Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Southlake Emergency Care Center
Docket No. A-11-56
Decision No. 2402
August 2, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Southlake Emergency Care Center (Petitioner, Southlake), a clinical laboratory in Southlake, Texas, requests review of the January 10, 2011 decision by Administrative Law Judge (ALJ) Joseph Grow, *Southlake Emergency Care Center (CLIA #45D1021990),* DAB CR2300 (2011) (ALJ Decision). The ALJ granted summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS), upholding the revocation of Southlake's certificate under the Clinical Laboratory Improvement Amendments (CLIA). The ALJ concluded that CMS had authority to revoke Southlake's CLIA certificate pursuant to 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) based on the undisputed fact that Dr. Charles O'Hearn, Southlake's owner and operator, owned or operated another laboratory, Coppell Laboratory (Coppell), whose CLIA certificate was revoked within the preceding two-year period. Although Coppell did not appeal the revocation of its CLIA certificate, Petitioner argues before the Board, as it did before the ALJ, that the revocation of that certificate was invalid.

As discussed below, we conclude that Petitioner has raised no dispute of material fact and has shown no basis in law for invalidating the revocation of Coppell's CLIA certificate. Thus, the ALJ did not err in concluding that CMS was authorized to revoke Southlake's CLIA certificate.

Applicable Law[1]

Section 263(a)(i) of 42 U.S.C. provides in part:

> (3) Ineligibility to own or operate laboratories after revocation. No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section.

[1] The general legal background of CLIA is set out in the ALJ Decision. ALJ Decision at 3.

Congress adopted this provision "to clarify that a revocation runs against an owner or operator, not merely against the laboratory." H.R. Rep. No. 100-899, at 36 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3828, 3856.

The implementing regulations provide in part:

> (a) *Adverse action based on actions of the laboratory's owner, operator or employees.* CMS may initiate adverse action to suspend, limit or revoke any CLIA certificate if CMS finds that a laboratory's owner or operator or one of its employees has--
>
> * * * * * *
>
> (8) Within the preceding two-year period, owned or operated a laboratory that had its CLIA certificate revoked. (This provision applies only to the owner or operator, not to all of the laboratory's employees.)

In adopting this regulation, CMS's predecessor agency stated that it had "no choice but to implement" the statutory provision "that the owner or operator of a laboratory that has had its certificate revoked may not own or operate a laboratory for two years after the revocation of the CLIA certificate of the initially sanctioned laboratory." 57 Fed. Reg. 7218, 7227 (Feb. 28, 1992).

Section 493.1844(f), captioned "*Appeal rights of laboratories*," provides in part:

> (1) *ALJ hearing.* Any laboratory dissatisfied with the suspension, limitation, or revocation of its CLIA certificate, with the imposition of an alternative sanction under this subpart, or with cancellation of the approval to receive Medicare payment for its services, is entitled to a hearing before an ALJ as specified in paragraph (a)(2) of this section and has 60 days from the notice of sanction to request a hearing.

Section (a)(2) states that hearings "are conducted in accordance with procedures set forth in subpart D of part 498 of this chapter . . . ." Section 493.1844(a)(3) provides for an extension of the 60-day period for requesting a hearing upon a showing of good cause.

Section 493.1844(g), captioned "*Notice of adverse action*," provides in part:

> (1) If CMS suspends, limits, or revokes a laboratory's CLIA certificate or cancels approval to receive Medicare payment for its services, CMS gives notice to the laboratory . . . .
>
> (2) The notice to the laboratory—
>
> (i) Sets forth the reasons for the adverse action, the effective date and effect of that action, and the appeal rights if any . . . .

Standard of review

Whether summary judgment is appropriate is a legal issue that we address de novo. *Lebanon Nursing and Rehabilitation* Center, DAB No. 1918 (2004). The party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986); *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1997). If a moving party carries its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Industrial Co. v. Zenith Radio*, 474 U.S. 574, 587 (1986) (quoting Fed. R. Civ. Pro. 56(e)). In evaluating a summary judgment motion, a tribunal must view the entire record in the light most favorable to the nonmoving party, drawing all reasonable inferences from the evidence in that party's favor. *Madison Health Care, Inc.*, DAB No. 1927 (2004). The Board's standard of review on a disputed issue of law is whether the ALJ decision is erroneous. *Board Guidelines—Appellate Review of Decisions of Administrative Law Judges in Cases Under CLIA and Related Statutes* (accessible at http:// http://www.hhs.gov/dab/divisions/appellate/guidelines/clia.html).

