Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Stat Lab I, Inc.,	)	Date: February 27, 2008
(CLIA No. 19D0990153),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-486
	)	Decision No. CR1743
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I grant summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) and against Petitioner, Stat Lab I, Inc. In doing so I sustain CMS's determination to impose remedies against Petitioner under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). Summary judgment is appropriate as there are no genuine issues of material fact in dispute and the controlling issues may be resolved as a matter of law. Petitioner's CLIA certificate is revoked effective the date of this decision due to the prior CMS suspension of the certificate based on a finding of immediate jeopardy. By operation of law, the owners and operators of Petitioner are prohibited from owning, operating, or directing a laboratory for two years pursuant to 42 U.S.C. § 263a(i)(3) in consequence of the revocation of Petitioner's certificate. The two-year prohibition runs from the date of the revocation of the laboratory's certificate pursuant to 42 U.S.C. § 263a(i)(3), which is the date of this decision.

I. Background

Petitioner is a clinical laboratory located in Baton Rouge, Louisiana. This matter arose as a result of a re-certification survey and subsequent revisit survey of Petitioner's laboratory by the Louisiana Department of Health and Hospitals (State agency).

On December 11, 2006 (December survey), the State agency concluded a re-certification survey of Petitioner's laboratory where conditions within the laboratory were found to pose an immediate jeopardy to patients. The State agency issued a statement of deficiencies (SOD) dated December 11, 2006. CMS reviewed the survey report and concurred that Petitioner was not in compliance with three condition-level participation requirements. By letter dated January 16, 2007, CMS served notice on Petitioner of its proposed sanctions.

On January 26, 2007, Petitioner submitted its Credible Allegation of Compliance listing various actions it would take to address the deficiencies. An on-site revisit to verify Petitioner's allegation of compliance and evidence of correction was conducted by the State agency on February 8, 2007, and its survey findings were issued in an SOD dated February 8, 2007. The State agency found that Petitioner had failed to adhere to its allegation of compliance, that it had failed to achieve full compliance, and that the immediate jeopardy situation still existed.

CMS concurred with the State agency's findings and, by letter dated April 3, 2007, served Petitioner notice of proposed sanctions which included: (1) canceling Petitioner's approval to receive Medicare payments, effective April 9, 2007; (2) suspending Petitioner's CLIA certification and denial of its laboratory's application for a certificate of compliance, effective April 9, 2007; and (3) revocation of Petitioner's CLIA certificate of compliance pending a decision from an Administrative Law Judge (ALJ).[1] Petitioner was also notified that if revocation of its CLIA certificate was effectuated, the owner and operator (including director) of the laboratory would be prohibited from owning or operating a laboratory for at least two years from the date of revocation pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).

By letter dated May 31, 2007, Petitioner timely requested a hearing before an ALJ to challenge the February 8, 2007 revisit findings and CMS's determination. The case was assigned to me on June 22, 2007 for hearing and decision. A prehearing order was issued on June 22, 2007, directing the parties to file prehearing exchanges. On September 24, 2007, CMS filed a motion and memorandum in support of summary judgment (CMS Brief). CMS's memorandum was accompanied by seven exhibits, CMS exhibits (CMS Exs.) 1-7.[2] Petitioner filed its opposition brief on October 22, 2007 (P. Response)

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[1] Because Petitioner filed an appeal, the revocation of the laboratory's CLIA certificate does not become effective until the date of an ALJ decision upholding the basis of the remedy. 42 C.F.R. §§ 493.1840(e), 493.1844(d)(2).

[2] P. Ex. 7 and P. Ex. 8 consist of affidavits from David Deshotels, Petitioner's owner, and Samuel Parker, Petitioner's Laboratory Director and Technical Consultant as of January 24,

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accompanied by eight exhibits, Petitioner exhibits (P. Exs.) 1-8.[3] CMS submitted its reply brief (CMS Reply) to Petitioner's opposition, filed November 5, 2007. Petitioner followed with a sur-reply (P. Reply) received on November 21, 2007.

For the reasons set forth below, I find that summary judgement is appropriate. Based on the record before me, arguments of the parties, and applicable law and regulations, I find that there are no material issues of fact in dispute requiring an evidentiary hearing, and that CMS is entitled to judgment as a matter of law.

II. Applicable Law and Regulations

The purpose of CLIA is to ensure the accuracy and reliability of laboratory tests, and therefore, 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. CLIA establishes requirements for all laboratories that perform clinical diagnostic tests on human specimens in addition to providing 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.

