Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	Date: August 1, 2007
Wade Pediatrics,	)	
CLIA No. 37D0965880	)	
	)	Docket No. C-07-06
Petitioner,	)	Decision No. CR1630
	)	
-v.-	)	
	)	
Centers for Medicare and Medicaid Services.	)	

DECISION

Petitioner's certificate to operate as a clinical laboratory under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)[1] is revoked for a period of one year effective the date of this decision. The Centers for Medicare and Medicaid Services' (CMS) motion for summary judgment is granted.

I. Background

Petitioner is a clinical laboratory located in Muskogee, Oklahoma. Petitioner was subjected to a re-certification survey by the Oklahoma Department of Health (the state agency) on June 28, 2006. CMS notified Petitioner by letter dated September 6, 2006, that the state agency survey found Petitioner was in violation of the condition for participation established by 42 C.F.R. § 493.801. CMS also advised Petitioner that it proposed to revoke Petitioner's CLIA certificate and to cancel Petitioner's authorization to receive Medicare payment for its services pursuant to 42 U.S.C. § 263a.

[1] Pub. L. 100-578, codified at 42 U.S.C. § 263a.

Petitioner requested a hearing by letter dated October 4, 2006. The case was assigned to me for hearing and decision on October 11, 2006. A Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on October 11, 2006. On December 6, 2006, CMS filed its motion for summary judgment (CMS Brief). Petitioner filed its brief in response (P. Brief) to the CMS motion on January 4, 2007, with exhibits (P. Ex.) 1 through 4.

II. Discussion

A. Findings of Fact

The following findings of fact are 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.

1. Petitioner possessed a valid CLIA certificate and was authorized to receive Medicare payments at all relevant times.

2. Petitioner was at all pertinent times enrolled in a proficiency testing (PT) program through the Wisconsin State Laboratory of Hygiene (WSLH). CMS Brief at 6.

3. Petitioner does not dispute that as part of the PT program, WSLH sent Petitioner samples to test for PT events 2006-1 and 2006-2. CMS Brief at 7.

4. Petitioner does not deny that PT hematology samples for PT event 2006-1 were sent to the Muskogee Regional Medical Center laboratory (Muskogee Regional) where they were tested in February 2006.

5. Petitioner does not deny that PT hematology samples for PT event 2006-2 were also sent to and tested at Muskogee Regional in June 2006.

6. It is not disputed that the PT samples were also tested by Petitioner, which had the capability to do such testing, and that the results of Petitioner's testing were reported to WSLH. CMS Brief at 7-9; P. Brief at 2, 4; P. Ex. A.

7. 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.

8. Petitioner's laboratory was surveyed by the state agency on June 28, 2006.

9. CMS notified Petitioner by letter dated September 6, 2006, that it proposed to revoke Petitioner's CLIA certificate and authorization to receive Medicare payments based on the findings of the survey completed on June 28, 2006, that Petitioner sent PT samples to another laboratory.

10. Petitioner requested a hearing on October 4, 2006.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.

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

3. The motives of the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform, are irrelevant and not a defense to violation of 42 C.F.R. § 493.801(b)(4).

4. The fact that the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform, never reports the analysis of the proficiency samples to the proficiency program is irrelevant and not a defense to a violation of 42 C.F.R. § 493.801(b)(4).

5. CMS is not bound or estopped by prior agency action when that action was based on an erroneous interpretation and application of the statute and regulations.

6. There are no material facts in dispute and the only issues may be resolved as questions of law, therefore summary judgment is appropriate.

7. Petitioner violated 42 C.F.R. § 493.801(b)(4) by admittedly sending PT samples to another laboratory.

8. CMS is required to revoke Petitioner's CLIA certificate for a period of not less than one year for sending PT samples to another laboratory. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b).

9. CMS must cancel Petitioner's approval to receive Medicare payments when its CLIA certificate is revoked. 42 C.F.R. § 493.1842(a).

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

C. Issues

Whether summary judgment is appropriate in this case.

Whether there is a basis for Respondent's revocation of Petitioner's CLIA certificate.

