Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Academic Institute of Pathology,
(CLIA No.: 45D0722508),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-881

Decision No. CR3808

Date: April 22, 2015

DECISION

Petitioner, Academic Institute of Pathology, appeals the determination of the Centers for Medicare & Medicaid Services (CMS) to suspend and revoke Petitioner's Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate and to cancel Petitioner's approval to receive Medicare payments. For the reasons explained below, I find that there is a legitimate basis for CMS to suspend Petitioner's CLIA certificate and cancel Petitioner's Medicare payments effective February 11, 2014, and to revoke Petitioner's CLIA certificate, effective as of the date of this decision.

I. Background

Petitioner is a non-waived laboratory located in Bellaire, Texas, and holds a CLIA certificate to perform high-complexity testing. CMS issued two notice letters to Petitioner dated January 30, 2014. The first letter involved the findings from a complaint investigation survey ended on July 10, 2013, by the American Society of Cytotechnologists (ASCT). ASCT found Petitioner was not in substantial compliance with four conditions of participation: 42 C.F.R. § 493.803, *Successful participation*; 42 C.F.R. § 493.1221, *Cytology*; 42 C.F.R. § 493.1441, *Laboratories performing high*

complexity testing, laboratory director; and 42 C.F.R. § 493.1447, *Laboratories performing high complexity testing, technical supervisor*. Based on its determinations of noncompliance, CMS informed Petitioner that it was proposing the cancellation of Petitioner's approval to receive Medicare payments for laboratory services, and suspension of Petitioner's CLIA certificate effective February 11, 2014. CMS also informed Petitioner that if it imposed these sanctions and Petitioner filed an appeal, its CLIA certificate would not be revoked pending a decision from an administrative law judge (ALJ).

The second letter, also dated January 30, 2014, involved the findings from a recertification survey by the Texas Department of State Health Services (DSHS) ending on July 11, 2013. DSHS found that Petitioner was out of compliance with the conditions required for participating in the CLIA program and also found that the deficiencies posed immediate jeopardy to the patients that Petitioner serves. Specifically, CMS found Petitioner out of compliance with the following conditions: 42 C.F.R. § 493.801, *Enrollment and testing of samples*; 42 C.F.R. § 493.1240, *Pre-Analytic System*; and 42 C.F.R. § 493.1441, *Laboratory Director, Laboratories performing high complexity testing*. CMS Ex. 1.

The notice further explained that DSHS determined that Petitioner was not in compliance with CLIA conditions because Petitioner took its proficiency testing samples to another CLIA laboratory for analysis and then reported those results to the proficiency testing agency as if they had been performed at Petitioner's laboratory. *See* 42 C.F.R. §§ 493.801(b)(4) (2012) and 493.1840(a)(3) and (b) (2012). These condition-level violations required revocation of a laboratory's certificate for at least one year. *Id*. Therefore, CMS informed Petitioner that, effective February 11, 2014, it was canceling Petitioner's approval to receive Medicare payments for its services and suspending Petitioner's CLIA certificate. CMS further informed Petitioner that its CLIA certificate would be automatically revoked if Petitioner did not timely file an appeal, and if Petitioner did appeal, the revocation would become effective on the date of the ALJ decision if CMS's determination was upheld.

On March 25, 2014, Petitioner filed an appeal. The case was assigned to me for hearing and decision, and I issued an Acknowledgment and Prehearing Order (Prehearing Order). I instructed the parties to make all of their arguments in their prehearing exchanges, including any motions for summary judgment. CMS timely filed a motion for summary judgment and prehearing brief (CMS Br.) together with its supporting exhibits, CMS Exs. 1-34. In its prehearing brief, CMS explains that although the two surveys in July 2013 found Petitioner out of substantial compliance with the CLIA requirements, CMS specifically imposed its sanctions based on the DSHS recertification survey findings. CMS Br. at 4, 5.

In my Prehearing Order, I directed Petitioner to file its prehearing exchange, including its list of proposed exhibits, copies of its proposed exhibits, a list of all proposed witnesses (including the written direct testimony of any witness filed as an exhibit), and prehearing brief by August 11, 2014. Petitioner did not file its prehearing exchange or a response to CMS's motion for summary judgment and prehearing brief by August 11, 2014.

I issued an Order to Show Cause on August 27, 2014, directing Petitioner to show cause, in writing, by no later than September 11, 2014, why its case should not be dismissed for abandonment and directing Petitioner to provide an explanation as to why I should find good cause for Petitioner's failure to timely file its required submission.

