Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Adeona Clinical Laboratory, LLC,
(CLIA No.: 14D1051026),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1133

Decision No. CR3919

Date: May 29, 2015

DECISION

Petitioner, Adeona Clinical Laboratory, LLC, appeals the determination of the Centers for Medicare & Medicaid Services (CMS) to cancel Petitioner's approval to receive Medicare payments for laboratory services and to revoke Petitioner's Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate. I find there is a legitimate basis for CMS to cancel Petitioner's approval to receive Medicare payments and to revoke Petitioner's CLIA certificate because the undisputed evidence establishes that Petitioner intentionally sent proficiency testing samples to another laboratory for testing and reported the results as its own.

I. Background

Petitioner had been performing high complexity testing as an accredited CLIA laboratory. On February 26, 2014, CMS notified Petitioner of its determination that Petitioner was not in compliance with applicable CLIA conditions of participation based on the findings from a January 22, 2014 survey by the Illinois Department of Public Health (IDPH). CMS Ex. 1, at 1-3. CMS found that based on the survey, Petitioner was not in compliance with the following CLIA conditions: 42 C.F.R. § 493.801: *Enrollment and*

Testing of Samples; 42 C.F.R. § 493.1441: *Laboratories performing high complexity testing, laboratory director;* and 42 C.F.R. § 493.1250: *Analytic Systems*.

That letter specifically notified Petitioner that CMS determined Petitioner improperly referred proficiency testing (PT) samples to another laboratory for analysis in violation of 42 C.F.R. § 493.801(b)(4). CMS further found that Petitioner's condition-level noncompliance constituted immediate jeopardy and was likely to cause serious harm to the individuals served by Petitioner's laboratory and to the health of the general public. CMS stated that the deficiencies found were determined to be of such a serious nature that they substantially limit Petitioner's capability to render accurate and reliable services and to protect the health and safety of its clients. Thus, CMS proposed revocation of Petitioner's CLIA certificate, cancellation of its approval to receive Medicare payments for its services, and provided Petitioner 20 days to submit in writing any evidence or information explaining why CMS should not impose the sanctions.

By letter dated March 24, 2014, CMS notified Petitioner that it had reviewed the information Petitioner provided, a Plan of Correction received on March 20, 2014, but found that the submission did not refute CMS's bases for its determination of noncompliance with CLIA conditions. CMS Ex. 1, at 4. Therefore, CMS informed Petitioner that because of Petitioner's failure to comply with CLIA certificate requirements and performance standards as evidenced by the finding of improper referral of the laboratory's PT samples to another laboratory for analysis, and the laboratory's failure to meet all condition-level requirements of CLIA, it determined to revoke Petitioner's CLIA certificate and its approval to receive Medicare payments. The letter also notified Petitioner that both sanctions would be effective as of the date of an administrative law judge (ALJ) decision if the appeal upholds CMS's determination of noncompliance. CMS Ex. 1, at 5.

On April 28, 2014, Petitioner filed an appeal, and this case was assigned to me for hearing and decision on May 19, 2014. Pursuant to my Acknowledgment and Prehearing Order (Prehearing Order), CMS timely filed a Motion for Summary Judgment and Prehearing Brief (CMS Br.) together with its supporting exhibits, CMS Exs. 1-15. Petitioner timely filed its Prehearing Brief and Cross Motion for Summary Judgment (P. Br.) together with one exhibit marked as Adeona Ex. 1. CMS submitted a reply to Petitioner's cross motion (CMS Reply).

II. Issue

> Whether the undisputed evidence establishes that CMS had a legitimate basis for revoking Petitioner's CLIA certificate and for cancelling Petitioner's approval to receive Medicare payments.

III. Findings of Fact and Conclusions of Law

1. This case is appropriate for summary judgment because there is no dispute of material fact for me to decide.

CMS filed a motion for summary judgment, and Petitioner filed a cross-motion for summary judgment. Both parties contend that summary disposition is appropriate because there are no issues of material fact in dispute and each party contends it is entitled to judgment as a matter of law. The Departmental Appeals Board (the Board) has explained the applicable standard:

> Summary judgment is appropriate when the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. . . . The party moving for summary judgment bears the initial burden of showing that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. . . . 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. . . . In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.

