Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Daniel M. Stewart,	)	Date: January 9, 2008
(CLIA ID #23D0363803)	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-429
	)	Decision No. CR1723
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION GRANTING SUMMARY DISPOSITION TO CENTERS FOR MEDICARE & MEDICAID SERVICES

I grant summary disposition to the Centers for Medicare & Medicaid Services (CMS) thereby sustaining its determination to revoke the CLIA certificate of Petitioner Daniel M. Stewart. In doing so I find to be without merit Petitioner's argument that there are issues of disputed material fact in this case that necessitate an in-person hearing.

I. Background

Petitioner does business in Michigan as a physician's office laboratory and was certified to perform laboratory testing pursuant to the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578 (section 353 of the Public Health Service Act, 42 U.S.C. § 263a) and implementing regulations at 42 C.F.R. Part 498. CMS, which has authority pursuant to CLIA and implementing regulations to make determinations concerning CLIA compliance by laboratories, determined to revoke Petitioner's CLIA certification. Petitioner requested a hearing and the case was assigned to me for a hearing and a decision.

I issued a pre-hearing order directing the parties to file pre-hearing exchanges. The parties complied with this order. CMS submitted a total of 20 proposed exhibits which it identified as CMS Ex. 1 - CMS Ex. 20. Petitioner submitted 12 proposed exhibits which it identified as P. Ex. 1 - P. Ex. 12.[1] I scheduled the case for an in-person hearing. Then, CMS moved for summary disposition. Petitioner opposed the motion.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are:

1. Whether summary disposition is appropriate; and

2. Whether the undisputed material facts establish that Petitioner contravened CLIA requirements thereby justifying CMS's determination to revoke Petitioner's CLIA certification.

B. Findings of fact and conclusions 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.

1. Summary disposition is appropriate because there are no disputed issues of material fact.

Petitioner's hearing rights in this case are governed by regulations at 42 C.F.R. Part 498. These regulations do not address explicitly the circumstances under which an administrative law judge may grant summary disposition or judgment. However, the regulations have been interpreted universally to allow summary disposition in those circumstances where summary judgment would be appropriate under Rule 56 of the Federal Rules of Civil Procedure.

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[1] For purposes of the record I receive CMS Ex. 1 - CMS Ex. 20 and P. Ex. 1 - P. Ex. 12. 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 disposition I rely only on the undisputed material facts and I make no evidentiary findings.

Rule 56 permits summary judgment in a case where there are no disputes as to material facts. A "material fact" is a fact which is necessary to deciding a case. Summary judgment may not be imposed where there is a genuine dispute as to a material fact. However, a fact must truly be material in order for a dispute concerning that fact to be an impediment to issuing summary judgment. Calling a fact "material" does not necessarily make it so.

Furthermore, a fact is not "disputed" simply because a party asserts that there is a dispute. A genuine dispute exists as to a fact only where the parties offer plausible contradictory versions of the same fact.

In this decision I discuss in detail the facts on which CMS relies to support its motion for summary disposition. I explain why these facts, if not disputed, support a conclusion that Petitioner contravened CLIA requirements and also why Petitioner's noncompliance justified revocation of its CLIA certificate. I discuss also the allegedly disputed facts cited by Petitioner and I explain why these facts either do not cause a legitimate dispute concerning the facts relied on by CMS or are not material to the outcome of this case.

CMS bases its motion for summary disposition on four specific allegations of noncompliance. First, it asserts that Petitioner contravened both CLIA and the requirements of an implementing regulation, 42 C.F.R. § 493.801(b)(4), by intentionally referring proficiency testing samples to another laboratory for testing. Second, CMS contends that Petitioner failed to comply with the CLIA condition stated at 42 C.F.R. § 493.801 because it failed to test proficiency testing samples in the same manner as it tested patients' specimens. Third, it asserts that Petitioner failed to comply with the CLIA condition stated at 42 C.F.R. § 493.803 in that it failed to participate successfully in a proficiency testing program. Finally, CMS alleges that Petitioner failed to comply with the CLIA condition stated at 42 C.F.R. §§ 493.1403 and 493.1407 in that it failed to have a laboratory director who provides overall management and direction in compliance with applicable CLIA regulations.

As I explain below, failure by Petitioner to comply with any of these requirements gives CMS sufficient grounds to impose the remedy that it determined to impose here, revocation of Petitioner's CLIA certificate. Consequently, summary disposition in favor of CMS is appropriate if the undisputed material facts establish a basis for summary disposition as to any one of the four allegations of noncompliance.

