Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Victor Valley Community Hospital/Clinical Laboratory
and Tomasz Pawlowski, M.D.
Docket No. A-10-74
Decision No. 2340
October 22, 2010

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

By submission dated July 8, 2010, Victor Valley Community Hospital/Clinical Laboratory (Victor Valley) and its laboratory director, Dr. Tomasz Pawlowski, appealed the June 15, 2010 decision of Administrative Law Judge (ALJ) Alfonso J. Montano upholding the Center for Medicare & Medicaid Services' (CMS's) revocation of Victor Valley's certificate to operate as a clinical laboratory. *Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D.,* DAB CR2156 (2010) (ALJ Decision). By submission dated August 11, 2010, CMS also appealed the ALJ Decision.

The ALJ upheld the laboratory's revocation running for one year from the date of the ALJ Decision and held that Victor Valley's owners and operators, including Dr. Pawlowski, are barred from owning or operating a clinical laboratory for two years from the same date. ALJ Decision at 1. For the reasons explained below, we uphold the ALJ Decision.

Case Background

The undisputed facts are set out in detail in the ALJ Decision with record citations and summarized here for the convenience of the reader. (Disputed facts are discussed in the analysis section.) During the period in question, Dr. Pawlowski served as laboratory director of Victor Valley in Victorville, California. Based on its accreditation with the American Osteopathic Association, Victor Valley was certified by CMS to perform bacteriological testing and deemed to meet the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Pub. L. No. 100-578, 101 Stat. 2903 (1988) (codified as 42 U.S.C. § 263a). ALJ Decision at 2. Maintaining its certification required Victor Valley to perform satisfactorily in proficiency testing (PT) and Victor Valley enrolled in a PT program with the College of American Pathologists (CAP).

On May 27, 2007, CAP sent Victor Valley two PT specimens for testing with results to be reported by June 29, 2007. Victor Valley performed tests required to be done on the PT samples but determined that Victor Valley was not able to perform in-house additional testing steps that would have been necessary to provide complete characterization of the bacteriological samples.[1] A Victor Valley laboratory technician then sent the PT samples on June 14, 2007 to another clinical laboratory, Quest Diagnostics (Quest), with a requisition asking that Quest perform testing procedures on the samples. The samples sent to Quest were clearly marked as proficiency testing samples rather than patient samples. Quest notified CMS, by telephone on June 18, 2007 and by letter dated June 22, 2007, that Victor Valley had sent it PT samples for analysis.

Legal authorities

CLIA and its implementing regulations at 42 C.F.R. Part 493 establish conditions that laboratories must meet to be certified to perform clinical diagnostic testing on human specimens and to bill for services under the Medicare program. *See* 42 C.F.R. § 493.1. Congress enacted CLIA to ensure that the results of tests are reliable and accurate. H.R. Rep. No. 899, 100th Cong., 2nd Sess. 8 (1988). The Secretary of the Department of Health and Human Services (HHS) administers CLIA, through CMS.

With limited exceptions not relevant here, a laboratory performing such tests is not in compliance with CLIA requirements unless it has one of the certificates specified in the regulations. 42 C.F.R. §§ 493.3, 493.5(c). Each certification condition represents a general requirement that must be met, and the standards set out under the conditions constitute their specific components. *See Associated Internists, P.C.*, DAB No. 2298 (2010); *Edison Medical Laboratories*, DAB No. 1713, at 2 (1999), *aff'd, Edison Medical Lab. v. Thompson*, 250 F.3d 735 (3rd Cir. 2001). Noncompliance with one or more individual standards relating to a condition may or may not be serious enough to cause a condition level deficiency. *See* 42 C.F.R. §§ 493.2, 493.1812-16; 57 Fed. Reg. 7218, 7219 (Feb. 28, 1992). The action CMS takes if a survey finds that a laboratory is not in compliance with the requirements depends in part on (1) whether the deficiencies are only at the level of one or more standards or rise to the level of noncompliance with one or more conditions and (2) whether the deficiencies pose an immediate jeopardy. 42 C.F.R. §§ 493.1812 to 493.1816.

The CLIA regulations define a condition level deficiency as "noncompliance with one or more condition level requirements," that is, any of the requirements identified as conditions in subparts G through Q of Part 493. 42 C.F.R. § 493.2. Where none of the

[1] As discussed in more detail below, Victor Valley did not dispute that the testing to be done by Quest included repeating the work done by Victor Valley before proceeding to any additional testing. Also, Victor Valley did not dispute that it was *certified* to perform the tests it requested from Quest because its certification was for the entire subspecialty of bacteriology, even though it was not equipped to perform some of them at the time in question,. *See generally* CMS Ex. 2, at 3, 11.

deficiencies are condition level deficiencies, the laboratory must submit a plan of correction and show on revisit that it has corrected the deficiencies. 42 C.F.R. § 493.1816.

Each certified laboratory performing nonwaived tests must enroll in and successfully participate in a PT program approved by HHS. 42 C.F.R. Part 493, subparts H, I. Organizations or state agencies that are approved to conduct PT programs must be able to assure the quality of test samples, distribute the samples, appropriately evaluate and score the testing results, and identify performance problems in a timely manner. *Id*. The following is identified as a condition of participation related to enrollment in a PT program and testing of samples:

> Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens.

