Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: February 11, 2008
Wade Pediatrics,	
Petitioner,	Civil Remedies CR1630 App. Div. Docket No. A-08-6
	Decision No. 2153
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Wade Pediatrics (Wade) appealed the August 1, 2007 decision by Administrative Law Judge Keith W. Sickendick upholding the revocation of Wade's certificate to operate as a clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) for a period of one year, effective on the date of the decision and cancelling Wade's approval to receive Medicare payments. Wade Pediatrics, CR1630 (2007)(ALJ Decision). The ALJ granted summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS).

For the reasons explained below, we conclude that the ALJ properly granted summary judgment to CMS although our rationale differs in some respects from that set out in the ALJ Decision. We conclude that Wade raised no genuine issue of fact material to deciding whether Wade intentionally referred proficiency testing samples to another laboratory for analysis that Wade was certified to perform. Accordingly, revocation of Wade's certificate for a period of at least one year was required by

statute and regulation and cancellation of Medicare payments was authorized.

Legal Background

CLIA (codified as 42 U.S.C. § 263a) and its implementing regulations (at 42 C.F.R. Part 493) establish conditions laboratories must meet to be certified to perform clinical diagnostic testing on human specimens and to bill for services under the Medicare program. Congress enacted CLIA to ensure that the results of tests are reliable and accurate. H.R. Rep. No. 899, 100th Cong., 2nd Sess. 8 (1988). The Secretary of the Department of Health and Human Services (HHS) administers CLIA, through CMS.

Part 493 "sets forth the conditions that all laboratories must meet to be certified to perform testing on human specimens under [CLIA]." 42 C.F.R. § 493.1. With the limited exceptions specified in 42 C.F.R. § 493.3(b), a laboratory performing such tests is not in compliance with CLIA requirements unless it has one of the certificates specified in the regulations or is CLIA exempt. 42 C.F.R. §§ 493.3, 493.5(c). Tests are categorized by complexity, and there are CLIA certification conditions (or requirements for "waived tests") specific to each category. See 42 C.F.R. §§ 493.5, 493.20, 493.25 and the subparts cited therein. Each certification condition represents a general requirement that must be met, and CLIA standards are the specific components of the conditions. See Edison Medical Laboratories, DAB No. 1713, at 2 (1999), aff'd, Edison Medical Lab. v. Thompson, 250 F.3d 735 (3rd Cir. 2001). Noncompliance with one or more particular standards relating to a condition may or may not be serious enough to cause a condition level deficiency. See 42 C.F.R. §§ 493.2, 493.1812-16; 57 Fed. Reg. 7218, 7219 (Feb. 28, 1992).

CMS retains broad discretion under CLIA to take action to ensure that laboratories remain in or promptly return to compliance with CLIA requirements. 42 C.F.R. § 493.1800(a)(2)(iii); see also 57 Fed. Reg. at 7224. The action which CMS will take if a survey finds that a laboratory is not in compliance with the requirements depends in part on (1) whether the deficiencies are only at the level of one or more standards or rise to the level of noncompliance with one or more conditions, and (2) whether the deficiencies pose an immediate jeopardy. See 42 C.F.R. §§ 493.1812 to 493.1816.

A laboratory's failure to comply with even a single applicable condition is a ground for CMS to impose one or more principal or

alternative sanctions. 42 C.F.R. § 493.1806(a); Ward General Practice Clinic, DAB No. 1624, at 2 (1997). Principal sanctions that CMS may impose include suspension, limitation, or revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions include directed plans of correction, state on-site monitoring, and civil money penalties. 42 C.F.R. § 493.1806(c). "Both alternative sanctions and principal sanctions are imposed only for condition-level deficiencies," however. 57 Fed. Reg. at 7227.[1] The CLIA regulations define a condition level deficiency as "noncompliance with one or more condition level requirements," that is, any of the requirements identified as conditions in subparts G through Q of Part 493. 42 C.F.R. § 493.2. Where none of the deficiencies are condition level deficiencies, the laboratory must submit a plan of correction and show on revisit that it has corrected the deficiencies. 42 C.F.R. § 493.1816.

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

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

42 C.F.R. § 493.801 (lead-in language).[2] Under this condition are two standards: the first relates to enrollment in a PT program, and the second relates to testing of PT samples with

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[1] To the extent that CMS's appeal brief (at 3) suggests that any failure to comply with a CLIA rule is a sufficient basis for a revocation, that position is clearly inconsistent with the regulations.

[2] The omitted language addresses the effective date of the condition.

patient specimens. The second standard includes requirements for ensuring that tests on PT samples are performed using the laboratory's routine methods and that this is documented, as well as the following provisions:

> (3) Laboratories that perform tests on proficiency testing samples must not engage in any inter-laboratory communications pertaining to the results of proficiency testing sample(s) until after the dates by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent. . . .
>
> (4) The laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least a year. . . .

42 C.F.R. § 493.801(b)(emphasis added). Both the requirement for testing PT samples with patient specimens and the requirement that CMS must revoke for at least a year the certification of any laboratory that it determines "intentionally referred" PT samples to another laboratory "for analysis" are based on CLIA statutory provisions. 42 U.S.C. § 263a.

A different condition of participation, at section 493.802, requires the laboratory to successfully participate in a PT program. If a laboratory fails to successfully participate in PT, CMS may, in some circumstances, direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both. 42 C.F.R. § 493.803(c). Each laboratory is also required to have a quality system to ensure, among other things, that analytic systems are calibrated and reliable and that there are control procedures to monitor the accuracy and precision of the complete analytical process for each test system. 42 C.F.R. Part 493, subpart K.

The enforcement provisions in subpart R of Part 493 include the provision at section 493.1840(b) that "[i]f CMS determines that a laboratory has intentionally referred its proficiency testing samples to another laboratory for analysis, CMS revokes the laboratory's CLIA certificate for at least one year, and may also impose a civil money penalty."