Case Background[2]

As noted above, Dr. O'Hearn, the owner and operator of Southlake, also owned and operated Coppell Laboratory (Coppell).[3] On February 18, 2010, the Texas Department of State Health Services (DSHS) conducted a recertification survey of Coppell and determined that Coppell was not in compliance with certain CLIA regulations, citing several deficiencies. ALJ Decision at 2. DSHS's Statement of Deficiencies (SOD) identified condition-level deficiencies involving the regulations at 42 C.F.R. §§ 493.803, 493.1403, and 493.1421. CMS Ex. 4, at 4.

On March 5, 2010, DSHS sent Dr. O'Hearn a written notice requesting a plan of correction (POC) for the deficiencies cited by DSHS. ALJ Decision at 2. Petitioner submitted a POC to CMS which CMS received on or about April 20, 2010. Petitioner's (P.) Request for Review (RR) at 3; CMS Br. at 5. CMS found the POC unacceptable but provided no written notice of that finding. P. hearing request dated 7/23/10, at 1-2; RR at 7-8.

On April 20, 2010 (on or about the same date CMS received Coppell's POC), CMS wrote to Dr. O'Hearn stating that as of April 14, 2010, DSHS had not received a POC and that

[2] The information in this section is drawn from the undisputed facts in the ALJ Decision and in the record before the ALJ.

[3] CMS identified this facility as "Coppell Minor Emergency Center LLC." CMS Ex. 2, at 1.

"the laboratory **must** submit a [POC] to DSHS with a copy to CMS" by April 30, 2010. CMS Ex. 2, at 1-2 (emphasis in original). CMS also stated: "Also by **April 30, 2010,** the laboratory must submit a credible allegation of compliance (AOC) to DSHS, with copies to CMS, in order to demonstrate that actions by the lab have addressed the immediate jeopardy and condition level deficiencies cited ...." *Id.* at 2. In a separate section of the April 20 letter captioned "Proposed Sanctions," CMS stated: "Based on, your laboratory's non-compliance with the CLIA Conditions, failure to submit an acceptable plan of correction, and the authority under 42 CFR 493.1804(b)(i)&(ii), **if an acceptable plan of correction is not obtained in order to assess compliance**, CMS will impose the following sanctions: . . . Principal Sanction: **Revocation** of your CLIA certificate and denial of your request for a certificate of compliance . . . , pending a decision from an Administrative Law Judge, if an appeal is filed."[4] *Id.* at 3 (emphasis in original). CMS continued:

> Your laboratory's CLIA certificate will be revoked effective **June 22, 2010** if one or all of the following occurs:
>
> - A request for a hearing is not received by **June 21, 2010**; or
> - DSHS finds continued condition level non-compliance conditions on the revisit; or status at the time of the revisit escalates to an immediate jeopardy; or
> - CMS and the State do not receive an AOC [allegation of compliance] and POC; or
> - The POC does not ensure correction of the condition level deficiencies.

Id. at 3 (emphasis in original). CMS also stated: "Please note that 42 U.S.C. 263a(i)(3) and 42 CFR 493.1840(a)(8) prohibit the owner(s) or operator(s) . . . from owning or operating . . . a laboratory for at least two years from the date of the revocation." *Id.* Finally, in a section captioned "Appeals Process," CMS stated: "If you believe this determination is not correct, you may request a hearing before an administrative law judge of the Department of Health and Human Services, Departmental Appeals Board. . . . A written request for hearing must be filed no later than 60 days from the date of receipt of this letter . . . ." *Id.* at 4.

Dr. O'Hearn did not request a hearing on the proposed revocation of Coppell's CLIA certificate by June 21, 2010, the date specified in CMS's April 20, 2010 letter. ALJ Decision at 2. By letter dated June 23, 2010, CMS informed Dr. O'Hearn that CMS had revoked Coppell's CLIA certificate effective June 22, 2010 "due to the laboratory's failure to ensure correction of condition level noncompliance and failure to file an appeal

[4] Section 493.1804(b) provides that CMS may impose one or more of the alternative or principal sanctions specified in the regulations when CMS finds that a laboratory has condition-level deficiencies.

by June 21, 2010." CMS Ex. 3, at 1. The letter also referred to the two-year prohibition required by 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8).