I find that it is appropriate to impose summary disposition in favor of CMS as to two of CMS's noncompliance allegations: Petitioner's failure to test proficiency testing samples in the same manner as patients' specimens, in contravention of the requirements of 42 C.F.R. § 493.801; and Petitioner's failure to conduct a successful proficiency testing program in contravention of the requirements of 42 C.F.R. § 493.803. It is unnecessary that I address the other two allegations of noncompliance.

The facts that are material to the two CLIA conditions for which I impose summary disposition are not necessarily congruent with those that relate to the CLIA requirements that I do not address in this decision. For example, it is not necessary that I find that Petitioner intentionally referred proficiency testing samples to another facility as an element of or as a prerequisite to a finding that it failed to conduct testing of proficiency testing samples in the same manner as it tested patients' specimens. For that reason, Petitioner's assertion that there are disputed issues of material facts relating to the issue of whether it intentionally referred proficiency testing samples to another facility is not relevant to deciding whether there are undisputed material facts supporting summary disposition on the issues of whether Petitioner conducted proficiency testing in the same manner as it tested patients' specimens or whether it maintained a successful proficiency testing program.

2. The undisputed material facts establish that Petitioner contravened two CLIA conditions of participation because it failed to test proficiency testing samples in the same manner as patients' specimens and because it failed to participate successfully in a proficiency testing program.

CLIA directs the Secretary of Health and Human Services (the Secretary) and, by implication his delegate CMS, to issue and enforce regulations to implement the statute's provisions. 42 U.S.C. § 263a(f)(1). The statute provides the Secretary and CMS with the authority to impose remedies – including revocation of a laboratory's CLIA certificate – where the Secretary finds that the laboratory has not complied with CLIA participation requirements prescribed by the Secretary. 42 U.S.C. § 263a(i)(1)(C).

The regulations governing CLIA participation include regulations governing proficiency testing. Proficiency testing is a process by which CLIA-certified laboratories must periodically test samples that are sent to them by a testing service in order to assure that the tests that they conduct are accurate. The Secretary's CLIA regulations make it a condition for CLIA participation that a laboratory test proficiency testing samples "in the same manner as patients' specimens." 42 C.F.R. § 493.801. Furthermore, participation in CLIA is conditioned on a laboratory "successfully particip[ating] in a proficiency testing program approved by CMS . . . ." 42 C.F.R. § 493.803.

Regulations define what constitutes testing proficiency testing specimens in the same manner as patients' specimens. They require, among other things, that a laboratory's proficiency testing samples must:

> be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods. The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.

42 C.F.R. § 493.801(b)(4).

The essence of proficiency testing is that it measure the actual performance of a laboratory under conditions that are precisely identical to the way in which the laboratory tests all of the same type of specimens. Proficiency testing would be meaningless if a laboratory uses: different protocol for testing proficiency testing samples than it uses for testing other specimens of the same type; different personnel to conduct proficiency testing than the personnel who test patients' specimens; or different equipment for performing proficiency testing than that which it uses to test patients' specimens. Consequently, the requirement that proficiency samples be tested in the same manner as patients' specimens consists of at least the following three mandatory elements: (1) proficiency testing samples must be integrated into a laboratory's regular workload of patient specimens; (2) the personnel who routinely perform testing on patient specimens must test proficiency testing samples; and (3) proficiency testing samples must be tested using the same methods and equipment as the laboratory uses to test patients' specimens.

Any failure by a laboratory to test proficiency testing specimens exactly as it tests other specimens of the same type, and as part of its integrated patient testing process, is a violation of the proficiency testing condition and also establishes that the laboratory failed to comply with the condition requiring it to participate successfully in an approved proficiency testing program.

a. Petitioner failed to comply with the condition stated at 42 C.F.R. § 493.801 because it failed to test proficiency testing samples in the same manner as it tested patients' specimens.

According to CMS, Petitioner failed to meet any of the requirements governing proficiency testing in conducting proficiency testing of mycology samples during the third testing event of 2005 and the first two testing events of 2006. Specifically:

• Petitioner is located in the Michigan Center for Dermatology and Cosmetic Surgery, a physician's office in Clinton Township, Michigan, a community about 30 miles from Detroit, Michigan.