Senior Rehab. & Skilled Nursing Ctr., DAB No. 2300, at 3 (2010) (citations omitted). The role of an ALJ in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the weight of conflicting evidence. *Holy Cross Vill. at Notre Dame*, DAB No. 2291, at 4-5 (2009).

Here, Petitioner did not come forward with specific evidence to dispute the material facts that CMS alleges: that it intentionally referred its PT samples to another laboratory for testing and reported those PT results as if it had tested the samples in its own laboratory.[1]

[1] CMS cites in its brief and motion for summary judgment that Petitioner also violated the conditions for multiple other requirements constituting immediate jeopardy. I do not discuss these violations because failure to comply with even a single condition is sufficient to impose a principal sanction. *Canal Med. Lab*., DAB No. 2041, at 13 (2006) ("CMS has discretion to impose one or more of the principal . . . sanctions based on a laboratory's failure to comply with even a single applicable condition.").

Petitioner argues that CMS failed to follow the requisite procedures and alleges that CMS cannot impose the principal sanctions here until it first imposes alternative sanctions to bring a non-compliant laboratory into compliance. Thus the issues in this case are issues of law related to the CLIA requirements. Accordingly, summary judgment is appropriate.

2. CMS had a legitimate basis for revoking Petitioner's CLIA certificate and cancelling Petitioner's Medicare payments because the undisputed evidence establishes that Petitioner intentionally referred its proficiency testing samples to another laboratory for testing.

The CLIA statute provides that the Secretary may suspend, revoke, or limit the CLIA certificate of a laboratory if it does not meet statutory and regulatory requirements. 42 U.S.C. § 263a(i)(1)(C). The applicable regulations authorize CMS to impose one or more of the alternative or principal sanctions specified in 42 C.F.R. §§ 493.1806 and 493.1807 when it determines that a laboratory has condition level deficiencies. 42 C.F.R. §§ 493.1804(b) and 493.1806(a). When CMS revokes a laboratory's CLIA certificate, it must cancel the laboratory's approval to receive Medicare payments for its services. 42 C.F.R. §§ 493.1808(a) and 493.1842(a).

CLIA directs the Secretary to establish requirements for PT programs for all laboratories. 42 U.S.C. § 263a(f)(3). In order to receive CLIA certification, a laboratory must agree to "treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business." 42 U.S.C. § 263a(d)(1)(E). To ensure the integrity of the PT program, the statute gives the Secretary the discretion to revoke the CLIA certificate of any laboratory for intentional referral of PT samples. 42 U.S.C. § 263a(i)(4).

The applicable regulations for the time period in question here require, as a condition for participation in the Medicare program, that a laboratory must enroll in a proficiency testing program and must examine proficiency testing samples it receives from the PT program in the same manner as it tests patient samples.[2] 42 C.F.R. § 493.801(b)(2013). This section further provided:

> 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

[2] There were amendments to the CLIA regulations, but these amendments were not effective until July 11, 2014 and therefore do not apply to the January 2014 survey and the March 24, 2014 notice letter here. 79 Fed. Reg. 25463 (May 2, 2014).

> certification revoked for at least one year. Any laboratory that 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)(2013). Similarly, 42 C.F.R. § 493.1840(b)(2013) required that CMS must revoke a laboratory's CLIA certificate for at least one year if it determines the lab intentionally referred its PT samples to another laboratory for analysis. Any failure to successfully participate in proficiency testing is per se a condition-level deficiency for which a sanction may be imposed. *See Canal Med. Lab.*, DAB No. 2041, at 9 (2006).

