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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Departmental Appeals Board

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Civil Remedies Division

California State
Department of Health Services

JAN 15 2004

LABORATORY FIELD
SERVICE

_____)
 In the Case of:)
)
 Alani Medical Management)
 Corp., d.b.a. Advanced)
 Diagnostic Services Laboratory,)
)
 Petitioner,)
)
 - v. -)
)
 Centers for Medicare &)
 Medicaid Services.)
 _____)

Date: JUN 16 2003

Docket No. C-03-203

**RULING DENYING MOTION TO DISMISS
AND MOTION FOR SUMMARY DISPOSITION**

I deny the motion of the Centers for Medicare & Medicaid Services (CMS) to dismiss the hearing request of Alani Medical Management Corp., d.b.a. Advanced Diagnostic Services Laboratory. I also deny Petitioner's motion for summary disposition.

I. Background and facts

The parties do not dispute the facts on which their respective motions are based. Petitioner offered five exhibits (P. Exs. 1 - 5) in support of its motion which describe all of these facts.

Petitioner operated a clinical laboratory at 5012 Sunset Boulevard, Los Angeles, California. Petitioner was certified to perform clinical testing pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a. Its continued certification was subject to the requirements of CLIA and the Public Health Services Act, 42 U.S.C. § 1395w-2. Additionally, Petitioner's CLIA certification was governed by regulations at 42 C.F.R. Part 493.

On September 25, 2002, an inspection was performed of Petitioner's laboratory to determine whether it remained in compliance with CLIA. The inspectors determined that Petitioner was not complying with CLIA conditions. The inspectors' findings are contained in a report that was provided to Petitioner. P. Ex. 2. The inspectors determined that Petitioner's noncompliance with CLIA conditions was so serious as to constitute immediate jeopardy to patients. The term "immediate jeopardy" is defined at 42 C.F.R. § 493.2 to mean noncompliance with a CLIA condition that has caused, is causing, or is likely to cause, at any time, serious injury, harm, or death to individuals served by a laboratory or to the health or safety of the public.

On October 24, 2002, CMS sent a notice to Petitioner (October 24 notice). P. Ex. 1. The notice advised Petitioner of the noncompliance findings. Among other things, CMS advised Petitioner that the inspectors had found that Petitioner failed to meet requirements for enrollment and testing of proficiency testing samples, including engaging in improper proficiency testing referral activities. *Id.* at 1.

In its October 24 notice, CMS also advised Petitioner that it might impose sanctions against Petitioner based on its allegedly having violated or aiding and abetting the violation of CLIA requirements, "as evidenced by its improper proficiency testing referral activities." P. Ex. 1, at 2. These possible remedies included "principal sanctions" consisting of suspension of Petitioner's CLIA certificate and, ultimately, revocation of that certificate. They also included the "alternative sanction" of civil money penalties of \$10,000 per occurrence "for each instance in which your laboratory engaged in improper proficiency testing activities." *Id.* at 3. In proposing this alternative sanction, CMS referred to a deficiency citation at Tag D2011 of the inspection report. *Id.*; P. Ex. 2, at 30 - 37. The tag in question cites as a deficiency the laboratory's failure to comply with the requirements of 42 C.F.R. § 498.801(b)(3). This section of the CLIA regulations prohibits a laboratory from engaging:

any inter-laboratory communications pertaining to the results of proficiency testing samples(s) until after the date by which the laboratory must report proficiency testing results to the program for the testing event in which the samples were sent.

This paragraph of the October 24 notice did not refer explicitly to another tag that was cited in the CLIA inspection report, Tag D2013. P. Ex. 2, at 37 - 40. At this tag the inspectors found that the laboratory had not complied with the requirements of 42 C.F.R. § 493.801(b)(4). This section explicitly prohibits a laboratory from sending proficiency

testing samples or portions of samples to another laboratory for any analysis which the sending laboratory is certified to perform. It provides further that any laboratory which intentionally refers proficiency testing samples to another laboratory will have its certification revoked for at least one year.

CMS sent a second notice to Petitioner on November 29, 2002 (November 29 notice). P. Ex. 3. The November 29 notice referred to the October 24 notice and to Petitioner's response to the survey findings that are the basis for the October 24 notice. *Id.* at 1. CMS advised Petitioner that it had reviewed Petitioner's response and found that it failed to demonstrate that Petitioner had corrected its deficiencies. *Id.* CMS further advised Petitioner that it intended to impose sanctions against it including civil money penalties for each day of Petitioner's noncompliance with CLIA requirements from November 29 through December 1, 2002. *Id.* at 2. CMS told Petitioner that the proposed civil money penalties totaled \$30,000. *Id.*

On December 4, 2002, CMS sent a third notice to Petitioner (December 4 notice). P. Ex. 4. CMS advised Petitioner that it had corrected an error relating to the amount of civil money penalties that was stated in the November 29 notice. *Id.* at 1. In the December 4 notice CMS told Petitioner that it was imposing:

A Civil Money Penalty in the amount of \$10,000 for each of the nine improper proficiency testing referrals that occurred, for a total of \$90,000.