• The tests conducted by Petitioner included specific types of mycology testing.[2] Until at least December 2006 these tests included reading fungal cultures at the genus/species level.

• CLIA regulations require that a laboratory which conducts tests that isolate or identify an organism at the genus or species level participate in proficiency testing of such tests. 42 C.F.R. § 493.15(a).

• For the third proficiency testing event of 2005 and the first two proficiency testing events of 2006 Petitioner sent its fungal proficiency testing samples to Dennis Babel, Ph.D., at his home in Holland, Michigan. Holland is a community that is located several hours' drive away from Petitioner's laboratory.

• Dr. Babel analyzed the proficiency testing samples at his home using his personal equipment to perform the tests. Petitioner then reported the test results to the proficiency testing agency, the College of American Pathologists.[3]

• Petitioner did not record the fungal testing samples for the third proficiency testing event of 2005 or the first two proficiency testing events of 2006 on its patient log sheets, which record tests conducted at Petitioner's laboratory.

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[2] CMS asserts that the mycology testing performed by Petitioner included fungal cultures and "KOH preps." It has not provided me with a definition of the term "KOH prep".

[3] In reporting the test results, Dr. Babel and Petitioner's director, Daniel M. Stewart, M.D., signed the following attestation:

> We the undersigned, recognizing that some special handling may be required due to the nature of proficiency testing materials, have as closely as is practical, performed the analyses on these specimens in the same manner as regular patient specimens.

CMS Ex. 8, at 2; CMS Ex. 9, at 2.

> • Although Petitioner sent proficiency testing samples to Dr. Babel for the third proficiency testing event of 2005 and the first two proficiency testing events of 2006, it continued during that same period of time to conduct the same types of tests on patient specimens at its Clinton Township office.

The facts relied on by CMS, if not disputed, establish a failure by Petitioner to perform proficiency tests in the same manner as it tests patients' specimens. The only reasonable conclusion that I can reach from these facts is that, during the third proficiency testing event of 2005 and the first two events of 2006, Petitioner had its fungal proficiency testing performed in a manner that was different from and not integrated with the way it tested patients' specimens.

The facts alleged by CMS show that Petitioner sent its proficiency testing samples to an individual who was located at a considerable distance from Petitioner's laboratory where he tested those samples using his own equipment. The facts support the additional conclusion that, when he conducted these proficiency tests, Dr. Babel was not part of Petitioner's regular workforce routinely performing tests at Petitioner's laboratory. Finally, the facts show that Petitioner continued, at its Clinton Township office, to conduct tests on patient specimens of the same type as the proficiency test samples it sent to Dr. Babel.

There is no significant dispute about these facts. Petitioner does not deny that the proficiency tests in question were performed by Dr. Babel at his home. Additionally, Petitioner does not deny, that, at the time Dr. Babel performed these tests he was not part of Petitioner's full time work force performing tests at Petitioner's laboratory. Nor does Petitioner contend that Dr. Babel conducted the tests as part of Petitioner's routine testing of patients' specimens at its Clinton Township laboratory. In fact, Petitioner admits that two of the three proficiency test events at issue were not tested as part of its regular testing workload:

> *While the . . . [proficiency testing] samples on two isolated occasions were not tested with . . . [Petitioner's] regular patient workload*, Dr. Babel's examination of the . . . [proficiency testing] samples during his transition to eventual retirement ensured consistency with the procedures he set up for . . . [Petitioner] and . . . [Petitioner's] compliance with the underlying policy basis for 42 C.F.R. § 493.801 of protecting patient safety. . . .

Petitioner's brief in opposition to CMS's motion (Petitioner's brief in opposition) at 12 emphasis added).

In opposing CMS's motion, Petitioner focuses on CMS's allegation that it intentionally referred proficiency testing samples to another facility for testing. And, for that reason, Petitioner offers facts and arguments to support its contention that it did not intentionally refer proficiency testing samples to another facility. However, Petitioner's intent is not material to the question of whether Petitioner failed to test proficiency samples in the same manner as it tested patients' specimens.

For purposes of this decision I am assuming that all of the facts alleged by Petitioner in opposition to CMS's motion are true. And, in addition, I have drawn all inferences that one reasonably could make from Petitioner's fact allegations. Notwithstanding, Petitioner has not established any dispute as to the material facts asserted by CMS.