42 C.F.R. § 493.801 (lead-in language).

Two standards under this condition deal with enrollment in a PT program and testing of PT samples with patient specimens. The testing standard requires documenting that tests on PT samples are performed using the laboratory's routine methods and also includes the following provisions:

> (1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods . . . .
> (2) The laboratory must test samples the same number of times that it routinely tests patient samples.
> (3) Laboratories that perform tests on proficiency testing samples must not engage in *any inter-laboratory communications pertaining to the results of proficiency testing sample(s)* until after the dates by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. . . .
> (4) The laboratory *must not send PT samples* or portions of samples to another laboratory *for any analysis which it is certified to perform* in its own laboratory. Any laboratory that CMS determines *intentionally* referred its proficiency testing samples to another laboratory for analysis *will have* its certification revoked for at least a year.

42 C.F.R. § 493.801(b)(emphasis added). Section 493.1840(b) further provides that, "[i]f CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty." The requirement for testing PT samples with patient specimens and the requirement that CMS *must* revoke for at least a year the certification of any laboratory that it determines "intentionally referred" PT samples to another laboratory "for analysis" are based on CLIA statutory provisions. 42 U.S.C. § 263a.

Besides the mandatory revocation requirement for intentional referrals, CMS retains broad discretion under CLIA to take action to ensure that laboratories remain in or promptly return to compliance with CLIA requirements. 42 C.F.R. § 493.1800(a)(2)(iii); *see also* 57 Fed. Reg. at 7224. A laboratory's failure to comply with even a single applicable condition is a ground for CMS to impose one or more principal or alternative sanctions. 42 C.F.R. § 493.1806(a); *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). Principal sanctions that CMS may impose include suspension, limitation, or revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions include directed plans of correction, state on-site monitoring, and civil money penalties. 42 C.F.R. § 493.1806(c).

An additional condition of participation requires the laboratory to participate successfully in a CMS-approved PT program. 42 C.F.R. § 493.803. If the laboratory fails to participate successfully, "CMS imposes sanctions" which include principal and/or alternative sanctions. 42 C.F.R. § 493.803(b). In non-immediate jeopardy situations, CMS may, in certain circumstances, instead direct personnel training or technical assistance. 42 C.F.R. § 493.803(c).

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies, including the suspension, limitation, or revocation of the laboratory's CLIA certificate, and may request review of the ALJ's decision by the Departmental Appeals Board. CLIA regulations at 42 C.F.R. §§ 493.1844(a)(2) and (3) incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, subparts D and E. *See also* 42 U.S.C. § 263a(i)(1).

Issues

(1) CMS takes exception to the following single finding of fact in the ALJ Decision:

> 10. By sending proficiency testing samples to Quest as it would with regular patient test samples, Victor Valley intended to comply with 42 C.F.R. § 493.801(b)(1), which requires treating proficiency testing samples the same as those of regular patient workload.

CMS Appeal of June 15, 2010 Decision of ALJ and Response to Appeal of Victor Valley (CMS Appeal) at 2, quoting ALJ Decision at 7 (citations omitted). CMS contends that this finding is not supported by substantial evidence in the record as a whole and conflicts with other statements in the ALJ Decision. CMS Appeal at 9-13. CMS also argues that the revocation must be upheld regardless of whether the referral was intentional because Victor Valley did not deny facts that establish condition level deficiencies authorizing revocation.

(2) Victor Valley does not challenge any finding of fact but argues that the ALJ's conclusions of law 5 through 19 are incorrect and require reversal. Victor Valley Appeal at 1. The contested conclusions are the following:

> 5. A laboratory must not send proficiency testing samples, or portions of samples, to another laboratory, intentionally or unintentionally, for analysis that it is certified to perform in its own laboratory, or for any other reason. 42 C.F.R. § 493.801(b)(4).
> 6. A laboratory that obtains analysis of its proficiency testing samples from another laboratory, regardless of whether the laboratory reports to the proficiency testing agency its own results or the results obtained from the other laboratory, violates 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1804(b).
> 7. Victor Valley's laboratory technician intentionally referred two proficiency samples to Quest for testing.
> 8. The fact that the laboratory technician committed the act of referring Petitioner's proficiency testing samples to another laboratory for analysis, with the knowledge the samples were proficiency testing samples, is sufficient evidence to show that Petitioner violated 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1804(b).
> 9. It is irrelevant that the laboratory technician was unaware that the law prohibits her referral of the proficiency testing samples to Quest.
> 10. If a laboratory has intentionally referred a proficiency testing sample to another laboratory, that laboratory's motive for referring the sample is irrelevant as a defense against CMS's revocation of its CLIA certificate.
> 11. The fact that Quest did not test the proficiency samples that Victor Valley referred to it for analysis, or that Victor Valley did not report to CAP any test results from Quest is irrelevant and not a defense to a violation of 42 C.F.R. § 493.801(b)(4).
> 12. The laboratory technician's motive in referring the proficiency testing samples to another laboratory for analysis is irrelevant under 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1804(b). *See Wade Pediatrics*, DAB No. 2153 (2008), *aff'd, Wade Pediatrics v. Dep't of Health & Human Servs.*, 567 F.3d 1202 (10th Cir. 2009).
> 13. That Quest did not retest the two proficiency specimens it received

