Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Victor Valley Community Hospital/Clinical Laboratory,
(CLIA No. 05D0663016),

and

Tomasz Pawlowski, M.D.,

Petitioners

v.

Centers for Medicare and Medicaid Services.

Docket Nos. C-07-715
C-07-721

Decision No. CR2156

Date: June 15, 2010

DECISION

The certificate of Victor Valley Community Hospital/Clinical Laboratory (Petitioner or Victor Valley) to operate as a clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[2] is revoked for a period of one year, effective the date of this decision, pursuant to 42 C.F.R. § 493.1844(d)(4)(ii). In addition, Petitioner's owners and operators, including its laboratory director Tomasz Pawlowski, M.D. (Dr. Pawlowski), are prohibited from owning or operating a CLIA laboratory for two years, which run from the date of the revocation of the laboratory's certificate, pursuant to 42 U.S.C. § 263a(i)(3).

[2] Pub. L. 100-578, 101 Stat. 2903 (1988) (codified as amended at 42 U.S.C. § 263a. (2000)).

I. Procedural History

Victor Valley, a non-profit hospital in Victorville, California, operates as a clinical laboratory under CLIA. During the relevant period at issue, Dr. Pawlowski served as the hospital's laboratory director. Victor Valley is certified to perform testing under a Certificate of Accreditation, based on the laboratory's accreditation with the American Osteopathic Association (AOA). AOA is an approved accreditation organization, and laboratories that AOA accredits are deemed to meet the CLIA program requirements. 42 U.S.C. § 263a(e); 42 C.F.R. § 493.551. Under 42 U.S.C. § 263a, a clinical laboratory may test human specimens only if the Secretary of Health and Human Services (Secretary) certifies it as meeting CLIA requirements. To maintain this certification, a laboratory must periodically undergo "proficiency testing," in which the laboratory's results are judged for acceptable accuracy. *See* 42 C.F.R. §§ 493.801 - 493.959.

The Centers for Medicare and Medicaid Services (CMS) certified Victor Valley to test in the subspecialty of bacteriology; accordingly, Victor Valley was subject to proficiency testing in bacteriology. Victor Valley enrolled in a proficiency testing program that the College of American Pathologists (CAP)[2] operated, which allowed it to perform all bacteriological tests listed in the CPT Code Book without limitation.

On May 27, 1997, CAP sent Victor Valley two specimens for proficiency testing. Victor Valley was required to report its proficiency test results to CAP not later than June 29, 2007. Victor Valley tested the samples and, on June 14, 2007, sent the proficiency testing samples to Quest Diagnostics (Quest) for further testing. Quest notified CMS by phone on June 18, 2007, and by letter dated June 22, 2007, of its receipt of Victor Valley's two bacteriology samples. Quest further reported to CMS that both requisition forms identified the name of the patient as "TEST, PROFICIENCY." CMS Ex. 5, at 2, 3.

Based on the information from Quest, CMS conducted a complaint survey of Victor Valley's laboratory on July 27, 2007 and found Victor Valley out of compliance with two CLIA conditions of participation, based on the two proficiency testing samples that Victor Valley submitted. The two condition-level deficiencies at issue both relate to the alleged improper proficiency testing sample referrals and include violations of 42 C.F.R. § 493.801(b)(4) (enrollment and testing of samples) and 42 C.F.R. § 493.1441 (laboratories performing high complexity testing; laboratory director). In particular, section 493.1445(e)(4)(i), which pertains to laboratory director responsibilities, is implicated.

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[2] CAP is a private accreditation organization. CLIA certifies private accreditation organizations as an alternative to survey and certification by CMS and/or its agent, the state agency. The Secretary and CMS, her delegee, bear responsibility for the selection of accrediting bodies and oversight of their performance. 42 U.S.C. § 263a(e); 42 C.F.R. Part 493, subpart E.

By letter dated July 27, 2007, CMS notified Victor Valley and Dr. Pawlowski of the specific deficiencies and of its determination that the improper proficiency sample referrals posed immediate jeopardy to patient health and safety. The letter further advised Petitioners that CMS proposed to sanction Victor Valley and provided it with an opportunity to submit, in writing, any evidence or information in support of its compliance. Victor Valley responded by filing additional information. After reviewing Petitioners' submission, CMS advised Petitioners, by letter dated September 11, 2007, that immediate jeopardy had not been removed. CMS further advised Petitioners that it planned to: limit the laboratory's CLIA certificate for the subspecialty of bacteriology, effective August 1, 2007; revoke its CLIA certification, effective September 25, 2007; cancel its approval to receive reimbursement from Medicare for any laboratory services performed as of September 25, 2007; and suspend the laboratory's approval to receive Medicare payments for the subspecialty of bacteriology, effective August 1, 2007.

By letter dated September 17, 2007, Victor Valley timely appealed CMS's proposed sanctions, contesting the revocation of its CLIA certificate and the revocation of approval to receive Medicare payments. The request for hearing was docketed as C-07-715, and assigned to me for hearing and decision on October 2, 2007. Based on 42 C.F.R. § 493.1844(d)(2)(ii), the appeal before me did not stay the limitation of Victor Valley's CLIA certificate for the subspecialty of bacteriology due to the finding of immediate jeopardy, and, therefore, that sanction went into effect on August 1, 2007. Although the regulation allowed for the immediate cancellation of Victor Valley's Medicare and Medicaid approval, Victor Valley filed a Motion for Preliminary Injunction against the Secretary on September 20, 2007 with the United States District for the Central District of California. On January 10, 2008, the court issued an injunction against the Secretary prohibiting the cancellation of Victor Valley's approval to receive Medicare and Medicaid payments for clinical laboratory services pending the resolution of the matter. CMS notified Victor Valley, by letter dated January 25, 2008, that it was rescinding the cancellation of the laboratory's approval to receive Medicare payments for any clinical laboratory services until after the conclusion of these proceedings. CMS Ex. 11.

CMS also proposes to impose a two-year prohibition against Dr. Pawlowski as laboratory director for Victor Valley, barring him from owning, operating, or directing another clinical laboratory. In response to CMS's July 27, 2007 notice, Dr. Pawlowski timely filed an appeal of the proposed sanction, by letter dated September 20, 2007, challenging CMS's allegations of condition-level deficiencies. Dr. Pawlowski's request for hearing was docketed as C-07-721 and initially assigned to administrative law judge (ALJ) Sickendick on October 9, 2007.

By unopposed motion filed October 16, 2007, CMS requested the consolidation of the two appeals. After conferring with ALJ Sickendick and agreeing that Dr. Pawlowski's case would be transferred to me, I issued an Order, dated November 5, 2007, consolidating the two requests for hearing under Docket No. C-07-715 and provided the

parties with a filing schedule. On November 19, 2007, CMS requested an extension to the filing deadlines of the Order dated October 2, 2007. The request was granted by Order dated November 30, 2007. On January 7, 2008, CMS moved for summary judgment. Victor Valley filed its opposition to CMS's motion for summary judgment and its own motion for summary judgment on April 3, 2008 accompanied by five supporting exhibits. Dr. Pawlowski filed his opposition styled as *Joinder in Opposition to Respondent's Motion for Summary Judgment and in Support of Petitioner Victor Valley Community Hospital's Motion for Summary Judgment* on April 7, 2008. CMS filed its reply on April 21, 2008.

A telephone conference was convened on June 3, 2008 to advise the parties of my ruling denying the cross-motions for summary judgment, as I found material facts in dispute. The discussions held during the conference are memorialized in my Order dated June 11, 2008. I discussed with counsel the Departmental Appeal Board's (Board) decision in *Wade Pediatrics,* which I believe controls this matter. Counsel was advised that the case was currently on appeal in the Unites States Court of Appeals for the Tenth Circuit. *Wade Pediatrics*, CR1630 (2007), *aff'd*, DAB No. 2153 (2008).