Petitioner recites a series of what it refers to as "questions" about the relationship between Dr. Babel and Petitioner which, it contends, can only be decided after a full hearing of this case. Petitioner's brief in opposition at 5-6. But, raising questions is not the same thing as averring facts. Petitioner does not say that it has evidence which, if offered at a hearing, would answer any of these questions in ways that dispute the material facts alleged by CMS.

For example, Petitioner contends that a question which must be answered at a hearing is: "The nature of Dr. Babel's relationship with . . . [Petitioner] at the time he tested the . . . [proficiency testing] samples. Petitioner's brief in opposition at 5. But, Petitioner did not aver that it possesses facts that raise any dispute with respect to facts offered by CMS establishing that Dr. Babel performed the proficiency tests at a location outside of Petitioner's laboratory and that the tests were not integrated into Petitioner's regular patient testing.

Similarly, Petitioner says that there is a question about: "When Dr. Babel ceased performing routine work for . . . [Petitioner]." Petitioner's brief in opposition at 5. But, as with the previous question, Petitioner doesn't offer any facts in response to this question that would call into dispute the facts alleged by CMS. For example, Petitioner does not aver that Dr. Babel routinely performed testing including the proficiency tests at issue at Petitioner's Clinton Township laboratory.

Petitioner also asserts that resolution of this case requires a determination of whether the proficiency testing samples at issue were tested by routine personnel in a manner consistent with patient specimens. Petitioner's brief in opposition at 5. I agree that this is a fair characterization of the issue of whether Petitioner conducted proficiency testing in compliance with the requirements of 42 C.F.R. § 493.801. But, Petitioner offers no facts

in response to this issue which dispute those alleged by CMS. Most importantly, Petitioner *does not* aver that it, in fact, integrated the proficiency tests into its regular patient sample testing routine at its Clinton Township laboratory.

Other facts alleged by Petitioner are simply not material to the issue of whether Petitioner performed the proficiency tests in question in the same manner as it tested patients' specimens. Petitioner asserts that Dr. Babel functioned as part of Petitioner's laboratory during the period of time that he performed the proficiency tests at issue here. Petitioner's brief in opposition at 6-7. It characterizes Dr. Babel as being semi-retired but asserts that he was still on Petitioner's payroll and "functioning as a testing person at . . . [Petitioner's laboratory] when he examined . . . [proficiency testing] samples at his home." Petitioner's brief in opposition at 7. "In fact," according to Petitioner, "the transmittal of the . . . [proficiency testing] samples to Dr. Babel in that capacity at his home was tantamount to sending them to him at a location that essentially functioned as an extension of . . . [Petitioner's laboratory] . . . ." *Id.* Petitioner also characterizes Dr. Babel's home as a "temporary testing location" for Petitioner's laboratory. *Id.* at 10.

These alleged facts are not material because they say nothing to rebut facts showing that the proficiency tests were not integrated into Petitioner's regular testing workload. For purposes of this decision I accept as true everything that Petitioner says about Dr. Babel and his role in Petitioner's operations. But, none of those allegations rebut the facts offered by CMS showing that Petitioner did not test proficiency testing samples in exactly the same way as it tested patients' specimens.

In fact, Petitioner's contentions about the relationship it had with Dr. Babel only serve to reinforce the facts alleged by CMS showing that the proficiency testing samples were not integrated into Petitioner's regular testing protocol. The fact that Dr. Babel may have been a semi-retired employee of Petitioner's laboratory who served Petitioner as a consultant or who performed proficiency tests for Petitioner at his home not only is insufficient to demonstrate that Petitioner integrated the proficiency tests at issue into its regular testing process, but it supports CMS's contention that the proficiency tests were not integrated into the normal testing process.[4]

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[4] Petitioner also argues that Dr. Babel was not operating a laboratory independently from Petitioner's laboratory. Petitioner's brief in opposition at 7-10. This argument, as I note above, is intended to address CMS's allegation that Petitioner intentionally referred proficiency testing samples to another laboratory. It is irrelevant to the issue of whether Petitioner performed proficiency tests in the same manner as it tested patients' specimens.

Petitioner asserts that: "Dr. Babel created and adhered to the routine and regular testing procedures established for patient and testing specimens utilized by . . . [Petitioner]." *Id.* at 11. According to Petitioner: "The . . . [proficiency testing] samples were tested by him in the same manner as testing is and has been performed routinely by Dr. Babel and others for patient specimens." *Id.* It asserts that Dr. Babel was "the regular testing person" for genus/species fungal tests and that he examined the proficiency testing samples at issue "in the routine manner that he established for . . . [Petitioner's laboratory]." Petitioner's brief in opposition at 12.