At the time of the survey, CMS had certified Petitioner under its CLIA certificate to perform general chemistry testing. During a tour of Petitioner's laboratory from the survey completed on January 22, 2014, Petitioner's testing personnel informed the surveyor that its Olympic AU400, the analyzer instrument it used for general chemistry testing, was broken and it had not been used since June 18, 2013. CMS Ex. 3, at 3; CMS Ex. 15, at 1-2. Petitioner nevertheless submitted results from its PT program, conducted by Wisconsin State Laboratory of Hygiene (WSLH)), for 21 different general chemistry analytes for a testing event in June 2013 and a testing event in September 2013. CMS Ex. 3, at 3-12; CMS Ex. 15, at 2-3. The surveyor found corroborating test reports from another laboratory with the results from these testing events. Petitioner then recorded these results on the WSLH Proficiency Testing forms as its own and transmitted them to WSLH as if it had performed these tests and found these results itself. CMS Ex. 15, at 2-3; CMS Exs. 5, 6. 7, 8, 9, and 10. At that time, Petitioner had not informed WSLH or CMS that its analyzer instrument was broken and that it was incapable of performing these tests.

Petitioner states that it is an undisputed fact that "Adeona sent proficiency samples and human specimens to O'Hare Clinical Lab Services, Inc. ("OCL"), for testing." P. Br. at 3. However, Petitioner asks that I infer Petitioner accidentally sent the PT samples to the other laboratory based on an attachment to the Statement of Deficiencies (SOD). P. Br. at 10-11; CMS Ex. 4, at 8. Yet, Petitioner does not specifically allege or come forward with evidence, such as an employee affidavit, suggesting it unintentionally sent the samples to OCL. Petitioner also does not dispute that it then reported those results to WSLH as its own. Therefore, I am not required by the summary judgment standard to make these unsupported inferences in favor of Petitioner. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586 n.11 (1986) ("To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists.").

3. The undisputed evidence establishes CMS provided Petitioner appropriate notice that it was imposing the principal sanctions based on the improper proficiency testing referral.

Petitioner also contends that I should grant its motion for summary judgment because CMS allegedly failed to give it prior notice that CMS based its revocation action on the fact that Petitioner intentionally referred its PT samples to another laboratory. P. Br. at 8-9.

The relevant documents unequivocally demonstrate that Petitioner received clear, proper and ample notice that it intentionally referred proficiency testing samples and was not in compliance with the CLIA condition at 42 C.F.R. § 493.801. CMS Exs. 1, 3. In the February 26, 2014 notice of proposed sanctions, CMS stated that Petitioner's noncompliance with the condition of *Enrollment and Testing of Samples* is specifically supported when it cited 42 C.F.R. § 493.801(b)(4) (Tag D2013) for Petitioner's improper referral of proficiency testing samples to another laboratory for analysis. CMS Ex. 1. That regulation states that "[a]ny laboratory that CMS determines intentionally referred its proficiency samples to another laboratory for analysis will have its certification revoked."

Moreover, the SOD from the survey of the laboratory, enclosed with the February 26, 2014 notice, cites Petitioner as out of compliance with Tag D2013, *Testing of Proficiency Samples*, pursuant to 42 C.F.R. § 493.801(b)(4). CMS Ex. 3. The SOD specifically articulates the relevant regulatory provision. CMS Ex. 3, at 2. The SOD then stated why, based on the evidence reviewed, the surveyor found Petitioner out of compliance with this section and why he found Petitioner intentionally referred its PT samples to another laboratory. CMS Ex. 3, at 3-12.

CMS does not need to prove intent to violate a CLIA referral requirement in order to find an intentional referral of PT samples occurred. *See Victor Valley Cmty. Hosp. / Clincal Lab. and Tomacz Pawlowski, M.D.* DAB No. 2340, at 11 (2010). CMS need only show that PT samples were sent or referred to another laboratory for purposes of analysis. *Wade Pediatrics*, DAB No. 2153 (2008), *aff'd, Wade Pediatrics v. Dep't. of Health & Human Servs.*, 567 F. 3d 1202 (10th Cir. 2009); *White Lake Family Medicine*, DAB No. 1951, at 12 (2004). Petitioner presented no evidence that it informed CMS or WSLH that it could not perform general chemistry tests because its analyzer instrument was broken. Instead, it sent its PT samples to another laboratory, took their results, and reported those results back to the PT program as its own without indicating it did not perform the tests itself.

4. CMS had the authority to first impose the principal sanctions of revocation and cancellation of Petitioner's Medicare approval to receive Medicare payments because CMS found Petitioner in violation of a CLIA condition.