> from Victor Valley is irrelevant. Quest contacted CMS as was required, pursuant to 42 C.F.R. § 493.801(b)(4).
> 14. Victor Valley's referral of proficiency testing specimens to a reference laboratory was intentional and was not inadvertent.
> 15. Under CLIA and applicable regulations, a laboratory intentionally submits a proficiency testing specimen to a reference laboratory when it does so deliberately, not inadvertently.
> 16. Victor Valley, through the action of its laboratory technician, intentionally referred its proficiency testing samples to another laboratory for analysis in violation of 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1804(b).
> 17. Victor Valley's lack of "knowing and willful noncompliance with CLIA conditions" is irrelevant.
> 18. Victor Valley violated 42 C.F.R. § 493.801(b)(4) by admittedly sending proficiency testing samples to another laboratory.
> 19. No conflict exists between 42 C.F.R. § 493.801(b)(1), which requires testing proficiency testing samples in the laboratory, with regular patient workload, using regular laboratory personnel and procedures, and 42 C.F.R. § 493.801(b)(4), which establishes an absolute ban on sending out proficiency testing samples to another laboratory.

ALJ Decision at 8-10. Dr. Pawlowski did not appeal the ALJ Decision and Victor Valley did not challenge the ALJ's conclusions relating to condition level deficiencies under the laboratory director requirements. ALJ Decision at 10.

Standard of review

Our standard of review of an ALJ decision on a disputed issue of law is whether the ALJ decision is erroneous. Our standard of review on a disputed issue of fact is whether the ALJ decision as to that fact is supported by substantial evidence in the record. *See* Guidelines - Appellate Review of Decisions of Administrative Law Judges in Cases Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Related Statutes (http://www.hhs.gov/dab/divisions/appellate/guidelines/clia.html)); *Mark Gary Hertzberg*, DAB No. 1805 (2001); *US Bio-Chem Medical Laboratories, Inc.*, DAB No. 1731 (2000).

Analysis

We first address Victor Valley's claims that the ALJ erred in his understanding of the law that led to his conclusion that Victor Valley's referral of the PT samples was intentional as the concept applies to the CLIA requirements at issue. We then consider CMS's challenge to the identified finding of fact. Finally, we discuss CMS's contentions that revocation was authorized even were the referral not intentional (which we find it was).

1. The ALJ did not err in concluding that Victor Valley's referral of PT samples to Quest was intentional within the meaning of the statute and regulations.

As noted above, the ALJ concluded that Victor Valley intentionally referred the two PT samples to Quest for analysis. ALJ Decision at 25. The gravamen of Victor Valley's appeal is its claim that its referral of PT samples to an outside laboratory should not have been treated as "intentional" within the meaning of CLIA and the implementing regulations. Victor Valley Appeal at 3-7. In support of that position, Victor Valley offers several arguments.

First, Victor Valley argues that a referral can be intentional only if CMS proves that the laboratory "knew it was violating the applicable statute and regulation." *Id.* at 7. Here, Victor Valley argues that "[i]mportantly" the ALJ found that Victor Valley's intent in referring out the samples was to comply with the requirement to treat them the same as patient samples. *Id.* at 2. Victor Valley points to the Board's decision in *Wade Pediatrics* as defining "intentional" in this context to mean "knowing and willful." *Id.* at 3, 6, *citing Wade Pediatrics*, DAB No. 2153 (2008), *aff'd*, *Wade Pediatrics v. Dep't of Health & Human Servs.*, 567 F.3d 1202 (10th Cir. 2009). The Board's decision 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. 42 C.F.R. § 493.2. A review of the Board's *Wade* decision, however, makes clear that the Board did not conclude that a knowing and willful act need be one taken with the specific intent to violate the law.

In *Wade*, the laboratory had a history of failing proficiency tests and was advised to seek technical assistance (training and comparison testing) from another laboratory. Wade did so, but then also sent later PT samples to the other laboratory for analysis. Wade contended, in an argument analogous to that of Victor Valley here, that, far from intending to violate the law by referring out the PT samples, it meant to comply with the advice to improve its testing standards by seeking comparison testing results. The Board's decision that this argument did not demonstrate that the referral was unintentional was upheld by the Court, which 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 Muskogee. Wade does not suggest, for example, that its technician negligently left the lab's proficiency testing samples at Muskogee and Muskogee 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 Muskogee 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).

We explain below why the record does not support a factual finding that Victor Valley's intent in making the referral was to comply with section 493.801(b)(1), but the *Wade* Court's analysis makes clear that Victor Valley would still be responsible for an intentional referral even had compliance with that provision been shown to be its ultimate end. 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). *Lackawanna* at 9-11. Lackawanna allegedly referred PT samples for parallel testing by another laboratory believing it was required to do so by its quality control policy. *Id*. at 7. An ultimate intent to accomplish some positive purpose simply does not make the act of knowingly referring out a PT sample unintentional.