These assertions dodge the allegations raised by CMS concerning Petitioner's proficiency testing. That Dr. Babel created and then adhered to Petitioner's testing procedures does not plausibly lead to the conclusion that the proficiency tests were done by the *same personnel using the same equipment at the same facilities* as were used to test patients' specimens. Doing a proficiency test following the same procedures as testing of patients' specimens, but with different personnel, with different equipment, and at a different location from that where patients specimens are tested is not the same thing as integrating the proficiency test into a laboratory's regular process. When a proficiency test is done by someone other than a laboratory's full time personnel all that the test records is the acumen and skill of the person doing the test. That is so even if that person, in performing the proficiency test, imitates what is done at the laboratory. Under those circumstances the test results say nothing about what is done on a daily basis at the laboratory by other personnel using other equipment and facilities than were used by the person performing the tests.

Finally, Petitioner argues that having Dr. Babel perform the proficiency tests was consistent with CLIA's "underlying policy of protecting patient safety." Petitioner's brief in opposition at 12. Apparently, Petitioner asserts that having someone other than the laboratory's full time personnel perform proficiency tests at a remote location is consistent with CLIA's proficiency testing requirements so long as that person is affiliated with the laboratory and replicates the procedures used by the laboratory to conduct patient testing. If that is Petitioner's argument I reject it. Neither CLIA nor regulations permit proficiency testing to be done in a manner that deviates from a laboratory's routine testing of patient specimens.[5]

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[5] Petitioner cites as support for its arguments my decision in the case of *Edward Ming-Che Lai*, DAB CR848 (2001). My decision in that case has no bearing on what I decide here. In *Edward Ming-Che Lai* I found that Petitioner proved, by the preponderance of the evidence, that he was not a medical director of a clinical laboratory at a time when the laboratory was out of compliance with CLIA conditions. That decision was based on the weight of the evidence. Here, Petitioner has offered no

b. Petitioner failed to comply with the condition that is stated at 42 C.F.R. § 498.803 because it failed to participate successfully in an approved proficiency testing program.

CLIA regulations state that failure by a laboratory to achieve an overall satisfactory score for proficiency testing for two consecutive testing events or for two out of three consecutive events is unsuccessful performance in proficiency testing. 42 C.F.R. § 493.827(e). The undisputed material facts asserted by CMS establish that Petitioner failed in two ways to comply with this requirement. First, Petitioner's failure to conduct proficiency testing in the same manner as it tested patients' specimens rendered Petitioner's entire proficiency testing unsuccessful. Second, the undisputed facts asserted by CMS establish that Petitioner actually failed to participate in proficiency testing or obtained zero scores for proficiency testing in three consecutive testing events.

A basis for concluding that Petitioner failed to participate successfully in an approved proficiency testing program arises from the facts that I describe at subpart a. of this Finding establishing that Petitioner failed to conduct proficiency tests in the same manner as it tested patients' specimens. Petitioner's noncompliance with that requirement rendered its proficiency testing invalid and, therefore, constituted unsuccessful participation in an approved proficiency testing program.

Petitioner asserts that the tests sent to Dr. Babel constituted isolated circumstances that were occasioned by a unique period of transition due to Dr. Babel's retirement. But, Dr. Babel's transition does not gainsay the fact that the proficiency tests performed by him outside of Petitioner's Clinton, Michigan laboratory deviated from Petitioner's routine testing process for patient specimens and thereby rendered the testing meaningless.

CMS asserts additional facts which also support a finding that Petitioner failed to participate successfully in an approved proficiency testing program. Facts alleged by CMS are that, in 2006, Petitioner had an unreported score for the first proficiency testing event of that year and scores of zero for the second and third proficiency testing events. CMS Ex. 10. Consequently, Petitioner was unsuccessful in proficiency testing for three consecutive proficiency testing events in contravention of the regulation.

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material facts that respond to the facts offered by CMS establishing that Petitioner failed to comply with CLIA conditions.