After I issued the Order to Show Cause, I received Petitioner's prehearing brief, on September 2, 2014, which was postmarked August 26, 2014. In its brief, Petitioner states:

> Petitioner notes its inadvertent oversight in failing to file this document by the date of August 11, 2014 set by the Court. Petitioner begs the indulgence of the Court and asks that it accept this filing only 15 days late.

P. Br. at 1. Petitioner indicated it had no proposed exhibits "apart from those already on file,"[1] and that it proposed Gonzales Uribe-Botero, M.D., the laboratory owner and director, as its only witness. P. Br. at 1. However, Petitioner did not submit written direct testimony for Dr. Uribe-Botero as required in my Prehearing Order. *See* paragraphs 1a, 2, 4, and 6. Petitioner did not object to any of CMS's exhibits, nor did it indicate it wished to cross-examine CMS's two proposed witnesses. I admit CMS Exs. 1-34 into the record.

On September 4, 2014, Petitioner submitted its response to my Order to Show Cause. Although Petitioner generally claims that good cause exists for its failure to meet the deadlines set in my Order, it nevertheless admits its failure to timely file was due to "its inadvertent oversight" and not because of any circumstances beyond its ability to control. Response to Order to Show Cause at 1. In fact, Petitioner states that, in light of CMS's exchange, it determined as of the due date for its submission that it had nothing further to add in the way of exhibits or argument other than what had previously been filed by the parties. Response to Order to Show Cause at 3. Petitioner contends that the resolution of the issues generally do not require any further extensive filing of documents or testimony

[1] With its hearing request, Petitioner submitted a copy of the January 30, 2014 notice letter from CMS regarding the ASCT survey, two email chains from CMS to Petitioner's counsel dated February 13, 2014 and February 14, 2014, and a copy of the Form 2567 from the survey completed on July 10, 2013 by ASCT.

by either party except for testimony regarding steps Petitioner took to bring itself back into compliance. *Id*.

I do not find Petitioner has shown good cause for the late filing of its submission under any reasonable definition. However, Petitioner is not disputing any material fact from either survey, specifically agreeing that it referred its Proficiency Testing (PT) samples to another laboratory for testing and that it reported those PT results as if it had tested the PT samples in its own laboratory. Thus Petitioner recognizes that its case involves a question of law, and it asks that I exercise discretion to allow Petitioner to continue to operate and to allow the lab director, Dr. Uribe-Botero, to continue to direct his other laboratory, which he used to test Petitioner's PT sample. CMS also did not believe it was necessary to conduct an in-person hearing. Therefore, I decide this matter on the merits of the written record.

II. Issue

Whether CMS had a legitimate basis to cancel Petitioner's Medicare payments and to suspend and revoke Petitioner's CLIA certificate.

III. Findings of Fact and Conclusions of Law

1. CMS had a legitimate basis for suspending and revoking Petitioner's CLIA certificate and for canceling Petitioner's Medicare payments.

The applicable regulation for the time period in question requires, as a condition for participation in the Medicare program, that a laboratory must enroll in a PT program and must test PT samples it receives from the PT program in the same manner as it tests patient samples. 42 C.F.R. § 493.801(b) (2012). That regulation further provides:

> The 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. Any laboratory that CMS determines intentionally referred its proficiency testing samples to another laboratory for analysis will have its certification revoked for at least one year. Any laboratory that CMS receives proficiency testing samples from another laboratory for testing must notify CMS of the receipt of those samples.

42 C.F.R. § 493.801(b)(4) (2012). Similarly, CMS must revoke a laboratory's CLIA certificate for at least one year if it determines the laboratory intentionally referred its PT samples to another laboratory for analysis. 42 C.F.R. § 493.1840(b)(2012).

After a surveyor determined Petitioner reported another laboratory's results as its own, Petitioner's director conceded he did not have a working hematology analyzer, and he

sent the samples to his other laboratory for testing. CMS Ex. 13, at 2. Because I find that CMS had a legitimate and undisputed basis to revoke Petitioner's CLIA certificate for at least one year pursuant to 42 C.F.R. §§ 493.801(b)(4)(2012), 493.1840(a)(3) and (b)(2012) for its PT practices, it is unnecessary for me to discuss the other deficiencies CMS cited at 42 C.F.R. §§ 493.1240(2012) and 493.1441(2012).

