Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Family Medical Center
(CLIA: 24D0405950)

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-129

Decision No. CR2402

Date: July 27, 2011

DECISION

I sustain the Centers for Medicare and Medicaid Services' (CMS) determination to revoke the certificate of registration issued to Petitioner, Family Medical Center, to engage in the testing of human specimens pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[1] 42 U.S.C. § 263a *et seq*. Pursuant to 42 C.F.R. §§ 493.1840(e) and 493.1844(d)(2), Petitioner's CLIA certificate is revoked for at least one year effective the date of this decision.[2]

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[1] Codified at 42 U.S.C. §§ 263a, 1302, 1395x(e). "CLIA" when used in this decision refers to both statutory and regulatory provisions governing the program, unless otherwise indicated.

[2] I note that 42 C.F.R. § 493.1840(d)(2) provides that the revocation of a CLIA certificate becomes effective on the date that the Administrative Law Judge (ALJ) upholds the decision, unless the lab's deficiencies pose immediate jeopardy. In this case, although CMS found that Petitioner's deficiencies posed immediate jeopardy, CMS notified Petitioner that the effective date of the sanctions would be the date of the ALJ decision. CMS Ex. 3, at 3; CMS Ex. 5, at 3.

I. Background

Petitioner is a Minnesota laboratory certified under CLIA to perform testing in the subspecialty of routine chemistry, including tests such as whole blood glucose and hemoglobin A1c testing. CMS Ex. 1, at 2. To maintain this certification, a laboratory such as Petitioner must periodically undergo proficiency testing, (PT) in which the laboratory's reported results are reviewed and assessed for acceptable accuracy. *See* 42 C.F.R. §§ 493.801 - 493.959. Petitioner enrolled in a CLIA certified proficiency testing program administered by the College of American Pathologists (CAP).

On February 2, 2010, the CAP sent Petitioner several specimens for proficiency testing. The specimens included a sample labeled "WBG-01" (the PT sample) that was to be subjected to a whole blood glucose test, and Petitioner was required to report its results to the CAP. Petitioner's staff twice tested the PT sample, mistakenly performing a hemoglobin A1c test rather than a whole blood glucose test and each time received an error code. On February 3, 2010, Petitioner sent the PT sample to another laboratory, Quest Diagnostics (Quest or reference lab), and requested hemoglobin A1c testing. P. Br. at 2; P. Ex. 1, at 2; CMS Ex. 2, at 1, 3, 5. Quest notified CMS by letter dated February 5, 2010, that it received the PT sample from Petitioner who requested that Quest conduct a hemoglobin A1c analysis on the PT sample. CMS Ex. 2. Quest further reported to CMS that the requisition form identified the name of the patient as "CAP, SURVEY." CMS Ex. 2, at 1, 3.

Based on the information from Quest, on April 13, 2010, CMS conducted a complaint survey and found that Petitioner was not in compliance with several applicable CLIA conditions of participation. CMS Ex. 1. CMS notified Petitioner that Petitioner improperly referred proficiency testing samples to another laboratory for testing and was therefore not in substantial compliance with two CLIA conditions: 42 C.F.R. §§ 493.801 (enrollment and testing of samples), and 493.1403 (laboratories performing moderate complexity testing; laboratory director). For this reason, CMS revoked Petitioner's CLIA certificate and cancelled the laboratory's approval to receive Medicare payments for its services. CMS Exs. 3, 5.

By letter dated December 1, 2010, Petitioner requested an ALJ hearing and on December 9, 2010, an Acknowledgement and Initial Docketing Order (Order) was issued at my direction. In accordance with the procedural schedule set out in my Order, CMS filed a motion for summary judgment and Petitioner filed an opposition. With its motion and brief (CMS Br.), CMS submitted five exhibits (CMS Exs. 1-5). With its response brief (P. Br.), Petitioner submitted one exhibit (P. Ex. 1).

II. Issue

The issue in this case is whether the undisputed facts establish that Petitioner violated CLIA and its implementing regulations by "intentionally referring" PT samples to another laboratory.

