Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Fairway Medical Clinic
&
Shadow Creek Medical Clinic
Docket Nos. A-17-48 & A-17-49
Decision No. 2811
August 18, 2017

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE RULING

Petitioners Fairway Medical Clinic (Fairway) and Shadow Creek Medical Clinic (Shadow Creek), clinical laboratories, appeal the December 20, 2016 Ruling No. 2017-5, *Ruling Dismissing Requests for Hearings* (Ruling), of an Administrative Law Judge (ALJ). In the Ruling, the ALJ granted the Centers for Medicare & Medicaid Services' (CMS's) motions to dismiss Petitioners' requests for hearing to challenge the revocation of their certificates under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as untimely and not supported by good cause to extend their respective appeal deadlines. For the reasons set forth below, the Board sustains the Ruling.

Legal Authorities

Under CLIA, laboratories that perform clinical diagnostic tests on human specimens must meet certain requirements and be federally certified. *See* Pub. L. No. 100-578, *amending* section 353 of the Public Health Service Act, *codified at* 42 U.S.C. § 263a *et seq*. CLIA grants the Secretary of Health and Human Services broad enforcement authority, including the ability to suspend, limit, or revoke the CLIA certificate of a laboratory that is not in compliance with certification requirements. 42 U.S.C. § 263a(i). The Secretary has delegated to CMS the authority to inspect, or to have its agents inspect, laboratories and to sanction laboratories that fail to comply with the certification requirements. *See generally* 42 C.F.R. Part 493, subparts Q (inspection) and R (enforcement).

The "suspension, limitation, or revocation of [a] laboratory's CLIA certificate" based on "noncompliance with CLIA requirements" is an appealable "initial determination." 42 C.F.R. § 493.1844(b)(1); *see also* 42 U.S.C. § 263a(i)(1) ("In general . . . the certificate of a laboratory . . . may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory,

that such owner or operator or any employee of the laboratory" has not complied with certain requirements as stated therein.). A laboratory that is dissatisfied with the decision to suspend, limit, or revoke its CLIA certificate may request a hearing before an ALJ with the Departmental Appeals Board. *Id.* § 493.1844(a), (b). Appeal may be taken "60 days from the notice of sanction." *Id.* § 493.1844(f)(1).

ALJ hearings are conducted in accordance with the regulations in 42 C.F.R. Part 498, subpart D. *Id.* § 493.1844(a)(2). The request for hearing must be filed, in writing, "within 60 days from receipt" of the notice of the determination (to revoke the certificate). 42 C.F.R. § 498.40(a). The date of receipt of the determination is "presumed to be 5 days after the date on the notice, unless there is a showing that it was, in fact, received earlier or later." *Id.* § 498.22(b)(3). If the request was not filed within 60 days, on written request, the ALJ may extend the filing deadline for good cause shown. *Id.* § 498.40(c). An ALJ may dismiss a request for hearing on his or her own motion or the motion of a party if the request was untimely and the time for filing has not been extended. *Id.* § 498.70(c). A party dissatisfied with an ALJ's dismissal may request Board review within 60 days from receipt of the notice of dismissal. *Id.* § 498.82(a).

Case Background

This appeal arose from CMS's determinations to revoke, first, the CLIA certificate of Shadow Creek and, subsequently, that of Fairway. We set out below a summary of the events leading up to Petitioners' appeals to the ALJ, drawn from the ALJ's Ruling and the exhibits on which the ALJ issued his Ruling. It is presented first to provide a context for the discussion of the ALJ's Ruling and the issues raised on appeal.

Shadow Creek

By faxed letter dated April 8, 2015, CMS notified Shadow Creek that an initial certification survey performed for CMS by the Texas Department of State Health Services, a state survey agency, found instances of "condition level noncompliance with immediate jeopardy" at Shadow Creek. Shadow Creek (SC) (CRD Docket No. C-17-40) CMS Ex. 1, at 2, citing, inter alia, 42 C.F.R. § 493.1215 (conditions for laboratories providing hematology services). The letter also informed Shadow Creek that it must submit, by April 20, 2015, an "acceptable" plan of correction (POC) that meets certain requirements as stated in the letter and a "credible" "allegation of compliance" (AOC) with the conditions, and that its certificate "will be revoked effective **June 9, 2015**" if it does not file a request for hearing "received by **June 8, 2015**" or if one of other specified events (e.g., no POC is submitted or the POC is unacceptable) occurs. *Id.* at 3-4, 5 (emphases in original). The letter informed Shadow Creek that if it wants to appeal CMS's determination it "must" file a "written request for hearing" before an ALJ "no later than 60 days from the date of receipt of this letter." *Id.* at 6, citing 42 C.F.R. § 493.1844.

