**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

J.B. and Greeta B. Arthur Comprehensive Cancer Center Laboratory
(CLIA No. 26D1047130),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-543

Decision No. CR2436

Date: September 21, 2011

# DECISION

Petitioner, J.B. and Greeta B. Arthur Comprehensive Cancer Center Laboratory (Cancer Center), did not intentionally refer its proficiency testing (PT) samples to another laboratory for analysis. Consequently, Centers for Medicare & Medicaid Services (CMS) does not have a basis to impose remedies against Petitioner pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[1] 42 U.S.C. § 263a *et seq.*, and its implementing regulations at 42 C.F.R. Part 493.

## I. Background

This case is before me based on Cancer Center's appeal of CMS's proposed sanctions against it. Cancer Center is a CLIA-certified laboratory located in Mexico, Missouri, that provides comprehensive care to cancer patients, including radiation therapy and chemotherapy. Cancer Center is certified to perform testing in the subspecialties of

[1] "CLIA" when used in this decision refers to both statutory and regulatory provisions governing the program, unless otherwise indicated. Pub. L. 100-578, codified at 42 U.S.C. §§ 263a, 1302, 1395x(e).

chemistry and hematology. Tr. at 192, 239-40; P. Ex. 1, at 24. To maintain this certification, Cancer Center enrolled in a CLIA-certified proficiency testing program administered by the American Association of Bioanalysts (AAB). Petitioner's Exhibits (P. Exs.) 2.1, at 3; 2.2, at 2; 2.3, at 2; 2.4, at 2.

In September 2009, Cancer Center underwent a routine survey by The Joint Commission (TJC). Following that survey Cancer Center received a letter dated September 30, 2009 from TJC. CMS Exhibit (CMS Ex.) 1; P. Ex. 7. The letter stated that after Cancer Center performed its PT sample tests for three testing events in 2008 and one testing event in 2009, the PT samples were also tested at Audrain Medical Center (AMC). AMC and Cancer Center are both operated by Audrain Health Care, Inc. (Audrain). The letter further advised that the testing at AMC occurred before Cancer Center's results were submitted to its PT provider AAB. TJC interpreted the circumstances as not being an intentional PT referral and granted Cancer Center its accreditation. However, the letter advised Cancer Center that based on its finding of a potential PT referral, TJC was required to report the information to CMS. A copy of the letter was provided to Regie Haug, CMS CLIA Region VII Office in Kansas City, because Mr. Haug served as a laboratory consultant for the CLIA program. CMS Ex. 1, at 1-2; P. Ex. 7, at 2.

Upon receiving the letter from TJC, Mr. Haug asked surveyors from the Missouri Department of Health & Senior Services to conduct a complaint investigation survey of Cancer Center. Tr. at 32. The survey was completed on October 20, 2009. Based on the survey's findings, CMS determined that Cancer Center improperly referred PT samples to another laboratory for analysis. In a letter to Petitioner dated January 14, 2010, CMS proposed to revoke Cancer Center's CLIA certificate for one year and to cancel Cancer Center's approval to receive Medicare payment for any services effective January 29, 2010. The letter also advised Cancer Center that upon revocation of its CLIA certificate, the owners and operators of the laboratory would be prohibited from owning or operating any laboratory for at least two years from the date of revocation. CMS Ex. 2. On January 21, 2010, Cancer Center asked CMS to reconsider its decision. CMS responded affirming its prior determination.[2] CMS Ex. 3.

By letter dated March 11, 2010, Petitioner requested an Administrative Law Judge (ALJ) hearing. The case was docketed as C-10-543, and assigned to me for hearing and decision.

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[2] I note that although the February 9, 2010 response letter from CMS references the prohibition of inter-laboratory communication, it is a separate standard identified at 42 C.F.R. § 493.801(b)(3), under the Condition of *Enrollment and testing of samples*. Cancer Center was not cited for failure to comply with the inter-laboratory standard. Rather, it was cited only for referring PT samples to another laboratory for analysis, which is a violation under 42 C.F.R. § 493.801(b)(4).