Victor Valley also repeatedly points to the fact that the samples were clearly marked as PT when they were sent to Quest as demonstrating that Victor Valley had no intent to "trick" Quest or to hide the referral. *See, e.g.*, Tr. at 47-48; Victor Valley Appeal at 1 (laboratory technician "intended to sent the two [PT] samples to Quest and marked them as 'test, proficiency.'"). Victor Valley did not, however, identify any basis for us to conclude that an intentional referral can only be one made deceptively or secretly. On the contrary, the 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, negligence or recklessness" about the referral of PT samples to Quest 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 suggests, however, that we should adopt a different standard for finding the laboratory's referral to be knowing and willful, i.e., that the laboratory knew its action violated the law, based on a Ninth Circuit decision involving charges of unlawful remuneration under federal anti-kickback law. Victor Valley Appeal at 6, citing *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995). The *Hanlester* Court required the government to show that each participant in an arrangement resulting in kickbacks knew of and had a specific intent to violate the applicable provisions. Violations of the anti-kickback provisions are the basis for civil money penalties and exclusions imposed by the Inspector General. They are entirely distinct from the regulatory requirements derived from CLIA.

In any case, even we viewed the issue addressed by the Ninth Circuit decision in *Hanlester* as analogous to the revocation of Victor Valley's CLIA certificate here (which we do not), that decision has been rejected by the majority of other Circuits considering its holding on mens rea. For example, the Second Circuit declined to reach the issue of actual intent to violate the anti-kickback statute in a 2002 case, noting the division among the Circuits on that point, citing a comparison of "*United States v. Starks*, 157 F.3d 833, 837-39 (11th Cir.1998) (knowledge of statute not required); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir.1998) (same); *United States v. Jain*, 93 F.3d 436, 439-41 (8th Cir.1996) (same), *cert. denied*, 520 U.S. 1273, 117 S.Ct. 2452, 138 L.Ed.2d 210 (1997), *with Hanlester Network v. Shalala*, 51 F.3d 1390, 1399-1400 (9th Cir.1995) (knowledge of statute required)." *U.S. v. Mittal*, 36 F. App'x 20 (2nd Cir. 2002). We therefore decline to extend the *Hanlester* holding to the present context.

Victor Valley's theory is in essence that conflicting regulations put it in an untenable position because complying with the requirement in the introductory language of section 493.801 to treat the PT samples in the way as patient specimens compels the laboratory to violate the prohibition in section 493.801(b)(4) on referring out PT samples for analysis. Victor Valley Appeal at 2-3. Therefore, Victor Valley reasons, it is unfair to treat an effort to comply with one regulatory provision as an intentional violation of another. This theory is both disingenuous and based on a false premise.

The argument is disingenuous because it ignores the undisputed fact (discussed further in the next section) that Victor Valley adopted an express policy against referring out PT samples for any reason. This fact undermines the claim that Victor Valley genuinely found itself in a dilemma caused by a wish to comply with regulatory provisions it viewed as in conflict. Furthermore, had Victor Valley actually been puzzled as to the proper course of action in dealing with testing PT samples when similar patient samples would be referred out for further testing, it could have contacted either the CAP or CMS for guidance, but it does not allege that it took any such step.

The premise that a conflict actually exists between the two parts of the regulation is furthermore false. The regulatory requirement is not that the treatment of the PT sample must be in all respects identical to the handling of a patient sample, but rather that "*the laboratory* must *test* the samples in the same manner as patients' specimens." 42 C.F.R. § 493.801(emphasis added). The relevant standard makes the intended focus on the laboratory's *own* testing processes even more explicit. Thus, the laboratory participating in the PT program "must examine or test [the PT samples] . . . in the same manner as *it* tests patient specimens." 42 C.F.R. § 493.801(b) (emphasis added). Specifically, the PT samples are to be "tested with the laboratory's regular workload" by the same personnel using the routine methods in use in the laboratory; the laboratory director must attest to the integration of the PT samples into the regular testing system; and the laboratory must test the PT samples the "same number of times that *it* routinely tests patient samples." 42 C.F.R. § 493.801(b)(1) and (b)(2) (emphasis added). In every case, the regulation

specifically refers to the laboratory performing its own testing in the same way, using the same staff and the same number of repetitions as it normally does with patient samples. Thus, the regulation does not on its face mandate that PT samples must be sent to outside laboratories to be tested by outside staff simply because that repeat or extended testing would be performed on patient samples.

In *Lackawanna*, the Board reached the same conclusion that the subsections of section 493.801 are not in conflict. In that case, we concluded that nothing in section 493.801(b)(1) "requires that, merely because some patient specimens are routinely sent to a different laboratory, PT samples must also be sent to the different laboratory. The routine methods referred to are the methods used in the laboratory . . . by the laboratory's personnel for analysis or testing of patient specimens." DAB No. 1870, at 10 (emphasis in original).

Even were we to conclude that the language cited above were silent or ambiguous about whether a laboratory is to proceed beyond its own testing procedures for PT samples if it would do so for patient samples, we find that reading that language in pari materia with subsections (b)(3) and (b)(4) of the same regulation makes such an interpretation untenable. As the Board has explained in prior cases, in pari materia is a rule of interpretation meaning that "regulations 'having the same purpose or object . . . should be read together as complementary, not contradictory.' New York Department of Social Services, DAB No. 908 (1987)." *North Ridge Care Center*, DAB No. 1857, at 17 (2002). Section 493.801 as a whole has the overarching purpose of implementing Congress's concern that the PT testing process be tightly targeted to assure that the results reflect the real capabilities of the participating laboratory. Thus, the House Report on CLIA states:

> The Committee was advised that some laboratories may treat proficiency test samples differently, knowing that the laboratory is being judged on its performance. It was alleged, for example, that some laboratories might run repeated tests on the sample, use more highly qualified personnel than are routinely used for testing or send the sample out to another laboratory. Such practices obviously undermine the purpose of proficiency testing . . . .