Shadow Creek responded to CMS's April 8, 2015 letter by submitting a POC, by fax, on May 15, 2015. *Id.* at 7-50 (Form CMS-2567, Statement of Deficiencies and Plan of Correction, bearing what appears to be Dr. Murtaza Mussaji's[1] signature, dated May 14, 2015), 51 (fax transmittal form dated May 15, 2015). We note that the documents Shadow Creek faxed to CMS on May 15, 2015 included the first page of CMS's April 8, 2015 fax to Shadow Creek, which shows that Shadow Creek received CMS's April 8, 2015 fax. *Id.* at 52.

By faxed letter dated July 8, 2015, CMS informed Shadow Creek that the "documents" submitted in response to CMS's April 8, 2015 letter were "found to be unacceptable" because no AOC was submitted, and the POC was "unacceptable" for the reasons given. SC CMS Ex. 4, at 2-3. The letter also informed Shadow Creek that, by July 13, 2015, it must submit a POC and AOC in response to a new Form CMS-2567 included with the letter, and that its certificate "will be revoked effective **September 9, 2015**" if it does not file a request for hearing "received by **September 8, 2015**" or if one of other specified events (e.g., if no "POC/AOC" is submitted or, if submitted, it is unacceptable) occurs. *Id.* at 3-4, 5 (emphases in original). The July 8, 2015 letter included notice of right to appeal, using language identical to that in the April 8, 2015 letter. *Id.* at 6 ("A written request for hearing must be filed no later than 60 days from the date of receipt of this letter . . . .").

On September 23, 2015, by faxed letter,[2] CMS notified Shadow Creek that its certificate was revoked effective September 9, 2015, noting specifically that Shadow Creek did not "file an appeal by September 8, 2015." SC CMS Ex. 6, at 3. In that letter CMS also stated that Shadow Creek had not "submit[ted] an acceptable [POC] and [AOC]." *Id.* Shadow Creek acknowledged receipt of this letter by email to CMS on September 29, 2015, and by letter to CMS dated October 20, 2015. SC CMS Ex. 7, at 1 (Dr. Mussaji's email to Sandra M. Pearson, laboratory consultant and surveyor for CMS, stating, "I received your fax last week about revoking my CLIA license effective 9/9/15."); SC P. Ex. 3, at 1 (Dr. Mussaji's letter to CMS). In the email and letter, Dr. Mussaji wrote that Shadow Creek completed the corrective actions and was ready to undergo a site visit. *Id.*

[1] Murtaza Mussaji, D.O. is the laboratory director and owner of Shadow Creek and Fairway. SC CMS Ex. 3, at 2, 5, 10, 11, 14; SC P. Ex. 6, at 1 ¶ 1; Fairway (F) (CRD Docket No. C-17-41) P. Ex. 1, at 1 ¶ 1. All CMS notices discussed in the case background section were addressed to Dr. Mussaji, at either Shadow Creek or Fairway.

[2] The date on the first page of CMS's letter is "September 23, 2016." SC CMS Ex. 6, at 3. The reference to "2016" in the letter appears to have been error and should have been "2015." The fax transmittal form and cover sheet indicate that the letter was faxed to Shadow Creek on September 23, 2015. *Id.* at 1, 2.

By faxed letter dated October 30, 2015, CMS again informed Shadow Creek that its certificate was revoked effective September 9, 2015 due to, inter alia, the "failure to file an appeal by the deadline date of September 8, 2015," and that "[a]t this time . . . there is nothing CMS can do to reactivate" the certificate. SC CMS Ex. 8, at 2-3.

Fairway

By faxed letter dated January 12, 2016, CMS informed Fairway it "must impose" on Fairway the sanction of revocation of its certificate because the law prohibits the owner or operator (including the director) of a laboratory that has had its certificate revoked (Shadow Creek) from owning or operating (or directing) a laboratory (Fairway) for at least two years from the date of the revocation. F CMS Ex. 2, at 2 (citing 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8), and referring to revocation of Shadow Creek's certificate). That is, since Dr. Mussaji owned and served as laboratory director for both laboratories and Shadow Creek's certificate had been revoked, the applicable law mandated revocation of Fairway's certificate. The letter also notified Fairway that its certificate "will be revoked effective **March 15, 2016** if a request for a hearing is not received by **March 14, 2016**." *Id.* (emphases in original); *see also id.* at 3 (citing 42 C.F.R. §§ 493.1844(a)(1)-(2) and 498.40-498.78, and stating that Fairway has 60 days "after the date this letter is received" to request a hearing).