An in-person hearing was conducted in Kansas City, Missouri, from January 19-20, 2011. A 272-page transcript (Tr.) of the proceedings was prepared and the parties were afforded an opportunity to review the transcript for errata.[3] CMS offered CMS Exs. 1-4, and Cancer Center offered P. Exs. 1-17, 20-22.[4] All of the exhibits were admitted into evidence at the hearing. Tr. at 14-16, 20-21. Cancer Center's objections to CMS Exs. 2 and 4 were overruled. Tr. at 15-16. CMS called as a witness Regie Haug, a CMS medical technologist and a laboratory consultant to the CLIA program. Petitioner called as witnesses Louis J. Leonatti, a private attorney who represented Audrain and three Audrain employees: David A. Neuendorf, President and CEO of AMC; Carmen Oberlag, an AMC medical technologist; and Judith K. Hammettt, a clinical laboratory technician at Cancer Center's laboratory. Following the hearing, the parties filed post-hearing briefs (CMS Br. and P. Br.) and Cancer Center filed an answer brief (P. Reply).

## II. Issue

The issue in this case is whether Cancer Center violated CLIA and its implementing regulations by "intentionally referring" PT samples to another laboratory for analysis.

## III. Controlling Statutes and Regulations

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* § 353 of the Public Health Service Act, *codified at* 42 U.S.C. §§ 263a, 1302, and 1395x(e). The purpose of the CLIA requirements is to ensure the accuracy and reliability of laboratory tests, and hence the health and safety of those tested. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3829. CLIA was designed to establish a single set of standards applicable to all laboratory services. The Secretary of the Department of Health and Human Services (Secretary) administers CLIA, through CMS. To be certified, a laboratory must meet the conditions of certification set out in the statute and regulations. 42 U.S.C. § 263(a)(f)(1)(E); 42 C.F.R. Part 493.

A laboratory that holds a CLIA certificate must enroll in an approved PT program that meets the specific criteria set out at subpart I of Part 493. 42 C.F.R. §§ 493.801, 493.803. Proficiency testing is designed to determine a laboratory's accuracy in performing testing for its patients. Regulations governing performance of proficiency tests provide that a

[3] Cancer Center filed its suggested errors and proposed corrections on March 7, 2011, and the transcript was amended as outlined in my Order Settling Transcript issued May 11, 2011.

[4] Cancer Center's exhibits 18 and 19 were withdrawn. Tr. at 19-21.

participating laboratory must test PT samples it receives in the same manner as it tests patient samples; must not engage in inter-laboratory communications pertaining to PT results prior to the deadline for reporting results; must not refer PT samples to another laboratory for analysis; and must document and maintain documentation for the handling, preparation, processing, examination, and each step in the testing and reporting of results for all PT samples. 42 U.S.C. § 263(a)(1)(4); 42 C.F.R. § 493.801(b), (b)(1), and (b)(4). If a laboratory intentionally refers a PT sample to another laboratory for analysis, CMS must revoke its license for at least one year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. § 493.1840(b); *accord Wade Pediatrics v. Department of Health and Human Services*, 567 F.3d 1202, 1204 (10th Cir. 2009); *Lackawanna Medical Group Lab.*, DAB No. 1870 (2003).

A laboratory that is dissatisfied with a determination by CMS to impose sanctions against it may request a hearing before an ALJ to contest CMS's determination. 42 C.F.R. § 493.1844. The standard of proof that is employed is a preponderance of the evidence. CMS has the burden of coming forward with sufficient evidence to prove a *prima facie* case that the laboratory is not complying with one or more CLIA conditions. The laboratory has the ultimate burden of rebutting, by a preponderance of the evidence, any *prima facie* case of noncompliance that is established by CMS. *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999); *Hillman Rehabilitation Center*, DAB No. 1611 (1997).