Petitioner does not deny these facts. It argues, essentially, that it was exempt from conducting genus/species proficiency testing during 2006 because it had determined, following Dr. Babel's semi-retirement:

> that the needs of . . . [Petitioner's owner's medical] practice ultimately could be met by reading results as either positive or negative instead of at the genus/species level. . . Therefore, while . . . [Petitioner] was remiss in its documentation, its decision to transition to reading mycology tests as positive/negative, meant that . . . [Petitioner] was not required to participate in the . . . proficiency testing program for the second and third events of 2006.

For purposes of this decision I assume that Petitioner would not have had to perform genus/species proficiency tests if it was not, in fact, conducting such tests of patients' specimens. But, Petitioner has not alleged that it ceased all testing at the genus/species level in 2006. All that Petitioner says is that it had decided to make a "transition" during 2006 from conducting genus/species tests to conducting positive/negative mycology tests. The facts alleged by Petitioner concerning its transition, therefore, are insufficient on their face to establish a defense to CMS's assertions.

Moreover, the undisputed material facts rebut any possible inference that Petitioner would have been excused from genus/species proficiency testing in 2006 by virtue of its transition from genus/species testing to positive/negative testing. The facts alleged by CMS establish that Petitioner's "transition" in 2006 did not include complete cessation of genus/species testing during that period. CMS offered facts to show that, until at least December 6, 2006, Petitioner's laboratory procedure for fungal cultures required that they be read at the genus/species level. P. Ex. 1 at ¶ 20; P. Ex. 10. Petitioner didn't deny these facts.

3. CMS is authorized to revoke Petitioner's CLIA certificate.

Remedies that CMS may impose against a laboratory for noncompliance with CLIA conditions include principal sanctions consisting of: suspension from participating in CLIA; limitation of the laboratory's CLIA certificate; and revocation of the laboratory's CLIA certificate. 42 C.F.R. § 493.1806(a), (b). The regulations give CMS discretion to choose which of these principal sanctions it will impose where condition level noncompliance exists.

There is nothing in the regulations which gives me authority to second-guess CMS's exercise of discretion. In other words, I may not substitute my judgment for that of CMS where condition level noncompliance exists and 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 revocation as a remedy.

Here, the undisputed material facts show that Petitioner failed to comply with two CLIA conditions. Petitioner's noncompliance with either of those conditions authorized CMS to impose one or more of the principal sanctions stated at 42 C.F.R. § 493.1806(b). CMS determined to revoke Petitioner's CLIA certificate. That is a determination that is within CMS's discretion to make and, therefore, I must sustain it.

Petitioner argues that I should conduct a de novo review of CMS's determination to revoke Petitioner's CLIA certificate and make an independent decision as to what remedy is appropriate based on the entire record of the case. As support for this argument Petitioner cites an administrative law judge decision in *California Medical Associates Laboratory*, DAB CR476 (1997). Petitioner's reliance on the decision is misplaced. In *California Medical Associates* the administrative law judge did not conduct a de novo review of the evidence in order to decide whether CMS reasonably determined to impose revocation as a remedy. To the contrary, the administrative law judge held only that there was no evidence establishing that CMS had abused its discretion in determining to revoke a laboratory's CLIA certificate.[6]

Petitioner also cites the language of 42 C.F.R. § 493.1804(d) as support for its theory that I should be making a de novo determination of the appropriate remedy. That regulation recites a non-inclusive list of various factors that CMS may use in determining what remedy to impose against a noncompliant laboratory. Petitioner argues that I should consider those factors as well in deciding what, if any, remedy is appropriate in this case and contends that I cannot make findings of appropriateness without first holding an evidentiary hearing.

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[6] As I read the applicable regulation there is no abuse of discretion by CMS if it chooses to impose revocation as a remedy where a laboratory has failed to comply with a CLIA condition. 42 C.F.R. § 493.1806(b). The regulation makes it plain that the remedy of revocation is within CMS's discretionary authority so long as there is condition level noncompliance. Furthermore, I question whether I have the authority to decide that CMS abused its discretion in imposing a remedy, notwithstanding the decision in *California Medical Associates.* The regulations which authorize me to hear and decide cases involving CLIA do not state or suggest that I have such authority.

Petitioner misreads the regulation. It does not confer authority on me to make de novo evidentiary findings. Nor does it give me the authority to second guess what CMS has decided to impose. All that it does is set forth a list of factors that *CMS* may consider in exercising its discretion as to what remedy to impose.

/s/
Steven T. Kessel
Administrative Law Judge