**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

OnSite OHS, Inc. & Kyle Johnson,

Petitioners,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1560

Decision No. CR3557

Date: January 7, 2015

# DECISION

I grant summary judgment in favor of the Centers for Medicare & Medicaid Services (CMS) sustaining its determination to impose remedies against Petitioners, OnSite OHS, Inc. (OnSite) and Kyle Johnson.

## I. Background

Petitioner OnSite OHS, Inc. is a clinical laboratory. Petitioner Kyle Johnson was at one time an owner of OnSite. Both Petitioners filed hearing requests challenging CMS's determination to impose remedies against them pursuant to the Clinical Laboratory Improvement Amendments (CLIA). CMS moved for summary judgment. Petitioners opposed CMS's motion and cross-moved for summary judgment. CMS filed seven proposed exhibits that are identified as CMS Ex. 1 – CMS Ex. 7. Petitioners filed five exhibits that are identified as P. Ex. 1 – P. Ex. 5. I receive all of the exhibits into the record.

## II. Issues, Findings of Fact and Conclusions of Law

### A. Issues

The issues are whether:

1. Petitioner OnSite received notice of CMS's determination to impose remedies; and

2. Petitioner Johnson qualifies as an "owner" of Petitioner OnSite pursuant to CLIA.

### B. Findings of Fact and Conclusions of Law

CMS determined to impose remedies against Petitioners based on its determination that Petitioner OnSite violated provisions of CLIA. Neither Petitioner OnSite nor Petitioner Johnson challenges the merits of this determination. Rather, the two Petitioners raise collateral issues. Petitioners contend that CMS has no authority to impose remedies because CMS failed to comply with regulatory requirements governing the notification of a clinical laboratory of adverse findings and remedy determinations. Petitioners assert that CMS's remedy determinations are ineffective as a consequence of allegedly defective notice. Additionally, Petitioner Johnson argues that he is not subject to CMS's remedy determination because he was not an owner of Petitioner OnSite at the time that the event that triggered CMS's determination to impose remedies occurred.

In summary, Petitioners' notice arguments are as follows: CMS is required by regulation to provide notice to an affected party of any adverse determination. CMS failed to provide notice to Petitioners of its adverse determination because it never mailed, faxed, or e-mailed a written notice of its determination to Petitioner OnSite's president or its laboratory director at its corporate headquarters. Rather, CMS sent several notices to the laboratory at its business address that CMS directed to the attention of a "former employee" (Petitioners do not deny that this individual was employed by the laboratory when the notices were sent to him) and to the medical director of the laboratory. Petitioners characterize these notifications as ineffective as a matter of law.

I disagree. The regulations governing notice of adverse actions taken by CMS pursuant to CLIA require only that CMS provide "written notice" to the affected "laboratory." 42 C.F.R. §§ 493.1810(a), 493.1842(b). Neither regulation specifies the form of notice other than requiring that it be written. Neither regulation specifies the manner of delivery nor does it specify to whom a notice must be delivered other than "the laboratory." As I shall discuss, Petitioners received ample and adequate notice of CMS's determinations that fell squarely within the requirements of these two regulations.

"Notice" pursuant to these regulations is not synonymous with "service" as that latter term is commonly used under rules of civil procedure. The rules governing service of process generally prescribe a precise and technical form in which that service must be effectuated. *See, e.g.*, Fed. R. Civ. Proc. 5. Under these rules, "service" is a formal act that must fall within strict parameters. "Notice" is different in that the requirements are looser and generally interpreted more loosely. The purpose of notice requirements is to assure that an affected party is apprised of an action and has an opportunity to exercise his, her, or its rights. If that end is accomplished, then notice is effectuated. Form should not be exalted over substance when notice is the issue.

The CLIA notice requirements at 42 C.F.R. §§ 493.1810(a) and 493.1842(b) are consistent with the broader and less strict concept of "notice." They specify who must be provided with notice in the event of an adverse determination by CMS and they specify that the notice must be in writing. Beyond that, they are silent, allowing CMS great flexibility in the manner in which it gives notice of its determinations. So long as notice is effective – i.e., so long as the affected party is apprised of CMS's action in writing and given an opportunity to challenge it – notice requirements are satisfied.

These requirements are also entirely consistent with the notice requirements contained in CLIA. The form of notice is not specified in CLIA. The statute requires only that CMS provide an affected party with "reasonable notice and an opportunity for hearing." 42 U.S.C. § 263(i)(1).

The undisputed material facts establish clearly that CMS provided notice of its determinations entirely consistent with statutory and regulatory requirements. CMS sent notice, which was received by OnSite's laboratory, in the case of each action taken by CMS. The notices that CMS provided comprise the following:

- On March 28, 2014, CMS prepared a letter directed to Dr. Brian Carlile, medical director of OnSite's laboratory. That letter communicated adverse survey findings and it directed the laboratory to submit an acceptable plan of correction. CMS Ex. 2. CMS sent the letter as an e-mail attachment to Brad Barnhart, who was employed by Petitioner's laboratory at that time. CMS Ex. 3 at 2-3.

- On that same date, CMS sent the March 28 letter to Mark Kimbereley, another employee of Petitioner. CMS Ex. 3 at 1-3.

- On May 19, 2014, CMS sent a letter to the attention of Dr. Carlile, Petitioner Johnson, and Petitioner OnSite announcing the imposition of sanctions against Petitioner OnSite, including revocation of Petitioner OnSite's CLIA certificate. The letter was addressed to and sent to Petitioner OnSite's laboratory's Fort Worth, Texas, mailing address. CMS Ex. 2 at 4-7.