I also advised counsel that a conflict appeared to exist between Petitioners as to their defenses. Victor Valley maintained in its motion for summary judgment that the laboratory technician's actions in referring the test samples to Quest were an intentional referral, while Dr. Pawlowski argued that the referral was an accident or mistake. Neither Petitioner provided an affidavit from the laboratory technician who actually made the referrals. I also raised the question as to what the laboratory technician should have done when she received the proficiency test specimens from the testing agent, since all parties have indicated that the laboratory lacked the proper resources to complete the testing of the proficiency test specimens. Although the affidavit CMS filed from its expert witness Gary Yamamoto provided some guidance, it did not sufficiently address the questions raised. As these were material facts in dispute, I denied the parties' cross-motions for summary judgment and ordered Petitioners to confer and advise me as to whether: (1) the defenses each Petitioner articulated in their pleadings conflicted; (2) both appeals should continue to be consolidated or be bifurcated; and (3) an in-person hearing was necessary. *See* Order dated June 11, 2008. CMS was also afforded an opportunity to file a response.

Victor Valley filed its response on July 1, 2008, stating that it wished to continue both appeals on a consolidated basis and that an in-person hearing was necessary to address disputed factual issues. Victor Valley asserted that the improper referral must be deemed a "mistake" by an employee rather than an intentional act on the part of the hospital. Victor Valley also stated that there existed a factual issue as to whether its laboratory could have completed the analysis of the testing at issue. Dr. Pawlowski filed his response on July 1, 2008, indicating that he did not wish bifurcation of the requests for hearing. He further stated that an in-person hearing was necessary and that testimony

from the parties, and possibly experts, should be presented for me to determine if an improper referral had occurred. CMS filed its response on July 31, 2008, and concurred with Petitioners' requests to continue the appeals on a consolidated basis.

A telephone conference was convened with the parties on August 21, 2008 to set a date for hearing in this case. The matters discussed during the conference call have been memorialized in an order issued at my direction on September 15, 2008. During the conference call the parties were advised that two material issues of fact required testimonial evidence. The first was whether Petitioners' laboratory technician's proficiency testing sample referral was an intentional referral or a mistake. The second was what the laboratory technician should have done when she reached the limits of the laboratory's ability to test the two proficiency testing samples. *See* Tr. 3-4.

Victor Valley filed its witness list on November 3, 2008, indicating that it would likely call Helen Rahbar, the medical technologist involved. CMS's witness list filed November 3, 2008 indicated that it would call Gary Yamamoto, CLIA Medical Technologist for CMS Regional Office in San Francisco,[3] and Denise Driscoll, Director of Regulatory Affairs, or another person at CAP to testify as to what types of results would have been acceptable for proficiency sample testing purposes. The parties entered into a Joint Stipulation of Undisputed Facts (Jt. Stip.), which was filed on January 23, 2009.

A hearing was conducted on February 10, 2009, in Los Angeles, California. During the hearing CMS offered CMS exhibits (CMS Exs.) 1-12. Tr. 7. Victor Valley offered Petitioners' exhibits (P. Exs.) 1-2. Tr. 8-9. Absent any objection, I admitted all exhibits. CMS called as witness Gary Yamamoto. Victor Valley and Dr. Pawlowski did not call any witnesses.[4] Tr. 9, 10. At the conclusion of the hearing, I asked Victor Valley why it had not presented Helen Rahbar, the laboratory technician who actually referred the specimens, for testimony. Victor Valley responded that "we weren't able to get her. I didn't subpoena her or anything like that. We believe that the record here already shows what the facts were . . . ." Tr. 106. I then ordered Victor Valley to file copies of its policies, within two weeks, concerning referral of specimens to other laboratories when Victor Valley had reached the limits of the laboratory's ability to test laboratory

[3] The parties stipulated that Gary Yamamoto's affidavit could be accepted as his direct examination with some supplemental questioning by CMS at hearing. Tr. 10-11.

[4] In their prehearing filings, Petitioners proffered various witnesses whom they intended to call at the hearing, including Helen Rahbar, Dr. Pawlowski, and possibly some expert witnesses. However, at hearing, neither Petitioner offered the testimony of any witness, and both Petitioners limited their presentation to cross-examination of CMS's one witness, Gary Yamamoto. Tr. 106.

specimens. Tr. 106. On February 19, 2009, Victor Valley filed three exhibits (P. Exs. 3-5), which included copies of its specimen referral policies.

CMS filed its post-hearing brief on May 21, 2009, while Victor Valley filed its post-hearing brief on May 6, 2009. Dr. Pawlowski also submitted a filing on May 6, 2009, which consisted of a motion joining in Victor Valley's post-hearing brief. CMS filed its reply on May 21, 2009. On June 3, 2009, CMS filed a supplement to its reply, which included as an attachment a copy of the Tenth Circuit's judgment in *Wade Pediatrics* filed June 2, 2009. *See Wade Pediatrics v. Dep't of Health & Human Servs.*, 567 F.3d 1202 (10th Cir. 2009).

On June 9, 2009, Victor Valley filed a motion for leave to file a supplemental memorandum. Dr. Pawlowski filed a similar motion on June 11, 2009. Victor Valley sought opportunity to address the Tenth Circuit's recent decision in *Wade Pediatrics*. By email correspondence on June 11, 2009, CMS noted its objection to Petitioners' request. On June 17, 2009, I overruled CMS's objection and granted Petitioner the opportunity to file a supplemental brief. CMS was provided the opportunity to file a rebuttal brief.

The record in this matter was closed on June 29, 2009. On July 8, 2009, Victor Valley transmitted a copy of a December 10, 2008 letter from CAP along with a request for leave to file a motion to have the letter admitted as an exhibit. Victor Valley indicated it also sought an opportunity to comment on the document. I issued an Order on July 9, 2009, asking the parties to brief their respective positions as to the relevance of the December 10, 2008 letter. On July 21, 2009, Victor Valley filed its brief accompanied by four supporting attachments, and CMS filed its opposition brief on July 29, 2009. Dr. Pawlowski did not file a substantive brief but, instead, filed a motion on July 30, 2009, indicating that it was joining in Victor Valley's arguments on the issue. By Ruling issued August 13, 2009, I reopened the record to admit the exhibit that was marked as P. Ex. 3 and ordered the record in this matter closed as of August 13, 2009.

The issues presented here were vigorously contested and have been extensively briefed. Although the Board addressed similar issues in *Wade Pediatrics*, it was under appeal at the time of these proceedings. Ample opportunity existed for the parties to present evidence and argument to support their respective positions. As such, this decision is based on the complete record.

II. Findings of fact and conclusions of law

A. Findings of Fact

The following findings of fact are based upon the admitted exhibits and the transcript of the proceedings. Citations to transcript pages and exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not listed in this section.

1. Victor Valley possessed a valid CLIA certificate to perform human specimen testing, based on its AOA accreditation, at all relevant times. Jt. Stip. ¶ 1; CMS Ex. 1, at 2.

2. CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens. 42 U.S.C. § 263a; 42 C.F.R. § 493.1800.

3. CMS certified Victor Valley to perform certain tests, including tests in the subspecialty of bacteriology. Jt. Stip. ¶ 1; CMS Ex. 1, at 1.

4. Petitioner's laboratory was enrolled in an approved proficiency testing program, pursuant to 42 C.F.R. § 493.801, that CAP conducted. Jt. Stip. ¶¶ 3 and 4.