In a letter to Dr. O'Hearn dated July 20, 2010, CMS proposed revocation of Southlake's CLIA certificate. ALJ Decision at 3. The letter stated in part:

> This is to inform you that we revoked the CLIA Certificate 45D0996638 for Coppell Minor Emergency Center, LLC., in Coppell, TX, effective June 22, 2010. Because of that revocation, CMS will revoke the certificate of Southlake Emergency Care Center, 60 days from the date of this letter because you owned and operated Coppell Minor Emergency Center, LLC, when it was surveyed on February 18, 2010. The revocation of your certificate is based on . . . 42 CFR 493.1840(a)(8), which prohibits the present owner from owning a laboratory for two years from the date of revocation.

CMS Ex. 1, at 1. Southlake timely requested a hearing on the revocation of its CLIA certificate. ALJ Decision at 3.

CMS filed a Motion for Summary Judgment, which Petitioner opposed. The ALJ granted CMS's motion in his January 10, 2011 decision upholding the revocation of Southlake's CLIA certificate. The ALJ Decision contains the following numbered conclusions:

1. Petitioner may appeal the initial determination of CMS to impose a sanction against it by revoking its CLIA certification.
2. No further discovery shall be permitted, as estoppel against the federal government is unavailable.
3. CMS is entitled to summary judgment because undisputed facts demonstrate that the revocation of Petitioner's CLIA certificate was legally authorized.

ALJ Decision at 5-7.

In his discussion of the second numbered conclusion, the ALJ stated that Petitioner had requested "limited discovery of CMS's file to demonstrate that fundamental due process was denied [Dr. O'Hearn], regarding the Coppell Lab's revocation." *Id.* at 6. The ALJ read the discovery request as an attempt to obtain evidence to support Petitioner's allegation that a CMS employee "suggested that O'Hearn give notice that his intent was to surrender the Coppell Lab's certificate and that doing so would solve the issue of the potential of the Southlake Lab's certificate being revoked." *Id.*, quoting P. Br. at 6. The ALJ denied discovery on the ground that "such evidence could not affect the outcome here," concluding that estoppel against the federal government was not available on the facts alleged. ALJ Decision at 6.

In his discussion of the third numbered conclusion, the ALJ addressed Petitioner's argument that CMS should not have revoked Coppell's CLIA certificate "because Dr. O'Hearn closed the Coppell Laboratory prior to the revocation of its CLIA certificate." ALJ Decision at 7. The ALJ held that the "voluntary closure of a laboratory . . . does not preclude CMS from proceeding with revocation of the laboratory's certificate." *Id.* The ALJ continued: "After CMS revoked the Coppell Laboratory's CLIA certificate, Dr. O'Hearn was banned, by operation of law, from owning or operating a laboratory for a two-year period. I have no authority to declare the statute or the regulation invalid or ultra vires. ... Thus, CMS has the authority to revoke Petitioner's CLIA certificate pursuant to 42 C.F.R. § 493.1840(a)(8)." *Id.* at 8.

Petitioner takes exception to the second and third numbered conclusions as well as to the statement in the ALJ's discussion of the first numbered conclusion that "Dr. O'Hearn did not surrender Coppell Laboratory's CLIA certificate to CMS" (ALJ Decision at 2).

Analysis

On appeal, as before the ALJ, Petitioner does not dispute the facts on which CMS's revocation of its CLIA certificate was based, i.e., that Dr. O'Hearn, Southlake's owner and operator, was within the preceding two years the owner and operator of another laboratory, Coppell, whose certificate was revoked, nor does Petitioner deny that the statute and regulations authorized revocation of Southlake's CLIA certificate on that basis. Petitioner nevertheless argues that the ALJ erred in upholding the revocation of Southlake's CLIA certificate because the revocation of Coppell's certificate was invalid on the following two grounds.