Under CLIA, the Secretary of the United States Department of Health and Human Services (Secretary) is authorized to inspect clinical laboratories and, in effect, license them to perform tests. CLIA prohibits a clinical laboratory from soliciting or accepting specimens for testing unless it has first received from the Secretary a certificate authorizing it to perform the specific category of tests which the laboratory intends to perform. 42 U.S.C. § 263a(b). Additionally, CLIA directs the Secretary to establish standards to assure that clinical laboratories certified by the Secretary perform tests that are valid and reliable. 42 U.S.C. § 263a(f).

The Secretary has exercised his authority under 42 U.S.C. 263a(f) and issued regulations implementing CLIA. These are codified at 42 C.F.R. Part 493. The regulations establish both conditions and standards of participation under CLIA. Each condition-level requirement of the regulations represents a major division of laboratory services to be offered by the laboratory or establishes an important environmental protection for the laboratory. *RNA Laboratories, Inc*., DAB No. 1820, at 3 (2002). Standards of

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[2](...continued)
2007.

[3] For purposes of the record I receive CMS Exs. 1-7 and P. Exs. 1-8. Although I may cite to some of these exhibits in this decision for the purpose of describing undisputed material facts, I do not make findings as to the exhibits' evidentiary weight. In issuing summary judgment I rely only on the undisputed material facts and I make no evidentiary findings.

participation are set forth as specific quality requirements which must be met by a laboratory in order to meet the more general requirements of conditions of participation. Thus, standards are subparts of the more broadly stated conditions. A failure by a laboratory to comply with one or more standards may be so serious as to constitute a failure to comply with the condition of which the standards are a subpart. *Vijay Sakhuja, M.D.*, DAB No. 1958 (2005).

The Secretary's 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 or its designee conduct validation inspections to determine a laboratory's compliance with CLIA requirements. 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); *see also Edison Medical laboratories, Inc.*, DAB No. 1713 (1999). Principal sanctions include suspension, limitation, or revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1806(b). Alternative sanctions which CMS may impose include a directed plan of correction, state monitoring, and/or a civil money penalty (CMP). 42 C.F.R. § 493.1806(c). Additionally, if a laboratory which has approval to receive Medicare payment for its services is out of compliance with one or more CLIA conditions, CMS may cancel the laboratory's approval to receive Medicare payment for its services. 42 C.F.R. § 493.1806(a). Generally, the suspension, limitation, or revocation of a CLIA certificate is not effective if appealed, until the ALJ makes a decision. However, when CMS declares immediate jeopardy, there is no delay in the suspension, limitation, or revocation of the offending laboratory's CLIA certificate. 42 C.F.R. § 493.1844(d)(2).

A laboratory is entitled to a hearing before an ALJ to contest the imposition of CLIA remedies. 42 C.F.R. § 493.1844(a). The determination as to which alternative sanctions to impose and the determination that a laboratory's deficiencies pose immediate jeopardy are not appealable. 42 C.F.R. § 493.1844(c). The CLIA regulations incorporate by reference the hearing procedures and the request for review provisions in 42 C.F.R. Part 498, subparts D and E. 42 C.F.R. § 493.1844(a).

III. Issues, findings of fact and conclusions of law

A. Issues:

1. Whether summary judgment is appropriate;

2. Whether Petitioner failed to comply with one or more conditions of participation under CLIA; and

3. Whether CMS had the authority to impose sanctions against Petitioner.

B. Findings of fact and conclusion of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

1. Summary judgment is appropriate in this case.

Pursuant to 42 C.F.R. § 1844(f) it is presumed 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, an ALJ may decide a case on summary judgment, without an evidentiary hearing, when either there are no disputed issues of material fact and the only questions that must be decided involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made.

A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party. *See, e.g.,* FED. R. CIV. P. 56(c); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). Appellate panels of the Departmental Appeals Board (Board) have 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 v. Thompson*, 373 F.3d 743, 750 (6th Cir. 2004). 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. *Matsushita Elec. Industrial Co. v. Zenith Radio*, 475 U.S. 574, 586 n.11 (1986).

In deciding a summary judgment motion, an ALJ may not make credibility determinations or weigh conflicting evidence but must instead view the entire record in the light more favorable to the nonmoving party, drawing all reasonable inferences from the evidence in that party's favor. *Brightview Care Center*, DAB No. 2132 (2007); *Madison Health Care, Inc*. DAB No. 1927 (2004).