Fairway did not request a hearing by March 14, 2016 and, accordingly, by faxed letter dated April 5, 2016, CMS informed Fairway as follows:

> In our January 12, 2016 letter, you were provided information for filing an appeal. The deadline for filing this appeal was March 14, 2016. As of March 15, 2016, CMS did not receive notification of a formal hearing request . . . for Fairway . . . . Therefore CMS has proceeded with revocation of your CLIA Certificate effective March 15, 2016.

F CMS Ex. 4, at 2; *see also* F CMS Ex. 7 (declaration of Ms. Pearson), at 3 ¶ VIII (stating that Fairway "failed to respond" to the January 12, 2016 letter notifying it of revocation "due to the owner/operator ban").

On April 24, 2016, Dr. Mussaji sent an email to Ms. Pearson in which he acknowledged receipt of CMS's April 5, 2016 faxed letter, but stated that he had not received CMS's January 12, 2016 letter and that he "would like to appeal and request a hearing." F CMS Ex. 6, at 1. On April 25, 2016, Ms. Pearson evidently emailed Dr. Mussaji a copy of the January 12, 2016 letter. *Id.* (email message stated "Dr. Mussaji, attached is the letter for Fairway Medical Clinic"; attached to the email was a document named "E16-14 – revoke ltr.pdf").

Requests for Hearing and ALJ's Ruling

On October 14, 2016, Petitioners Shadow Creek and Fairway each filed a request for a hearing before an ALJ. CMS filed motions to dismiss both requests, asserting that Petitioners filed their requests late despite actual notice of enforcement action and appeal rights to both Petitioners by fax, as evidenced by successful fax transmission confirmations submitted as CMS exhibits, and despite Petitioners' acknowledgment of receipt of notice as indicated by Petitioners' responses to CMS. In its motions, CMS noted the claims in each case that the laboratories did not receive notices of revocation "by mail" as was allegedly required and, in its motion for Shadow Creek, expressly acknowledged Dr. Mussaji's declaration attesting that Shadow Creek did not receive the notice by mail. CMS's motions to dismiss at 3. CMS took the position, however, in each case, that neither 42 U.S.C. § 263a(i)(1), nor the applicable regulations in Part 493, mandate requisite written notice to be delivered by any specific means, such as U.S. mail. CMS's motions at 1-2; SC CMS Ex. 5, at 1 and F CMS Ex. 3, at 1-2 (fax transmission confirmations for the July 8, 2015 notice to Shadow Creek and the January 12, 2016 notice to Fairway, respectively).

Petitioners opposed the motions, asserting, first, that the only valid method of notice recognized by 42 C.F.R. § 498.20(a) (which states that CMS "*mails* notice of an initial determination to the affected party") is U.S. mail and, accordingly, CMS's fax notices are without legal significance for purposes of establishing the appeal due dates. Second, Petitioners maintained that they did not receive CMS's notices of right to appeal, namely the July 8, 2015 notice to Shadow Creek and the January 12, 2016 notice to Fairway, even by fax. In support of this assertion, Petitioners submitted the sworn declarations of Dr. Mussaji in which he attested that the laboratories have a procedure for gathering written correspondence sent to them, which was followed, and neither laboratory received the notice purportedly faxed by CMS. Third, Petitioners argued that, because they were not afforded due process inasmuch as CMS did not use a legally valid method of notice, and did not actually effectuate notice, they have shown good cause for filing their requests late so the ALJ should have extended the filing due dates in both cases. Petitioners' responses to CMS's motions at 1-3; SC P. Exs. 6 and 7; F P. Exs. 1 and 2.[3]

[3] Each laboratory submitted two sworn declarations of Dr. Mussaji, one dated October 12, 2016, and one dated December 5, 2016. In his earlier declarations, Dr. Mussaji attested that the laboratories did not receive the notices in question by mail. In the later declarations he attested that the laboratories did not receive those notices by mail or any other means. *Compare* SC P. Ex. 6 and F P. Ex. 1 *to* SC P. Ex. 7 and F P. Ex. 2.