## IV. Findings of Fact and Conclusions of Law

1. Cancer Center received five PT samples per testing event from its PT provider AAB for three events in 2008 and one event in 2009.

2. It is undisputed that Cancer Center tested each of the PT samples in its own laboratory on February 29, 2008 for the first testing event in 2008; on June 4, 2008 for the second testing event in 2008; on October 28, 2008 for the third testing event in 2008; and on March 6, 2009 for the first testing event in 2009.

3. It is undisputed that AMC also tested the unused portions of the PT samples that were directed to Cancer Center as part of Cancer Center's participation in a PT program on February 29, 2008 for the first testing event in 2008; on June 4, 2008 for the second testing event in 2008; on October 28, 2008 for the third testing event in 2008; and on March 6, 2009 for the first testing event in 2009.

4. It is undisputed that the electronic report submitted to the PT provider AAB shows that the results were submitted online by the AMC laboratory technician on February 29, 2008, at 12:45 p.m., for the first testing event in 2008; on June 6, 2008, at 9:51 a.m., for the second testing event in 2008; on October 30, 2008, at 7:58 a.m., for the third testing event; and on March 7, 2009, at 12:56 p.m., for the

first testing even of 2009.

5. The AMC laboratory technician reported to the PT provider AAB only the results Cancer Center's laboratory technician performed on each of Cancer Center's PT samples for the three testing events in 2008 and the first testing events in 2009. There were no test results from AMC's testing of Cancer Center's PT samples reported to AAB.

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

7. Under CLIA and applicable regulations, a laboratory intentionally submits a proficiency testing specimen to a reference laboratory when it does so deliberately, and not inadvertently.

8. CMS made a *prima facie* case of noncompliance based on the facts it pleaded in the Statement of Deficiencies.

9. Cancer Center met its burden of rebutting, by a preponderance of the evidence, CMS's *prima facie* case of noncompliance.

10. Cancer Center did not send the PT samples or portions of its samples to AMC for analysis.

11. Cancer Center's actions in bringing its unused portions of its PT samples to AMC for storage did not constitute an intentional referral for analysis.

12. The revocation of Petitioner's CLIA certificate for a period of one year is unreasonable in light of its compliance with CLIA requirements.

13. CMS improperly canceled Cancer Center's approval to receive Medicare payment for its services, effective January 29, 2010.

14. There is no basis to impose against Cancer Center's owners or operators the two-year prohibition against owning or operating any laboratory.

## V. Discussion

This is a case in which CMS cites Cancer Center for the violation of intentionally referring PT samples to another laboratory for analysis. At issue here are four PT

samples related to testing events that had occurred in 2008 and during the first testing event in 2009. The other laboratory is part of a hospital called Audrain Medical Center which is also referenced in this decision as AMC. A preliminary discussion of the relationship between Cancer Center and AMC is relevant.

Cancer Center is operated by Audrain. Audrain also operates AMC. Tr. at 23-24. AMC is an acute care hospital and Cancer Center is part of AMC. AMC and Cancer Center each have clinical laboratories with different CLIA certificates. Although they use some of the same protocols, they basically operate independently of each other, including having separate directors for each laboratory. Request for Hearing at 3; P. Br. at 1, 10; P. Ex. 1; Tr. at 127, 131, 145.