CMS has moved for summary judgment arguing it is entitled to judgment as a matter of law as there are no material facts in dispute with respect to all three of the cited condition-level deficiencies: (1) Petitioner resumed coagulation testing on February 5, 2007 without authorization from either the State agency or CMS in violation of 42 C.F.R. § 493.1250; (2) between January 24, 2007 and February 8, 2007 Petitioner was without a

laboratory director in violation of 42 C.F.R. § 493.1403; and (3) between January 24, 2007 and February 8, 2007 Petitioner was without a Technical Consultant in violation of 42 C.F.R. § 493.1409.

Petitioner argues that there are material facts in dispute as to each of the alleged condition-level deficiencies identified and that Petitioner was actually in compliance with all CLIA requirements at the time of the February 8, 2007 revisit survey. Petitioner bears the burden of showing that there are material facts that are disputed. *Everett Rehabilitation and Medical Center*, DAB No. 1628 (1977). If Petitioner cannot show that there exists some genuine issue for trial, then summary judgment is appropriate and CMS must prevail as a matter of law. Moreover, in this case the CMS citation of condition-level deficiencies makes Petitioner's task of overcoming summary judgment even more burdensome. CMS imposed the principal sanction of suspension of Petitioner's CLIA certificate which will become a revocation of that certificate if I affirm the CMS action. Any one of the three condition-level deficiencies if proved may be sufficient to sustain the suspension by CMS. Therefore, if there is no disputed, material fact and no genuine issue for trial as to even one of the condition-level deficiencies, summary judgment may be entered as to that deficiency. The issue then is whether the one deficiency is sufficient to support CMS's decision to impose the remedy, i.e. , whether the remedy is warranted given the deficiency.

As previously noted, three condition-level deficiencies are alleged in this case: (1) violation of 42 C.F.R. § 493.1250; (2) violation of 42 C.F.R. § 493.1403; and (3) violation of 42 C.F.R. § 493.1409. Section 1250 sets the conditions for a laboratory to monitor and evaluate the overall quality of the analytic systems it employs. Section 1403 establishes conditions to be met by the individual holding the laboratory director position in a laboratory performing moderate complexity testing with specific reference to technical supervision of laboratory operations and personnel, including management responsibilities. *See also* 42 C.F.R. § 493.1407. Section 1409 provides the conditions that must be met by the individual holding the technical consultation position in a laboratory that performs moderate complexity testing

I have reviewed the record and arguments before me and conclude that there are no material issues of fact regarding at least one of the condition-level violations and therefore, judgment should be entered for CMS on those violations as a matter of law.[4]

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[4] I note that on further analysis of the other condition-level deficiencies I might also have found no genuine issues for trail. However, because the violation for analytic systems under 42 C.F.R. § 493.1250 is serious enough to justify the remedy imposed by CMS and the eventual revocation of Petitioner's CLIA certificate, for reasons of judicial economy I see no reason to

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2. Petitioner was out of compliance with the condition of analytic systems as set forth in 42 C.F.R. § 493.1250.

During the on-site visit to Petitioner's laboratory on February 8, 2007, the State agency determined that Petitioner failed to demonstrate compliance with the CLIA condition of analytic systems. CMS states that coagulation testing at Petitioner's laboratory had been discontinued as of January 25, 2007, yet Petitioner resumed coagulation testing for eight patients from February 5-7, 2007 without prior authorization. CMS Brief at 5.

Petitioner does not deny that it was advised of the serious nature of its deficiencies by CMS notice dated January 16, 2007, and that the laboratory's CLIA certificate was being suspended effective January 22, 2007, based on the finding of immediate jeopardy. P. Response at 2; P. Ex. 2. Petitioner does not deny that it resumed coagulation testing on February 5, 2007. P. Response at 5. Petitioner does not deny that it failed to seek prior authorization for the resumption of testing from either the State agency or CMS. P. Response at 5-6. Finally, Petitioner does not deny that eight patients were tested at its laboratory from February 5-7, 2007, after its coagulation testing had been discontinued.

In fact, Petitioner admits numerous times in the record before me, including in the sworn affidavits of its owner David Deshotels, and its laboratory director, Samuel Parker, that it did resume coagulation testing on February 5, 2007 - without obtaining prior approval from CMS of the policy it had implemented to resume testing. P. Request for hearing - Allegation of Compliance 1; P. Exs. 7, 8. In defending its action, Petitioner claims that it was not informed during the December survey that the laboratory required authorization to resume coagulation testing once the issue had been corrected. P. Request for hearing - Allegation of Compliance 1. Petitioner states that even its laboratory technician was unaware that CMS required authorization or approval before resuming testing that may have been considered performed in error during the December survey. *Id; see also* P. Exs. 7, 8.