The ALJ found the evidence of successful fax transmissions of the July 8, 2015 (Shadow Creek) and January 12, 2016 (Fairway) notices to the laboratories to be "persuasive." Ruling[4] at 3. The ALJ stated:

> I find CMS's evidence to be persuasive, consisting of a record of fax transmissions showing that the two faxes in question actually were received. However, I find it unnecessary to resolve the dispute between the Petitioner in each case and CMS as to whether the Petitioner received the fax in question. In each case, Petitioner knew that CMS had imposed the final sanction against it of revocation of its CLIA certificate. In each case, CMS mailed a copy of the allegedly non-received fax to the Petitioner after Petitioner asserted that it hadn't received it.[5]
>
> But, in neither case did that knowledge prompt Petitioner to request a hearing. Neither Petitioner requested a hearing for months, notwithstanding its knowledge that CMS had imposed sanctions against it including revocation of its CLIA certificate.

Id. (citations to the record omitted).

[4] The requests for hearing were docketed under numbers C-17-40 (Shadow Creek) and C-17-41 (Fairway). The ALJ decided not to consolidate the appeals, but issued one ruling for both since one individual owns both laboratories and the appeals involve similar facts, legal issues, and arguments. Ruling at 1 n.1; *see generally* 42 C.F.R. § 498.54 (if the parties agree, the ALJ may hold joint pre-hearing and hearing proceedings in two or more appeals involving the "same or substantially similar matters"). Petitioners allege ALJ "error in issuing a consolidated ruling in cases that were not consolidated." Shadow Creek's brief (SC Br.) at 3 ¶ 3; Fairway's brief (F Br.) at 3 ¶ 3. Petitioners do not explain on what basis they believe the ALJ was precluded from issuing one dismissal for both appeals where the threshold issue was whether the two similarly situated laboratories had timely appealed, or address how they were harmed by the issuance of one ruling. We accept the ALJ's issuance of one ruling as a reasonable exercise of discretion under these circumstances. Moreover, the Board finds the reasons the ALJ cited for issuing one ruling are equally apt here, and therefore issues one decision for both appeals, docketed under numbers A-17-48 (Fairway) and A-17-49 (Shadow Creek).

[5] As noted, below, Petitioners denied receipt of the July 8, 2015 (Shadow Creek) and the January 12, 2016 (Fairway) notices by any means. They take the same position before the Board. In their reply briefs submitted to the Board (Reply Brs.), at 6-7, Petitioners assert that the ALJ erroneously said that CMS eventually mailed copies of the allegedly non-received faxes. We do not see proof that CMS later "mailed" the allegedly non-received faxes as the ALJ indicated, and CMS does not represent that it did. However, we note, as the ALJ did, that CMS faxed the notices to Petitioners and that CMS has produced evidence of successful fax transmissions on July 8, 2015 and January 12, 2016. SC CMS Ex. 5, at 1; F CMS Ex. 3, at 1, 2. But, more to the point, as we explain, evidence of other CMS notices, the receipt of some of which Dr. Mussaji expressly acknowledged, and the course of communication between CMS and Dr. Mussaji together indicate that Petitioners were provided notice.

The ALJ rejected Petitioners' position that CMS's notices were invalid because they were not mailed to them. *Id.* at 4. The ALJ stated:

> I find to be unpersuasive Petitioners' assertions that CMS's notices are invalid because they were not sent to Petitioners by United States mail. Petitioners rest their argument on the language of 42 C.F.R. § 498.20(a), which provides that CMS "mails" notice of its initial determination to an affected party. Petitioners argue that CMS contravened the plain meaning of the regulation and that, therefore, its notices are invalid. Petitioners' arguments exalt form over substance. The issue here is not whether CMS jumped through all of the regulatory hoops in order to provide Petitioners with notice. Rather, the issue is whether Petitioners *actually had notice* of CMS's determinations. Clearly, they did. The knowledge that Petitioners obtained should have motivated them to act. They failed to do so and so, forfeited their hearing rights.

Id. (ALJ's emphasis). The ALJ also said that subsection 498.20(a) does not limit CMS to providing notice by mail because the term "mail" does not suggest that the only form of "mail" is U.S. mail, "especially when read in the context of all of the forms of reliable electronic communications that are now available to CMS and to private parties." *Id.* (second para.). Electronic mail, the ALJ reasoned, would be one form of "mail" consistent with the regulation's plain meaning, and its terms do not preclude the faxing of documents. *Id.* (second para.).

Lastly, the ALJ determined that no good cause was shown for late filing since "nothing . . . suggest[s] that either Petitioner was prevented from filing timely by circumstances that were beyond its ability to control," but neither appealed until long after the appeal period had passed or offered a credible explanation for not filing earlier. *Id.* (third para.).