Cancer Center's building and equipment are owned by Audrain County and are provided to AMC under a lease agreement. Cancer Center originally did not have its own mailing address. When PT samples arrived for Cancer Center they would be delivered to AMC. An AMC staff member would bring the PT samples to Cancer Center for testing by Cancer Center's staff in its own laboratory. Cancer Center initially also did not have a refrigerator to store PT samples, nor did it have a computer with internet access to provide electronic reporting of the test results. Tr. at 193. After a PT sample was tested by Cancer Center's laboratory technician at its laboratory, the unused portion of the PT sample would be brought back to the AMC laboratory for storage. Cancer Center's PT sample test results would be transcribed by Cancer Center's technician onto a form, which would be brought to AMC, and then the sample test results would be reported by AMC's laboratory technician to the PT provider AAB from a computer located in AMC's laboratory. The PT result form would then be brought back to Cancer Center. When AMC received the PT provider results of Cancer Center's PT testing, someone at AMC would bring them to Cancer Center. Tr. at 191-96. The unused portion of the PT samples remained stored in AMC's refrigerator until the test results were received from the PT provider, after which they would be discarded. P. Br. at 10-11; Tr. at 227.

### A. CMS made a *prima facie* case of noncompliance based on the facts it pleaded in the Statement of Deficiencies (Form 2567), but Cancer Center successfully rebutted it in its case-in-chief.

According to CMS, the October 20, 2009 complaint survey and the follow-up investigation on January 6, 2010, confirmed that in 2008 and the beginning of 2009, Cancer Center sent PT samples for four testing events to AMC for analysis prior to its reporting those results to the PT provider AAB. CMS maintains that all of the PT samples at issue were clearly marked as test samples, and that Cancer's Center's actions were an intentional referral. CMS Br. at 1-3, 9-11; CMS Ex. 4, at 2; Tr. at 33.

There is no dispute between the parties that Cancer Center's laboratory technician brought the PT samples to AMC on each of the three testing events in 2008 and the first

testing even in 2009. The parties' arguments, however, center on whether there was an "intentional referral" of these PT samples to the AMC laboratory "for analysis."

The relevant regulation requires, in pertinent part, that –

> (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).

The facts, as pleaded by CMS in the CMS 2567 and on which I base this decision, are uncontroverted. As noted already, they involve PT samples for three testing events in 2008 and one testing event in 2009. They are based on a review of Cancer Center's hematology PT reports, PT reports from AMC, electronic reports submitted electronically online to the PT provider, and surveyor interviews with laboratory staff. CMS Ex. 4, at 1-2. Specifically:

- **First PT Sample Event in 2008** - PT report forms show that for each of the five PT samples from the first testing event of 2008, the samples were tested by Cancer Center on February 29, 2008 between 11:42 a.m. and 11:57 a.m., and also tested by AMC on that same day between 11:17 a.m. and 12:18 p.m. The electronic report submitted to the PT provider AAB shows that the results were submitted online by the AMC technician at 12:45 p.m. on February 29, 2008. CMS Ex. 4, at 2; CMS Br. at 2-3.

- **Second PT Sample Event in 2008** - PT report forms show that for each of the five PT samples from the second testing event of 2008, the samples were tested by Cancer Center on June 4, 2008 between 10:37 a.m. and 10:49 a.m., and also tested by AMC on that same day between 11:41 a.m. and 11:44 a.m. The electronic report form submitted to the PT provider AAB shows that the results were submitted online by the AMC technician at 9:51 a.m. on June 6, 2008. CMS Ex. 4, at 3; CMS Br. at 2.

- **Third PT Sample Event in 2008** - PT report forms show that for each of the five PT samples from the third testing event of 2008, the samples were tested by Cancer Center on October 28, 2008 between 11:30 a.m. and 11:49 a.m., and also tested by AMC that same day between 12:08 p.m. and 12:11 p.m. The electronic report form submitted to the PT provider AAB shows the results

were submitted electronically on October 30, 2008, at 7:58 a.m., by the AMC technician. CMS Ex. 4, at 3; CMS Br. at 2.

• **First PT Sample Event in 2009** - PT report forms show that for each of the five PT samples from the first testing event of 2009, the samples were tested by Cancer Center on March 6, 2009 between 10:46 a.m. and 10:58 a.m., and also tested by AMC that same day between 11:34 a.m. and 12:15 p.m. The electronic report form submitted to the PT provider AAB shows the results were submitted online on March 7, 2009, at 12:56 p.m., by the AMC technician. CMS Ex. 4, at 3-4; CMS Br. at 3.