Id. at 2.

Petitioner filed a hearing request on December 16, 2002. P. Ex. 5. The case was assigned to me for a hearing and a decision. CMS then moved to dismiss Petitioner's hearing request on the ground that Petitioner did not have "standing" to request a hearing. Petitioner opposed CMS's motion and cross-moved for summary disposition. CMS opposed Petitioner's cross-motion.

II. Issues and rulings on the parties' motions

A. Issues

CMS's motion to dismiss raises the issue of whether Petitioner may challenge CMS's imposition of civil money penalties against it. Petitioner's motion for summary disposition raises two issues, consisting of whether: CMS may, as a matter of law, impose

civil money penalties against Petitioner as an "alternative sanction"; and, CMS is barred from imposing civil money penalties against Petitioner because its notices to Petitioner allegedly failed to state legally permissible grounds for imposing civil money penalties as alternative sanctions.

B. Rulings

1. Petitioner has a right to a hearing because Petitioner's hearing request is not based on a challenge to CMS's discretion to impose civil money penalties.

CMS asserts in its motion that the *only* basis for Petitioner's hearing request is that CMS should not have imposed civil money penalties against Petitioner. It contends that Petitioner concedes the presence of the deficiencies that are the basis for CMS's sanction determinations. It argues that Petitioner's hearing request is, in effect, a challenge to CMS's choice of remedy in this case. It contends that CMS's choice of remedy is an exercise of discretion by CMS which Petitioner has no right to challenge. CMS contends that, under regulations governing hearings in cases involving CLIA determinations, Petitioner may not challenge CMS's exercise of discretion as to which alternative sanctions to impose.

I find these arguments not to be persuasive. Petitioner is not challenging the discretionary determination by CMS to impose penalties. Rather, it is challenging the legal authority and conclusions of fact on which CMS's determination rests.

The hearing request in this case was filed on behalf of Petitioner and an individual, Jamal Taha. The addressees of CMS's notice letters included Mr. Taha as "owner" of Petitioner. The request for hearing states six reasons which allegedly support a conclusion that CMS's determination to impose civil money penalties is unlawful. These consist of the following:

1. The civil money penalties are alternative sanctions which may, by law, be imposed only in lieu of principal sanctions. Here, CMS has imposed principal *and* intermediate sanctions (civil money penalties) without statutory authority for such action.
2. The notice of imposition of civil money penalties is deficient and, therefore, CMS is without authority to impose the penalties.

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3. CMS allegedly stated erroneously in its October 24 notice that there were nine proficiency testing violations by Petitioner. If, in fact, there were any violations, there was only one.

4. No civil money penalties could have accrued after October 28, 2002, because Petitioner ceased doing business on that date.

5. Civil money penalties may not be imposed against on an individual owner, operator, or director of a laboratory. Arguably, the three notices imposed civil money penalties against Petitioner and against an individual who is a principal in Petitioner.

6. The allegations which are the basis for civil money penalties are not accurate and do not justify imposition of the penalties.

P. Ex. 5, at 1 - 3. After the case was assigned to me I concluded, based on CMS's representation that it had not imposed civil money penalties against Mr. Taha, that Mr. Taha had no right to a hearing. I dismissed the hearing request as it pertained to him. That ended the proceedings insofar as they concerned reason 5 in Petitioner's hearing request.

The remaining reasons advocated by Petitioner for challenging CMS's civil money penalty determination (reasons 1 - 4, and 6) address issues that are clearly within my authority to hear and decide. These remaining reasons fall into two categories of arguments consisting of arguments that: even if the facts of this case are as CMS asserts them to be, CMS is without authority to impose civil money penalties because there is no *legal* basis for imposition of penalties (reasons 1 and 2); and, there is no basis *in fact* to support CMS's penalty determination (reasons 3, 4, and 6).

Although I find below, at Rulings 2 and 3, that Petitioner's arguments 1 and 2 are without merit, they are certainly legal arguments which I have authority to hear and decide. None of Petitioner's challenges to CMS's legal authority attack CMS's exercise of discretion to impose civil money penalties.

As for reasons 3, 4, and 6, Petitioner is asserting that penalties may not be imposed against it because it was not contravening CLIA conditions as is alleged by CMS. In reason 3 Petitioner contends that CMS's penalty determinations are erroneous because there were arguably fewer proficiency testing violations than CMS asserts to have

occurred. In reason 5 Petitioner asserts that it was not violating CLIA conditions on the dates for which penalties were imposed and, therefore, CMS has no authority to impose penalties for those dates. In reason 6 Petitioner asserts that the deficiency findings that are the basis for CMS's penalty determinations are erroneous.