Standard of Review

The Board reviews a disputed finding of fact to determine whether the finding is supported by substantial evidence on the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. *Guidelines – Appellate Review of Decisions of Administrative Law Judges in Cases Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and Related Statutes*, available at http://www.hhs.gov/dab/divisions/appellate/guidelines/clia.html. "The standard of review for an ALJ's exercise of discretion to dismiss a hearing request where such dismissal is committed by regulation to the discretion of the ALJ is whether the discretion has been abused." *High Tech Home Health, Inc.*, DAB No. 2105, at 8 (2007), *aff'd, High Tech Home Health, Inc. v. Leavitt*, Civ. No. 07-80940 (S.D. Fla. Aug. 15, 2008).

Discussion

In summary, Petitioners' arguments before the Board are that the ALJ erred in concluding that: (1) the manner of notice of CMS's sanctions and Petitioners' appeal rights is of no legal import; (2) subsection 498.20(a)'s reference to "mail" means methods of delivery other than U.S. mail; and (3) CMS had effectuated the required notices despite having failed to mail them as required and despite affirmative evidence that Petitioners did not receive them. On the third point of error, Shadow Creek and Fairway continue to state that they did not receive, respectively, the July 8, 2015 and January 12, 2016 fax notices. We find no legal error or abuse of discretion. Accordingly, we uphold the ALJ's Ruling.

A. *The ALJ did not err or abuse his discretion in dismissing the requests for hearing because Petitioners were actually made aware of CMS's revocation action, but did not then take action until many months later.*

We first address Petitioners' position that the ALJ concluded that the means of notice is of no legal import. We disagree that the ALJ did so. Rather, considered as a whole, the ALJ's rationale, particularly that in the first paragraph of page 4 of the Ruling, which we have quoted in full above, conveys that the essential procedural due process inquiry presented here is whether Petitioners were made aware of the proposed sanction and their appeal rights and given an opportunity to respond.[6] In these cases, the ALJ determined that Petitioners "knew" about CMS's action and of their appeal rights. Ruling at 3. Stating that the central question is whether Petitioners actually knew about CMS's action does not necessarily imply that the means employed is of no legal import such that any means CMS employed would be acceptable.

We also reject the argument that the ALJ determined that the word "mails" in subsection 498.20(a) means that particular methods of notice other than U.S. mail are specifically authorized by regulation. The ALJ observed only that the terms of subsection 498.20(a) do not, by use of the word "mails," preclude or rule out forms of notice other than U.S. government postal mail that are currently in common use and which arguably could be just as reliable, e.g., email or fax. Ruling at 4 (second para.). While the word "mails" as used in subsection 498.20(a) may be interpreted as intended to refer to U.S. postal mail,

[6] "'An elementary and fundamental requirement of due process in any proceeding which is to be accorded finality is notice reasonably calculated, under the circumstances, to apprise interested parties of the pendency of the action and afford them the opportunity to present their objections.'" *Peralta v. Heights Medical Ctr.*, 485 U.S. 80, 84 (1988) (quoting *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950)). Due process does not require rigid conformity in terms of the kind of notice that must be given, and, where a party received actual notice of pendency of the action and was given an opportunity to respond, the due process clause is not offended. *See Lehner v. United States*, 685 F.2d 1187, 1190-91 (9th Cir. 1982) (and cases cited therein), *cert. denied*, 460 U.S. 1039 (1983).

we do not conclude that the term can only refer to U.S. government postal mail, to the exclusion of all other means of notice. In a modern era of electronic mailing and messaging, the term "mails" is not unambiguous. The core question for due process is whether the transmission method is as capable of accomplishing the essential purpose of notice. We conclude that the ALJ's rationale is not inconsistent with subsection 498.20(a).