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

Case Background

The following facts are undisputed, except as indicated. At all relevant times, Wade was a clinical laboratory located in Muskogee, Oklahoma, and was enrolled in a PT program run by the Wisconsin State Laboratory of Hygiene (WSLH). In 2005, Wade failed to successfully participate in PT in subsequent occurrences for "Cell ID or WBC Differential." P. Ex. 3.[3] Wade asserts (and provides an affidavit to show) that "[b]elieving the result was due to equipment failure, a CMS field investigator suggested to Kevin Wade, M.D., Lab Director of Petitioner, Wade Pediatrics, that it would be beneficial for Wade Pediatrics to receive training and comparison testing of their equipment from another CLIA certified lab, such as Muskogee Regional Medical Center." Wade Affidavit (Aff.) ¶ 3. In October 2005, Wade arranged with Lawrence Moore, who was a medical technician at Muskogee Regional Medical Center, to provide training and technical assistance to it. P. Ex. 4, at 6. In December 2005, Wade had its equipment serviced. P. Ex. 4, at 9.

For the February 2006 PT testing event (2006-1 event), the following PT samples were tested at Muskogee Regional Medical Center and the results were printed on Muskogee's letterhead:

Specimen ID AT/HE 06-1-1 - tested on 02/22/06 at 12:23
Specimen ID AT/HE 06-1-2 - tested on 02/22/06 at 12:25
Specimen ID AT/HE 06-1-3 - tested on 02/22/06 at 12:27
Specimen ID AT/HE 06-1-4 - tested on 02/22/06 at 12:30
Specimen ID AT/HE 06-1-5 - tested on 02/22/06 at 12:23

[3] Cell identification is a qualitative hematology test and white blood cell differential is a quantitative hematology test; a PT program for hematology must include at least five challenges per testing event for cell identification or white blood cell differential. 42 C.F.R. § 493.941.

CMS Exs. 2, 4.[4] A Wade staff person, identified by CMS as "Testing Person #1," told the Oklahoma state survey agency that on February 22, 2006, the laboratory had taken their hematology PT specimens to the local hospital (Muskogee Regional Medical Center) for testing, and the Laboratory Director verified at the conclusion of the survey that the specimens had been taken to the local hospital for comparison testing. CMS Ex. 2, at 3. Wade then tested the same five specimens at Wade Pediatric's laboratory on February 23, 2006. CMS Ex. 5. Wade reported the results it got in its own laboratory to WSLH on February 24, 2006. CMS Ex. 3, at 16-17.

On March 13, 2006, based on a desk audit of Wade's PT results for 2005 that CMS's Regional Office conducted on February 28, 2006, CMS sent notice to Wade, proposing the principal sanction of limiting the laboratory's CLIA certificate for the test Cell ID or WBC Differential for not less than six months effective March 28, 2006, based on Wade's failure to successfully perform PT in 2005. P. Ex. 2. CMS also suspended approval for Medicare payments for Cell ID or WBC Differential and imposed a directed plan of correction, effective the same date, as follows:

> The laboratory is directed to 1) address any actual negative patient outcome or potential negative patient outcome during the period of unsuccessful proficiency testing performance for the test Cell ID or WBC differential . . . ; 2) demonstrate that the laboratory has established an effective oversight mechanism to prevent recurrences of proficiency testing failure for all testing including the test Cell ID or WBC differential . . . ; and 3) demonstrate that the laboratory has a system in place to ensure that the Cell ID or WBC Differential is not reported on the final patient result; and 4) demonstrate satisfactory performance in two consecutive proficiency testing events for the test Cell ID or WBC Differential before the limitation of the laboratory's certification for the test Cell ID or WBC Differential can be lifted.

P. Ex. 3, at 3.

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[4] The PT tests at issue are described as including Complete Blood Counts (CBCs) and also as being specimens for the Hematology Automated Differential (AT) Survey. CMS Ex. 2. Results were reported for WBC differential, as well as for other parameters. See, e.g., CMS Ex. 3, at 6.

On March 21, 2006, Wade submitted a plan of correction. P. Ex. 4. In this plan, Wade said that it would "continue internal proficiency testing with assistance and support/guidance at Muskogee Regional Medical Center lab." P. Ex. 4, at 1. Wade also said that the "[a]nalyte used for February 2006 Proficiency Testing has been reviewed by [Muskogee Regional Medical Center]" and "[t]his review will continue with subsequent proficiency test; the corrective action plan to ensure successful participation in proficiency testing will be followed." P. Ex. 4, at 4.

For the second PT event of 2006 (2006-2 event), the laboratory's PT testing folder showed that the same five PT specimens for "ID AT/HE" were tested at Wade on May 24, and then were tested at Muskogee Regional Medical Center on June 1 (from 8:55 to 9:00), and retested at Wade on June 1 (from 9:27 to 9:33). CMS Exs. 2, 6. The results Wade reported to WLSH on June 2, 2006 were the results obtained in Wade's laboratory on June 1. Id.

Based on a survey by the Oklahoma state survey agency, CMS determined that Wade had intentionally referred PT samples to Muskogee Regional Medical Center and that, therefore, CMS was required to revoke Wade's CLIA certificate for one year. CMS also determined that Wade had failed to meet conditions for quality assurance and laboratory director.

Wade appealed, and CMS moved for summary judgment on the ground that there was no dispute of material fact concerning whether Wade had intentionally referred PT samples to another laboratory. In granting summary judgment to CMS, the ALJ made ten numbered findings of fact (FFs) "based upon the pleadings and exhibits submitted related to the motion for summary judgment, considering the facts and all inferences drawn therefrom in a light most favorable to the nonmovant, the Petitioner [Wade]." ALJ Decision at 2-3. In FF 7, the ALJ found for purposes of summary judgment that--

> Petitioner relied upon the suggestion of a CMS field investigator and the fact that its plan of correction from a earlier survey was accepted when it decided to send PT samples to another laboratory for testing. P. Brief at 3-4; P. Ex. 4, at 1-2, 4.