5. Dr. Pawlowski was the laboratory director at Victor Valley at all relevant times. Jt. Stip. ¶ 2.

6. On May 27, 2007, CAP sent Victor Valley two bacteriology proficiency testing samples for testing. CAP asked for the results not later than June 29, 2007. CMS Ex. 4, at 5; Tr. 84-95; Victor Valley Br. at 1.

7. Victor Valley tested the proficiency samples to its laboratory's capacity. Victor Valley Br. at 2, 9; Tr. 49-50; CMS Ex. 8, at 3; CMS Ex. 2, at 4.

8. On June 14, 2007, the laboratory technician at Victor Valley referred the proficiency testing samples to Quest for testing. Victor Valley Br. at 2; CMS Ex. 2, at 4; CMS Ex. 5, at 2, 3.

9. The laboratory technician intended to send the two proficiency testing samples to another laboratory and marked them as "test, proficiency." Victor Valley Br. at 2; CMS Ex. 5, at 2, 3.

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. Tr. 49-50; Victor Valley Br. at 2.

11. Quest did not test Victor Valley's proficiency samples; instead, Quest called CMS on June 18, 2007 and subsequently provided written correspondence to CMS on June 22, 2007 of its receipt of the two samples. CMS Ex. 2, at 10-12; Tr. 24; CMS Ex. 5, at 1.

12. On June 29, 2007, Victor Valley reported to CAP the results its laboratory technician performed on the two proficiency samples. These were the only results reported, as Quest did not test the CAP proficiency samples Victor Valley had sent to it. Tr. 49-50; Victor Valley Br. at 2.

13. On July 27, 2007, Gary Yamamoto surveyed Victor Valley's laboratory for CMS to determine whether Petitioner was in compliance with CLIA requirements. CMS Ex. 6.

14. Pursuant to the survey, CMS determined that Victor Valley was in violation of two condition level deficiencies: (1) 42 C.F.R. § 493.801 (Condition: Enrollment and Testing of [Proficiency Testing] Samples); and (2) 42 C.F.R. § 493.1441 (Condition: Laboratories Performing High Complexity Testing; Laboratory Director). CMS Ex. 6.

15. By letter dated July 27, 2007, CMS notified Petitioners that the improper referral of the proficiency samples posed immediate jeopardy to patient health and safety. CMS also indicated its intent sanction Victor Valley. CMS Ex. 7.

16. By letter dated September 11, 2007, CMS notified Petitioners of its imposition of the proposed sanctions of: revocation of the laboratory's CLIA certificate, effective September 15, 2007; limitation of the laboratory's CLIA certificate for the subspecialty of bacteriology, effective August 1, 2007; suspension of the laboratory's approval to receive Medicare payments for any service performed for the subspecialty of bacteriology, effective August 1, 2007; and, effective September 25, 2007, cancellation of the laboratory's approval to receive Medicare payments for any clinical laboratory services.

17. By letter dated January 25, 2008, CMS notified Victor Valley that it was delaying the cancellation of the laboratory's approval to receive Medicare payments for any clinical laboratory services until after the conclusion of these proceedings. CMS Ex. 11.

B. Conclusions of Law

1. On September 17, 2007, Victor Valley timely filed a request for hearing.

2. On September 20, 2007, Dr. Pawlowski, in his capacity as laboratory director, timely filed a request for hearing.

3. Violation of one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1804(b); *Edison Med. Labs., Inc.*, DAB No. 1713 (1999), *aff'd, Edison Med. Labs., Inc. v. Health Care Fin. Admin.*, 250 F.3d 735 (3d Cir. 2001).

4. It is well-settled that a CMS determination of immediate jeopardy is not subject to appeal by a provider.

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.

20. As laboratory director, Dr. Pawlowski was responsible for the overall management and direction of Petitioner in accordance with 42 C.F.R. §§ 493.1445 and 493.1441.

21. As laboratory director, Dr. Pawlowski was responsible for the actions of the laboratory technician who intentionally referred proficiency testing samples to another laboratory for analysis. The fact that Dr. Pawlowski lacked knowledge of the laboratory technician's intentional referral of proficiency testing samples is irrelevant.

22. Dr. Pawlowski failed to ensure that Petitioner's proficiency testing samples were tested as required under subpart H of 42 C.F.R. Part 493. Dr. Pawlowski had the ultimate responsibility to ensure that Petitioner's proficiency testing was performed in accordance with 42 C.F.R. § 493.801.

23. Dr. Pawlowski, as laboratory director for Victor Valley, failed to meet the condition for laboratory director, in violation of 42 C.F.R. § 493.1441.

24. Victor Valley's failure to meet the condition for laboratory director forms an independent basis for CMS's revocation of Victor Valley's CLIA certificate under 42 C.F.R. § 493.1814(a)(2).

25. CMS's notices, dated July 27, 2007 and September 11, 2007, provided Petitioners with adequate notice that non-compliance with respect to the laboratory director condition would independently support revocation of Victor Valley's CLIA certificate.

26. The CLIA statute and applicable regulations require CMS to revoke a laboratory's CLIA certificate for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another laboratory for analysis. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4), 493.1804(b).

27. Neither I nor CMS has the discretion to revoke Victor Valley's CLIA certificate for less than the mandatory minimum period of one year, or to substitute any lesser sanction.

28. CMS must cancel Victor Valley's approval to receive Medicare payments when its CLIA certificate is revoked. 42 C.F.R. §§ 493.1808(a), 493.1809, 493.1842(a).

29. Revocation of Petitioner's CLIA certificate is effective the date of this decision. 42 C.F.R. § 493.1844(d)(2).

30. Victor Valley's owner and operator (including Dr. Pawlowski) are prohibited from owning or operating a laboratory for at least a two-year period from the effective date of revocation. 42 U.S.C. § 263a(i)(3); 42 C.F.R. § 493.1840(a)(8).

III. Applicable Law

CLIA establishes requirements for all laboratories that perform clinical diagnostic testing on human specimens and provides for federal certification of such laboratories. Pub. L. No. 100-578, *amending* Public Health Service Act § 353 (codified as amended at 42 U.S.C. §§ 263a, 1302, and 1395x(e)). The Secretary's implementing regulations are found at 42 C.F.R. Part 493 and set forth the conditions all laboratories must meet to be certified to perform testing on human specimens under CLIA. Regulations governing performance of proficiency tests by clinical laboratories are set forth in 42 C.F.R. § 493.801. A clinical laboratory must enroll in an approved proficiency testing program. 42 C.F.R. § 493.801. The laboratory must notify the Department of Health and Human Services of each program or programs in which it chooses to participate to meet proficiency testing standards. 42 CF.R. § 493.801(a)(1). The laboratory is obligated to examine or test each proficiency testing sample that it receives in the same manner as it tests patient specimens. 42 C.F.R. § 493.801(b). The laboratory must document the handling, preparation, processing, and examination, as well as each step in the testing and reporting of results for all proficiency testing samples. 42 C.F.R. § 493.801(b)(5).

Under the regulations, laboratory tests are categorized by complexity, and CLIA certification conditions (or requirements for "waived tests") exist specific to each category. *See* 42 C.F.R. §§ 493.5, 493.20, 493.25. CMS retains broad discretion under CLIA to take action that ensures that laboratories remain in compliance. The action that CMS will take if a survey finds that a laboratory is not in compliance with the requirements depends in part on whether the deficiencies: (1) are only at the level of one or more standards or rise to the level of noncompliance with one or more conditions; and (2) pose an immediate jeopardy. 42 C.F.R. §§ 493.1812 - .1816.

CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory." The implementing regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an ALJ. 42 C.F.R. § 493.1844(a). The hearing procedures found in subpart D of Title 42, Part 498 are incorporated by reference.