Petitioner argues that there was no prohibition applicable to or communicated to Petitioner regarding its resumption of coagulation testing, and argues that there is no clear regulatory requirement of such approval. P. Response at 3, 5. Petitioner admits that coagulation testing was suspended as of January 25, 2007, due to its need to implement an established policy to determine Platelet Poor sampled. P. Response at 5. Petitioner's Credible Allegation of Compliance states that it suspended testing of all coagulation testing until it could establish proper quality controls. P. Response at 5; P. Ex. 3. Petitioner admits that once it implemented a policy to determine Platelet Poor samples

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spend further time or resources upon an analysis of Petitioner's alleged violation of 42 C.F.R. §§ 493.1403 and 493.1409.

and established appropriate polices, and in-serviced personnel regarding quality controls, it resumed coagulation testing. P. Response at 5. P. Ex. 7. However, Petitioner failed to obtain prior approval from CMS of the policy it implemented to resume testing.

Here, Petitioner wants CMS or the State agency to assume responsibility for this serious lapse and protests that neither agency provided Petitioner with oral or written instructions stating that prior authorization was required in order for Petitioner to resume testing. P. Response at 5. Petitioner further argues that there was no basis for CMS to assert that Petitioner was obligated to obtain prior approval before resuming testing as its Credible Allegation of Compliance gave no indication that such approval would be sought. P. Response at 6.

Even accepting Petitioner's claim that its actions were done in good faith, Petitioner has failed to offer any evidence to rebut CMS's allegations, nor has it directed me to any facts that point to a material issue for hearing. Petitioner admits that it failed to obtain prior approval from CMS as to the policy it implemented to determine Platelet Poor samples prior to the laboratory resuming testing. P's Request for hearing at 1-2.

Petitioner's arguments reflect its apparent inability to grasp the critical point. The purpose of CLIA and the implementing regulations is to ensure public health and safety by ensuring that laboratories provide accurate and reliable test results. Under CLIA regulations, the test is not merely whether small errors were made or whether patients were harmed. Rather, it is whether the laboratory established and followed general quality procedures for monitoring and evaluating the quality of the analytical testing process of each testing method to assure the accuracy and reliability of patient test results and reports. By failing to wait to be checked by the State agency before retesting patients and reporting patient test results, Petitioner violated the standard established by 42 C.F.R. § 493.1250.

The law is clear: laboratories that do no meet CLIA conditions may not be certified for participation in the CLIA program. 42 U.S.C. § 263a(b); *see also* 68 FR 3640, January 24, 2003:

> [*A*]*ll* laboratories, regardless of whether they receive payment from the Medicare or Medicaid programs must have a current and valid CLIA certificate to test human specimens (emphasis added).

CMS's task, as delegated to it by the Secretary, is ensuring consistent performance by laboratories that are issued CLIA certificates. 42 U.S.C. § 263a(f). It was the intent of Congress, with the enactment of the CLIA legislation, to make certain that federal oversight of clinical laboratories would be strengthened thus assuring that test results obtained in those laboratories were accurate and reliable. *See* H.R. Rep. No. 899, 100th

Cong. 2d Sess. 8, 18 (1988), *reprinted* in 1988 U.S.C.C.A.N. 3828, 3829. Congress did not intend laboratories to be self-regulating. In fact, just the opposite was plainly the goal. In addressing laboratory tests, the committee reported that:

> These tests are critical to proper patient care when properly used and when the test are accurate and reliable. Whey they are inaccurate or unreliable, however, the consequences are improper treatment, unnecessary mental and physical anguish for patients, and higher health care costs. Because of the critical role played by laboratory testing in the delivery of health services and in maintaining good health, patients expect such tests to be done properly and rely heavily on others to make sure that is the case. Patients assume, quite reasonably, that their interests and the public health are being protected by appropriate government agencies.

Id. at 3831. Further in the text of the committee's report, additional emphasis appears: "Federal regulation is reasonable and appropriate to promote public health and welfare and protect commerce." *Id*. at 3839.

Based on Petitioner's admissions, and in viewing the record before me in a light most favorable for the Petitioner, and in drawing all inferences favorable to Petitioner that the record can reasonably support, I find as matters of fact that when Petitioner resumed coagulation testing on February 5, 2007, it did so without proper prior authorization. Petitioner therefore failed to demonstrate compliance with CLIA requirements as of the February 8, 2008 revisit survey. I therefore conclude as a matter of law that this constituted a violation of 42 C.F.R. § 493.1250 during this period.

As noted earlier, having found Petitioner in violation of at least one condition-level, I need not decide whether Petitioner was out of compliance with the condition of Laboratory Director and Technical Consultant, moderate complexity testing as set forth in 42 C.F.R. §§ 493.1403 and 493.1409.