H.R. Rep. No. 899, 100th Cong., 2nd Sess., 24. Clearly, the requirements to use the laboratory's routine methods to test PT samples and the requirement not to send PT samples out to other laboratories for analysis are both designed to prevent the very problems identified by Congress as undermining the validity of PT results.

Reading these provisions as internally consistent is also strongly supported by the regulatory history. When these regulations were adopted, CMS noted in the preamble that some commenters sought to have the requirement for testing PT samples in the same manner as patient samples deleted or diluted and, in particular, suggested that laboratories be permitted to "apply the same criteria for referral of PT samples as used for referral of

patient specimens." 57 Fed. Reg. 7002, 7037-38 (Feb. 28, 1992). CMS rejected this suggestion because referring PT samples out was not necessary for the purpose of accurately assessing a laboratory's proficiency "since a laboratory is being evaluated on the basis of its own level of service, not on any combination of service between it and another laboratory." *Id.* Furthermore, CMS would need to "investigate any allegation that a PT sample might be referred to another laboratory, but such allegations may require other laboratories to report suspicious behavior." *Id*. Had the regulation been read to require referral of PT samples to outside laboratories under some circumstances, laboratories receiving requests to test PT samples would not know when or whether to report the requests as suspicious.

Victor Valley also contends that CMS has interpreted CLIA to define improper referrals as only those where a sending laboratory used the receiving laboratory's results as its own in the CAP process. Victor Valley Appeal at 3. Victor Valley points as support to provisions of the State Operations Manual issued in October 1992 which advised that a Regional Office of CMS –

> may initiate an enforcement action when a laboratory has intentionally referred its PT samples to another laboratory for analysis and submits the other laboratory's results as its own. If you determine that this has occurred, recommend that the laboratory's CLIA certificate be revoked for a minimum of one year. In addition, recommend the imposition of a civil money penalty, as appropriate. Such occurrences may also warrant referral to OIG [Office of the Inspector General].

P. Ex. 1 (excerpt of Special Procedures for Laboratories, SOM, Part 6, § 6330.A (1992)). Victor Valley contends that this manual provision is binding on CMS and the Board so as to bar a finding of intentional referral here. Victor Valley Appeal at 4. This argument is not supported because (1) the manual provision was based on a regulation which was later revised to removed the relevant language and is therefore no longer applicable, and (2) even were the manual provision in effect, it would not bar the finding here.

On the first point, we note that, when section 493.801(b)(4) was initially published in 1992, it read as follows:

> Any laboratory that [CMS] determines intentionally referred its proficiency testing samples to another laboratory for analysis *and submits the other laboratory's results as their own* will have their certification revoked.

57 Fed. Reg. 7002, 7146 (Feb. 28, 1992)(emphasis added). The italicized language was inconsistent, however, with the language of section 493.1840(b), published the same day (57 Fed. Reg. 7218, 7241), which provided:

> If [CMS] determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, [CMS] revokes the laboratory's CLIA certificate for at least one year . . . .

Thus, the regulations in 1992 stated both that all intentional referrals would result in revocation and that intentional referrals where the results are substituted for those obtained by the laboratory itself would result in revocation.

Technical amendments issued January 19, 1993 removed this conflict by deleting the reference to the results of the other laboratory from section 493.801(b)(4) and requiring only a determination of intentional referral for analysis that the laboratory is certified to perform as a basis to revoke. 58 Fed. Reg. 5212, 5228.

The manual provision on which Victor Valley relies was issued after the original section 493.801(b)(4) was published and before the correction in 1993 that removed the reference to reporting the receiving laboratory's results to the CAP. While there are restrictions on agencies changing their interpretations of legal requirements without publishing the changes in the Federal Register, the situation here is precisely the opposite. *See, e.g., Dismas Charities, Inc. v. U.S. Dep't of Justice*, 401 F.3d 666, at 682 (6th Cir. 2005). The change *was* published in the Federal Register and changed the underlying regulation itself not merely the interpretation of the prior regulation. The regulatory language clearly takes precedence over a prior policy statement regardless of whether the language in the SOM was promptly revised to conform to the corrected regulatory language.

On the second point, the manual provision, and, for that matter, the previous version of section 493.801(b)(4), state only that revocation *will* occur in a subset of intentional referrals. The manual further states that such cases may call for civil money penalties in addition to revocation and may warrant referrals to OIG, presumably for possible additional sanctions. SOM, Part 6, § 6330.A (1992)). Neither provides that no other cases of intentional referral will require revocation, and the simultaneous publication of 493.1840(b) makes clear that no such restriction of CMS's authority was intended. *See Wade*, DAB No. 2153, at 21 ("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.") Hence, the manual provision may best be read as pointing out that, in cases where a laboratory has gone so far as to dishonestly report another laboratory's results as its own, a Regional Office *must* act and must consider remedies beyond revocation. We do not read it as narrowly defining the scope of the phrase "improper referral of PT," as Victor Valley suggests. Victor Valley Appeal at 3.