The ALJ also reached ten conclusions of law. Id. at 3. The ALJ stated that Wade had "conceded that it sent [PT] samples to another laboratory for analysis that it was certified to perform," and found this fact to be determinative since CLIA regulations prohibit sending PT samples to another laboratory for

analysis when the sending laboratory is certified to do the analysis. ALJ Decision at 8. The ALJ concluded that the "motives of the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform are irrelevant." ALJ Decision at 3. The ALJ did not conclude that Wade intentionally referred the PT samples to another laboratory, but nonetheless concluded that CMS was required to revoke Wade's certificate for at least one year. ALJ Decision at 3, 8-9.

On appeal, Wade does not contest the factual findings made by the ALJ, but argues that FF No. 7 is incomplete and challenges nine of the ten Conclusions of Law reached by the ALJ. Request for Review at 3-4. Wade's arguments are based on three general propositions. First, Wade asserts that the express language of CLIA prohibits only the intentional referral of PT samples to another laboratory for purposes of analysis. Wade asserts that it did not violate this provision because it allowed the PT samples to be tested in another laboratory only as part of a comprehensive training and equipment testing program and submitted only its own results to WSLH, the PT testing organization. According to Wade, the ALJ erred in concluding that the motive for sending PT samples to another laboratory is irrelevant. Second, Wade argues that the legislative history of CLIA indicates that Congress' intent was to prohibit only referrals made in order to falsify or alter results. Therefore, Wade argues, CMS's regulations prohibiting any referral for any reason whatsoever do not constitute a reasonable construction of the statute. Third, Wade asserts that its claim of estoppel (based on the combination of advice allegedly given Wade by a CMS field investigator and CMS's acceptance of Wade's plan of correction for deficiencies previously found in its PT performance) should be considered and that, under these facts, imposing revocation amounts to civil entrapment.

With its request for review, Wade submitted three exhibits, labeled A-C. Exhibits B and C are affidavits that were not submitted to the ALJ.[5] Exhibit B is an affidavit by Valerie Turner, a registered medical assistant formerly employed by Wade, and Exhibit C is an affidavit by Lawrence Moore, a medical technician formerly employed by Muskogee Regional Medical Center,

[5] Exhibit A submitted with the request for review is an affidavit regarding when Wade received the ALJ Decision, and asserts no facts material to the issues before us. Wade also labeled as Exhibit A the affidavit by Dr. Wade that it submitted to the ALJ and which we discuss below.

whom Wade hired as a consultant to provide it with training and technical assistance. The procedural regulations at 42 C.F.R. § 498.86 permit the Board to admit new evidence that the Board determines is relevant and material, after following certain procedures. The Board asked Wade to explain why it had not submitted these affidavits to the ALJ. In its reply brief, Wade gave the following reason:

> The ALJ's Decision in this matter was rendered upon CMS's Motion for Summary Judgment. Consequently, Wade's time for preparation of its evidence was abbreviated. Wade's counsel was unable to contact and interview either of these affiants prior to the deadline for filing Wade's Response to CMS's Motion for Summary Judgment.

Wade Reply Br. at 3, n. 3. Wade requested and the ALJ granted a nine-day extension of time for Wade to respond to CMS's motion for summary judgment. Wade does not explain why it could not have requested an additional extension of time from the ALJ if needed in order to produce these affidavits. Although we might in other circumstances find Wade's reasons for not submitting the affidavits sooner to be inadequate and therefore decline to admit the affidavits, here we have considered these affidavits as part of Wade's proffer of evidence for the limited purpose of considering whether summary judgment is appropriate.

Standard of review

In White Lake Family Medicine, P.C., DAB No. 1951 (2004), the Board concluded that, even though the procedures at 42 C.F.R. Part 498, subpart D, applicable to CLIA cases do not specifically provide for summary judgment, those provisions (and the CLIA statute) permit resolution of a case without an in-person hearing in some circumstances. White Lake at 10-11, citing Madison Health Care, Inc., DAB No. 1927 (2004); Lebanon Nursing and Rehabilitation Center, DAB No. 1918 (2004); Crestview Parke Care Center, DAB No. 1836 (2002), rev'd sub nom, Crestview Parke Care Center v. Thompson, 373 F.3d 743 (6th Cir. 2004); Everett Rehabilitation and Medical Center, DAB No. 1628, at 3 (1997), citing Travers v. Shalala, 20 F.3d 993, 998 (9th Cir. 1994). Thus, as the Board concluded in White Lake:

> [I]n reviewing a case where an ALJ did not either obtain a written waiver or hold an oral hearing, we may nonetheless uphold the decision if the affected party either had conceded all of the material facts or proffered testimonial evidence only on facts which, even

> if proved, clearly would not make any substantive difference in the result. Big Bend Hospital Corp., DAB No. 1814 (2002), aff'd, Big Bend Hospital Corp. v. Thompson, No. P-02-CA-030 (W.D. Tex. Jan. 2, 2003). As the Crestview court pointed out, "it would seem strange if disputes could not be decided without an oral hearing when there are not genuine issues of material fact" and "bizarre if administrative agencies, which are in many respects modeled after the federal courts and which indeed often have more informal proceedings than federal courts, could not follow a similar rule" to the federal summary judgement rule. 373 F.3d 743, at 750, citing Fed. R. Civ. P. 56.

White Lake at 10-11.

Whether summary judgment is appropriate in a particular case is a legal issue that we address *de novo*. Lebanon Nursing and Rehabilitation Center, DAB No. 1918 (2004). If we determined that summary judgment is not appropriate, based on our analysis of the law and the undisputed facts, we would remand the case to the ALJ to provide further proceedings.

Analysis

Below, we first examine the relevant legal requirements and then examine whether there are genuine disputes of fact material to those requirements.

> ***Section 493.801(b)(4) of the CLIA regulations contains two separate but consistent provisions, one establishing a participation requirement and one requiring revocation if a laboratory has intentionally referred a PT sample.***

Wade's arguments about the CLIA regulations being inconsistent with the statute are based on an erroneous premise, but raise relevant issues about how to apply section 493.801(b)(4).

