the simple act of sending PT samples to another laboratory. As the *Wade* panel pointed out, for example, sending samples to another lab for disposal after the end of the testing event would not constitute an improper referral. Sending the samples to another lab by mistake, never intending that they be analyzed, would not constitute an improper referral. *Wade*, DAB No. 2153, at 13-15, 20. But where the lab's employee "voluntarily" took samples "that she knew were PT samples" to another laboratory and there "knowingly and voluntarily" tested them on equipment similar to her own lab's, her actions were not "accidental" or "mistaken." She "analyzed the samples" within the meaning of the statute and regulations. *See Wade*, DAB No. 2153, at 20, 21. That she sent the samples out "for training" purposes and to determine whether her equipment functioned properly, not "for analysis," did not change that result. As the Departmental Appeals Board (Board) pointed out, nothing in the statute or regulations requires CMS to determine that the referring laboratory *intended* to report the results obtained in the referral laboratory to the PT agency or organization. Similarly, in *Lackawanna*, where the lab deliberately sent its PT samples to another lab

because it thought that its own quality control policy required it to do so, the Board found that it "intentionally referred" its PT samples and that CMS justifiably revoked its certificate. *See also Wade*, 567 F.3d at 1204 ("But nothing in the text of § 263a(i)(4) suggests that a test-taker must pass off another lab's results before a violation has occurred. Under the statute's plain terms, any intentional 'referral' of a proficiency testing sample 'for analysis' in another lab is forbidden.").

B. The State Operations Manual does not limit the definition of "intentional referral" to a situation in which a laboratory submits another laboratory's results as its own.

Notwithstanding the multiple Board decisions and the Tenth Circuit opinion that say otherwise, Petitioner points to a provision in the State Operations Manual (SOM) and argues that "intentional referral" is limited to situations in which a laboratory has referred its PT samples to another lab for analysis and has "submitted the other laboratory's results as its own." SOM, Chapter 6, § 6061. That SOM provision cites the regulation, 42 C.F.R. § 493.801(b)(4), and tells surveyors not even to solicit a plan of corrections if the lab has submitted another lab's results. But just because submitting another lab's results will *always* violate the regulation (as the SOM plainly says) does not mean that no other conduct violates the regulation. The SOM simply does not list every situation in which the regulation is violated.

Moreover, not only is Petitioner's logic flawed, but its interpretation of the SOM provision would be inconsistent with the plain language -- not to mention the spirit -- of the statute and regulation. As the Tenth Circuit observed 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.

Wade, 567 F.3d at 1204.

Interpretive guidelines "must be read in light of the regulations and cannot override them." *Sonali Diagnostic Lab.*, DAB No. 2008, at 8, n.7 (2006) (*citing Alden-Princeton Rehab. and Health Care Ctr.*, DAB No. 1873, at 8 (2003)). The SOM provision describes one particularly egregious example of an intentional referral but, consistent with the statute and regulation, does not suggest that it is the only example of an intentional referral.

IV. Conclusion

Accepting as true all of Petitioner's factual assertions, I find that Petitioner violated 42 U.S.C. § 263a(i)(4) and 42 C.F.R. § 493.801(b)(4), because it intentionally referred its PT samples to another lab for analysis. 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