D. Law Applicable

CLIA establishes requirements for all laboratories that perform clinical diagnostic tests 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 *et seq*. The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and hence the public health of all Americans. *See* H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3839. CMS certification of a laboratory under CLIA is dependent upon whether the laboratory meets the conditions for certification set out in the statute and regulations. 42 U.S.C. § 263a(f)(1)(E); 42 C.F.R. § 493.1 *et seq*. Pursuant to CLIA the Secretary of Health and Human Services (the Secretary) has broad enforcement authority, including the ability to suspend, limit, or revoke the certificate of a laboratory that is out of compliance with one or more requirements for certification.

The Secretary has exercised his authority under 42 U.S.C. 263a(f) and issued regulations implementing CLIA codified at 42 C.F.R. Part 493. The regulations specify standards and the specific conditions for certification that a laboratory must meet to achieve compliance and must maintain in order to be certified to test human specimens and to participate in Medicare . The regulations confer broad authority on CMS to ensure that laboratories perform as Congress intended, including authority to inspect and sanction laboratories that fail to comply with the regulatory requirements. CMS has the delegated authority to suspend, limit, or revoke the CLIA certificate of a laboratory that is out of compliance with one or more CLIA conditions, and may also impose alternative sanctions such as a directed plan of correction or monitoring by the state. 42 C.F.R. § 493.1806.

The regulations provide as a condition for participation that a laboratory conducting moderate or high complexity testing, as was Petitioner, must enroll in an approved PT program or programs that cover all the specialties and sub-specialties for which the laboratory seeks certification. The laboratory is required to test PT samples in the same manner as its regular patients' specimens. 42 C.F.R. § 493.801. Standards established to satisfy this condition level requirement are set forth at 42 C.F.R. § 493.801(b)(1) through (6). Subsection 493.801(b)(4) provides that a laboratory must not send PT samples or portions thereof to another laboratory for any analysis that it is certified to perform and if it intentionally does so, CMS must revoke its CLIA certificate for a year. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b). CMS must also cancel a laboratory's approval to receive Medicare payments when CMS suspends or revokes the laboratory's CLIA certificate. 42 C.F.R. § 493.1842(a).

CLIA provides at 42 U.S.C. § 263a(i)(1) that a laboratory's certificate may be suspended, revoked, or limited only after reasonable notice and opportunity for hearing to "the owner or operator of the laboratory...." The Secretary's regulations provide that a laboratory or prospective laboratory dissatisfied with an initial determination listed in 42 C.F.R. § 493.1844(b) is entitled to a hearing before an administrative law judge (ALJ). 42 C.F.R. § 493.1844(a). The hearing procedures found in subpart D of 42 C.F.R. Part 498 are incorporated by reference. 42 C.F.R. § 493.1844. The "suspension, limitation or revocation of the laboratory's CLIA certificate ... because of noncompliance...." is the first listed initial determination subject to hearing before an ALJ. 42 C.F.R. § 493.1844(b)(1). Generally when a hearing is requested, suspension or revocation of a CLIA certificate is not effective until after a hearing decision is issued by the ALJ. 42 C.F.R. § 493.1844(d)(2).

E. Analysis

1. Summary judgment is appropriate.

Pursuant to 42 C.F.R. § 493.1844(f), I presume that Petitioner has a right to a hearing in this case. *See Garden City Medical Clinic*, DAB No. 1763 (2001), citing 42 U.S.C. § 263a(i)(1) and 42 C.F.R. § 493.1844(a). However, the Departmental Appeals Board (the Board) has recognized that the use of summary judgment procedures may be

appropriate in cases before the Board or an ALJ pursuant 42 C.F.R. Parts 498 and 1005.[2] *See, e.g., Vandalia Park*, DAB No. 1939 (2004); *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). Summary judgment may be entered for a party when the record shows that there is no genuine dispute as to any material fact, and the moving party is entitled to judgment as a matter of law. *Lebanon Nursing and Rehabilitation Center*. The party moving for summary judgment bears the initial burden of showing the basis for its motion and identifying the portions of the record that it believes demonstrate the absence of a genuine factual dispute. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). This burden may be discharged by showing that there is no or insufficient evidence to support a judgment for the non-moving party. *Id.* at 325. If a moving party carries its initial burden, the non-moving party must "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) (quoting Fed. R. Civ. P. 56(e)). To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact — a fact that, if proven, would affect the outcome of the case under governing law. *Id.* at 586, n.11; *Celotex*, 477 U.S. at 322. In deciding a summary judgment motion, an adjudicator may not make credibility determinations or weigh conflicting evidence but must instead view the entire record in the light most favorable to the non-moving party, drawing all reasonable inferences from the evidence in that party's favor. *Madison Health Care, Inc.*, DAB No. 1927 (2004). [3]