The applicable regulations also provide that CMS cancel a laboratory's approval to receive Medicare payment for its services if CMS suspends or revokes the laboratory's CLIA certificate. The cancellation may be imposed before a petitioner files a hearing request when, as here, CMS determines the condition-level violations pose immediate jeopardy. *See* 42 C.F.R. §§ 493.1842(a) and (c)(2012), 493.1844(b)(4) and (d)(2), (4)(2012).

2. I may not review CMS's discretion to enforce CLIA and impose sanctions against Petitioner.

Petitioner contended that, shortly after its filing deadline, it became aware that the Taking Essential Steps for Testing (TEST) Act of 2012 (Pub. L. 112-202), approved on December 4, 2012, amended, in part, 42 U.S.C § 263a. It argues that section 263a(i)(4) now states that "[a]ny laboratory that the Secretary [of Health and Human Services] determines intentionally refers its proficiency testing samples to another laboratory for analysis *may* have its certificate revoked for at least one year . . . ." Emphasis added. Petitioner asserts that since the TEST Act amendments changed the "shall" to "may," the Secretary now has discretion about when to revoke a laboratory's CLIA certificate for intentional referral of PT samples.[2]

Petitioner does not dispute that it intentionally referred its PT samples and reported the results as its own. P. Br. at 3. Petitioner claims to have "misunderstood the CLIA regulations and made a mistake." *Id*. Petitioner asks that I use my discretion to deny the "harsh penalty of decertification" because this laboratory serves an "urban, generally lower-income section" of Houston and CMS's sanctions "would decrease the availability of health services in the community." P. Br. at 2. However, here the Secretary exercised her discretion when CMS issued the January 30, 2014 letter notifying Petitioner of CMS's determination that Petitioner intentionally referred PT samples. CMS also determined that this deficiency, as well as the other two condition-level deficiencies cited in the survey, posed immediate jeopardy to the patients whom Petitioner served. Petitioner does not dispute that these condition-level deficiencies existed. Rather, Petitioner contends that it cooperated with CMS during the investigation and took remedial measures to correct the alleged deficiencies.

[2] The regulations implementing the TEST Act changes, however, were not effective until July 11, 2014, and therefore do not apply to the July 2013 survey or to the January 30, 2014 notice letter. *See* 79 Fed. Reg. 25,463 (May 2, 2014).

I am bound by the extant regulations, and there is no dispute here that Petitioner intentionally referred its PT samples to another laboratory. I am unable to substitute my discretion for the Secretary's. My authority here is limited to determine if there was a legitimate basis for the sanctions CMS imposed because Petitioner did not comply with CLIA requirements, regardless of how well Petitioner may have cooperated or later complied.

3. CMS's enforcement actions were appropriate.

Petitioner cites *Medimex Clinical Laboratory*, DAB CR1025 (2003), for the proposition that the purpose of CLIA is not to punish laboratories but to strengthen federal oversight of laboratories in order to ensure that tests are accurate and reliable. P. Br. at 4. Therefore, Petitioner argues CMS's goals can be accomplished without revocation of its CLIA certificate. However, in *Medimex*, the ALJ did not reverse CMS's sanctions as punitive measures but rather affirmed the sanctions.

The ALJ explained—

> The purpose of the CLIA is not to punish laboratories, but to strengthen federal oversight of laboratories in order to ensure that test results are accurate and reliable. 57 Fed. Reg. 7218 (1992). Thus, the regulatory enforcement scheme is designed to protect all individuals served by laboratories against substandard testing of specimens, and to safeguard the general public against health and safety hazards that might result from laboratory activities. 42 C.F.R. § 493.1804(a)(1), (2). In light of the principles here enunciated, I must consider whether the evidence supports a finding of noncompliance and whether Petitioner violated one or more conditions of participation. Once a basis for the imposition of principal sanctions is established, the inexorable results will ensue, with the purpose of protecting the public from improper and incompetent laboratory activities.

DAB CR 1025 at VI.F.1. I find that the Secretary's determination to revoke Petitioner's CLIA certificate under the circumstances here, where Petitioner acknowledges there were condition-level deficiencies, is an appropriate act to protect patients from inaccurate and unreliable laboratory testing and comports with the purpose of CLIA.

IV. Conclusion

It is undisputed that Petitioner violated a condition-level requirement when it intentionally referred its proficiency testing samples to another laboratory and reported the results as its own. I find a legitimate basis, therefore, for CMS's determination to

suspend Petitioner's CLIA certificate and cancel Petitioner's Medicare payments, effective February 11, 2014, and to revoke Petitioner's CLIA certificate, with the revocation effective for at least one year from the date of this decision.

/s/
Joseph Grow
Administrative Law Judge