42 C.F.R. § 493.1844(a)(2). The "suspension, limitation, or revocation of the laboratory's CLIA certificate . . . because of noncompliance . . ." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1). The imposition of alternative sanctions is also an initial determination subject to appeal (42 C.F.R. § 493.1844(b)(3)), but the determination as to which alternative sanctions to impose and the amount of the CMP to be imposed are not. 42 C.F.R. § 493.1844(b)(3), (c)(4). The general rule is that suspension, limitation, or revocation of a CLIA certificate does not go into effect if appealed and is not imposed until the ALJ issues a decision, unless CMS declares immediate jeopardy. Alternatively, if the laboratory has refused a reasonable request for information, then no delay exists in the suspension or limitation of the offending laboratory's CLIA certificate. 42 C.F.R. § 493.1844(d)(2). Additionally, a laboratory may not appeal a CMS determination not to reinstate a suspended CLIA certificate, where CMS has concluded that the reason for the suspension had not been removed or that insufficient assurance exists that the reason for the suspension will not recur. 42 C.F.R. § 493.1844(c)(3). Section 498.74 of 42 C.F.R. provides that, absent appeals to the Board, or federal district courts, my decision is final.

Pursuant to 42 U.S.C. § 263a(i)(3), in addition to sanctions directed against laboratories, CLIA provides: "[n]o person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section." Although the implementing regulations do not include any express provision implementing or imposing this two-year prohibition against an offending owner or operator, they do provide for the suspension, limitation, or revocation of a laboratory's CLIA certificate if a finding exists that the owner or operator has "[w]ithin the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)" 42 C.F.R. § 493.1840(a)(8). Moreover, although CLIA does not include a definition of the term "operator," the regulations define an "operator" as:

> the individual or group of individuals who oversee all facets of the operation of a laboratory and who bear primary responsibility for the safety and reliability of the results of all specimen testing performed in that laboratory. The term includes –
>
> (1) A director of the laboratory if he or she meets the stated criteria . . . .

42 C.F.R. § 493.2. It is a condition-level requirement that a CLIA-certified laboratory have a qualified laboratory director who is required to assume oversight and responsibility for the laboratory and the results of its testing. *See* 42 C.F.R. §§ 493.1403, 493.1405, 493.1407, 493.1441, 493.1443, 493.1445. Thus, the regulation creates a rebuttable presumption that a laboratory director is an operator of the laboratory within the meaning of the regulations and CLIA.

The allocation of the burden of proof in an appeal of CMS's sanctions is set forth in *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Center v. Department of Health and Human Services*, No. 98-3789 (GEB), slip. op. (D.N.J. May 13, 1999); *Edison Medical Laboratories, Inc.*, DAB No. 1713 (*Hillman* burden of proof applicable in CLIA appeals), *aff'd* 250 F.3d 735 (3d Cir. 2001). CMS bears the burden of coming forward with sufficient evidence to prove a prima facie case of noncompliance with one or more CLIA conditions. The petitioner then has the ultimate burden of showing by a preponderance of the evidence that it was not out of compliance with the conditions that CMS placed at issue. The ALJ should decide whether a basis existed for the imposition of sanctions under governing statutory and regulatory authorities based upon the evidence before the ALJ. *Cf. Emerald Oaks*, DAB No. 1800 (2001).

It is well-established that CMS has discretion to determine which sanction to impose. 42 C.F.R. § 493.1804(d); *Edison Med. Labs.*, DAB No. 1713, at 13 (A single condition-level deficiency would suffice to establish CMS's authority to impose a principle sanction.); *see* 42 C.F.R. § 493.1806(a) ("A laboratory's failure to comply with even a single applicable condition is ground for CMS to impose one or more principle or alternative sanctions."). Therefore, if it is determined that Victor Valley was noncompliant with one or both condition-level requirements, then the sanctions CMS proposed must be upheld. *See Wade Pediatrics*, DAB No. 2153, at 2-3; *Edison Med. Labs.*, DAB No. 1713, at 21; *Ward Gen. Practice Clinic*, DAB No. 1624, at 2 (1997); *see also* 42 C.F.R. §§ 493.1806, 493.1807.

IV. Issues

The issues before me are whether CMS has authority under CLIA to impose the sanctions of:

1. Revoking the laboratory's CLIA certificate, effective September 25, 2007;

2. Limiting the laboratory's CLIA certificate for the subspecialty of bacteriology, effective August 1, 2007;

3. Cancelling the laboratory's approval to receive Medicare payments for any services, effective August 1, 2007; and

4. Imposing a two-year prohibition against Dr. Pawlowski, Victor Valley's laboratory director, from owning, operating, or directing another clinical laboratory.

V. Discussion

A. Victor Valley was in violation of the condition-level requirement of 42 C.F.R. § 493.801(b)(4) (Testing of Samples), based on its intentional referral of two proficiency testing samples to Quest on June 14, 2007 for analysis.

CMS's arguments in the case before me focus on whether Victor Valley intentionally submitted the proficiency testing samples to a reference laboratory. CMS claims that Victor Valley improperly referred two proficiency testing samples to another laboratory for analysis and, therefore, was not in compliance with all conditions for CLIA certification. CMS further alleges that the improper referral posed immediate jeopardy to patient health and safety.

The Board in *Wade Pediatrics* determined that for Petitioner Wade:

> CMS was required to revoke the [CLIA] certificate for at least one year only if Wade "intentionally referred" PT samples for analysis that it was certified to perform. If Wade's violation of the regulatory prohibition against sending PT samples for any analysis was non-intentional, on the other hand, the regulations authorized CMS to revoke Wade's certificate only if CMS determined that the violation constituted a condition level deficiency.

Wade Pediatrics, DAB No. 2153, at 12-13 (emphasis in original).

The language of 42 C.F.R. § 493.801(b)(4) clearly indicates that a "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." The statute and regulations allow for no exceptions to the prohibition. Moreover, the motives of the laboratory that sends proficiency testing samples to another laboratory for analysis are irrelevant.

Even if the non-disputed material facts in favor of Victor Valley – that the laboratory technician did not intentionally refer the proficiency sample to Quest – were established, Victor Valley would still not prevail, unless it could establish that the technician's actions were a mistake.

CMS argues that Victor Valley has admitted that an improper proficiency test referral occurred and, therefore, it was in violation of 42 C.F.R. § 493.801(b)(4). CMS asserts that the regulation requires a laboratory director to "[e]nsure that . . . the proficiency testing samples are tested as required under subpart H" of 42 C.F.R. Part 493, and Dr. Pawlowski failed to comply with this requirement. CMS cites *Wade Pediatrics* in maintaining that it may revoke a laboratory's certificate regardless of whether the referral was intentional or non-intentional.

Petitioners admit that a referral to Quest did occur. However, Petitioners advance several arguments in asserting that the referral did not violate CLIA and its implementing regulations. Petitioners argue that: (1) the laboratory technician was unable to complete the testing for the two proficiency test samples at Victor Valley's own laboratory and had no choice but to refer the samples to Quest for analysis; (2) the improper referral was a mistake by an employee, rather than an intentional act on the part of the hospital; (3) when its laboratory technician sent the proficiency test samples to Quest for analysis, she did not intend to violate the CLIA statute and regulations; (4) the laboratory technician followed the laboratory's usual procedure for testing patient samples; and (5) no violation existed, because Petitioner reported to CAP only the results from its own laboratory technician's testing on the two samples.