Specifically, Wade assumes that the first sentence in section 493.801(b)(4) prohibiting a laboratory from sending PT samples or portions of samples to another laboratory for any analysis which it is certified to perform interprets the CLIA provision at 42 U.S.C. 263a(i)(4), which requires revocation of a certificate for intentional referral. The prohibition on sending PT samples was, however, proposed as part of a regulatory standard to be used to determine whether a laboratory was meeting the condition for enrolling in a PT program and testing PT samples with patient specimens. The prohibition was originally proposed as section

493.21(b)(3). 53 Fed. Reg. 29,590, 29,595 (Aug. 5, 1988); see also 57 Fed. Reg. at 7037. Wade cites to nothing in the history of the provision indicating that the Secretary viewed the prohibition as interpreting the CLIA provision on intentional referral.

As the ALJ concluded, CLIA provides that the Secretary shall establish standards for laboratories, including that the laboratory "meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures." 42 U.S.C. 263a(f). Thus, it was clearly within the Secretary's authority to establish a requirement prohibiting a laboratory from sending PT samples to another laboratory "for any analysis." The Secretary could (and did) reasonably determine that such a blanket prohibition on sending PT samples to another laboratory for any analysis would further the goal of assuring consistent performance by laboratories of accurate and reliable examinations and procedures by permitting the Secretary to address circumstances suggesting improper referral, even if intent could not be proven.

The statutory provision at 42 U.S.C. 263a(i)(4) requires the Secretary to revoke a certificate if the Secretary determines that a laboratory has intentionally referred a PT sample to another laboratory for analysis that it is certified to perform. Nothing in the statute, however, precludes the Secretary from also establishing a regulatory requirement that laboratories not send PT samples to other laboratories or from considering a violation of that prohibition in determining whether a laboratory has met the condition for PT enrollment and testing and, if so, what sanction to apply.

Moreover, Wade's assertion that the regulatory prohibition is inconsistent with the statute is based on Wade's erroneous view that Congress intended to address referrals only in circumstances where the referring laboratory not only sent the PT samples to another laboratory for analysis but also reported the results of that analysis as its own. The 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. The legislative history, moreover, indicates that Congress was more broadly concerned about the integrity of PT testing than Wade's argument would suggest. Specifically, the House Report states:

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

H.R. Rep. No. 899, 100th Cong. 2d Sess., 24. Elsewhere in the report, the Committee emphasized the critical importance of proficiency testing as a "method of externally validating the level of a laboratory's performance" and indicated that it believed 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." Id. at 15, 28. Reading the statutory provision on improper referral as narrowly as Wade would have us read it would frustrate the intent of Congress to protect the integrity of PT testing. 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 tests in its own laboratory until it obtained a similar result to report as its own. In that circumstance, the result (although obtained in the referring laboratory) does not fairly represent the proficiency of that laboratory in achieving accurate outcomes on patient specimens.

Thus, we reject Wade's contention that CMS may take action against a laboratory that refers PT samples to another laboratory for analysis only if the results of that analysis are reported by the referring laboratory to the PT organization or agency.

Wade's arguments based on the statute, however, reflect an inconsistency in the ALJ's reasoning. In concluding that a non-intentional referral could violate CLIA requirements, the ALJ relied on the first sentence of section 493.801(b)(4), prohibiting a laboratory from sending PT samples to another laboratory for any analysis. The ALJ nonetheless concluded, based on his determination that the undisputed facts showed that Wade had sent PT samples to Muskogee Regional Medical Center for analysis, that "CMS is required to revoke Petitioner's CLIA certificate for a period of not less than one year from the date of this decision." ALJ Decision at 3, 9. In so concluding, the ALJ conflated the two provisions in section 493.801(b)(4). Under that section, CMS was required to revoke the 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. CMS made no such determination, merely adopting instead the survey agency finding that the referral was intentional and that revocation was therefore required. Moreover, CMS moved for summary judgment on the ground that the referral was intentional as a matter of law, not on the alternative ground that, even if not intentional, the violation was a condition level deficiency.

Under the regulations, "intentional" means "knowing and willful."

In responding to Wade's appeal of the ALJ Decision, CMS seems to recognize the inconsistency between the ALJ's analysis and the conclusion the ALJ reached. CMS does not argue that summary judgment in its favor is warranted even if there was no intentional referral. Instead, CMS argues that the undisputed facts show that Wade intentionally referred PT samples to the local hospital. According to CMS, "the very act of sending PT samples to another laboratory for analysis indicates the laboratories [sic] intent to do so." CMS App. Br. at 13.

This position is inconsistent with the regulations, however. While the regulations do not define the term "intentionally," they do define the term "intentional violation" as follows:

> *Intentional violation* means knowing and willful noncompliance with any CLIA condition.

42 C.F.R. § 493.2 (emphasis added). There is no indication in the regulation or its history or in CMS policy guidance that the Secretary meant to interpret the term "intentionally" to mean anything other than knowingly and willfully. On the other hand, CLIA rulemaking has linked the concept of intentional violation with intentionally referring PT samples. In discussing when matters would be referred to the Office of the Inspector General, the preamble to the final CLIA enforcement rule published February 28, 1992 states:

> We plan to inform the OIG of any adverse actions we impose against laboratories if we determine there has been a violation of any of the laws enforced by the OIG. For example, the violations listed at § 493.1840(a)(1),

> (a)(2), (a)(6), or (b) involve misrepresentation, fraud against the Medicare and Medicaid programs, or some other type of intentional violation of requirements for the Medicare, Medicaid, or CLIA program that may warrant action by the OIG.

57 Fed. Reg. 7218, at 7227 (emphasis added). Section 493.1840(b) is the enforcement provision on improper referral.

Thus, reading the regulations in light of their history makes clear that revocation for at least one year is required only if CMS determines that a laboratory made a knowing and willful referral to another laboratory of a PT sample for analysis that it was certified to perform. Under the regulations, CMS may revoke a certificate where the referral was non-intentional, but only if it determines that a condition level deficiency exists.

This does not mean, as Wade suggests, that intentional referral will be found only if a laboratory had specific intent to violate CLIA requirements. Neither the CLIA regulations nor CMS guidance defines the phrase "knowing and willful," but that phrase is generally distinguished from specific intent (although its meaning may vary, depending on the context). 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.[6] Thus, we conclude that CMS's position that the only fact material in determining whether revocation is required is the fact that Wade sent the PT samples to another laboratory is inconsistent with the CLIA regulations and their history.