All of these arguments are traditional fact-driven arguments. Reasons 3, 4, and 6 are not challenges of CMS's exercise of discretion. They challenge the basis for CMS's determination to impose remedies.

2. CMS would have authority to impose civil money penalties against Petitioner if Petitioner is found to have referred proficiency testing samples to another laboratory.

Petitioner grounds its motion for summary disposition on two arguments. First, Petitioner contends that, as a matter of law, CMS lacks authority to impose civil money penalties against Petitioner. That is so, according to Petitioner, because the determination to impose civil money penalties is based on a deficiency for which CMS may impose either principal sanctions (suspension and revocation of Petitioner's CLIA certificate), or alternative sanctions (civil money penalties), but not both remedies. Petitioner asserts that there is no authority in this case to impose civil money penalties because CMS opted to impose principal sanctions against Petitioner.

Petitioner argues that, in most instances, CLIA and the Public Health Services Act arguably only permit CMS to impose civil money penalties "in lieu of" and not "in addition to" principal sanctions such as revocation of a laboratory's CLIA certificate. Petitioner contends that these "in lieu" provisions apply here because the allegedly stated reason for imposing civil money penalties – prohibited inter-laboratory communications between Petitioner's laboratory and another laboratory – are grounds for remedies which fall within the "in lieu of" provisions of the statutes.

Petitioner concedes that there is an exception to the asserted "in lieu of" requirement. The exception exists in the case where a laboratory refers proficiency testing samples to another laboratory. Petitioner acknowledges that, in such circumstance, CMS may impose both principal and alternative sanctions, including civil money penalties, against the laboratory. Petitioner also concedes that the inspection report cites proficiency test referrals as a deficiency. P. Ex. 2, at 30 - 37. But, according to Petitioner, CMS did not rely on this alleged deficiency as a basis for its determination to impose principal and alternative sanctions against Petitioner. Therefore, according to Petitioner, there is no basis in this case to impose both principal and alternative sanctions against Petitioner.

It is unnecessary that I address at this time the statutory distinctions that Petitioner raises because I find it to be clear that CMS determined to impose principal and alternative sanctions against Petitioner based on proficiency test referrals and on prohibited inter-laboratory referrals.¹ That determination is evident from the language of the notices that Petitioner received from CMS, which refer repeatedly to all of the allegations of the inspection report and not just to findings about prohibited inter-laboratory communications. Allegations of unlawful referrals are made specifically at Tag D2013 of the inspection report and in the three notices that CMS sent to Petitioner.

It is true that the October 24 notice explicitly references Tag D2011 (unlawful exchange of information) as a basis for imposing civil money penalties against Petitioner and does not explicitly reference Tag D2013 (proficiency test referrals) as a basis for imposing that remedy. But, the failure to refer explicitly to Tag D2013 does not support a conclusion that CMS excluded proficiency test referrals as a basis for its determination to impose civil money penalties. All three of the notices – and in particular, the October 24 notice – state explicitly in various places that remedies were being based on Petitioner's proficiency test referrals. Indeed, the segment of the October 24 notice in which CMS told Petitioner that it was imposing civil money penalties states that if civil money penalties were imposed against Petitioner, they would:

be in the amount of \$10,000 per occurrence for each instance in which your laboratory engaged in improper proficiency testing referral activities.

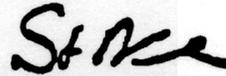
P. Ex. 1, at 3 (emphasis added).

3. Petitioner received adequate notice of the basis of CMS's determination to impose civil money penalties against Petitioner.

CMS gave Petitioner adequate notice of its intent to impose civil money penalties against Petitioner based on proficiency test referrals. As I have discussed above, the alleged

¹ The alleged statutory distinction that Petitioner advocates between proficiency test referrals and prohibited communications would arguably become relevant only if I were to find ultimately that Petitioner engaged in prohibited communications but did not make proficiency test referrals. In that event, I might revisit Petitioner's arguments concerning CMS's authority to impose alternative sanctions. It is unnecessary that I resolve the issue at this time because, as I discuss in these rulings, CMS based its remedy determinations, including the determination to impose civil money penalties, on both findings of prohibited communications and proficiency test referrals.

proficiency test referrals are unambiguously described in the CLIA inspection report, and the three notices cite such referrals as the basis for imposition of remedies, including civil money penalties. The reference to Tag D2011 and not to Tag D2013 in the October 24 notice does create some uncertainty. But, I find that the uncertainty is dispelled when that reference is read in context with the remainder of the notice and with the inspection report.



Steven T. Kessel
Administrative Law Judge