1. Victor Valley was certified to perform tests in the subspecialty of bacteriology.

Petitioners maintain that the laboratory technician tested the two proficiency testing samples to its laboratory's capacity before referring the proficiency testing samples to Quest for testing. Victor Valley maintains that the laboratory technician was unable to complete the testing of the two proficiency testing samples at Victor Valley's own laboratory and, therefore, had no other choice but to refer the samples to Quest for testing. Dr. Pawlowski maintains that the laboratory technician's action of referring the proficiency testing samples to Quest was a mistake or inadvertent.

CMS maintains that Victor Valley was certified in the subspecialty of bacteriology and, therefore, should have tested the specimens to its laboratory's limits and then reported the test results to CAP. Victor Valley and Dr. Pawlowski disagree, claiming the laboratory was unable to perform the analysis on the two proficiency testing samples.

I first determine whether Victor Valley was certified to perform the analysis on the two specimen samples it received from CAP and subsequently referred to Quest. If Victor Valley was unable to complete the analysis, what should its laboratory technician have done relative to those tests Victor Valley was unable to perform? If Victory Valley was not certified to perform the particular type of analysis for which it referred the two proficiency testing samples to Quest, then an improper referral provision may not have occurred. *Wade Pediatrics,* DAB No. 2153, at 15. However, if Victory Valley was certified to perform the tests on the two samples, then a mistake is not a defense for a laboratory to send out samples it was certified to perform. 42 C.F.R. § 493.801(b)(4).

At hearing, Gary Yamamoto testified on behalf of CMS. Mr. Yamamoto conducted the on-site complaint survey of Victor Valley's laboratory on July 27, 2007 and produced the Statement of Deficiency. In weighing his opinions in both his affidavit (CMS Ex. 2) and his testimony at the in-person hearing, I consider his training, education, experience, knowledge, and skills. Mr. Yamamoto has been a laboratory consultant with CMS since

1997. He has reviewed and participated in numerous surveys performed by state agencies, since his employment with CMS. CMS Ex. 2, ¶ 2. Mr. Yamamoto had prior work experience as a CLIA surveyor with the State of California for five years, averaging 100 CLIA surveys per year. Prior to working as a state surveyor, Mr. Yamamoto worked in both reference and hospital laboratories after receiving his license to do such work from the State of California in 1985. His laboratory work experience includes chemistry and hematology and immuno-hematology testing. CMS Ex. 2, ¶ 3.

At hearing, Mr. Yamamoto testified as to why a laboratory could be certified to perform a test that it is unable to perform. Mr. Yamamoto discussed the distinction:

> [w]hen laboratories are certified under the CLIA program, they're certified in these broad categories of specialties and subspecialties. We don't certify laboratories down to a level any lower that that. So, in this particular case, Victor Valley Community Hospital was certified under the CLIA program for the subspecialty of bacteriology. . . . Under their CLIA certification, it allows them to be able to perform and report patient test results for laboratory tests that are considered bacteriology laboratory tests. . . . We do not certify the laboratory just for that specific test under a specific specialty. So, yes, the laboratory may be certified but may not – may not and most of the times do not perform all tests that may be considered under that particular specialty and subspecialty.

Tr. 26-29; *see* CMS Ex. 2 ¶¶ 8, 9, 31, 32.

A review of Victor Valley's Certificate of Accreditation, effective January 3, 2007 through January 2, 2009, shows that its laboratory was certified to perform all tests in microbiology. CMS Ex. 1. Although Petitioners argue that the laboratory technician was not capable of performing the required test and, as such, she had no other choice but to refer the proficiency tests to Quest, the evidence before me does not support this assertion.

2. Victor Valley's laboratory technician should not have referred the two patient testing samples to Quest for analysis.

Regulations that implement CLIA parallel the Social Security Act's (Act) requirement that the Secretary revoke a laboratory's CLIA certificate where that laboratory improperly refers a proficiency testing sample to a reference laboratory. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.1840(b). The laboratory must not send proficiency testing samples to another laboratory for any analysis that the laboratory is itself certified to perform. 42 C.F.R. § 493.801(b)(4). Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that receives proficiency

testing samples from another laboratory for testing must notify CMS of the receipt of those samples. 42 C.F.R. § 493.801(b)(4).

Proficiency testing is designed to determine a laboratory's accuracy in performing testing for its patients. Each laboratory enrolls in a proficiency testing program and is sent proficiency samples for testing, approximately three times a year. The specimens are clearly marked as proficiency testing samples, so the technician receiving them knows that they are test materials, not patient specimens. The laboratory that is being tested is required to test the proficiency samples the same way it tests patient specimens.

Congress noted the importance of proficiency testing as a means of measuring and ultimately ensuring laboratory competence:

> Proficiency testing is a method of externally validating the level of a laboratory's performance. . . . A significant deficiency in the current proficiency testing regime is its inability to assure that proficiency samples are treated like patient specimens. Samples are mailed to laboratories, and although proficiency testing organizations recommend that tests be treated in the same manner as patient samples, there was evidence that laboratories retest samples repeatedly to ensure satisfactory results and send proficiency testing samples out to other laboratories for analysis. The only way to guarantee that samples are treated by the same personnel, at the same speed, using the same equipment as patient specimens is though [sic] blind or on-site proficiency testing. . . .

H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3836-37.

CAP sent the proficiency samples to Victor Valley to specifically test Victor Valley's, not Quest's, laboratory's proficiency. In enacting CLIA, Congress was concerned that laboratories were sending their proficiency testing samples to other laboratories for analysis, or retesting the samples to ensure a satisfactory result. It is within this context that Congress authored the prohibition on intentional referrals of proficiency testing.

At hearing, Mr. Yamamoto addressed what Victor Valley's laboratory technician should have done when she reached the limits of the laboratory's testing capability with the proficiency testing samples:

> The tech should've tested it down to as far as they do within the laboratory and then report that answer back to the proficiency testing sample, not – not refer the specimen itself either back to the proficiency testing organization or to another laboratory for additional testing.

Tr. 31. Quest did not test the proficiency samples that Victor Valley sent it and, instead, notified CMS of their receipt. However, Mr. Yamamoto testified as to what would have resulted had Quest actually performed the tests.

> In the process of Quest testing those samples, Quest would have repeated the test that Victor Valley performed. . . . Quest Laboratories would've gotten to the same point in the testing process that Victor Valley did and that Quest too would have then referred the sample out to another laboratory. So, sending the sample out to Quest Laboratories, Quest Laboratories would have confirmed the test results that Victor Valley had obtained. . . . there would be the potential there for Quest to have repeated testing that Victor Valley had done and would have confirmed their test results.

Tr. 76.

I find Mr. Yamamoto's testimony credible, and Petitioners do not dispute Mr. Yamamoto's testimony. I therefore conclude that when Victor Valley's laboratory technician reached the limits of the laboratory's testing capability with the proficiency testing samples, she should have reported the test results directly to CAP and should not have referred the two patient testing samples to Quest.

3. The actions of Victor Valley's laboratory technician were not a mistake or inadvertent.

Victor Valley's laboratory technician's motives at the time she referred the two patient testing samples to Quest for testing are irrelevant. What is relevant is whether the laboratory technician's action of referring the proficiency testing samples to Quest was a mistake or inadvertent. Although Dr. Pawlowski has repeatedly advanced the argument that the referral was inadvertent or a mistake, he has offered no evidence throughout these proceedings to support these assertions. Tr. 9, 17, 18-19, 20, 21. Irrespective of Dr. Pawlowski's claim of mistake or inadvertence, nothing in the record suggests that the referrals were a mistake or inadvertent. In current practice, where proficiency testing samples are clearly marked thus enabling a laboratory technician who receives them to know they are test materials, not patient specimens, it is difficult to conceive of an inadvertent referral. In fact, the laboratory technician's volitional act of labeling the samples sent to Quest as proficiency testing samples establishes that she knew that the specimens she was handling were proficiency testing samples. She clearly labeled them as such when she referred them to Quest, and she intended to send them to Quest for further testing. These actions show that she intentionally referred the proficiency samples to another laboratory for analysis.