Victor Valley also refers repeatedly to the undisputed fact that the results which it sent to the CAP for these samples were those obtained by its in-house analysis. *See, e.g.,* Victor Valley Appeal at 2. Quest first contacted CMS on June 18, 2007 to report Victor

Valley's referral of PT samples to them for analysis, and followed up with a letter dated June 22, 2007. CMS Ex. 2, at 3; CMS Ex. 5, at 1. Victor Valley's requisitions for analysis of the referred samples by Quest are stamped as sent on June 14, 2010. Victor Valley was not required to report its PT testing results to the CAP until June 29, 2007. CMS Ex. 4, at 5. Victor Valley does not allege that it sent its results to the CAP before sending the samples to Quest for analysis or that it had time to receive results from Quest before the due date of Victor Valley's report to the CAP. *See* 42 C.F.R. § 493.801(b)(3).

Since Quest was obligated as a laboratory receiving PT samples from another laboratory to "notify CMS of receipt of those samples," Quest contacted CMS promptly after receiving samples identified as PT samples. *See* 42 C.F.R. § 493.801(b)(4). Consequently, Quest never performed the analyses requested by Victor Valley. In these circumstances, Victor Valley's reporting of its own test results says nothing about what it would have done if it had received Quest's results.

The situation is again similar to that in *Wade*, which the Court described as follows:

> 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. While consultation between labs may be permissible in other circumstances, before or after a proficiency test, asking an outsider for help during a test corrupts the process and defeats its purpose. Indeed, this type of double-checking is exactly what Congress sought to prevent in the CLIA. It is not just passing off another's work as one's own that concerned Congress: "Run[ning] repeated tests on the sample, us[ing] more highly qualified personnel than are routinely used for testing, or send[ing] the sample out to another laboratory" are all among the many practices that "obviously undermine the purpose of proficiency testing." H.R. Rep. No. 100-899, at 16, 24 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 3828.

567 F.3d at 1204-5.

We conclude that CMS did not have to wait for Quest to actually perform the improper testing and then see whether Victor Valley would use results for comparison to check its own results or would report Quest's results as its own, but rather could reasonably act once Quest alerted it that Victor Valley had referred PT samples and had requisitioned analysis of the samples by Quest.

In sum, we hold that Victor Valley's action in referring out the PT samples was the product of a conscious decision to send the samples to another laboratory for analysis (including repetition of tests done by Victor Valley) while well aware that these were PT samples. Such a knowing and willful action establishes that the referral was intentional within the meaning of the regulations. We therefore uphold the ALJ's conclusion that

Victor Valley intentionally referred out PT samples for analysis in violation of CLIA and its implementing regulations and was therefore properly subject to revocation.

2. Finding of Fact No. 10 is not supported by substantial evidence.

CMS argues that ALJ Finding of Fact No. 10 is not supported by substantial evidence in the record. The contested factual finding was that, in sending its PT samples to another laboratory "as it would with regular patient test samples, Victor Valley intended to comply with 42 C.F.R. § 493.801(b)(1)," requiring PT samples to be treated the same as regular patient samples. ALJ Decision at 7. The ALJ cited two bases for this finding – a page in Victor Valley's brief before the ALJ and two pages from the hearing transcript.

In evaluating whether a finding of fact is supported by substantial evidence, we look at the evidence on which the ALJ relied and consider the evidence in the record as a whole. Where other evidence detracts from the ALJ's finding, we look at whether the ALJ explained why he did not credit or give weight to that evidence and whether, despite the conflicting evidence, the evidence supporting the finding is substantial as that term has been elucidated in the court and Board decisions referenced above.

The cited page in Victor Valley's brief to the ALJ states that the laboratory employee identified that the analysis of the specimens had reached a step at which the laboratory's practice was to refer specimens to another laboratory and then "the employee 'treating proficiency testing samples like patient specimens, referred the two proficiency testing samples to Quest.'" Victor Valley Prehearing Memorandum (January 22, 2009) at 2, quoting CMS Ex. 7, at 2 (CMS's notice of proposed sanctions). Argument does not constitute evidence, except perhaps when it forms a party admission. Therefore, statements in a brief cannot in themselves be the source of evidentiary support for the ALJ's finding that Victor Valley sent out the PT test *because* it intended to comply with the requirements on treating PT samples in the same manner as patient samples.

The only record citation on that page of the brief was to CMS's notice of proposed sanctions reporting that the laboratory's manager told CMS in a July 29, 2007 telephone conversation the laboratory technician treated the PT samples like patient specimens. CMS Ex. 7, at 2. It is not disputed that similar patient samples would have been sent out for further analysis by another laboratory if they needed analytical tests which Victor Valley could not perform in-house. That fact alone does not establish, however, Victor Valley's *intent* in sending the PT samples to Quest. The laboratory manager's reported statement merely alleges that a practice existed of sending out specimens at a certain stage in the bacteriological identification process and that these samples were also sent out at that stage. That could be factually true even if one reason that practice was followed in the case of the PT samples was in order to have another laboratory confirm Victor Valley's results before they were reported to the CAP.