We further note that, contrary to Petitioners' apparent reading of *Riverview Village*, DAB No. 1840 (2002), Reply Brs. at 3-4, *Riverview* did not hold that the only valid notice recognized under Part 498 is notice by U.S. mail. CMS sent Riverview, a nursing facility participating in Medicare and Medicaid, notice of imposition of penalties by both fax and certified U.S. mail; CMS's notice on its face stated that it was being sent by both methods. The basic notice and filing question presented in *Riverview* was whether the date of CMS's fax transmission or the date of delivery by certified mail controlled for purposes of calculating the due date for timely requesting an ALJ hearing. CMS argued that the earlier date of transmission by fax controlled, making the hearing request untimely, i.e., received after the 60-day period from the fax delivery. Riverview's chief argument, in essence, was that while CMS could provide a courtesy copy of its notice by fax, for purposes of determining timeliness of appeal under the applicable regulations, the facility must be afforded 65 days from the date of notice (60 days plus five days for presumption of receipt of mail) and, based on application of the five-day presumption, Riverview had more time to file than if the due date had been calculated based on the date of the fax transmission, making its hearing request timely. *Riverview* at 2, 6-7. Vacating the ALJ's dismissal for untimely filing, which was based on a determination that Riverview was required to file its hearing request within 60 days of receipt of the notice regardless of the means of notice, the Board stated:

> [A]s a general rule, Part 498, which provides that CMS' notice of its initial determination to impose remedies against a facility will be sent by mail, controls when calculating the due date for the filing of a request for hearing. **We do not rule out the use of a FAX for notice purposes where the FAX clearly and unambiguously specifies that it is the notice document.** However, under Part 498, when a facility receives both a FAX and a mailed notice it would be reasonable for it to assume, in the absence of any specific admonition to the contrary, that the FAX is a "courtesy" copy and the mailed notice is the operative document for the purposes of calculating the period within which a hearing must be requested. At the very least, sending of both a FAX and a mailed notice . . . presents a confusing and ambiguous situation for a facility in attempting to determine when it must request a hearing, and we will not deprive a facility of its right to a hearing under such circumstances.

Id. at 8 (emphasis added). Thus, the Board did not hold in *Riverview* that the only valid form of notice recognized under Part 498 is notice by mail. Rather, the Board found that since Part 498 generally contemplates notice by mail, the facility could reasonably view fax notice as an additional, courtesy copy where the notice was sent by both fax and mail. More relevant to this case, the Board expressly commented that notice of appeal rights could be served by fax alone, so long as the document served is clearly the notice document. We find that the ALJ reasonably viewed the notices faxed to Petitioners here as providing such clarity, especially since here, in contrast to *Riverview*, CMS consistently sent its notices to Petitioners by fax.

We observe, moreover, that the statute setting out appeal rights for CLIA laboratories challenging revocation of their CLIA certificates does not by its terms prescribe any specific means of notice. 42 U.S.C. § 263a(i)(1) ("In general . . . the certificate of a laboratory . . . may be suspended, revoked, or limited if the Secretary finds, after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory" has not complied with certain requirements as stated therein.). Nor does subsection 493.1844(a)(2), which states that ALJ hearings are conducted in accordance with Part 498, subpart D regulations,[7] or any other applicable Part 493 regulation.

The relevant inquiry, then, is whether Petitioners were actually given notice and made aware of what sanction CMS was imposing and of their appeal rights, in accordance with Part 498, subpart D regulations. Subsection 498.40(a)(2), within subpart D, states in part:

> The affected party . . . must file the request in writing within 60 days from **receipt** of the notice of initial . . . determination unless that period is extended in accordance with paragraph (c) of this section.

Emphases added. If Petitioners were so made aware, then section 498.70 permits the ALJ discretionary authority to issue a "[d]ismissal for cause." Section 498.70 states, in part:

> On his or her own motion, or on the motion of a party to the hearing, the ALJ may dismiss a hearing request either entirely or as to any stated issue, under any of the following circumstances:
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> *****

[7] Subsection 493.1844(a)(2) states that ALJ hearings on revocation of CLIA certificates are conducted pursuant to "subpart D of part 498." Subsection 498.20(a) is in Part 498, subpart B. Thus, arguably, under a strict, narrow reading of subsection 493.1844(a)(2), reliance on subsection 498.20(a) in an appeal of a CLIA certificate revocation is misplaced. But we need not resolve the question here given that we do not find the use of fax notice violative of subsection 498.20(a) under the circumstances here, as explained in the text.

> (c) *Hearing request not timely filed.* The affected party did not file a hearing request timely and the time for filing has not been extended.

(Underline added.)

The evidence on which the ALJ relied indicates that Petitioners were indeed made aware. As outlined earlier in "Case Background," CMS sent multiple notices to Petitioners, by fax notices to Dr. Mussaji, concerning noncompliance with certification requirements and the sanction of revocation of the CLIA certificates, throughout a one-year period beginning with the April 8, 2015 fax notice to Shadow Creek, and ending with the April 5, 2016 fax notice to Fairway. But, as the ALJ found, neither Petitioner acted until many months later. On this basis, we uphold the ALJ's Ruling.

