IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

No. 17-60694 Summary Calendar United States Court of Appeals Fifth Circuit

FILED

July 23, 2018

Lyle W. Cayce Clerk

MURTAZA MUSSAJI, D.O., P.A., doing business as Fairway Medical Clinic, doing business as Shadow Creek Medical Clinic,

Petitioner

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent

Petition for Review of a Decision of the United States Department of Health and Human Services, Departmental Appeals Board, Decision No. 2811 HHS Nos. A-17-48 & A-17-49

Before KING, ELROD, and HIGGINSON, Circuit Judges. STEPHEN A. HIGGINSON, Circuit Judge:*

The United States Department of Health and Human Services Departmental Appeals Board dismissed Murtaza Mussaji's request for a hearing to challenge revocation of two laboratory certificates issued pursuant

 $^{^*}$ Pursuant to 5TH CIR. R. 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIR. R. 47.5.4.

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to the Clinical Laboratories Improvements Act of 1988. Mussaji now petitions our court for review of the Board's decision. The petition is denied.

I.

The Clinical Laboratories Improvements Act of 1988 (CLIA) regulates labs that conduct diagnostic tests on human specimens. 42 U.S.C. § 263a. The law requires that such labs obtain a certificate from the U.S. Department of Health and Human Services (HHS). *Id.* § 263a(b). Certified labs must conform to regulations promulgated by HHS, and HHS is authorized to inspect labs to ensure compliance. *Id.* §§ 263a(c)(1), (g). If HHS discovers that a lab no longer meets HHS's certification requirements, the agency may impose sanctions including revocation of the certificate. *Id.* § 263a(i). Before revoking a certificate, HHS must provide the lab owner or operator "reasonable notice and opportunity for hearing." *Id.*

Under CLIA's implementing regulations, the Centers for Medicare and Medicaid Services (CMS), a division of HHS, gives notice to laboratories when it makes an initial determination to revoke a CLIA certificate. 42 C.F.R. § 493.1844(g)(1). A lab "has 60 days from the notice of sanction to request a hearing" before an Administrative Law Judge (ALJ). *Id.* § 493.1844(f)(1); *see also id.* § 498.40(a)(2) ("The affected party or its legal representative or other authorized official must file the [hearing] request in writing within 60 days from receipt of the notice of initial, reconsidered, or revised determination unless that period is extended"). The ALJ may extend the 60-day period "[f]or good cause shown." *Id.* § 498.40(c)(2).

Murtaza Mussaji operated two CLIA certified labs, Shadow Creek Medical Clinic and Fairway Medical Clinic. On January 29, 2015, the Texas Department of State Health Services notified Mussaji that a recent inspection had revealed that Shadow Creek was not in compliance with CLIA requirements. The letter further asserted that Shadow Creek's "deficient

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practices . . . pose[d] immediate jeopardy to patient health and safety." The letter stated that if Shadow Creek did not come into compliance, the case would be referred to CMS.

CMS faxed Mussaji a letter on July 8, 2015. The letter stated that Shadow Creek's CLIA certificate would be revoked if, among other things, Shadow Creek did not request a hearing by September 8, 2015. CMS faxed Mussaji a similar letter regarding Fairway on January 12, 2016. This letter explained that operators of labs that have had a certificate revoked are prohibited from owning or operating any lab for two years. *See* 42 U.S.C. § 263a(i)(3). Therefore, because Shadow Creek's certificate had been revoked, Fairway's certificate would be revoked as well. Mussaji denies receiving either fax.

The parties agree, however, that Mussaji received several other related letters from CMS. In an April 8, 2015 letter to Shadow Creek, CMS stated: "Your laboratory's CLIA certificate will be revoked effective June 9, 2015, if one or all of the following occurs: . . . a request for a hearing is not received by June 9, 2015." (emphasis omitted). Mussaji responded to this letter, and sent CMS back a plan to correct Shadow Creek's deficiencies.

