Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Lab Site Inc., (CLIA No. 16D1020985),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-411

ALJ Ruling No. 2014-30

Date: May 1, 2014

DISMISSAL

For the reasons set forth below, I conclude that Petitioner, Lab Site, Inc., is not entitled to Administrative Law Judge (ALJ) review of a determination made by the Centers for Medicare & Medicaid Services (CMS), because CMS has rescinded all remedies against it. I therefore dismiss its hearing request pursuant to 42 C.F.R. § 498.70(b).

Discussion

Petitioner is a clinical laboratory, located in Chalmette, Louisiana, that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and participates in the Medicare program. On July 30, 2013, the Louisiana Department of Health and Hospitals (State Agency) attempted to survey the lab, but could not find it at the address provided. In a letter dated September 24, 2013, CMS advised Lab Site that it would cancel its approval to receive Medicare payments and suspend its CLIA certificate.

Petitioner timely requested review.

Subsequently, on March 18, 2014, surveyors were able to locate the lab at the appropriate address, although they noted some irregularities.

Nevertheless, CMS revised its determination and rescinded the sanctions. By letter dated March 24, 2014, CMS advised the lab that it had done so. On the same day, CMS asked that Petitioner's appeal be dismissed. Petitioner did not respond, and the deadline for response has passed. 42 C.F.R. § 498.17(b).

A CLIA-certified laboratory's hearing rights are established by federal regulations at 42 C.F.R. Part 498. 42 C.F.R. § 493.1844(a) and (f). A lab dissatisfied with an initial determination is entitled to further review, but administrative actions that are not initial determinations are not subject to appeal. 42 C.F.R. §§ 493.1844; 498.3(a). The regulations specify which actions are "initial determinations" and set forth examples of actions that are not. Suspension of a lab's CLIA certificate and denial of a lab's approval to receive Medicare payments are initial determinations for which a facility may request an ALJ hearing. 42 C.F.R. § 493.1844(b)(1) and (4). But a lab has no right to a hearing unless CMS imposes one of the specified remedies. *See* 42 C.F.R. § 493.1844(c); *Premium Diagnostic Lab., Inc.*, DAB No. 1790 (2001).

Because CMS has imposed no remedies, Petitioner has no right to an ALJ hearing, and this matter must be dismissed. 42 C.F.R. § 498.70(b). I therefore grant CMS's motion.

/s/
Carolyn Cozad Hughes
Administrative Law Judge