Notably, by the April 8, 2015 fax notice to Shadow Creek, Dr. Mussaji, who was laboratory director and owner of Shadow Creek and Fairway, was given actual notice that noncompliance with certain CLIA provisions authorized CMS to impose sanctions that include revocation of a laboratory's CLIA certificate, and that the imposition of such a sanction entails the right to appeal CMS's action by filing a request for hearing within 60 days of receipt of notice of that sanction. SC CMS Ex. 1, at 1-6. While Shadow Creek opted only to attempt to make the corrective actions as stated in CMS's notice rather than also appealing, by responding to the April 8, 2015 fax, Shadow Creek acknowledged actual receipt of that fax and thus is presumed to have actual knowledge of the contents of that fax. *Id.* at 7-52; SC P. Ex. 2, at 1 (Dr. Mussaji's June 4, 2015 letter to Ms. Pearson stating that Shadow Creek has taken corrective actions as stated in the POC he faxed to CMS on May 15, 2015). CMS then followed up with fax notices to Shadow Creek dated September 23, 2015 and October 30, 2015, informing Dr. Mussaji of revocation of Shadow Creek's certificate, which took effect on September 9, 2015. SC CMS Exs. 6, 8. Dr. Mussaji acknowledged receipt of both. SC CMS Ex. 7, at 1; SC P. Ex. 3, at 1; SC P. Ex. 4, at 1. By the April 5, 2016 fax notice to Fairway, CMS notified Dr. Mussaji of the legal basis for revocation of Fairway's certificate, that is, the law prohibits the owner or operator (or director) of a laboratory whose certificate has been revoked (Shadow Creek) from owning or operating (or directing) another CLIA laboratory (Fairway). F CMS Ex. 4. By his April 24, 2016 email to Ms. Pearson, Dr. Mussaji acknowledged receipt of the April 5, 2016 fax. F CMS Ex. 6, at 1.

The Board appreciates Petitioners' argument that notice of a sanction and right to appeal is only meaningful when the affected party has an opportunity to decide whether to act. Dr. Mussaji's declarations deny ever having received either the July 8, 2015 notice to

Shadow Creek or the January 12, 2016 notice to Fairway.[8] Even if we accepted these claims (which the ALJ did not find plausible in light of the evidence of successful transmission), the multiple notices Petitioners admit to receiving provided sufficient actual notice of the sanctions being imposed, the legal bases for the sanctions, and their right to seek further review of CMS's determinations to impose those sanctions by an ALJ to ensure Petitioners had the opportunity to act, had they chosen to do so. The last CMS fax notice (to Fairway) was sent on April 5, 2016. Even were we to assume that neither Petitioner was notified of its appeal rights until April 5, 2016, neither filed its request for hearing until October 14, 2016, more than six months later. We note, moreover, that, while Dr. Mussaji's April 24, 2016 email to Ms. Pearson stated that Fairway did not receive CMS's January 12, 2016 notice, it appears that by her April 25, 2016 email response (with attachment) to Dr. Mussaji, Ms. Pearson sent Fairway an electronic copy of the January 12, 2016 notice. F CMS Ex. 6, at 1.

B. *The ALJ did not abuse his discretion in determining that Petitioners did not show good cause to extend the filing due dates.*

Before the Board, Petitioners maintain that they did not, as the ALJ found, wait for an unreasonably long time without taking action, forfeiting their appeal rights. They state that because they were not provided the procedural due process that were due to them, in the form of notice of sanction and appeal rights that meets subsection 498.20(a)'s "mail" requirements, and because they allegedly did not receive the July 8, 2015 and January 12, 2016 notices CMS claims to have faxed, they have cause for not having filed their appeals earlier. Petitioners now essentially repeat what they said to the ALJ, almost verbatim. SC Br. at 20-21; F Br. at 19-20; Petitioners' responses to CMS's motions, at 15-16 (SC), 13-14 (F).