First, Petitioner argues that the ALJ erred in concluding that CMS was not estopped from revoking Southlake's CLIA certificate based on advice Dr. O'Hearn allegedly received from a CMS employee that he could avoid revocation of Southlake's CLIA certificate by surrendering Coppell's CLIA certificate to CMS. *See* RR at 2-3, 9-10. Petitioner also makes the related argument that the ALJ erred in finding that Dr. O'Hearn did not surrender Coppell's CLIA certificate. *See* RR at 4-5.

Second, Petitioner argues that Coppell's CLIA certificate was revoked without due process because CMS did not advise Dr. O'Hearn before revoking that certificate that the April 20, 2010 POC was not acceptable. *See* RR at 7-8. Although the ALJ did not address this argument, we conclude that it is properly before us because Petitioner asserted below that "CMS did not respond to Coppell Lab's proposed POC, leaving the

impression that due process had not been followed." P. Response to CMS's Motion for Summary Judgment at 2.[5]

We explain below why we conclude that Petitioner's arguments have no merit.

1. CMS was not estopped from revoking Southlake's CLIA certificate by any advice Dr. O'Hearn received from a CMS employee that he could avoid revocation of Southlake's CLIA certificate by surrendering Coppell's CLIA certificate.

As indicated above, Petitioner argued before the ALJ that it was entitled to discovery regarding its assertion that a CMS employee had suggested to Dr. O'Hearn that he could avoid revocation of Southlake's CLIA certificate by giving notice that he intended to surrender Coppell's CLIA certificate. According to Petitioner, the CMS employee gave Dr. O'Hearn the alleged advice after CMS had already revoked Coppell's CLIA certificate. *See* RR at 3-4 (alleging that Dr. O'Hearn contacted CMS after DSHS's July 7, 2010 inspection of Southlake). Thus, Petitioner apparently meant that the advice given was that the surrender of Coppell's CLIA certificate would somehow void CMS's revocation of that certificate, so that there would no longer be a basis for the revocation of Southlake's CLIA certificate. The ALJ addressed Petitioner's argument as follows:

> Petitioner asks me, in effect, to estop the government from applying federal law and regulations, based on the fact that Petitioner received information from a CMS employee indicating that surrendering the Coppell Laboratory's CLIA certificate would resolve the issue in the instant case. P. Br. at 2. Even if I accept as true that CMS provided bad advice to Petitioner, it is well-settled that the government cannot be estopped, even after providing bad advice. As the Board has repeatedly held, estoppel against the federal government, if available at all, is presumably unavailable absent "affirmative misconduct." *See, e.g., Pacific Islander Council of Leaders*, DAB No. 2091, at 12 (2007); *Office of Pers. Mgmt. v. Richmond*, 496 U.S. 414, 421 (1990). Petitioner has not demonstrated that incorrect understandings of legal requirements on the part of CMS or its contractors rises[] to the level of affirmative misconduct. *See, e.g., Huron Potawatomi, Inc.*, DAB No. 1889, at 5 (2003) (holding allegation that incorrect advice was provided was not to be evidence of affirmative misconduct). No affirmative misconduct has been alleged here; therefore, I deny Petitioner's request for limited discovery of CMS's files because it would not alter my determination in this case.

[5] While the Board and the ALJs are bound by applicable laws and regulations, this does not preclude us from considering an argument of unconstitutionality to the extent it challenges the manner in which CMS has interpreted or applied a regulation. *See Sentinel Medical Laboratories, Inc.*, DAB No. 1762, at 11-12 (2001), *aff'd, Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. March 15, 2002), *reh'g denied* (9th Cir. May 22, 2002).

ALJ Decision at 6-7.

On appeal, Petitioner asserts that estoppel should be available in this case because the employee who gave the advice was "acting within the scope of [her] authority." RR at 9. According to Petitioner, "the premise that the government may only be [e]stopped after a showing of 'affirmative misconduct'" is "dicta from several courts" that is "not the law[.]" RR at 10. This argument has no merit. It is well-established that "the government cannot be estopped absent, at a minimum, a showing that the traditional requirements for estoppel are present (i.e., a factual misrepresentation by the government, reasonable reliance on the misrepresentation by the party seeking estoppel, and harm or detriment to that party as a result of the reliance) and that the government's employees or agents engaged in "affirmative misconduct." *Oaks of Mid City Nursing and Rehabilitation Center*, DAB No. 2375, at 31 (2011), citing *Office of Personnel Management v. Richmond*; *see also Rosewood Living Center*, DAB No. 2019, at 13 (2006), citing *Schweiker v. Hansen*, 450 U.S. 785, 788 (1981) and *Heckler v. Community Health Servs.*, 467 U.S. 51, 59 (1984). Thus, even if the traditional requirements of estoppel were met here, estoppel would not be available because there is no allegation or evidence of any affirmative misconduct.