Petitioners have not denied that its laboratory technician sent proficiency samples to Quest, nor has Dr. Pawlowski established that the act of sending the samples was a mistake or inadvertent, rather than intentional. Petitioners indicated on their pre-hearing witness list that they would call the laboratory technician to testify at hearing; however, Petitioners ultimately did not call the laboratory technician.

I therefore conclude that the unequivocal and unchallenged evidence establishes that the laboratory technician deliberately referred the proficiency testing samples to Quest for analysis. Further, the evidence establishes that Victor Valley's laboratory technician's referral of the two proficiency testing samples was not a mistake or an inadvertent act.

4. Victor Valley's laboratory technician intentionally referred the two patient testing specimens to Quest for analysis on June 14, 2007.

The regulations pertaining to proficiency testing include requirements ensuring that tests are performed using a laboratory's routine methods and that the testing is documented. The regulation at section 493.801(b) requires:

> (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 date 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 one year. . . .

42 C.F.R. § 493.801(b) (emphasis added). As quoted above, 42 C.F.R. § 493.801(b)(4) establishes an absolute ban on sending out proficiency testing samples to another laboratory if the laboratory is certified to perform the testing.

Congress enacted CLIA to assure that clinical laboratories perform medical tests accurately. Congress intended CLIA to establish a single set of standards to govern all providers of laboratory services, including those which provide laboratory services to Medicare beneficiaries. *See* H.R. Rep. No. 899, *reprinted in* 1988 U.S.C.C.A.N. at 3839. It is apparent, both from the Act itself and its legislative history, that Congress considers proficiency testing, conducted pursuant to standards the Secretary developed, to be an important factor in assuming that clinical laboratories conduct tests accurately and reliably. The House of Representatives Committee Report that supported the Act provides:

> To maintain its certification under the bill, a laboratory would have to participate successfully in a proficiency testing program that met standards established by the Secretary. The Committee believes that proficiency testing should be the central element in determining a laboratory's competence, since it purports to measure actual test outcomes rather than merely gauging the potential for accurate outcomes.

H.R. Rep. No. 899, *reprinted in* 1988 U.S.C.C.A.N. at 3849. Further, implicit in CLIA is Congress' finding that, to be meaningful, a laboratory must perform proficiency tests at its own premises.

The regulations do not define the term "intentionally referred," which is contained in the regulations at 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b). "Intentionally refers" is found in the statute at 42 U.S.C. § 263a(i)(4). Neither Congress nor the Secretary has defined "intentionally" as used in the context of 42 U.S.C. § 263a(i)(4), and 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b).

However, as guidance, the Board in *Wade Pediatrics* discussed extensively the legislative intent of CLIA and what constitutes an intentional referral. The Board determined that:

> 1. A referral is intentional if it is knowing and willful, that is, not done by accident or mistake. *Wade Pediatrics*, DAB No. 2153, at 13-14.
>
> 2. A laboratory does not need to report results to be considered improper. The plain language of the statute, however, requires revocation upon a determination that the proficiency test was intentionally referred for analysis. No language in the statutory provision indicates that Congress considered a referral improper only when the results obtained in the referral laboratory were reported to the proficiency organization or agency. "Even if PT results obtained in a referral laboratory were not reported to the PT organization or agency, they might cause the referring laboratory to repeat the test in its own laboratory until it obtained a similar result to report as its own." The Board goes on to say that this would not fairly represent the proficiency of that laboratory in achieving accurate outcomes on patient specimens. *Id.* at 12.
>
> 3. If a non-intentional referral has occurred, the regulation authorizes CMS to revoke a laboratory's CLIA certification only if CMS determined that the violation constituted a condition-level deficiency. *Id.* at 13.

In discussing the phrase "knowing and willful" the Board in *Wade Pediatric* states:

> It is more consistent with the purpose of CLIA to read the phrase "knowing and willful" fairly broadly. At the very least, however, defining the term "intentional" to mean knowing and willful excludes a situation where the referral was a mistake or an accident.

Id. at 14.

The facts in this case show that: (1) Victor Valley's proficiency sample referral policy was to not refer proficiency testing under any circumstances (Victor Valley Br. at 11); (2) Victor Valley's laboratory technician referred the proficiency samples to Quest for analysis; and (3) the laboratory technician intended to refer the two proficiency samples for analysis. Therefore, proficiency testing samples were intentionally referred to Quest for analysis.

Victor Valley is responsible for the actions of its staff and, in this case, for the intentional referral of the two proficiency testing samples to Quest for analysis. As CMS correctly points out in its brief, the Board articulated in its decision in *Oakland Medical Group* that a laboratory is responsible for the actions of its employees. *Oakland Med. Group, P.C.*, DAB No. 1755, at 8 (2000). As the ALJ held in *Melvin C. Murphy, M.D., P.C.*, and applying the Board's logic in *Oakland Medical Group*, I also determine that Victor Valley is liable for the acts of its employees whether it authorized, or even knew that, the employee had intentionally referred its proficiency testing samples to another laboratory for analysis. *Schweiker v. Hansen*, 450 U.S. 785, 789, *reh'g denied*, 451 U.S. 1032 (1981); *Melvin C. Murphy, M.D., P.C.*, DAB CR590 (1999); *see Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004); *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 750 (6th Cir. 2004).

5. That Victor Valley did not report as its own any Quest laboratory test results to CAP is irrelevant.

Victor Valley argues that, for it to have committed an "intentional referral" within the meaning of the statute and regulations, it must have referred its proficiency testing samples to another laboratory with the intent of reporting such results as its own. Tr. 14-15; Victor Valley Br. at 8-9. Victor Valley states that it only reported its own testing of the proficiency testing specimens to CAP. CMS does not dispute that Victor Valley only reported its own testing to CAP, and the evidence also supports Victor Valley's assertion. Moreover, no dispute exists between the parties that Victor Valley actually tested the two proficiency testing specimens up to its laboratory's capacity. However, even accepting as true Victor Valley's assertion that it reported to CAP only its own test results, this

assertion does not controvert my finding that Petitioner intentionally referred the proficiency tests samples to Quest.[5]

It is irrelevant whether Victor Valley intended to report the results of its referral to Quest as its own results. The statute requires revocation of a CLIA certificate where a laboratory intentionally refers its proficiency testing to another laboratory for analysis. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.801(b)(4). The requirement ensures that the reported proficiency test results are those of the reporting laboratory – both the statute and implementing regulation clearly prohibit referral "for any analysis" and requires license revocation if referral is intentional. Therefore, the prohibition is for intentional referral for *any* analysis of proficiency testing samples, not for the reporting of proficiency tests obtained contrary to the statute and implementing regulations.

Victor Valley's argument, that an intentional referral occurs only when a laboratory intends to report the test results as its own, fails before me for the same reasons the same argument failed before ALJ Sickendick in *Lackawanna Medical Group Laboratory* and before the Tenth Circuit in *Wade Pediatrics*. *See Lackawanna Med. Group Lab.***,** DAB CR957 (2002), *aff'd,* DAB No. 1879 (2003); *Wade Pediatrics*, 569 F.3d 102 (10th Cir. 2009). In *Lackawanna Medical Group Laboratory*, ALJ Sickendick was not persuaded that the statutes or regulations do not mention as an exception or defense to the prohibition the fact that the sending laboratory never reports the analysis of the proficiency testing samples to the proficiency program. Rather, ALJ Sickendick found that what the act prohibits is the sending of a proficiency test sample to another laboratory for analysis when the sending laboratory is certified to do the analysis. *See Lackawanna Med. Group Lab.*, DAB CR957; *see also White Lake Family Med., P.C.*, DAB No. 1951 (2004); *Primary Care Med. Group*, DAB No. CR439 (1996) (holding motive is irrelevant).