III. Controlling Statutes and Regulations

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 Medicine., 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 moderate 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. Department of Health and Human Services*, 567 F.3d 1202, 1204 (10th Cir. 2009); *Lackawanna Medical 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.

IV. Findings and Conclusions

I find the following facts are undisputed:

1. On February 2, 2010, Petitioner received several PT samples, including a sample labeled "WBG-01," the PT sample that was to be subjected to a whole blood glucose test. P. Br. at 2; P. Ex. 1, at 1.

2. Petitioner was at that time certified to perform testing in the subspecialty of routine chemistry, including both whole blood glucose and hemoglobin A1c tests. CMS. Ex. 1, at 2.

3. Petitioner's employees mistakenly performed a hemoglobin A1c test rather than a whole blood glucose test on the PT sample on two occasions, each time resulting in an error code. P. Br. at 2; P. Ex. 1, at 1.

4. When a patient sample receives multiple error codes, Petitioner's policy is to send it to a reference laboratory for analysis. It is Petitioner's policy to treat PT samples in the same manner as patient samples. P. Ex. 1, at 2; P. Br. at 2.

5. After receiving two error codes, Petitioner's Lab Coordinator sent the PT sample to Quest and requested it perform a hemoglobin A1c test. P. Ex. 1, at 2 (" . . . I sent the PT sample to Quest Laboratory to be analyzed on or about February 3, 2010."); P. Br. at 2 ("[O]n February 3, 2010, after obtaining the second error code result, Ms. Strahl sent the PT sample to [Quest] to be tested."); CMS Ex. 1, at 2; CMS Ex. 2.

6. A laboratory must not intentionally send PT samples, or portions of samples, to another laboratory for analysis that it is certified to perform in its own laboratory. 42 C.F.R. § 493.801(b)(4).

7. Petitioner intended to send and did send the PT sample to another laboratory to perform a hemoglobin A1c test analysis, which Petitioner is certified to perform, in violation of 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1804(b).

8. CMS *must* revoke for at least a year Petitioner's CLIA certification because it "intentionally referred" a PT sample to another laboratory "for analysis." 42 U.S.C. § 263a; *Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D.*, DAB No. 2340, 3-4 (2010).

9. There are no disputed issues of material fact and summary disposition is therefore appropriate in this matter. *Brightview Care Center*, DAB No. 2132 (2007); *Residence at Kensington Place*, DAB No. 1963 (2005); *Community Hospital of Long Beach*, DAB No. 1928 (2004); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004).

V. Discussion

Pursuant to 42 C.F.R. § 1844(f) it is presumed that Petitioner has a right to a hearing in this case. *See Garden City Medical Clinic*, DAB No. 1763 (2001), *citing* 42 U.S.C. § 263a(i)(1) and 42 C.F.R. § 493.1844(a). However, 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 Medicine., 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 Center. v. Department of Health & Human Services*, 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. Center*, DAB No. 1918 (2004). The rule may be stated succinctly thus:

> 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 Center*, 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 Center,* DAB No. 2132, at 2, 9; *Livingston Care Center*, 388 F.3d at 172; *Guardian Health Care Center,* DAB No. 1943, at 8 (2004); *but see Brightview*, DAB No. 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 Center*, 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. Department of Health and Human Services*, 567 F.3d at 1204; *White Lake Family Medicine., 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.").

For purposes of resolving this motion for summary judgment, I accept as true Petitioner's version of the facts. On February 2, 2010, Petitioner received its PT samples from the College of American Pathologists (CAP), including one PT sample marked "WBG-01." P. Br. at 2; P. Ex. 1, at 1. The PT sample marked "WBG-01" was to be subjected to a whole blood glucose test, but an unnamed lab technologist mistakenly performed a hemoglobin A1c test on the sample which produced an error code rather than a test result. *Id*. The unnamed lab technologist brought the sample to another employee, Lab Coordinator Roberta Strahl. *Id*. Without checking the label to determine the appropriate test, Ms. Strahl conducted a second hemoglobin A1c test on the PT sample rather than the whole blood glucose test, and she also received an error code instead of a result. *Id*.