CMS may impose one or more of the sanctions specified in 42 C.F.R. § 493.1806 on a laboratory that is out compliance with one or more CLIA conditions. Section 493.1806 specifically states:

> Available sanctions: All laboratories.
>
> (a) *Applicability*. CMS may impose one or more of the sanctions specified in this section on a laboratory that is out of compliance with one or more CLIA conditions.
> (b) *Principal sanction.* CMS may impose any of the three principal CLIA sanctions, which are suspension, limitation, or revocation of any type of CLIA certificate.
> (c) *Alternative sanctions.* CMS may impose one or more of the following alternative sanctions in lieu of or in addition to imposing a principal sanction, except on a laboratory that has a certificate of waiver.
> (1) Directed plan of correction, as set forth at § 493.1832.
> (2) State onsite monitoring, as set forth at § 493.1836.
> (3) Civil money penalty, as set forth at §493.1834.
> (d) *Civil suit.* CMS may bring suit in the appropriate U.S. District Court to enjoin continuation of any activity of any laboratory . . . if CMS has reason to believe that continuation of the activity would constitute a significant hazard to the public health.

For laboratories that participate in the Medicare program that are found out of compliance with one or more CLIA conditions, the additional principal sanction of cancellation of the laboratory's approval to receive Medicare payments for its services is available. 42 C.F.R. § 493.1807(a).

Petitioner's cross-motion for summary judgment relies on two basic arguments: 1) CMS was precluded from imposing principal sanctions, such as revocation and cancellation of Medicare payments, because it did not first give Petitioner a revisit with regard to CMS's immediate jeopardy determination and because CMS did not file an injunction in Federal Court. Petitioner relies on 42 C.F.R. § 493.1812, as requiring CMS to impose alternative sanctions against it prior to imposing principal sanctions. P. Br. at 6. Petitioner argues that this regulation provides that if the laboratory's deficiencies pose immediate jeopardy, CMS requires the laboratory to take immediate action to remove the jeopardy and may impose one or more alternative sanctions to help bring the laboratory into compliance. P. Br. at 6. Petitioner further argues that therefore CMS cannot "suspend the laboratory's

CLIA certificate until after" CMS has determined pursuant to a revisit survey that the laboratory has not eliminated the jeopardy. P. Br. at 6 citing *Center Clinical* Laboratory, DAB CR358, at 13 (1995). Petitioner therefore contends that CMS's principal sanctions of revocation of the CLIA certificate and cancellation of Petitioner's Medicare approval must be lifted as untimely because CMS failed to comply with its own enforcement procedures, and I should deny CMS's motion for summary judgment. P. Br. 6-9.

However, the Board reversed the ALJ's finding in *Center Clinical Laboratory* on which Petitioner relies, explaining that section 493.1812 does not require CMS to first respond with procedures pertaining to an alternative sanction in every instance of immediate jeopardy. *Center Clinical Laboratory*, DAB No. 1526, at 8 (1995). The Board explained, with respect to 42 C.F.R. 493.1812(b), that:

> [T]his provision of the regulations, which admittedly is not as clear as it might be, simply does not apply to the situation where [CMS] decides to impose an immediate suspension. Rather, it was designed to respond to the type of immediate jeopardy situation where [CMS] in its discretion does not impose an immediate principal sanction such as suspension but rather an alternative sanction that may or may not ultimately lead to a principal sanction. . . Section 493.1812(a), however, does not require [CMS] to respond with procedures pertaining to an alternative sanction in every instance of an immediate jeopardy.

Id. I find CMS thus appropriately exercised its authority here to impose principal sanctions without first imposing alternative sanctions.

IV. Conclusion

I find that CMS had a legitimate basis to cancel Petitioner's approval of Medicare payments and to revoke Petitioner's CLIA certificate, effective as of the date of this decision for at least one year, because the undisputed evidence supports that Petitioner improperly referred proficiency testing to another laboratory and reported the other laboratory's results as its own. I further conclude, as a matter of law, that CMS was not required to impose alternate sanctions prior to its imposition of the principal sanctions.

/s/
Joseph Grow
Administrative Law Judge