The petitioner in *Wade Pediatrics* appealed its case to the U.S. Court of Appeals for the Tenth Circuit. The court upheld the Board's decision, rejecting petitioner's argument that it did not violate CLIA, because it made no attempt to pass off the laboratory's test results as its own. The court held that nothing in the statute even "suggests that a test-taker must pass off another lab's results before a violation has occurred." The court stated that "[u]nder the statute's plain terms, *any* intentional 'referral' of a proficiency testing sample 'for analysis' in another lab is forbidden." *Wade Pediatrics*, 567 F.3d 1202 (emphasis in original). Victor Valley attempts unsuccessfully to distinguish the facts and arguments in the case before me with that of the petitioner in *Wade Pediatrics*.

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[5] I am also unpersuaded by the December 10, 2008 letter from CAP to Thomas E. Hamilton, Director of Survey and Certification Group at CMS, that offers CAP's opinion regarding the CLIA statute and congressional intent of the legislation. The letter has been entered into the record as P. Ex. 3, at Petitioners' request.

While the actions of Victor Valley and its laboratory technician may not have been as egregious as that of the petitioner in the *Wade Pediatrics* case, they still violated the purpose of the CLIA statute and regulations.

Victor Valley's interpretation of the statute represents a too narrow view of what constitutes an intentional referral. Its interpretation of 42 U.S.C. § 263a(i)(4) would make it almost impossible for CMS to revoke a CLIA certificate pursuant to that provision, as CMS would be required to prove a laboratory's intent to submit another laboratory's proficiency test results as its own. As such, Victor Valley's defense that it did not report as its own the test results of the referred test samples it had sent to Quest fails. Additionally, Victor Valley is misguided in its interpretation of the statute. It erroneously believes that Congress intended to address referrals only in instances where the laboratory both sent the samples to another laboratory for analysis *and also* reported the results of the analysis as its own. A review of the legislative history indicates that Congress was concerned about a laboratory's competence and determined to measure *actual test outcomes* rather than merely gauging the potential for accurate outcomes.

A House Committee Report reveals:

> The Committee was advised that some laboratories may treat proficiency testing 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 and the Committee seeks to prevent them through this agreement.

H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 24. Therefore, given the purposes underlying CLIA, I find Victor Valley's position that CMS's ability to take action against a laboratory that refers a proficiency testing sample to another laboratory for analysis only if the referring laboratory reports the results of that analysis as its own is without merit. In promulgating section 493.801(b)(4), CMS explained:

> PT specimen referral is not necessary for purposes of PT, 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. We understand that this violates the condition of treating the PT sample like it would treat a patient's specimen in this instance. It was the intent of the paragraph (b)(4) for the regulatory agency 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.

57 Fed. Reg. 7002, 7037-38 (Feb. 28, 1992). The fact that Victor Valley may engage in parallel testing of some of its patient specimens at another laboratory is not a basis for implying an exception to the statutory and regulatory prohibition against a referral of proficiency testing samples. CLIA is designed to ensure the accuracy and reliability of laboratory tests for the public, and the proficiency testing required under CLIA is, in effect, the federal program for ensuring the accuracy of laboratory tests.

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.

Victor Valley has not offered its policy on how it handles proficiency samples. However, Victor Valley's counsel argued at hearing:

> From my client's standpoint, Victor Valley, as the documents show, the referral was a mistake under their policies. Their policy was that you are not supposed to refer under any circumstances proficiency testing.

Tr. 19; *see* Victor Valley Br. at 11. Here, although Victor Valley represented that its policy on proficiency samples forbade the referral, the evidence demonstrates that its laboratory technician nonetheless knowingly and willfully sent the samples to Quest for analysis.

I also find that Victor Valley's argument that its laboratory technician attempted to comply with the requirements of 42 C.F.R. § 493.801(b), which requires a laboratory to test the proficiency testing samples in the same manner as it tests patient samples, fails. My review of section 493.801(b)(1) shows that the regulation is clear: "[t]he 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." The subsection goes on to require that the laboratory director must certify that the proficiency testing samples were integrated into the regular patient workload and tested using the laboratory's routine methods. Subsection 493.801(b)(1) mentions testing within the laboratory using the laboratory's routine methods, and, does not mention the possibility of sending out samples for analysis. As the laboratory technician was not called as a witness, no evidence exists that her referral of the proficiency samples was an attempt to comply with the regulations. Therefore, Petitioner's argument is unavailing.

I note that to prove "intention" in the context of 42 U.S.C. § 263a(i)(4) and 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b), CMS is not required to prove what the laboratory technician was thinking when she referred the proficiency samples to Quest on June 14, 2007. Rather, the issue is whether the laboratory technician's actions were intentional, i.e., deliberate (not inadvertent).

A copy of the requisition forms that Victor Valley prepared and CMS offered as CMS Ex. 5 supports the finding that the laboratory technician intentionally sent the proficiency testing samples to Quest. Therefore, no evidence exists of inadvertent referral, or, using the standard articulated by the Board in *Wade Pediatrics*, there was no accident or mistake since the laboratory technician intended to send the proficiency samples to Quest. The Board in *Wade Pediatrics* has made it clear that intentional referral is not limited to only when a laboratory has a specific intent to violate CLIA. Therefore, whether Victor Valley's laboratory technician intended to violate the CLIA requirement is irrelevant; rather, it is the act of the intentional referral that provides the basis of the violation here. Victor Valley itself has admitted that the referral was intentional, and, for the reasons discussed later, Dr. Pawlowski has failed to prove that the referral was an accident or a mistake. Tr. 17-18, 19; CMS Ex. 8, at 3.

The weight of the uncontroverted evidence in this case establishes that the laboratory technician intentionally referred proficiency testing samples to another laboratory, and Victor Valley has admitted such. Thus, regardless of her motivation, the laboratory technician acted with the requisite general intent to satisfy the civil penalty provision of CLIA, that is, the intent to act.

6. Victor Valley's reliance on language in the State Operations Manual to support its assertion that the proficiency test samples referred to Quest do not constitute an improper referral is unavailing.

Victor Valley argues that sections of CMS's State Operations Manual (SOM), and its interpretive guidelines for survey procedures for clinical laboratories, support its position that referral of a proficiency test sample to another laboratory for analysis is improper only if the sending laboratory uses the other laboratory's results as its own. Specifically, Victor Valley maintains that the written policy CMS was required to follow in June 2007, when its laboratory underwent a complaint survey, prohibited proficiency testing sample referrals only if the referring laboratory "intended to use the other laboratory's results as its own." Victor Valley Br. at 5. However, the language in the SOM that Victor Valley relies upon[6] does not support its assertions and provides no defense to its intentional referral of proficiency testing samples to Quest on June 14, 2007. Moreover, the SOM

[6] Victor Valley relies on CMS Publication 7, which includes the "Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services," Appendix C to the SOM. *See* P. Exs. 1 and 2.

and interpretive guidance Victor Valley relies upon do not have the force and effect of law. The Act and regulations, interpreted clearly, are the controlling law in this case. *Erringer v. Thompson*, 371 F.3d 625 (9th Cir. 2004).

I also note that in addressing a similar argument to that made by Victor Valley, the Board in *Wade Pediatrics* clearly articulated its position when it held that:

> [t]he plain language of the statute, however, requires revocation upon a determination that the PT sample was intentionally referred *for analysis*. There is no language in the statutory provision indicating that Congress considered a referral improper only when the results obtained in the referral laboratory were reported to the PT organization or agency.