The transcript pages cited by the ALJ are from the cross-examination of CMS's expert witness and include this exchange –

> Q. Do you see any evidence of any test -- of any intent on the part of Victor Valley to have Quest perform the testing on these proficiency testing specimens?
> A. Well, yes. I mean, they -- they requested testing of these proficiency testing samples via the requisition.
> Q. They referred them and made a requisition sheet just like they would have done if they were patient specimens, correct?
> A. I would assume that that would be their process, yes.
> Q. But they used the term proficiency testing samples on it, didn't they?
> A. That's how they labeled the -- that's how it's labeled on the requisition.

Tr. at 48-49. The witness then testified that, while Victor Valley properly followed the same processes in testing the PT samples as patient specimens up through the point it was able to do so in-house and ultimately reported those results to the CAP, Victor Valley nevertheless violated the law by sending the PT samples to Quest for further analysis. *Id*. at 49-50. This expert testimony went largely to the interpretation of the regulatory requirement; the only factual statement made by the witness in relation to intent was that Victor Valley manifested an intent that Quest do an analysis of the PT samples by requesting Quest to perform tests on them by means of a requisition. *Id.* at 48-49. This testimony provides no support for the ALJ's finding that Victor Valley's intent in referring the samples was to treat them in the same way as patient specimens.

Indeed, Victor Valley acknowledges on appeal that it presented no testimony at the hearing "regarding the reason why the two [PT] specimens were referred" to Quest.[2] Victor Valley Opposition at 1; *see also* Tr. at 9, 106 (Victor Valley informing ALJ that the laboratory technician who sent the PT samples to Quest would not be testifying). Victor Valley argues that the ALJ's finding was nevertheless supported by "undisputed documentary evidence contained in the record." *Id*. We review each item to which Victor Valley pointed and find that none of this material, individually or collectively, provides support for the finding.

Victor Valley relies first on a paragraph in Mr. Yamamoto's declaration referring to the telephone conversation he had on June 29, 2007 with the laboratory manager in which the manager reportedly stated that Victor Valley treated the PT samples as it would have treated patient specimens in referring them to Quest. Victor Valley Opposition at 2,

[2] Indeed, despite earlier identifying several witnesses, neither Victor Valley nor Dr. Pawlowski chose to present any direct testimony by any witness at the hearing.

citing CMS Ex. 2, at 4. The manager also reportedly stated that the referral was "unintentional" and "was done by a testing person . . . without the knowledge of anyone else on [Victor Valley's] staff." CMS Ex. 2, at 4. Victor Valley stresses that CMS expressly based the sanctions on the information from the conversation which included that the PT samples were referred out as patient samples would have been. Victor Valley Opposition at 2. But again, this merely reiterates the factual premise that Victor Valley treated the PT samples in the same way it treated patient samples, but says nothing about what Victor Valley's intention (or motivation or state of mind) was in taking those actions.

Victor Valley further argues that it, "through counsel, had informed CMS of this reason for the referral of the proficiency testing specimens in its August 13, 2007 letter to CMS . . . ." Victor Valley Opposition at 2, citing CMS Ex. 8, at 3. The reference is to a letter that Victor Valley's lawyer sent to CMS after receiving notice of the proposed sanctions. CMS Ex. 8, at 4. Counsel does assert that the employee involved in the "isolated and unfortunate" incident "thought she was to treat [the PT sample] like a patient sample." *Id*. at 3. Statements of counsel in an unsworn letter to an opposing party hardly constitute evidence of the truth of the matter asserted in support of the client's claims.

In any case, the letter makes further statements that undercut any possible inference by the ALJ from the quoted language to the finding that Victor Valley intended to comply with section 493.801(b)(1) by sending the PT samples to Quest. Counsel's letter goes on to assert that Victor Valley had "instituted policies, procedures and continued education" on the PT requirements, including training the staff person involved, and that it was "unclear why the testing staff person took it upon herself to send it to Quest *without following policy* or consulting with supervising staff." CMS Ex. 8, at 3 (emphasis added).[3] This statement avers that it was *not* Victor Valley's intent that PT samples be sent to Quest for further analysis in order to comply with section 493.801(b)(1), but rather that Victor Valley knew referral was improper in the case of PT samples and had issued policy against doing so which this staff person did not follow.[4]

We conclude that nothing in the cited sources, or elsewhere in the record that we discern, establishes that Victor Valley's actual intent for sending the PT samples out was to comply with the requirements for processing them in the same way as patient samples.

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[3] As the ALJ noted, Victor Valley failed to produce the alleged policy, but its counsel argued at the hearing that the referral violated the policy which was "that you are not supposed to refer under any circumstances proficiency testing." ALJ Decision at 24, quoting Tr. at 19.

[4] In this sense, the "motive" of the laboratory technician is, as the ALJ concluded, "irrelevant" where the referring laboratory knew that it was sending a PT sample to another laboratory for analysis. ALJ Decision at 9. As the Board explained in *Wade*, however the motive for referring out PT samples is "not wholly irrelevant" because the statute and regulations do require a showing that the sending laboratory sent the PT samples with the purpose of having analysis performed by the receiving laboratory. DAB No. 2153, at 14-15.