The motive for sending PT samples to another laboratory is not wholly irrelevant.

The ALJ concluded, and we agree, that a laboratory's motive in sending PT samples to another laboratory for analysis is irrelevant in determining whether the prohibition on sending PT samples to another laboratory has been violated. On the other hand, since every word of a provision (including the phrase "for analysis which the laboratory is certified to perform") should be

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[6] The term "willful" has multiple meanings in the law — from "malicious" to "not accidental" — depending on the context in which it is used. See McLaughlin v. Richland Shoe Co., 486 U.S. 128, 137 (1988)(Marshall, J., dissenting).

given effect, motive is not entirely irrelevant, as CMS's arguments suggest. For example, if a laboratory had an agreement with another laboratory for disposal of hazardous materials and sent PT samples to that laboratory for disposal after the end of the testing event, the laboratory might be able to show that it had not sent the samples "for analysis" and therefore had not violated the prohibition. Also, if a laboratory was not certified to perform the particular type of analysis for which it referred PT samples, the improper referral provision would not apply.

Contrary to what the ALJ stated, Wade did not concede that it sent the PT samples to the Muskogee Regional Medical Center for analysis. Wade's arguments regarding the reasons why it sent PT samples to Muskogee (while framed partly in terms of estopping CMS from revoking its certificate) raise the question of whether its purpose in sending the samples was encompassed by the phrase "for analysis that the laboratory is certified to perform."

We have already rejected Wade's argument that Congress intended to prohibit referral only for an analysis leading to results reported by the referring laboratory as its own. That is not a reasonable reading of the statute. Wade is also relying, however, on its assertions regarding what it was told by a CMS field investigator (which CMS does not appear to dispute), what was in Wade's "accepted" plan of correction, and how Wade viewed what it was doing as only "comparison testing." Wade asserts (and proffers affidavits to show) that its sole purpose in sending PT samples to Muskogee Regional Medical Center was to test the calibration of its recently-serviced equipment and that no samples were sent for analysis, since they were sent only for comparison testing.

The ALJ stated that, viewing the evidence in the light most favorable to Wade, he was accepting Wade's contention that Wade did not send the PT samples to Muskogee Regional Medical Center for the purpose of reporting the Muskogee results to WSLH "or for any other purpose than to see how Muskogee Regional test results compared with its own." ALJ Decision at 8. The ALJ nonetheless considered Wade's admission that it had sent the samples for "comparison testing" as establishing a violation of the regulatory prohibition against sending PT samples "for any analysis that the laboratory is certified to perform." Id. The ALJ did not, however, specifically discuss his basis for concluding that Wade had conceded that the PT samples were sent "for analysis" despite his acceptance (for purposes of summary judgment) of Wade's contention that the only purpose of sending the PT samples to Muskogee Regional Medical Center was for

comparison testing. A material issue under both the statutory and regulatory requirements, however, is whether the PT samples were sent to another laboratory "for analysis."

Whether there was a genuine dispute of fact concerning this issue should have been addressed, and we discuss it below.

In determining whether summary judgment is appropriate, we are guided by federal rules and case law applying those rules.

The Part 498 procedures do not set out rules for determining whether summary judgment is appropriately granted. Some ALJs have notified parties that they will apply Rule 56 of the Federal Rules of Civil Procedure (FRCP). The pre-hearing order in this case did not give such notice, but did give notice that "declarations submitted in support of a motion must be executed in accordance with 28 U.S.C. §1746." Pre-hearing order of 10/11/06, at 6. We have held that an ALJ may not hold parties to the Rule 56 procedures without notice, but that the federal rule nonetheless provides helpful guidance on the standard to apply. Thelma Walley, DAB No. 1367 (1992). In analyzing whether summary judgment is appropriate, the Board therefore has set out a framework drawn from the federal rule and from the case law developed under it, as well as from an informed consideration of the nature and purpose of the administrative proceedings to which it is being adapted.

Summary judgment is generally appropriate when the record shows that there is no genuine issue as to any material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 322-25 (1986). The moving party must show that it is entitled to judgment as a matter of law and that no genuine issues of material fact remain for trial, which it may do by showing that no evidence in the record supports a judgment for the non-moving party. Id. at 322-323, 325. The non-moving party must then "come forward with 'specific facts showing that there is a genuine issue for trial.'" Matsushita Elec. Industrial Co. v. Zenith Radio, 475 U.S. 574, 587 (1986). The non-moving party will not prevail by mere denials, but must furnish evidence of a dispute concerning a material fact. Id. at 586, n.11; Celotex, 477 U.S. at 322. Ultimately, summary judgment lies "[w]here the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party . . . ." Matsushita, 475 U.S. at 587.

In the context of a summary judgment motion, all reasonable inferences supported by the evidence should be drawn in favor of the non-moving party. See, e.g., U.S. v. Diebold, Inc., 369 U.S.

654, 655 (1962). The Sixth Circuit articulated the decisionmaker's role as follows:

> In deciding a motion for summary judgment, the court must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. See Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986). The judge is not to "weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).