After receiving the second error code, on February 3, 2010, Ms. Strahl sent the PT sample to their reference lab, Quest, for additional testing. When Ms. Strahl "sent the PT sample to Quest, [she] believed [she] was complying with [Petitioner's] policy and with the CLIA requirement that PT samples be treated in the same way as patient samples are treated and did not realize that [her] action was not in compliance with [Petitioner's] policy or CLIA." P. Ex. 1, at 2; P. Br. at 2.

On February 4, 2010, when reviewing the PT samples, Ms. Strahl noticed that the PT sample for whole blood glucose testing was not among the other PT samples. At that point, Ms. Strahl recognized that she likely sent the whole blood glucose sample to the reference lab. Further, she realized that the reason for the error code was that Petitioner had performed the wrong test on the PT sample and therefore she should not have sent

the PT sample to the reference lab. Ms. Strahl opined that the PT sample "likely would have yielded normal results had it simply been subjected to the proper test, and therefore required no additional analysis [by the reference lab]." P. Ex. 1, at 2; P. Br. at 2-3. She immediately contacted the reference lab and asked them to return the PT sample. Quest explained that it could not return the PT Sample because it was a survey sample. *Id*. In Petitioner's report to the American Proficiency Institute of its February 2010 PT survey, Petitioner reported no result for the WBG-01 PT sample. *Id*.

Both parties agree that Petitioner referred the PT sample to Quest. The parties' arguments, however, center on whether the referral was "intentional." Petitioner argues that the referral was not "intentional" in the respect that its Lab Coordinator did not intend to violate the regulation. Rather, argues Petitioner, its goal was quite the opposite: according to Petitioner, its Lab Coordinator referred the PT sample to the reference lab with the specific intent to *comply* with Petitioner's policy and CLIA requirements to treat PT samples in the same manner as it tests patient specimens. P. Br. at 8; P. Ex. 1, at 2.

Petitioner contends that the statute's "intentionality" requirement includes both "knowing" and "willful" components, and that although Petitioner may have knowingly referred the PT sample to the reference lab, CMS has failed to proffer evidence that Petitioner "willfully" referred the PT sample to Quest. Petitioner bases this argument principally on the Merriam Webster definitions and synonyms for the term "willful."[3] P. Br. at 6-7. Petitioner provides several synonyms for the term and asserts that "[e]ach of these terms connotes a mental state far beyond that encompassed by 'knowing,' and indeed each suggests some degree of intent not to adhere to a rule or directive." P. Br. at 7. Petitioner concludes that in order to willfully refer a PT sample to another laboratory, it must have done so with "intent to circumvent or disobey CLIA's proficiency testing requirements." *Id*.

There are a number of cases that address the issue of "intentionality" in the context of this statute. Most recently, the Departmental Appeals Board (Board) in *Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D.*, DAB No. 2340 (2010), explained:

> [T]he very fact that Victor Valley plainly marked the samples as PT makes it clear that here, as in *Wade*, there was 'was no mistake, accident,

[3] In Petitioner's attempt to create a factual dispute as to the intent of Petitioner, it relies on *Vandalia Park* DAB No. 1939 (2004). P. Br. at 5-6. *Vandalia Park*, however, has nothing to do with the CLIA statute or regulations nor does it define the term "willful" in any sense favorable to Petitioner. *Vandalia Park* only notes that under certain circumstances, "willful" may sometimes require a finding of fact. The definition of "intentional" in respect to the case before me is an application of law and not an issue of disputed sentient fact.

> negligence or recklessness' about the referral of PT samples to [another laboratory] for analysis. Victor Valley knew it was referring out PT samples and willed, based on its requisition, that the PT samples be subjected to analysis. The referral was thus made knowingly and willfully and was intentional within the meaning of CLIA's requirements.

Victor Valley, DAB No. 2340, at 8, *citing Wade Pediatrics*, DAB No. 2153 (2008), *aff'd, Wade Pediatrics v. Department of Health & Human Services*, 567 F.3d 1202 (10th Cir. 2009).