Moreover, the traditional elements of estoppel were not met here because Petitioner did not show that it reasonably relied on the alleged advice that Coppell's surrender of its CLIA certificate would preclude CMS from revoking Southlake's CLIA certificate. Petitioner points to nothing in the language of section 493.1840(a)(8) or to any other authority in the statute or regulations that could have reasonably led it to believe that surrendering a CLIA certificate after it has already been revoked would somehow void the revocation. Indeed, the alleged advice would be contrary to Congress's clear intent, apparent from the plain language of the statute and the implementing regulation, to preclude the owner or operator of a laboratory whose CLIA certificate is revoked from owning or operating any laboratory within two years after the revocation. In addition, as discussed in the next section of this decision, the official written notice from CMS clearly indicated that Coppell's CLIA certificate would be revoked under the circumstances that existed here. Thus, Petitioner could not reasonably rely on oral advice to Dr. O'Hearn to the contrary. Furthermore, Petitioner's reliance on the alleged advice was not detrimental. Inasmuch as the alleged advice was given after Coppell's CLIA certificate was revoked, surrender of Coppell's certificate put Petitioner in no worse position than it was already in.[6]

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[6] We note also that Petitioner does not dispute the ALJ's conclusion that the "voluntary closure of a laboratory . . . does not preclude CMS from proceeding with revocation of the laboratory's certificate." *See* ALJ Decision at 7, citing *Sentinel Medical Laboratories, Inc.*; *see also HRT Laboratory, Inc.*, DAB No. 2118 (2007), at 14, citing *Center Clinical Laboratory*, DAB No. 1526, at 11 (1995). Thus, Petitioner can hardly argue that the fact that a laboratory surrenders its CLIA certificate after CMS has revoked it voids the revocation.

Accordingly, we conclude that the ALJ did not err in concluding that CMS would not be estopped from revoking Southlake's CLIA certificate by any advice from a CMS employee that Dr. O'Hearn could avoid revocation of Southlake's CLIA certificate by surrendering Coppell's CLIA certificate.

As noted above, Petitioner also disputes the ALJ's finding that Dr. O'Hearn failed to surrender Coppell's CLIA certificate. Petitioner alleges that Dr. O'Hearn submitted "a letter requesting surrender of" Coppell's CLIA certificate three months after Coppell closed. P. Ex. A, at 2 (unnumbered). For purposes of summary judgment, the ALJ should have accepted Petitioner's allegation. However, his failure to do so constitutes harmless error because, as the preceding discussion indicates, it is immaterial whether Dr. O'Hearn surrendered Coppell's certificate.

2. Coppell's CLIA certificate was not revoked without due process.

Petitioner argues that CMS's April 20, 2010 letter "created the expectation" that Coppell's CLIA certificate would not be revoked without a response by CMS to a timely-submitted POC. RR at 8. Petitioner points out that the letter states that Coppell "must" submit a POC by June 30, 2010 but does not state that Coppell "must" request a hearing by June 21, 2010. RR at 3. Noting that the April 20, 2010 letter states that a "request for hearing should identify the specific issues, and the findings of fact and conclusion of law with which you disagree," Petitioner also argues that Coppell reasonably believed that any findings and conclusions would be provided if and when CMS determined that the POC was unacceptable. *See* RR at 7-9. Petitioner asserts that Dr. O'Hearn did not know that CMS had not accepted Coppell's POC and that the time for requesting a hearing on the proposed revocation had expired until he received notice on June 23, 2010 that Coppell's CLIA certificate was revoked. RR at 7. Thus, in Petitioner's view, Coppell's CLIA certificate was revoked without an opportunity to request a hearing, "amount[ing] to a denial of due process." RR at 9.