CMS has established a *prima facie* case that PT samples directed to Cancer Center as part of its participation in the PT program were also tested by another laboratory, here AMC. However, for the reasons outlined below, Cancer Center has provided evidence to rebut CMS's *prima facie* showing.

**B. Cancer Center's actions in bringing its PT samples to AMC after completion of its PT testing were not an intentional referral.**

Cancer Center disagrees that it improperly referred its PT samples to AMC for analysis. Cancer Center claims that AMC's testing of the samples was totally unrelated to the proficiency testing event. Cancer Center's fundamental position is that simply because a PT sample is tested by another laboratory is not in and of itself a basis to find that a sample had been "referred . . . to another laboratory for analysis" according to 42 C.F.R. § 493.801(b)(4). P. Br. at 10-22; P. Ex. 1, at 1-2.

CMS's position is that by allowing AMC staff to test its PT samples and submit its test results to the PT provider, Cancer Center violated the prohibition against a laboratory intentionally referring its PT samples to another laboratory for analysis. CMS Br. at 12.

At the hearing Cancer Center called Judith Hammett to testify. Ms. Hammett held the position of clinical laboratory technician at Cancer Center, and participated in PT by testing samples for Cancer Center during the first three proficiency testing events in 2008 and the first testing event in 2009. Tr. at 238, 240-41, 243.

She testified that she never requested that AMC test Cancer Center's unused PT samples, nor did she ask AMC about the results of AMC's testing of the PT samples. She further testified that there never was an occasion where AMC tested the PT samples for Cancer Center's 2008 and 2009 PT events before the samples had been tested by Cancer Center, or before she had provided AMC with Cancer Center's test results. She testified that it would not have been possible for anyone at AMC to test the specimens prior to Cancer Center's testing because, when she received the PT samples, they were in sealed vials. Tr. at 244-45. Under cross-examination Ms. Hammett testified that it was Carmen

Oberlag, an AMC technician, and not she, who entered the results of the PT sample events into AMC's computer for electronic transmission to the PT provider AAB. Tr. at 247, 249. She also testified under cross-examination that she was aware that AMC had a policy and practice of testing PT samples, but that there was not a policy which required AMC to retest Cancer Center's PT samples. Ms. Hammett stated that she took the unused portions of Cancer Center's PT samples to AMC for the sole purpose of storing them in AMC's refrigerator. She also testified that she took the results of Cancer Center's testing to AMC at the same time she took the unused PT samples. Tr. at 241, 243-45, 247, 250.

Carmen Oberlag was the AMC laboratory technician who both performed the AMC tests of Cancer Center's PT samples and who entered Cancer Center's PT test results into the computer. Tr. at 182. At hearing she testified that the unused portions of the PT samples from Cancer Center for the events at issue were tested at AMC for quality assurance. She stated that Cancer Center had not requested that AMC test the unused portions of the PT samples, nor did Cancer Center ever request the results from AMC's testing of these unused portions of the PT samples. Tr. at 196-97. She explained that PT samples from Cancer Center were retained in case the reported results were incorrect. This would allow opportunity for the samples to be retested to determine what went wrong. Tr. at 225. She asserted that AMC never tested the unused PT samples from the 2008 and 2009 PT sample events before Cancer Center had tested the samples. She explained that this was not possible since AMC would receive the unused PT samples from Cancer Center "[a]t the same time they brought their results over." Tr. at 197. She stated that she did not compare the test results before she reported Cancer Center's PT results to the PT provider. Tr. at 197.

CMS claims that the instrument printouts for the first testing event for 2008 show that some of the PT samples were tested by AMC before they were tested by Cancer Center's laboratory. CMS notes that for the first testing event in 2008, Cancer Center tested the samples on February 29, 2008, between 11:42 a.m. and 11:57 a.m. Cancer Center's test results were reported to the PT provider AAB that day at 12:45 p.m. However, a PT report form shows that AMC tested the samples earlier that day between 11:17 a.m. and 12:18 p.m. On its face, and in the absence of contradiction or explanation, this data is powerfully suggestive of a violation.

