

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)	
)	
Associated Internists, P.C.,)	
(CLIA Number 23D0983891),)	Date: September 16, 2009
)	
Petitioner,)	
)	
- v. -)	Docket No. C-09-477
)	Decision No. CR2005
Centers for Medicare & Medicaid)	
Services.)	

DECISION DISMISSING REQUEST FOR HEARING

I dismiss the hearing request filed by Petitioner, Associated Internists, P.C. because it fails to state a meaningful challenge to the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner.

I. Background

Petitioner is a clinical laboratory doing business in Southfield, Michigan. Its operations are subject to the requirements of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). CLIA authorizes CMS to survey clinical laboratories for compliance and to impose remedies against them in appropriate cases.

On March 20, 2009 CMS informed Petitioner that it was imposing remedies against Petitioner consisting of: revocation of Petitioner’s CLIA certificate; suspension of its CLIA certificate; cancellation of its approval to receive payments from Medicare for its services; and a directed plan of correction. CMS Ex. 2, at 2.¹ These remedy determinations were based on findings of noncompliance with CLIA requirements that were made at a survey of Petitioner’s laboratory on March 5, 2009 (March survey). The

¹ CMS filed five exhibits with its motion to dismiss which it designated as CMS Ex. 1 – CMS Ex. 5. I receive all of these exhibits into the record of this case.

findings of noncompliance included immediate jeopardy level findings of noncompliance with three CLIA conditions and were in turn premised on findings of noncompliance with 22 separate CLIA performance standards.² CMS afforded Petitioner the opportunity to file a plan of correction. Additionally, it informed Petitioner of its right to request a hearing challenging CMS's findings of noncompliance and remedy determinations. It told Petitioner specifically that:

[t]he request for hearing must contain a statement as to the specific issues and findings of fact and conclusions of law in this determination with which the laboratory disagrees and the basis for the laboratory's contention that the specific issues and/or findings and conclusions are incorrect.

CMS Ex. 2, at 4.

Petitioner submitted a written allegation of compliance and a plan of correction to CMS on April 4, 2009. CMS Ex. 3, at 1. CMS reviewed the plan and determined that Petitioner had removed the immediate jeopardy. However, it concluded also that the plan of correction did not satisfactorily address the substance of the deficiencies that were made at the March survey. CMS wrote to Petitioner on April 15, 2009 and in that letter it advised Petitioner of its determinations. *Id.* at 1-4. It told Petitioner that it would impose the remedies that had been proposed in the March 20 letter effective April 15, 2009. *Id.* at 4.

Petitioner wrote a second letter to CMS on April 23, 2009. *See* CMS Ex. 4. After reviewing the contents of this letter, CMS again determined that Petitioner's compliance allegations were not credible. On April 30, 2009 CMS wrote to Petitioner and explained in detail why Petitioner's allegations were not credible. *Id.* CMS reiterated that it was imposing against Petitioner the remedies that were described in the March 20 letter.

On May 4, 2009 Petitioner requested "an appeal to remove the sanctions imposed upon . . . [Petitioner] due to Allegation of Compliance Not Credible on the cited deficiencies during . . . [the March survey]" CMS Ex. 5. The case was assigned to me for a hearing and a decision. CMS then filed its motion to dismiss Petitioner's hearing request. Petitioner did not reply to the motion.

² The three condition-level noncompliance findings consisted of failures to comply with the requirements of: 42 C.F.R. §§ 493.1230 (general laboratory systems); 493.1250 (analytic systems); and 493.1441 (laboratory director for laboratories performing high complexity testing).

II. Issue, findings of fact and conclusions of law

A. Issue

The issue in this case is whether I should dismiss Petitioner's hearing request because it has failed to state a meaningful challenge to CMS's determination to impose remedies against Petitioner.

B. Findings of fact and conclusions of law

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

1. I may dismiss a hearing request which fails to satisfy the specificity requirements of 42 C.F.R. § 498.40(b).

Hearings in cases involving CLIA are governed by regulations at 42 C.F.R. Part 498. These regulations provide that a hearing request in any case must:

- (1) Identify the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees; and
- (2) Specify the basis for contending that the findings and conclusions are incorrect.

42 C.F.R. § 498.40(b)(1), (2).

An administrative law judge may dismiss a hearing request that does not comply with these specificity requirements.

2. Petitioner's hearing request did not comply with the specificity requirements of 42 C.F.R. § 498.40(b)(1) and (2). Therefore, I dismiss it.

CMS's noncompliance findings were drawn from a survey report that is 30 pages in length and which addresses in considerable detail the specific standards and conditions which CMS determined Petitioner contravened. CMS Ex. 1, at 1-30. The survey report put Petitioner on notice of that which it had to address in its hearing request if it intended to raise any issue which I could hear and decide.

Petitioner's hearing request is deficient. It fails to come to grips with nearly all of the noncompliance findings on which CMS based its remedy determination and, for that reason, it does not comply with the specificity requirements of 42 C.F.R. § 498.40(b)(1) and (2). I dismiss the hearing request because it does not state an issue that I may hear and decide.

When read closely, the hearing request is not really a challenge to CMS's determinations so much as it appears to be yet another attempt by Petitioner to assert that it has regained compliance with CLIA requirements. Additionally, Petitioner seems to be saying that some of its admitted noncompliance caused no harm. However, for the most part, the hearing request simply avoids confronting the essential question of Petitioner's compliance with CLIA conditions. Instead, it focuses on corrective actions concerning some small part of CMS's noncompliance findings that Petitioner allegedly accomplished *after* CMS made and implemented its determinations. CMS Ex. 5.

The hearing request discusses only two of the allegations of noncompliance. First, in an evident admission of noncompliance, the request states: "[t]he laboratory was not in compliance for using calibrators for Triglycerides Lot # 5104010 with expiration date 03/01/2009 on March 3, 2009." CMS Ex. 5. Petitioner then asserts that there was no harm or adverse effect on patients resulting from this admitted noncompliance. Then, Petitioner discusses post-survey remediation actions that it had taken, referring to a staff meeting of April 7, 2009 and additional steps taken on April 21, 2009. *Id.* These allegations are insufficient to raise an issue that I can hear or decide because they address post-survey remediation by Petitioner and not the question of compliance at the time of the survey.

Petitioner makes similar assertions concerning "the issue on Folate Testing." CMS Ex. 5. There is nothing in the hearing request which I can reasonably construe as a challenge to CMS's findings on this issue.

Moreover, and as I have discussed, the hearing request is silent as to the many other noncompliance findings that were made at the March survey. Even if I were to construe Petitioner's assertions about triglycerides and folate testing as challenges to two of CMS's noncompliance findings, I would have no choice but to conclude that CMS's many other findings of noncompliance remain unchallenged.

/s/
Steven T. Kessel
Administrative Law Judge