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[2] Regulations at 42 C.F.R. Part 498 establish the procedures applicable in appeals by providers and suppliers subject to enforcement proceedings by CMS. The regulations do not mention summary judgment. However, the Board has long recognized the availability of summary judgment and the Board's interpretative rule has been recognized by the Sixth Circuit Court of Appeals. *Crestview Parke Care Center*,373 F.3d, at 749-50 (6th Cir. 2004). Furthermore, a summary judgment procedure was adopted as a matter of judicial economy within my authority to regulate the course of proceedings and made available to the parties in the litigation of this case by my Notice of Case Assignment and Prehearing Case Development Order, paragraph A5b, dated October 11, 2006.

[3] The Board's views on summary judgment are generally consistent with that of the majority of courts. *See* 10A Charles Alan Wright, Arthur R. Miller, Mary Kay Kane, *Federal Practice and Procedure Civil*, § 2727 (3d ed. 1998); 11 James William Moore, *Moore's Federal Practice*, § 56.11 (3d ed. 2005).

Summary judgment is appropriate in this case. As discussed in detail hereafter, there is no genuine dispute as to any material fact necessary to establish the CMS prima facie case. Petitioner raises the defense of estoppel. However, even accepting all the facts related to the defense as true for purposes of this motion, the defense fails as a matter of law.

2. Petitioner violated 42 C.F.R. § 483.801(4).

The regulation requires that a clinical laboratory must enroll in an approved PT program. 42 C.F.R. § 493.801. There is no dispute that Petitioner was at all pertinent times enrolled in a PT program through WSLH. CMS Brief at 6. Petitioner does not dispute that as part of the PT program, WSLH sent Petitioner samples to test for PT events 2006-1 and 2006-2. CMS Brief at 7.

The regulation requires that PT samples must be tested in the same manner as a laboratory's patient specimens. 42 C.F.R. § 493.801. The methods or procedures necessary to satisfy the requirement to test PT samples in the same manner as patient specimens are explained in 42 C.F.R. § 493.801(b). Subsection § 493.801(b)(4) of 42 C.F.R. specifies that a "laboratory must not send PT samples or portions of samples to another laboratory for any analysis which it is certified to perform in its own laboratory." The plain language of the regulation is that a PT sample may not be sent to another laboratory, either intentionally or unintentionally. The regulation establishes an absolute bar to sending PT samples to another laboratory for testing if the sending laboratory is certified to do the same testing.

The regulation further provides that if CMS determines that a laboratory "intentionally" sent a PT sample to another laboratory, then the sending laboratory's CLIA certificate must be revoked for at least a year. 42 C.F.R. § 493.801(b)(4). The regulation is based upon the statutory requirement that: "(a)ny laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis shall have its certificate revoked for at least one year...." 42 U.S.C. § 263a(i)(4). Section 493.1840(b) of 42 C.F.R. directs that CMS revoke a laboratory's CLIA certificate for one year if CMS determines the laboratory intentionally referred PT samples to another laboratory for analysis and authorizes the imposition of a civil money penalty (CMP). The statute and regulations allow for no exceptions to the prohibition on sending PT samples to another laboratory. Although CMS has discretion as to whether a CMP will be imposed for a violation, the regulation does not give CMS discretion to choose not to terminate an offending laboratory's CLIA certificate once there is a determination that there was an intentional referral of a PT sample.

Petitioner does not deny that PT hematology samples for PT event 2006-1 were sent to the Muskogee Regional where they were tested in February 2006. Petitioner also does not deny that PT hematology samples for PT event 2006-2 were also sent to and tested at Muskogee Regional in June 2006. It is not disputed that the PT samples were also tested by Petitioner, which had the capability to do such testing, and that the results of Petitioner's testing were reported to WSLH. CMS Brief at 7-9; P. Brief at 2, 4; P. Ex. A.