Sagan v. U.S., 342 F.3d 493, 497 (6th Cir., 2003). Thus, the ALJ deciding a summary judgment motion does not "make credibility determinations, weigh the evidence, or decide which inferences to draw from the facts," as would be proper when sitting as a fact-finder after a hearing, but instead should "constru[e] the record in the light most favorable to the nonmovant and avoid[] the temptation to decide which party's version of the facts is more likely true." Payne v. Pauley, 337 F.3d 767, 770 (7th Cir. 2003). It follows that it cannot be said to be sufficient to support a grant of summary judgment that one "may" draw a conclusion favorable to the moving party based on the proffered evidence, if one might also reasonably reach inferences which would support a conclusion favoring the non-moving party. Nor is it appropriate to evaluate at this stage where the truth is most likely to lie or which party's evidence is more persuasive. The focus is rather on whether the non-moving party has so failed to meet the challenge of demonstrating that evidence exists on an element material to deciding the matter as to require an adverse judgment.[7]

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[7] While the non-moving party does not have to prove its case to avoid summary judgment, the evidentiary burdens borne by the parties under the applicable substantive law are a factor in evaluating whether a rational trier of fact could find in favor of the non-moving party. See Lebanon; Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986) (in ruling on a motion for summary judgment, the judge must view the evidence presented through the prism of the substantive evidentiary burdens). In a CLIA revocation case, CMS has the initial burden of presenting a prima facie case (either through undisputed facts or evidence) that is legally sufficient to show that the laboratory has not met one or

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Finally, while the non-moving party is entitled for purposes of summary judgment to the benefit of any favorable factual finding or inference which a "rational trier of fact" could reach on the proffered evidence, that does not imply that the decision-maker must accept that party's thinking as to how the law should be applied to those facts. See, e.g., McCoy v. Harrison, 341 F.3d 600 (7th Cir. 2003)(court is not required to credit mere speculation or conjecture by non-moving party). In other words, the decisionmaker need not resolve a purely legal dispute in favor of the non-moving party (as opposed to drawing favorable inferences from the proffered evidence). In that sense, a dispute between the parties as to the correct conclusion to draw from undisputed facts is not an impediment to the entry of summary judgment.

There is no genuine dispute about whether the PT samples at issue here were knowingly and willfully referred to Muskogee Regional Medical Center "for analysis."

As noted above, the ALJ accepted for purposes of summary judgment Wade's assertion that the PT samples were sent for no purpose other than comparison testing. In our opinion, even if the evidence proffered by Wade is viewed in the light most favorable to Wade, that evidence, when considered as a whole, does not raise a genuine dispute about whether the PT samples were knowingly and willfully sent "for analysis."

The situation in this case is like that in Lackawanna, DAB No. 1870, where the Board stated:

> Petitioner did not deny that it sent its PT samples to Med Science, nor allege that the acts of sending the samples were somehow unknowing or unwilling, rather than intentional. As the ALJ noted, Petitioner's own affidavits, if accepted as true, show that Petitioner deliberately sent the PT samples to Med Science because it thought this was

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[7](...continued)
more conditions of participation; the laboratory then has the ultimate burden of persuasion to show by a preponderance of the evidence that it met the conditions. Edison Medical Laboratories, Inc. DAB No. 1713 (1999), aff'd, Edison Medical Laboratories, Inc., v. Thompson, 250 F.3d 735 (3rd Cir. 2001); cf. Hillman Rehabilitation Center, DAB No. 1611 (1997), aff'd, Hillman Rehabilitation Center v. United States, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

> required by its own quality control policy. Petitioner argued, however, that it did not send PT samples to Med Science "for any analysis which it is certified to perform in its own laboratory" but instead sent them for quality control purposes. Petitioner did not, however, specifically assert (nor offer any evidence) that the analysis that Med Science performed on the PT samples was any different from the analysis that Petitioner was certified to perform on those samples. While there is some indication in the record that Med Science may have used equipment different from Petitioner's, the term "analysis" in the context of the CLIA regulations is not tied to the type of equipment, but to the type of testing or examination that is being performed and what is to be determined, for example, whether a particular virus is present or what is the red blood cell count. Nor is it reasonable to interpret the reference to "any analysis which the laboratory is certified to perform" to exclude analysis on the basis that it is performed solely for quality control purposes. Quality control testing in a different laboratory would not make sense if the different laboratory performed a different analysis. Indeed, Petitioner itself referred to the acts done in the Med Science laboratory as "parallel tests." See, e.g., Petitioner Br. at 2.

Lackawanna at 8-9 (footnotes omitted).

Here, Wade relies on the statements in its affidavits. The affidavits aver that the sole purpose was for training and to compare the test results at the two laboratories in order to determine whether Wade's equipment was functioning properly. The affidavits also aver that the PT samples were not sent for analysis. Whether the PT samples were sent "for analysis" is a legal conclusion, however. Wade's affidavits make no assertions regarding facts that would distinguish "comparison testing" from analysis under some reasonable reading of the term "analysis." As we noted in Lackawanna, the preamble to the CLIA regulations describes the regulation as prohibiting "referral of PT samples to another laboratory for testing . . . ." 57 Fed. Reg. at 7035; see also 57 Fed. Reg. at 7037 ("repeated analysis of PT samples is not appropriate unless patient specimens are similarly tested").

Moreover, Wade proffers no evidence from which a rational trier of fact could infer that Wade could in fact obtain test results to compare without having Muskogee Regional Medical Center's equipment analyze the PT samples. Indeed, the record contains a statement by Lawrence Moore, the medical technician who worked at

Muskogee Regional Medical Center, describing the equipment used there (the Cell-Dyne 3500) as a "Hematology analyzer," and his affidavit describes the reported PT results as those "obtained through analysis at Wade Pediatrics on the Cell-Dyn 1700." P. Ex. 4, at 6; Wade Aff. at ¶ 7. Valerie Turner, the person whom he was training, admits that she "tested" the PT samples on Muskogee Regional Medical Center's equipment, and describes what she did on the Cell-Dyne 1700 at Wade as analyzing the samples. Turner Aff. at ¶ 4.

Thus, even accepting (as the ALJ did) that the sole purpose of sending the samples to Muskogee Regional Medical Center was to do "comparison testing" in order to determine if Wade's equipment was working properly, it does not follow that the samples were not sent for analysis. The evidence proffered by Wade, viewed as a whole, effectively admits that comparison testing on the Cell-Dyne 3500 necessarily resulted in that equipment analyzing the PT samples. Thus, we conclude that Wade failed to show that there is a genuine dispute about whether the PT samples were sent to the Muskogee Regional Medical Center for analysis.