Victor Valley is consistent with the Board's previous position on the issue. The Board's decision in *Wade Pediatrics* noted that the CLIA regulations do not specifically define "intentional" referral, but do define "intentional violation" in general to mean "knowing and willful" noncompliance with any CLIA condition. *Wade Pediatrics*, DAB No. 2153 (2008); 42 C.F.R. § 493.2. Petitioner argues that it referred the PT sample to Quest with the specific intent to follow the regulation to treat PT samples the same as other samples. However, the laboratory in *Wade* also contended that its PT sample referral to another laboratory for analysis was not made with intent to violate the law, but to improve its testing standards. The Board found this argument did not demonstrate that the referral was unintentional within the meaning of CLIA. The Tenth Circuit upheld the Board's decision and stated:

> Even assuming Wade's *ultimate* or *end* intent was to improve its work product, as a *means* of effecting that intent Wade surely referred its proficiency test results "knowingly and willfully" to [another laboratory]. Wade does not suggest, for example, that its technician negligently left the lab's proficiency testing samples at [the other laboratory] and [the other laboratory] went ahead, without Wade's knowledge, to analyze them. Instead, it is undisputed that Wade's technician took the lab's proficiency testing samples to [the other laboratory] with the express purpose of testing them there-that is, with the express purpose of referring them for analysis. There was no mistake, accident, negligence or recklessness about it. And under the statute's plain language, such a "knowing and willful" action is sufficient to trigger liability, even if it was undertaken only in service of some further and ultimate intent. Simply put, Wade is responsible for its intended *means*, whatever its intended *ends* might have been.

567 F.3d at 1205 (emphasis in original).

Similarly in *Lackawanna Medical Group Laboratory*, DAB No. 1870 (2003), the Board rejected the position that an intent to carry out a legal purpose in referring out a PT sample does not establish that the referral is not "intentional" for purposes of section 493.801(b)(1). *Id.* at 9-11.

Petitioner's argument that when any sample receives multiple error codes it sends the sample to a reference laboratory, and thus was simply intending to follow the rule to treat PT samples like any other patient sample, is clearly invalidated by *Wade, Lackawanna,* and *Victor Valley*. It is irrelevant whether Petitioner's intended *end* was benign, or even benevolent. Petitioner is responsible for its intended *means* of following its reference policy by knowing and willfully sending the PT sample to its reference lab for analysis. That action is sufficient to trigger liability.

Petitioner argues that the referral was accidental in the sense that it "accidentally" performed the wrong test on the PT sample, thus creating a sequence of events leading to the intentional referral to Quest. It is Petitioner's position that but for the mistakenly-conducted test, the referral would not have been initiated. P. Br. at 2. 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 in this case, where Petitioner referred what it knew to be a PT sample to another laboratory and requested that laboratory perform an analysis, that referral was not "accidental" or "mistaken" under the CLIA statutes and regulations, and as those statutes and regulations have been interpreted consistently in the case law of this forum. *See Wade*, DAB No. 2153, at 20, 21; *Victor Valley*, DAB No. 2340, at 8, 13-14. The law is very clear: unless such a referral is accidental or the result of a mistake such as a misrouting of a sample or something suggesting that the referral for analysis was not intended, then the referral is a violation. The motive or purpose for the referral is immaterial, and in this case that means that Petitioner's efforts to establish a question of fact surrounding its motive in making the referral to Quest do not create a genuine issue of material fact.

Petitioner does not dispute that it is certified under CLIA to perform testing in the subspecialty of routine chemistry, including tests such as whole blood glucose and hemoglobin A1c testing. Petitioner concedes that it received PT samples from the CAP including a PT sample for a whole blood glucose test. Petitioner openly admits that it intended to send the PT sample to another lab for analysis. Petitioner acknowledges that it sent that PT sample to another lab and requested analysis. The undisputed facts clearly illustrate that, without reference to or consideration of its motivation in doing so, this deliberate action established that Petitioner "intentionally referred" the PT sample to "another laboratory for analysis which it is certified to perform." 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.1840(b). In doing so, Petitioner 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 Medical Group Lab.*, DAB No. 1870.

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 sample to another lab for analysis which it is certified to perform. I therefore grant CMS's motion for summary judgment, and uphold the revocation of Petitioner's CLIA certificate.

/s/
Richard J. Smith
Administrative Law Judge