Wade Pediatrics, DAB No. 2153, at 11 (emphasis in original). It is clear from the Board's analysis and holding that the prohibition is against sending the proficiency samples to another laboratory for analysis and not limited to only instances where the referring laboratory uses the results it obtained as its own. Therefore, Victor Valley's attempt to distinguish its argument from that of the petitioner in *Wade Pediatrics* by arguing that it did not report as its own any test results from Quest to CAP as its own also fails. *See* Victor Valley Br. at 8.

Petitioners in this case had constructive notice of the pertinent implementing regulations for CLIA. Moreover, both Victor Valley and Dr. Pawlowski had a duty to familiarize themselves with applicable standards before applying to be certified pursuant to those standards. Inasmuch as it was Petitioners' duty to be aware of the standards, CMS cannot be held responsible for Petitioners' failure to be aware of the applicable standards.

7. The fact that Victor Valley referred the two proficiency testing samples to another laboratory because its patient specimens are usually sent to an outside laboratory is irrelevant.

Victor Valley asserts that the laboratory technician who referred the two specimens in question to an outside laboratory did so believing that the CLIA statute and regulations required her to send the proficiency test specimens to the outside laboratory for further testing. Victor Valley further argues that the employee never intended to violate any rule or circumvent the proficiency test requirements. Rather, she attempted to comply with her understanding of the CLIA requirements. Tr. 14-16; Victor Valley Br. at 4-5, 11.

A laboratory contravenes the prohibition against referrals of proficiency tests by deliberately referring proficiency testing samples to another laboratory for analysis. The necessary elements of a violation consist of: (1) a referral of a proficiency testing sample by a laboratory to another laboratory; and (2) knowledge by the referring laboratory that the sample it is referring is a proficiency testing sample. If it is established that Victor

Valley deliberately referred a proficiency testing sample to Quest, then Victor Valley's motive for referring the sample is irrelevant. The Act and regulations do not distinguish between deliberate referrals that are motivated by good intentions and those that are motivated by some other purpose. Therefore, even if I accept that the laboratory technician did not know that her actions of referring the proficiency samples to another laboratory for analysis was prohibited by law and that she did not have the specific intent to violate a CLIA condition, these facts are irrelevant and are not a defense for Victor Valley. Moreover, the laboratory technician was under the impression she was supposed to treat proficiency testing specimens the same as she treated patient specimens; however, this does not minimize the fact that she intentionally referred proficiency samples to a reference laboratory in violation of CLIA and implementing regulations. CMS need only establish a general intent to act and not, as Victor Valley suggests, the specific intent to refer the proficiency samples.

Petitioners have not presented any substantive evidence that would establish that the referral of the test samples was non-intentional or that the cited deficiency was not a condition-level deficiency. While each Petitioner listed the lab technician that actually made the referral as a witness for the hearing, the technician was not produced as a witness at trial. Thus, the evidence that CMS presented establishes that Victor Valley violated the condition-level requirement of 42 C.F.R. § 493.801(b)(4), based on its intentional referral of two proficiency testing samples to Quest on June 14, 2007 for testing.

I conclude that Victor Valley violated 42 C.F.R. § 493.801(b)(4) by intentionally sending proficiency testing samples to another laboratory and that this conduct requires CMS to revoke its CLIA certificate for a period of not less than one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4), 493.1840(b). CMS must also cancel the laboratory's approval to receive Medicare payments. 42 C.F.R. § 493.1842(a).

B. Victor Valley was in violation of the condition-level requirement of 42 C.F.R. § 493.1441 (Laboratory Director), based on its intentional referral of two proficiency testing samples to Quest on June 14, 2007, and this violation formed an independent basis for CMS to revoke Victor Valley's CLIA certificate.

The condition that 42 C.F.R. § 493.1441 established requires that a laboratory have a director who meets the qualification requirements of section 493.1443 and who provides overall management and direction in accordance with section 493.1445, which outlines the specific responsibilities of the director. CMS alleges that this condition was violated when Victor Valley's laboratory director failed to ensure that proficiency testing samples were tested as subpart H required. CMS Ex. 6, at 2.

Dr. Pawlowski, as the laboratory director, was responsible to train his staff as to how to handle both patient specimens and proficiency samples, and he was responsible for the overall operation and administration of Victor Valley's laboratory, in accordance with 42 C.F.R. § 493.1445. Part of that responsibility was to ensure that quality control and quality assurance programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. 42 C.F.R. § 493.1445(e)(5). Dr. Pawlowski had a duty to keep apprised of the day-to-day operations of his laboratory and to exercise proper supervision over his employees. He was also obligated to familiarize himself with the specific CLIA regulations. With respect to proficiency testing, Dr. Pawlowski bore the ultimate responsibility for ensuring that proficiency testing was performed in accordance with the requirements set forth at 42 C.F.R. § 493.801. Dr. Pawlowski failed to adequately supervise Victor Valley's operations and employees.

Both Victor Valley and Dr. Pawlowski had adequate notice and opportunity to present evidence on the issue as to whether the condition that 42 C.F.R. § 493.1441 established was met. Victor Valley's violation of 42 C.F.R. § 493.1441, specifically its failure to meet the condition of laboratory director, forms an independent basis for CMS's revocation of Victor Valley's CLIA certificate.

C. CMS is required to revoke Petitioner's CLIA certificate for a one-year period.

The evidence in this case establishes that at least two condition-level violations existed at Victor Valley's laboratory at the time the July 27, 2007 survey was conducted. Failure by a laboratory to comply with even a single applicable condition can represent a critical breakdown in one of the major health care delivery or safety systems of the laboratory. *Ward Gen. Practice Clinic*, DAB No. 1624, at 2. As previously noted, a violation of just one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1804(b); *Edison Med. Labs.*, DAB No. 1713.

The CLIA statute and applicable regulations require CMS to revoke a laboratory's CLIA certificate for at least one year if the laboratory "intentionally refers" its proficiency testing samples to another laboratory for analysis. No opportunity exists for a less severe sanction as the statute itself specifies the sanction. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4), 493.1840(b). In this case, the sanction of revocation is consistent with the purpose of CLIA, because it serves the remedial purposes of protecting individuals against substandard testing by Petitioners and safeguarding the general public against health and safety hazards that might result from their activities. 42 C.F.R. § 493.1804(a). For the reasons already discussed, the violations that CMS have proven establish a basis for revocation of the laboratory's certificate.

By law, Dr. Pawlowski is prohibited from owning or operating a CLIA laboratory for two years due to the revocation of Victor Valley's CLIA certificate. 42 U.S.C. § 263a(i)(3). The two-year prohibition runs from the date of the revocation of the laboratory's certificate, pursuant to 42 U.S.C. § 263a(i)(3), which is also the date of this decision. This prohibition is automatic by operation of law and not subject to appeal. *See Rustom Ali, Jahan Fedours, & Scottsdale Med. Lab.*, DAB No. 2016 (2006).

VI. Conclusion

Based on my review of all of the evidence presented in this case, I conclude that a basis exists for CMS to: (1) revoke Victor Valley's CLIA certificate for a one-year period, effective the date of this decision; (2) limit the laboratory's CLIA certificate for the subspecialty of bacteriology, effective August 1, 2007; (3) cancel the laboratory's approval to receive Medicare payments for any services, effective August 1, 2007; and (4) impose a two-year prohibition against Victor Valley's owners and operators, including its laboratory director Dr. Pawlowski, from owning, operating, or directing another clinical laboratory.

/s/
Alfonso J. Montaño
Administrative Law Judge