Also, Wade's own proffered evidence establishes that the PT samples were knowingly and willfully brought by Valerie Turner to Muskogee Regional Medical Center for analysis on the Cell-Dyne 3500. For example, Ms. Turner states with respect to the 2006-1 testing event that she "took the proficiency testing samples received at Wade Pediatrics to MRMC, and went through the testing process with Mr. Moore" and states with respect to the 2006-2 testing event that she performed her "analysis" of the PT samples at Wade and then "decided to run through the test again at MRMC." Turner Aff. at ¶¶ 4 and 5. As discussed above, the "knowing and willful" regulatory standard for intent would exclude an accidental or mistaken sending of a PT sample to another laboratory, but does not require specific intent to violate a requirement. Ms. Turner's own affidavit shows she voluntarily took samples that she knew were PT samples to another laboratory and knowingly and voluntarily tested them there on equipment that, like similar equipment in Wade's laboratory, analyzed the samples.

Nothing in the other evidence proffered by Wade is sufficient to raise a genuine dispute about Wade's intent, even when viewed in the light most favorable to Wade. The affidavit by Kevin Wade, M.D., the Laboratory Director, states conclusorily that Wade "did not intentionally refer proficiency testing samples to another lab for analysis" and that "[n]o samples were sent for analysis only for comparison testing." Wade Aff. at ¶¶ 7, 5. But that affidavit also asserts that Wade "made clear its intention to

send proficiency testing samples for comparison testing of its equipment at Muskogee Regional Medical Center." Id. at ¶ 5. Dr. Wade proffers no explanation for how comparison testing could be done without having the sample analyzed on Muskogee's equipment.

Wade asserts that it did not have the intent required under the statute to cheat on the PT testing by reporting the PT results obtained at Muskogee Regional Medical Center as its own. Wade proffers evidence by Ms. Turner that Wade reported its own results to WSLH and that the results obtained at Muskogee Regional Medical Center were "not used to influence or alter the PT sample results obtained at Wade Pediatrics and reported to WSLH." Turner Aff. at ¶ 6. We note that Ms. Turner does not specifically state that the results obtained at Muskogee Regional Medical Center did not influence her decision to retest the PT samples at Wade for the 2006-2 testing event. In any event, as we discussed above, the statute requires revocation of a CLIA certificate for at least one year if the laboratory intentionally referred PT samples to another laboratory for analysis that it is certified to perform. Nothing in the statute or regulations requires CMS to also determine that the referring laboratory intended to report the results obtained in the referral laboratory to the PT agency or organization.

Wade proffered no evidence from which one could reasonably infer that Wade reasonably relied on CMS's actions in sending its PT samples to Muskogee Regional Medical Center.

Wade tries to distinguish the Lackawanna case on the basis that Wade sent the PT samples to another laboratory only for a short period of time and did so in reliance on what it was told by a CMS investigator and included in its plan of correction, in order to correct a documented deficiency in its equipment. This is different, Wade argues, than Lackawanna's actions in routinely sending PT samples to another laboratory as part of its quality control (QC) system. Wade also argues that the ALJ erred by rejecting Wade's estoppel argument based on case law that applies only when a party seeks to obtain a benefit from the Federal Government. Wade suggests that it relied on CMS's actions as indicating that it could legally send PT samples to another laboratory for purposes of training and comparison testing. According to Wade, it is seeking only to preclude CMS from imposing a harsh penalty on Wade, in circumstances that could be considered entrapment by CMS.[8]

[8] Wade argues on appeal that it has an entrapment defense against CMS because CMS induced Wade "to engage in the

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There might be circumstances where a laboratory's reasonable reliance on CMS's actions or guidance could be relevant in determining intent or in determining how to apply an ambiguous regulatory provision. Thus, while arguments about reasonable reliance are usually framed as establishing estoppel, the underlying facts might in some circumstances provide part of the rationale for overturning revocation of a CLIA certificate even though estoppel does not generally lie against the federal government.[9] We do not need to definitively decide here what

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[8](...continued)
very behavior that threatens to bring about the punishment." Id. at 10, citing Sorrells v. U.S., 287 U.S. 235 (1932) and Rodriquez v. U.S., 534 F.Supp. 370 (D.C. Puerto Rico, 1982). Wade did not timely raise this issue before the ALJ, but, in any event, it has no merit. While Rodriquez noted that a defense of entrapment had been applied in some state administrative proceedings that were quasi-criminal in nature, it distinguished the proceeding there on the ground that the action being taken was protective, not punitive. Similarly, here the revocation of Wade's certificate results from a statutory provision meant to ensure the integrity of proficiency testing programs, and therefore protect patients whose health may depend on accurate and reliable laboratory results. Moreover, the circumstances in Sorrells, where a federal agent repeatedly and aggressively induced the defendant to act in a criminal manner, despite the lack of any predisposition to do so, are clearly distinguishable from the facts alleged here.

[9] According to the ALJ, the decisions of the United States Supreme Court in Office of Personnel Management v. Richmond, 496 U.S. 414 (1990) and Heckler v. Community Health Services of Crawford County, Inc., 467 U.S. 51 (1984), "make clear that equitable estoppel will not lie against the federal government in cases involving benefits to be paid from the Treasury, particularly in the complicated area of Medicare." ALJ Decision at 9. In its request for review, Wade argues that these decisions (as well as ALJ and Board decisions cited by the ALJ) all "involved individuals asserting estoppel to obtain affirmative relief." RR at 9. The court in Heckler, Wade argues, "expressly acknowledged that there are circumstances in which the government is subject to the principles of equitable estoppel." Id. The circumstances mentioned in Heckler, however, are ones in which a federal employee has engaged in affirmative misconduct, and the court specifically left open the issue of

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those circumstances might be, however, since we conclude that the evidence proffered by Wade, even when viewed in the light most favorable to Wade, would not establish such reasonable reliance.

For purposes of summary judgment, the ALJ found (in FF 7) that "Petitioner relied upon the suggestion of a CMS field investigator and the fact that its plan of correction from an earlier survey was accepted when it decided to send PT samples to another laboratory for testing." Even assuming this finding is required in the context of summary judgment, it would not be sufficient since Wade proffers no evidence that would show that this reliance was reasonable under the circumstances.