But Cancer Center was able to offer both explanation and contradiction. In response to CMS's allegation, Ms. Oberlag testified that the instrument printouts were not accurate as there was "a time problem on the instrument." She explained:

> The time was not correct. There was two samples that were – that were sent through the instrument in the - - on the sample loader. And they said 11:17, I realized at that point in time that it was actually 12:17 or 12:18. So I stopped the sample loader and pushed the samples back through, you

> know. And then I changed the time on the instrument. And I - - then I re-put the other three samples along with patient samples back through the instrument.

Tr. at 198. Ms. Oberlag attributed the AMC's hematology analyzer clock's incorrect time to a possible power surge. She stated that:

> [i]t's happened before where I've had to go in and change the time. It loses - - it might lose time, it might have a problem with the internal thing with the daylight savings time type stuff. I'm not sure. But I do know for a fact that that is what happened, because it was exactly one hour.

Tr. at 199.

A review of the record before me shows that Ms. Oberlag's testimony is supported by P. Exs. 2.1, at 3-10, 2.2, 2.3, and 2.4, as well as by CMS Ex. 4. At hearing, Ms. Oberlag provided a credible and very detailed explanation of the time discrepancy – that none of the documents reflect any testing of the same PT specimen more than once, and that what was reported to the PT provider AAB corresponds to the laboratory instrument printouts from Cancer Center. P. Exs. 2.1, 2.2, 2.3, and 2.4; CMS Ex. 4; Tr. at 200-07, 212-14. The records show that the PT test results reported to AAB for all three testing events in 2008, and for the first testing event of 2009, were identical to the results Ms. Hammett transcribed onto Cancer Center's laboratory log. I find credible Ms. Oberlag's explanation that a power surge more than likely occurred on February 29, 2008 which affected the clock on the laboratory's hematology analyzer causing it to be incorrect. This would account for the approximate one hour time differential.

Although the term "intentionally referred" is contained in the regulations at 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b), and the term "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). As guidance, an appellate panel of the Departmental Appeals Board (Board) in *Wade Pediatrics* discussed both the legislative intent of CLIA, as well as what does and does not constitute an intentional referral. In *Wade Pediatrics*, CMS argued that the very act of sending PT samples to another laboratory for analysis was an indication of the laboratory's intent to intentionally refer PT samples. The Board found that CMS's position was inconsistent with both the CLIA regulations and the legislative history of the statute. The Board determined that a referral is intentional if it is knowing and willful, that is, not done by accident or mistake. In discussing the phrase "knowing and willful" the Board 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 accident.

*Wade Pediatrics*, DAB No. 2153, at 13-14 (2008), *aff'd*, *Wade Pediatrics v. Department of Health & Human Services,* 567 F.3d 1202; *see also Victor Valley Community Hospital/Clinical Laboratory and Tomasz Pawlowski, M.D.*, DAB No. 2340 (2010).

Cancer Center maintains that the mere fact that its PT samples were tested by AMC is not a sufficient basis for determining, as CMS has done here, that the samples had been improperly referred to another laboratory for analysis. P. Br. at 9-10. Petitioner provided a copy of the surveyor notes from the October 20, 2009 survey of its laboratory. P. Ex. 17, at 18. In a note to file, under a category identified as "Conclusion," the surveyors note:

> On the surface it appears to be proficiency testing referral. But the investigation shows no intent on either party to change proficiency testing results. . . .This investigation shows unintentional proficiency testing referral.