On September 23, 2015, CMS faxed Mussaji a letter informing him that Shadow Creek's CLIA certificate had been revoked due to, among other things, Mussaji's failure to file an appeal by September 8, 2015. Mussaji acknowledged receiving this fax in an email dated September 29 2015, and again in a letter to CMS dated October 20, 2015.

On October 30, 2015, CMS sent Mussaji a letter reiterating that Shadow Creek's CLIA certificate had been revoked and that the appeal deadline of September 8, 2015 had passed. Mussaji responded to this letter and acknowledged receiving it.

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On April 5, 2016, CMS sent Mussaji a letter stating that Fairway's CLIA certificate had been revoked. The letter referenced the January 12, 2016 letter and explained that Fairway's deadline for appealing the revocation passed on March 14, 2016. Mussaji again responded and acknowledged receiving CMS's letter.

On October 14, 2016—more than eighteen months after the first letter Mussaji acknowledged and more than six months after the last—Mussaji requested a hearing before an ALJ for both Shadow Creek and Fairway. The ALJ found that Mussaji had actual knowledge that both certificates had been revoked more than 60 days before he sought review, and held that his hearing requests were therefore untimely. The ALJ further found that Mussaji failed to show good cause for the delay and dismissed the request for a hearing. HHS's Departmental Appeals Board sustained the ALJ's ruling, and Mussaji now petitions this court for review.

II.

CLIA gives this court "jurisdiction to affirm . . . , or to set . . . aside in whole or in part, temporarily or permanently" HHS's decision to suspend a laboratory's certificate. 42 U.S.C. § 263a(k)(3). HHS's factual findings are conclusive "if supported by substantial evidence." *Id*.

The ALJs finding that Mussaji had actual notice that Shadow Creek and Fairway's certificates had been revoked months before he requested a hearing is supported by substantial evidence. As detailed above, Mussaji repeatedly acknowledged receipt of various letters from CMS explaining that his CLIA certificates had been revoked.

Mussaji argues however that CMS was required to send him notice by U.S. mail, and the agency's failure to do so rendered notice ineffective. He cites 42 C.F.R. § 498.20(a)(1), which states that, as a "[g]eneral rule" CMS "mails

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notice of an initial determination to the affected party." (emphasis added). HHS disputes whether § 498.20(a)(1) applies, and argues that, even if it does, faxing Mussaji notice satisfied the regulation. HHS further argues that, even assuming it was required to send notice by U.S. mail, its procedural error was rendered harmless by Mussaji's actual knowledge of the revocations.

"Procedural perfection in administrative proceedings is not required' as long as 'the substantial rights of a party have not been affected." *Audler v. Astrue*, 501 F.3d 446, 448 (5th Cir. 2007) (quoting Mays v. Bowen, 837 F.2d 1362, 1364 (5th Cir. 1988)). Accordingly, this court will not set aside agency action for mere harmless error. *See, e.g, Graves v. Colvin*, 837 F.3d 589, 592– 93 (5th Cir. 2016).

In Shinseki v. Sanders, the Supreme Court held that an agency's notice error was harmless where petitioner "ha[d] not explained . . . how the notice error to which he point[ed] could have made any difference." 556 U.S. 396, 413 (2009); see also Gov't of Canal Zone v. Brooks, 427 F.2d 346, 348 (5th Cir. 1970) (government agency's noncompliance with own notice regulation was *de minimis* error). Similarly here, given the ALJ's finding that Mussaji waited more than a year after first learning of the revocations to seek review, Mussaji makes no showing that receiving notice by U.S. mail made any difference. Therefore, even assuming that the relevant regulations require notice by U.S. mail, which we do not decide today, CMS's error in faxing the notice was harmless. Similarly, given Mussaji's actual knowledge of the revocation, the ALJ's finding that Mussaji failed to show good cause for his delay is supported by substantial evidence.

III.

The petition for review is DENIED.