The CLIA regulations discussed above plainly prohibit sending PT samples to another laboratory for any analysis and also prohibit any inter-laboratory communications about PT results prior to the date for reporting the results. Wade had constructive notice of the regulatory requirements and a duty to comply with them. Yet, as discussed above, Wade did not proffer any evidence or cite any legal precedent to suggest that Wade could reasonably interpret the term "analysis" in the regulations to exclude comparison testing. Instead, Wade is relying only on the bald assertions by its witnesses that the PT samples were sent for comparison testing, not for analysis, and, as discussed above, these assertions are undercut by the witnesses' own descriptions of what was being done in order to make the comparison – i.e., analysis of the PT samples on the Cell-Dyne equipment in each laboratory. Nor does Wade provide any basis on which it could have reasonably thought that communications about the results of testing PT samples at Muskogee Regional Medical Center could permissibly occur prior to when Wade reported PT results to WSLH.

In discussing whether reliance on a representation is reasonable, the Supreme Court has said that if, at the time a party acted, the party "had knowledge of the truth, or had the means by which with reasonable diligence he could acquire the knowledge so that it would be negligence on his part to remain ignorant by not using those means, he cannot claim to have been misled by relying on the representation or concealment." Heckler, *supra*, 367 U.S. at 61, n.10. Here, as Laboratory Director of Wade, Dr. Wade had

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[9](...continued)
whether estoppel could ever lie against the federal government. 367 U.S. at 61. Wade does not specifically allege affirmative misconduct here, and, in any event, a basic element of any estoppel defense is reasonable reliance, as Heckler held.

the responsibility "for assuring compliance with the applicable regulations." 42 C.F.R. § 493.1407.

Therefore, we conclude that Wade could not reasonably rely on what the field investigator said and what it put into its Plan of Correction as meaning that Wade was permitted to take PT samples to Muskogee Regional Medical Center, to test them there, and to communicate about the results before reporting its results to WSLH.

We also note that Wade's arguments concerning its reliance are in the nature of an affirmative defense. In the absence of a genuine dispute about facts material to CMS's basis for the revocation, therefore, Wade's proffer should have been sufficient to make a prima facie case based on which it might prevail if it had a hearing. In other words, it should have addressed all of the elements of the defense. Otherwise, Wade's proffer is insufficient to overcome CMS's showing that it was entitled to summary judgment as a matter of law. The proffer by Wade, however, does not include any evidence that Wade in fact relied on CMS actions when it sent PT samples to Muskogee, particularly when considered in light of the undisputed facts regarding the 2006-1 testing event. As CMS points out, it is undisputed that at the time of that event in February 2006, Wade had not even submitted its Plan of Correction. Thus, Wade could not have relied on any acceptance by CMS of Wade's Plan of Correction when it decided to send PT samples to Muskogee Regional Medical Center in February 2006.

Wade proffers the following statements in Dr. Wade's affidavit as proof that Wade relied on CMS actions:

> 3. After the lab's first failed testing event, it was suggested to me by a field investigator for CMS that it would be beneficial for Wade Pediatrics to receive training and comparison testing of equipment from another CLIA certified lab, such as the lab at Muskogee Regional Medical Center.
>
> 4. No samples had been sent to Muskogee Regional Medical Center for comparison testing prior to that suggestion.
>
> 5. Wade Pediatrics included the CMS investigator's suggestion in the Plan of Correction they submitted to CMS on March 21, 2006 and made clear its intention to send proficiency testing samples for comparison testing of its equipment at Muskogee Regional Medical Center. No samples were sent for analysis, only for comparison testing.

> 6. Wade Pediatrics was at all times attempting to comply with the approved Plan of Correction and the direction of the CMS field investigator.
>
> * * *
>
> 7. But for the suggestion of the CMS field investigator, Wade Pediatrics would not have utilized the services of Muskogee Regional Medical Center to test the calibration of its equipment.

Nothing in that affidavit (or any other proffered evidence) purports to show that the field investigator suggested that PT samples could be used for comparison testing at another laboratory. The conclusion in Wade's brief to that effect (cited by the ALJ) is not consistent with Dr. Wade's affidavit, or any inference that could reasonably be drawn from it. There is no statement in the affidavit that the field investigator made any suggestion whatsoever about what was to be tested for comparison purposes, much less that he made a suggestion that could reasonably be interpreted as referring to the PT samples Wade received from WLSH. Nor did Wade proffer any evidence that could be read as indicating that comparison testing would necessarily involve those PT samples or as indicating that the CMS field investigator was representing that comparison testing is not "analysis."

While Dr. Wade's affidavit avers generally that Wade would not have utilized the services of Muskogee Regional Medical Center but for the advice of the CMS field investigator and that Wade thought at all times it was complying with the investigator's "direction," one cannot reasonably infer from these statements that the investigator ever directed Wade to bring or send PT samples to Muskogee. Moreover, nothing in the affidavit of Valerie Turner, the Wade technician who brought the PT samples to Muskogee, indicates that she was even aware of any statement by the CMS field investigator when she brought the PT samples to Muskogee for testing on its equipment in February 2006. Nor does Dr. Wade aver that he told Ms. Turner that she could take PT samples to Muskogee in reliance on what the CMS field investigator had told Dr. Wade.

The requirement that, for purposes of summary judgment, the decisionmaker must construe proffered evidence in the light most favorable to the non-moving party does not require the decisionmaker to read into proffered testimony assertions about material facts that are not even alluded to in the testimony.

Nor does it require that the decisionmaker ignore undisputed facts that render an inference unreasonable.

In any event, even assuming that Wade in fact relied on oral advice from the field investigator when it took PT samples for the 2006-1 testing event to Muskogee Regional Medical Center for testing, any such reliance was not reasonable in light of the plain wording of the regulations and Dr. Wade's duty to comply with those regulations.

Conclusion

For the reasons stated above, we uphold the ALJ's conclusion that summary judgment in CMS's favor is appropriate. Thus, we uphold the ALJ's determination that Wade's CLIA certificate is revoked for a period of one year effective on the date of the ALJ's decision and that Wade's approval to receive Medicare payments is cancelled.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member