The undisputed facts satisfy the CMS burden to make a prima facie showing of a violation of 42 C.F.R. § 483.801(b)(4). Petitioner concedes that it sent PT samples to another laboratory for analysis that it was certified to perform. Petitioner asserts in its response that it did not "intentionally" refer PT samples to another laboratory for analysis but only to test the calibration of Petitioner's equipment. P. Brief 1-2; P. Ex. A. The Affidavit of Kevin Wade, M.D., Petitioner's laboratory director, clearly shows that Petitioner's PT samples were sent to Muskogee and this is the determinative fact. For purposes of summary judgment, construing facts in a light most favorable to Petitioner, I accept that Petitioner did not send PT samples to Muskogee Regional with the intent to submit the results to WSLH or for any purpose other than to see how the Muskogee Regional test results compared with its own. However, the motives of the laboratory that sends PT samples to another laboratory for analysis that the sending laboratory is certified to perform, are irrelevant. The fact that the sending laboratory never reports the analysis of the proficiency samples to the proficiency program is not mentioned by the statutes or regulations as an exception or defense to the prohibition, and is also irrelevant. The act prohibited is the sending of PT samples to another laboratory for analysis when the sending laboratory is certified to do the analysis. *Lackawanna Group Medical Laboratory*, DAB No. 1870 (2003).

Petitioner also argues that CMS should be estopped from revoking its CLIA certificate and cancelling Petitioner's approval to received Medicare payments. Petitioner argues that in 2005, after Petitioner failed a PT test event, a "CMS field investigator" suggested to the laboratory director that it would be beneficial if Petitioner received training and comparison testing from another CLIA certified laboratory such as Muskogee Regional. P. Brief at 3. Petitioner also argues that it submitted a Plan of Correction to CMS in March 22, 2006, that indicated it had in the past and would continue to send PT samples to Muskogee Regional for comparison testing. Petitioner argues it detrimentally relied upon the suggestion of the CMS field investigator and the fact that its plan of correction was accepted. P. Brief at 3-4; P. Ex. 4, at 1-2, 4. Although Doctor Wade does not attest that the investigator told him to send PT samples to another laboratory and the language of the plan of correction may be subject to other reasonable interpretations, for purposes of summary judgment, I must construe the facts alleged in a light most favorable to

Petitioner. Even though I accept as true, for purposes of this motion only, the facts alleged by Petitioner as a basis for its estoppel defense, the estoppel defense must be resolved against Petitioner as a matter of law. CMS cannot be bound or equitably estopped by prior agency action where that action was based on an erroneous interpretation and application of the statute and regulations such as that discussed above. The decisions of the United States Supreme Court in *Office of Personnel Management v. Richmond*, 496 U.S. 414, 110 S.Ct. 2465, 110 L.Ed.2d 387 (1990) and *Heckler v. Community Health Services of Crawford County, Inc.*, 467 U.S. 51, 104 S.Ct. 2218, 81 L.Ed.2d 42, 5 Soc.Sec.Rep.Ser. 29 (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.[4]

I conclude that Petitioner violated 42 C.F.R. § 493.801(b)(4) by sending PT samples to another laboratory. I further conclude, as a matter of law, that estoppel will not lie against the government in this case. CMS is required to revoke Petitioner's CLIA certificate for a period of not less than one year from the date of this decision. 42 U.S.C. § 263a(i)(4); 42 C.F.R. §§ 493.801(b)(4) and 493.1840(b). CMS must also cancel the laboratory's approval to receive Medicare payments. 42 C.F.R. § 493.1842(a).

III. Conclusion

For the foregoing reasons, the CMS motion for summary judgment is granted. Petitioner's CLIA certificate is revoked for a period of one year effective the date of this decision and Petitioner's approval to receive Medicare payments is cancelled.

/s/

Keith W. Sickendick
Administrative Law Judge

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[4] It has been consistently held that ALJs do not have the authority to hear and decide claims of estoppel against CMS or the Secretary related to alleged dilatory processing of applications. *GranCare Home Health Service & Hospice*, DAB CR464 (1997); *The Rivers Health Care Resources, Inc.*, DAB CR446 (1996); *SRA, Inc. D/B/A St. Mary Parish Dialysis Center*, DAB CR341 (1994); *T.L.C. Mental Health Center*, DAB CR636 (1999); *Therapeutic Rehabilitation Centers, Inc.*, DAB CR531 (1998). However, I find no similar limit to my jurisdiction where Petitioner asserts estoppel as a defense to an enforcement action. *Accord Stacy Ann Battle, D.D.S.*, DAB 1843 (2002).