3. Because Petitioner was out of compliance with at least one condition, CMS is authorized to impose sanctions.

If, on inspection, a laboratory is found to have condition-level deficiencies that pose immediate jeopardy, CMS must require immediate action to remove the jeopardy and may impose alternative sanctions. If the deficiency remains on revisit, CMS may suspend or limit and later revoke the laboratory's CLIA certificate. CMS is also delegated authority to bring a civil suit for injunction against a laboratory in specified circumstances where there is immediate jeopardy. 42 C.F.R. § 493.1812.

Failure by a laboratory to comply with even a single applicable condition can represent a critical breakdown in one of the major health care delivery or safety systems of the laboratory. *Ward General Practice Clinic*, DAB No. 1624, at 2 (1997). Therefore, violation of just one condition-level deficiency can be grounds for a principal sanction, including revocation of a laboratory's CLIA certificate. 42 C.F.R. § 493.1804(b); *Edison Medical Laboratories, Inc.*, DAB No. 1713 (1999).

Petitioner avers that in light of its history of cooperation and the general nature of its defense, the penalties proposed by CMS should be reduced. Petitioner states that the revocation of its CLIA certification and cancellation if its Medicare participation in addition to the ongoing suspension are too severe. Petitioner proposes instead that its CLIA certificate remain suspended for a period of two years as of April 9, 2007. P. Response. at 10.

There is nothing in the regulations which gives me authority to review CMS's exercise of its discretionary authority. To put that point another way: I may not substitute my judgment for that of CMS where condition-level noncompliance has been found and where CMS chooses to impose one or more of the principal sanctions provided by the regulations. The applicable regulation makes it clear that the existence of condition-level noncompliance establishes a rational basis for imposing remedies against Petitioner.

The existence of the one condition-level deficiency in this case is sufficient to support the principal sanction of suspension and revocation of Petitioner's CLIA certificate. The purpose of the Act is to ensure "the accuracy and reliability of laboratory tests, and hence the public health of all Americans." H.R. Rep. No. 899, 100th Cong. 2d Sess. 8, 18 (1988), *reprinted* in 1988 U.S.C.C.A.N. 3828, 3839. The complete and admitted failure of Petitioner to obtain prior approval before it resumed coagulation testing on February 5, 2007 creates a significant risk of inaccuracy and unreliability detrimental to the health of the American public. As noted, I can make this determination without the need to assess and discuss the other two condition-level deficiencies. Petitioner has made no argument nor proffered any evidence that would lead to a different result.

4. The other arguments raised by Petitioner are unavailing to mitigate the sanctions imposed.

Petitioner has raised several subsidiary points, including its claim: (1) that insufficient time was afforded Petitioner to correct deficiencies and fully implement its corrective action plan before the state conducted a surprise revisit survey on February 8, 2007; (2) that CMS failed to investigate adequately the circumstances surrounding each allegation of noncompliance during the February 2007 survey; (3) that CMS and the State agency were unfair and discriminatory in their enforcement of the CLIA regulations against Petitioner; (4) that CMS and the State agency imposed unnecessary harsh sanctions

against Petitioner when it was in substantial compliance with its Credible Allegation of Compliance; and (5) that CMS and State agency refused to consider substantial evidence supporting Petitioner's compliance with its Credible Allegation of Compliance.

First, with respect to the sanctions imposed, since Petitioner failed to comply with conditions of participation, CMS is authorized to impose principal sanctions, including revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(b). CMS may also cancel the laboratory's approval to received Medicare payment for its services. 42 C.F.R. § 493.1807. The agency's decision not to accept Petitioner's plan of correction as outlined in its Credible Allegation of Compliance are not "initial determinations" and therefore are not reviewable. 42 C.F.R. § 493.1844.

Second, neither Congress nor the Secretary has placed a time limit on CMS's exercise of its enforcement authority under CLIA. Imposing such a time limit could undermine CMS's ability to carry out the enforcement purposes of CLIA - to protect individuals against substandard testing of specimens, to safeguard the public against health and safety hazards, and to motivate laboratories to comply with CLIA requirements to provide accurate and reliable test results.

Finally, Petitioner's complaints about CMS and the State agency are irrelevant to the question of the laboratory's compliance. Petitioner provides no basis in law or facts that supports those arguments, which are well beyond my authority to address in any case.

IV. Conclusion

For the foregoing reasons, I grant summary judgment in favor of CMS and against Petitioner, and in doing so sustain CMS's imposition of its sanctions against Petitioner.

/s/
Richard J. Smith
Administrative Law Judge