- On June 10, 2014, CMS sent another letter to the attention of Mark Kimbereley, Dr. Carlile, Petitioner Johnson, and Petitioner OnSite again announcing the imposition of sanctions. The letter, like the May 19 letter, was addressed to and sent to Petitioner OnSite's laboratory's Fort Worth mailing address. CMS Ex. 2 at 9-11.

Petitioners argue that the March 28 and the May 19 notices were not sent directly to Dr. Carlile nor were they sent directly to Petitioner OnSite's President, Petitioner Johnson, or its corporate offices. But, it was not required by regulation that CMS send its notices to anyone other than the laboratory. *See* 42 C.F.R. §§ 493.1810(a), 493.1842(b). CMS did that in each instance. Petitioners also seem to argue that the March 28 notice may have been ineffective because it was sent as an e-mail attachment and not through the mail or as a fax. However, there is no requirement in the notice regulations that a notice must be sent via a specific conduit like the U.S. mail. The only requirement concerning transmission is that the notice must be in writing. CMS complied with that requirement.

Petitioners' principal complaint seems to be that the March 28 and May 19 notices failed to find their way to Petitioner OnSite's corporate offices or to its laboratory director or to Petitioner Johnson. That may be so, but that is no basis for me to find that CMS's notices were ineffective. Petitioners do not deny that employees at Petitioner OnSite's laboratory received the notices. That satisfied CMS's regulatory obligation. The notices also provided Petitioners with an opportunity for a hearing, consistent with the statutory requirements, which Petitioners took advantage of in initiating this case. *See* 42 U.S.C. § 263(i)(1).

Petitioners make additional arguments, all of which I find to be without merit. They characterize Petitioner's corporate offices, Dr. Carlile, and Petitioner Johnson as "necessary parties" and argue that CMS failed to provide these asserted necessary parties with adequate notice of its determinations. Petitioners' Resp. to CMS' Mot. for Summ. J. and Petitioners' Cross-Mot. for Summ. J. (P. Br.) at 14. That is an incorrect characterization. The necessary parties are Petitioner OnSite and Petitioner Johnson. No other individual or entity is directly affected by CMS's determinations. CMS provided notice to Petitioners through the noncompliant laboratory in accordance with regulatory requirements. That it may not have sent notices directly to other individuals at the corporate office is irrelevant.

Petitioner argues also that regulations require that notices sent to affected parties must be sent by mail, citing 42 C.F.R. § 498.20. P. Br. at 15. That notice regulation is inapplicable here. The regulation cited by Petitioner is part of the general regulations governing adverse determinations by CMS in cases involving suppliers, providers, or prospective suppliers and providers. Regulations governing CLIA, including the notice

requirements of 42 C.F.R. §§ 493.1810(a) and 493.1842(b) are intended specifically to apply to clinical laboratories. The specific notice requirements of these regulations apply here and not the generic requirements of 42 C.F.R. § 498.20.

I note, furthermore, that Petitioners' argument concerning the ostensible requirement that notices of adverse determinations made pursuant to CLIA be sent by mail is truly an exercise in exalting form over substance. Petitioner does not deny that its laboratory received any of the notices that CMS sent.

Next, Petitioner OnSite asserts that CMS's June 10 notice contravened the regulatory requirement of 42 C.F.R. § 493.1844(g)(2)(i) in that it did not inform Petitioner of its appeal rights. P. Br. at 17. It concedes that the June 10 letter incorporated by reference the May 19, 2014 letter's notice of appeal rights, but it argues that this is ineffective because it is allegedly undisputed that "the May 19 letter was never sent to Petitioners." But, in fact, that assertion is only true if one buys Petitioner's "necessary party" argument, which I have considered and rejected. It is undisputed that the May 19 letter was sent to and received by Petitioner OnSite's laboratory.

Petitioner Johnson asserts that he was not an "owner" for CLIA purposes and thus, cannot be subject to sanctions. Petitioner Johnson argues that he sold his stock in OnSite on November 14, 2013 and was not an owner of Petitioner OnSite thereafter. He contends that this case really is about Petitioner OnSite's failure to submit a corrective action plan by April 7, 2014 and that he was not an "owner" of Petitioner when that transgression occurred.

Petitioner Johnson's argument rests on a fundamental mischaracterization of the basis for CMS's remedy determinations. The sanctions that CMS imposed against Petitioners emanated directly from a survey performed of Petitioner OnSite's Fort Worth, Texas Laboratory on October 11, 2013, more than a month prior to the date when Petitioner Johnson sold his stock. CMS Ex. 1.

The remedies that CMS determined to impose against Petitioners were plainly not based solely on Petitioners' untimely submission of a plan of correction. Those remedies were based on the many deficiencies that were identified at the October 11, 2013 survey. Indeed, no remedy *could be* imposed but for those deficiencies. Petitioner Johnson was an owner of Petitioner OnSite when the survey was conducted.

Petitioner Johnson was, in fact, the sole shareholder of the holding company that owns Petitioner OnSite as of October 11, 2013. CMS Ex. 7. Thus, as of the date of the survey, Petitioner Johnson met the regulatory definition of an "owner" of a clinical laboratory: "any person who owns any interest in a laboratory except for an interest in a laboratory whose stock and/or securities are publicly traded." 42 C.F.R. § 493.2.

Finally, Petitioner OnSite, noting that it ceased operations in January 2014, argues that no sanctions could be imposed against it for its failure to notify CMS of its cessation of operations, because there is no regulatory requirement that specifically requires a laboratory to advise CMS of its cessation of operations. It is unnecessary for me to address this argument. The uncorrected deficiencies identified at the October 11, 2013 survey are, in and of themselves, sufficient to justify the imposition of the remedies that CMS imposed.

/s/
Steven T. Kessel
Administrative Law Judge