Victor Valley did not rebut CMS's evidence, in Mr. Yamamoto's declaration, that Quest would normally repeat all of the testing performed by Victor Valley before moving on to perform additional tests. CMS Ex. 2, at 10. Nor did Victor Valley deny that it was aware of this procedure or that it would, in the normal course of events, therefore have received reports on all of Quest's analyses, including results of tests that Victor Valley had previously performed on the PT samples. Indeed, Mr. Yamamoto points to specific test codes on the requisition forms requesting repetition of tests already done by Victor Valley. *Id.* at 9-10, citing CMS Ex. 6, at 2-3. It is thus logically possible that Victor Valley treated these PT samples in the same way it treated patient samples not because of an intention to comply with section 493.801(b)(1) but instead (or in addition) because that would provide a check back to Victor Valley about whether its test results were replicated.

In any case, based on our review of the evidence in the record as a whole, including the evidence relied on by the ALJ and cited by Victor Valley, we conclude that no substantial evidence supports any affirmative finding about why Victor Valley or its laboratory technician evidence referred out these PT samples. Beyond the lack of evidence, we must also note that the discussion elsewhere in the ALJ Decision appears to contradict the numbered finding. For example, the ALJ later expressly rejected reliance on Mr. Yamamoto's testimony for this point (despite having cited that testimony as the only evidentiary basis for the challenged finding). The ALJ stated:

> Petitioners' attempt to rely on Mr. Yamamoto's testimony to establish that its laboratory technician referred the two proficiency testing samples to Quest, because she thought that was what she was supposed to do in treating the test specimens the same way as patient specimens are treated, also fails. Tr. 15. Moreover, although both Petitioners had opportunity to present testimony from laboratory technician Helen Rahbar, they did not, nor did they seek to subpoena her to testify. More importantly, contrary to what Petitioners represented before the hearing, they failed to present the testimony of Dr. Pawlowski or any experts to support their assertions.

ALJ Decision at 24.[5]

For these reasons, we strike Finding of Fact 10 from the ALJ Decision.

[5] The ALJ also concluded that, even were he to accept that the technician did not know her referral was prohibited by law and did not have a specific intent to violate CLIA, that would not alter the fact that she acted intentionally in sending the PT samples to Quest for further analysis within the meaning of the prohibition against intentional referral. ALJ Decision at 27. We agree, as we discussed above, that an intention to knowingly violate CLIA is not a prerequisite to finding that PT samples were intentionally referred to another laboratory for analysis.

3. Under the circumstances here, CMS would be authorized to revoke even if the referral were not "intentional" (as we have found it was).

CMS argues that the revocation should be upheld regardless of what conclusion we reached about whether the referral was intentional. First, CMS argues that Victor Valley did not challenge a second, independent basis for revocation, so the revocation must be upheld without regard to the resolution of the improper referral issue. Second, CMS argues that it had authority to revoke for any improper referral of a PT sample for analysis even if not intentional.

We disagree with CMS's first argument because the second condition for which Victor Valley was cited is not truly independent. The ALJ concluded that the laboratory director failed to meet the condition at 42 C.F.R. § 493.1441 to provide overall management in accordance with § 493.1445. ALJ Decision at 10. He based this conclusion on Dr. Pawlowski's "ultimate responsibility" for ensuring proper testing of PT samples. ALJ Decision at 10; 42 C.F.R. § 493.1445(e)(4). The ALJ referred to this condition level deficiency as an "independent basis" for revocation. ALJ Decision at 10. Victor Valley argues against CMS's claim that this deficiency is independent in the sense that the revocation would have to be upheld even if we found that the referral was not improper. Victor Valley Opposition at 4. We agree under the circumstances here where the only basis cited for violation of the laboratory director condition depended on finding that the director failed to prevent the improper referral. We therefore decline CMS's invitation to find that the revocation would stand on the unchallenged laboratory director condition alone. Of course, this makes little practical difference since we have indeed found that the ALJ correctly found the referral intentional and in violation of the law.

We need not finally resolve CMS's second argument that a finding of intentionality, while supported on the record, is not necessary to uphold the revocation here, since we do find the referral to be intentional. We note, however, that the regulations do provide for revocation for failure to meet participation conditions. As the Board held in *Wade*, section 493.801(b)(4) contains "two separate but consistent provisions, one a participation requirement [prohibiting improper referral of PT samples] and one requiring revocation if the a laboratory has intentionally referred a PT sample." DAB No. 2153, at 10.

Wade was before the Board on appeal of a summary judgment in favor of CMS. The Board found that the record did not show that CMS made any finding that the referral at issue constituted a condition level deficiency but rather simply adopted the survey agency finding that the referral was intentional so revocation was mandatory. *Id*. at 13.

In the present case, on the other hand, CMS specifically determined that the improper referral of these PT samples constituted lack of compliance with two CLIA conditions at the level of immediate jeopardy. CMS Ex. 7, at 2-3. Victor Valley also had ample notice of CMS's position through briefing and had a full hearing and opportunity to present any

contrary argument or evidence. *See*, *e.g.*, CMS Post-Hearing Br. at 8. In this case, therefore, the record would support a conclusion that the referral was improper and the deficiency was serious enough to violate the condition at section 403.801.

Conclusion

For the reasons explained above, we affirm the ALJ Decision, modifying it only to remove numbered Finding of Fact 10.

_____/s/_____
Judith A. Ballard

_____/s/_____
Constance B. Tobias

_____/s/_____
Leslie A. Sussan
Presiding Board Member