P. Ex. 17, at 18.

The PT results that were submitted to the PT provider AAB on behalf of Cancer Center were consistent with Cancer Center's own records of its proficiency tests. The logical inference is that the values reported were from the analysis of samples in Cancer Center's own laboratory. Both Ms. Hammett and Ms. Oberlag provided credible explanations as to what happened and the nature of the operational protocol between Cancer Center and AMC with reference to the testing of PT samples. The evidence which supports my conclusion includes the testimony of both of these individuals. Their testimony was based on their direct personal knowledge of the events at issue and the documentary evidence, including the PT sample reporting forms which pertained to the specific proficiency tests at issue in this case.

Although CMS's witness, Mr. Haug, asserted that there was an intentional referral between Cancer Center and AMC, I am unable to accord substantial weight to his testimony. Mr. Haug did not have direct personal knowledge of the underlying events, but instead relied almost completely on the statements in the SOD. When asked at the hearing whether he believed the statements in the SOD to be true because they were written or because he verified them himself, he testified that he believed them to be true "because they were written." Tr. at 56-57. Mr. Haug admitted at hearing that there was no determination in TJC's letter that Cancer Center's PT samples for the events at issue in this appeal were found to be intentional. Tr. at 52. He also testified that there were very few surveyor notes, so he basically based his determination on the SOD. Tr. at 57.

At hearing Mr. Haug was asked whether, if a laboratory requested another laboratory to store PT samples, would that situation constitute an improper referral of a PT sample. Mr. Haug responded that he was not sure if the regulation said "'referred to another laboratory for analysis' or just referred to another laboratory." Tr. at 61. As far as evidence regarding whether anything would have been different had AMC waited until receiving the PT results back from the PT provider before testing them, Mr. Haug responded that it could be a month or six weeks before Cancer Center would have received its test results back from the PT provider, and, by then, the PT "whole blood sample wouldn't be any good for comparing at that point in time." Tr. at 88.

When Mr. Haug was presented with P. Ex. 17 – an internal narrative report generated by the state surveyors after the October 20th survey, which notes that the surveyors opined that there was not an intentional PT referral – Mr. Haug stated that the surveyors' role was to collect the facts and documents to determine what had happened, and that it was not their job to determine whether there was an intentional referral or not. Tr. at 69. He admitted that he "did not use this document as a basis for [his] final confirmation that there had indeed been proficiency testing referral." Tr. at 72. Mr. Haug stated that "[o]ther than the fact that they were sent and that there was two sets of results," there was no evidence that the two laboratories compared test results before Cancer Center's test results were reported to the PT provider. Tr. at 89.

My credibility determination is based upon the overwhelming body of direct, first-hand evidence refuting Mr. Haug's assertion that Cancer Center intentionally referred PT samples to AMC for analysis. Both Ms. Oberlag and Ms. Hammett provided credible explanations as to what occurred. Ms. Oberlag outlined the AMC testing policy, and Ms. Hammett discussed the occurrences surrounding the three testing events in 2008 and the first testing event in 2009. CMS offered no specific evidence to show that Ms. Oberlag or Ms. Hammett's statements at hearing were incorrect.

In reaching my conclusion, I rely on my analysis of the testimony of each witness, having had the opportunity to observe the witness' demeanor in testifying, and on my examination of the records Cancer Center produced to support the PT results reported. I determine that the records contained data that was consistent with the results reported in concluding that Cancer Center did not arrive at these results through intentional referral, collaboration, or manipulation of the results.

Based on the documentary evidence and the testimony at hearing, I find that Cancer Center bringing its PT samples to AMC after completion of the PT testing was not an intentional referral.

### C. Even if what happened could be characterized as an intentional referral, it was not an intentional referral for the purposes of analysis.

Cancer Center states that as a quality assurance procedure used by its laboratory and AMC's laboratory, on a periodic basis, Cancer Center and AMC tested the same test specimen or specimens on their own individual, separate laboratory instruments and then compared results. If a significant difference in these results appeared, they then would suspect a problem with their lab instruments or with the related procedures used by one or both of the laboratories. Cancer Center claims that AMC's testing of the PT sample was an extension of this practice and that, even if there was a violation, it was inadvertent. P. Br. at 22; P. Ex. 1, at 2.