Petitioner's argument has no merit. Nothing in CMS's April 20, 2010 letter suggests that, if Coppell submitted a new POC by April 30, 2010, the date specified in that letter, the 60-day period for requesting a hearing would be tolled until CMS notified Coppell of its determination regarding the acceptability of any POC. The April 20, 2010 letter states in pertinent part: "Your laboratory's CLIA certificate will be revoked effective **June 22, 2010** if one or all of the following occurs: • A request for hearing is not received by **June 21, 2010,"** 60 days from April 20. *See* CMS Ex. 2, at 3. In addition, the April 20 letter states specifically that a "written request for hearing must be filed no later than 60 days from the date of receipt of this letter." *Id.* at 4. Although the time for filing an acceptable POC (until April 30) thus overlapped with the period for requesting a hearing, nothing in the regulations precludes this. Indeed, the regulations state only that there is an opportunity to correct condition-level deficiencies where CMS imposes alternative sanctions for condition-level deficiencies that do not pose immediate jeopardy. *See* 42

C.F.R. § 493.1814(b). The sanction of revocation at issue here is a principal sanction, not an alternative sanction. *See* 42 C.F.R. § 493.1814(a); *see also HRT Laboratory* at 11 n.7, citing 42 C.F.R. § 493.1814(a)(3), (b)(1) and *Rustom Ali, Jahan Ferdous, and Scottsdale Medical Laboratory*, DAB No. 2016, at 21-22 (2006), *pet. denied, Ali v. U.S. Dept. of Health and Human Services,* 2007 WL 2437809 (9th Cir. Aug. 23 2007) (holding that the regulations under which CMS may afford an opportunity to correct "are inapposite" where CMS has proposed revocation). Because the regulations did not require CMS to provide an opportunity correct here, CMS had discretion to provide an opportunity to correct while the 60-day period for requesting a hearing on a proposed revocation was running.

Moreover, CMS's April 20, 2010 letter clearly indicated that the proposed revocation was based on Coppell's non-compliance with the CLIA conditions at 42 C.F.R. §§ 493.803, 493.1403, and 493.1421. CMS's conclusion that Coppell failed to comply with these conditions was based on the findings in the SOD for DSHS's February 18, 2010 survey (at CMS Exhibit 4). Petitioner does not deny that Coppell had received the SOD, which CMS's April 20, 2010 letter states is enclosed. *See* CMS Ex. 2, at 2. Coppell had ample notice from the SOD of the findings of fact and conclusions of law on which the proposed revocation was based. CMS's reasons for determining that Coppell's April 20, 2010 POC was inadequate to correct Coppell's noncompliance were thus irrelevant.

Furthermore, Petitioner admits that Dr. O'Hearn voluntarily closed Coppell prior to the revocation of its CLIA certificate. *See* Petitioner's Ex. A at 3-16 (unnumbered) (submitted as evidence that Coppell was closed as of April 30, 2010); Hearing Request at 1. Thus, as of April 30, 2010, Dr. O'Hearn knew that Coppell would not be able to demonstrate that it was in compliance with the CLIA requirements and that Coppell's CLIA certificate was subject to revocation on the grounds stated in CMS's April 20, 2010 letter. If Dr. O'Hearn believed that CMS was not authorized to revoke Coppell's CLIA certificate on those grounds, Dr. O'Hearn could have filed a timely hearing request at that point (or requested an extension of time to file one) even if he was unaware that CMS had found Coppell's POC unacceptable.[7]

We conclude, therefore, that Coppell's CLIA certificate was not revoked without due process. To the contrary, Coppell failed to avail itself of the opportunity afforded by the CLIA regulations for a hearing on the revocation. *See* 42 C.F.R. § 493.1844(f). In the absence of an appeal, the revocation of Coppell's CLIA certificate was final on June 22, 2010 and provided authority for CMS's revocation of Southlake's CLIA certificate in July 2010.

[7] Nothing in the record suggests that Dr. O'Hearn disputed CMS's conclusion that Coppell failed to comply with the CLIA conditions at issue, however.

Conclusion

For the foregoing reasons, we sustain the ALJ's decision upholding the revocation of Southlake's CLIA certificate.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Stephen M. Godek
Presiding Board Member