It is clear that in enacting CLIA, Congress was concerned about laboratories that 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. H.R. Rep. No. 899, 100th Cong Sess. 8, 18, *reprinted in* 1988 U.S.C.C.A.N. at 3828, 3836, 3837. Although it is true that there is an interlocking relationship between the laboratories at Cancer Center and AMC, what happened during the time period at issue was not an intentional referral and not a referral for purposes of analysis. Cancer Center sent the unused PT samples to AMC for storage, and AMC performed tests to check its own equipment, not to verify Cancer Center's results. Cancer Center never asked AMC to do testing of any sort. Therefore, although Cancer Center did send the PT samples to AMC, it certainly did not intentionally refer them for analysis.

An appellate panel in *Oakland Medical Group, P.C.,* examined the definition of "refer" and concluded:

> As noted by the ALJ in *Blanding Urgent Care Center*, DAB CR438 (1996), the dictionary definition of 'refer' includes 'to direct the attention or thoughts of,' and 'to direct to a person, place, etc., for information or anything required.' *Id.* at 21 citing Random House College Dictionary, revised ed. 1980, at 1108.

*Oakland Medical Group, P.C.*, DAB No. 1755, at 21- 22 (2000).

For the reasons already discussed above, I find and conclude that Cancer Center did not *direct* AMC to test its PT samples, nor did Cancer Center require or suggest that AMC report back to it the results of AMC's testing of the samples. The facts of this case are clear and unequivocal. Simply put, Cancer Center did not intentionally refer its PT samples to AMC for the purposes of analysis. Rather, it is clear from the evidence

that the samples were brought to AMC for the purpose of storage and eventual disposal.

It is clear from the Board's analysis and holding in *Wade Pediatrics* that the prohibition is against the sending of the proficiency samples to another laboratory *for analysis*. The intent requirement is not met by the simple act of sending PT samples to another laboratory. The Board further notes that sending samples to another laboratory for disposal after the end of the testing event would not constitute an improper referral. Additionally, sending the samples to another laboratory by mistake, never intending that they be analyzed, would also not constitute an improper referral. *Wade Pediatrics*, DAB No. 2153, at 13-15, 20. The United States Court of Appeals for the Tenth Circuit, in upholding the Board's decision in *Wade Pediatrics*, agreed that the laboratory's referral was a "knowing and willful" action, and stated:

> it is undisputed that Wade's technician took the lab's proficiency testing samples to [the other laboratory] with the express purpose of testing them there – that is, with the express purpose of referring them for analysis. There was no mistake, accident, negligence or recklessness about it.

567 F.3d at 1205.

CMS has offered no evidence to counter Cancer Center's documentary and testimonial evidence, credible evidence that rebuts any suggestion of an intentional referral of PT samples for the purposes of analysis. Accordingly, I conclude that Cancer Center did not violate CLIA and its implementing regulations with its actions involving PT samples for the three testing events in 2008 and the one testing event in 2009.

### D. No violations having been found, it is not necessary to address Cancer Center's other arguments.

Cancer Center raises two general issues in its pleadings. The first is whether its actions involved noncompliance at all. The second is whether its Board of Directors can be prohibited from owning or operating any laboratory for a two-year period. P. Br. at 23-29. Because I have determined that Cancer Center was not out of compliance with CLIA regulations and therefore not subject to sanctions, I do not address Petitioner's additional arguments in this decision.

## VI. Conclusion

For the reasons stated above, I find that Petitioner did not violate 42 U.S.C. § 263a(1)(4) and 42 C.F.R. § 493.801(b)(4), because it did not intentionally refer its PT samples to

another lab for analysis. Consequently, CMS is not authorized to impose any enforcement actions against Petitioner.

/s/
Richard J. Smith
Administrative Law Judge