As the ALJ noted, the Part 498 regulations do not define what constitutes "good cause" to extend the filing deadline for a hearing request (42 C.F.R. § 498.40(c)). The ALJ said, however, that "good cause" has been "interpreted universally to mean a circumstance beyond a party's ability to control that prevents it from filing a timely hearing request." Ruling at 4. The ALJ then determined that Petitioners offered no credible explanation suggesting that they were prevented from taking action to challenge the revocation action due to circumstances beyond their control. *Id.*

[8] Citing 42 C.F.R. § 498.22(b)(3), Petitioners assert that, by affirmative evidence of non-receipt (Dr. Mussaji's declarations), they rebutted the presumption of receipt. SC Br. at 14; F Br. at 12. Petitioners' reliance on this regulation is misplaced. Subsection 498.40(a)(2), which states that a hearing request may be filed within 60 days, refers to subsection 498.22(b)(3). Under subsection 498.22(b)(3), for purposes of filing a request for reconsideration of an initial determination within 60 days (not the situation here), the initial determination is presumed to have been received five days after notice in the absence of evidence that it was received earlier or later. More to the point, we interpret the five-day presumption of receipt to be intended to apply in situations where, unlike the situation here, the initial determination was sent by U.S. mail, and where there is a gap in time between mailing and delivery. In contrast, certain other communication methods, e.g., email or fax, should generally result in delivery in real time, or in less time than it takes for mail to be delivered by the postal service.

The Board "has never attempted to provide an authoritative or complete definition of the term 'good cause' in section 498.40(c)." *Brookside Rehab. & Care Ctr.*, DAB No. 2094, at 7 n.7 (2007). The Board has stated, also, that it "need not decide the precise scope of 'good cause'" where the party seeking extension for late filing has "failed to establish 'good cause' for extending the deadline, under any reasonable definition of that term." *Rutland Nursing Home*, DAB No, 2582, at 5 (2014). The Board reviews an ALJ's "good cause" determination under 42 C.F.R. § 498.40(c)(2) for abuse of discretion. *Cf. Waterfront Terrace, Inc.*, DAB No. 2320, at 5 (2010); *see also* 42 C.F.R. § 498.70 (captioned "Dismissal for cause," stating that the ALJ "may" dismiss a hearing request that is untimely and for which he or she has not extended the time for filing).

Petitioners do not specifically assert that the ALJ's interpretation of "good cause" in these appeals was error or unreasonable. We find no abuse of discretion in the ALJ's determination that Petitioners offered no credible explanation for not taking action for months after they were actually put on notice of CMS's revocation actions. Petitioners' position, in essence, is that they cannot be penalized with dismissal for untimely appeal (or should not be held to the 60-day filing requirement) where they did not receive notice using the *method they assert is mandated by regulation*. However, as the ALJ indicated, the touchstone of the due process issue here is whether Petitioners "*actually had notice*" (Ruling at 4, ALJ's emphasis), that is, whether they actually knew about CMS's revocation action and the time period for appealing to the ALJ. Here, as the ALJ also said, the Petitioners do not explain why they allowed months to pass without acting after they clearly knew about the adverse action and their appeal rights.

Referring to Dr. Mussaji's email to Ms. Pearson on April 24, 2016,[9] in which Dr. Mussaji said that he "would like to appeal and request a hearing," F CMS Ex. 6, at 1, Petitioners say that they sought the assistance of an attorney after having complained to CMS that they had not received CMS's notices and after CMS "failed to process" Dr. Mussaji's April 24, 2016 email as a request for hearing.[10] SC Br. at 2 at n.2, 21; F Br. at 2 n.2, 19.

[9] At various times throughout their briefs to the Board Petitioners state that Dr. Mussaji emailed Ms. Pearson on April 21, 2016. The record indicates, however, Dr. Mussaji emailed Ms. Pearson on April 24, 2016. F CMS Ex. 6, at 1.

[10] Petitioners belatedly assert before the Board that Dr. Mussaji's April 24, 2016 email constituted requests for hearing. *See* Reply Brs. at 7-8. This argument is to no avail. Below, Petitioners did not make the assertion. The Board does not consider issues that could have been presented to the ALJ but were not. *Guidelines*. In any event, aside from the fact that April 24, 2016 was after Dr. Mussaji was indisputably given actual notice that the appeal periods had passed and both certificates had been revoked, Petitioners do not even articulate how the April 24, 2016 email to Ms. Pearson constituted a valid request for hearing. The first fax notice to Shadow Creek, sent April 8, 2015 (the receipt of which Shadow Creek effectively acknowledged by responding to it by submitting a POC), informed Dr. Mussaji that a hearing request must be filed, in writing, with the Civil Remedies Division of the Departmental Appeals Board, and, using language that closely tracks that in 42 C.F.R. § 498.40(b), explained the content requirements of a valid hearing request. SC CMS Ex. 1, at 57.

But, as discussed, it appears that by email on April 25, 2016, Ms. Pearson sent Dr. Mussaji the January 12, 2016 notice for Fairway which explained the process for filing an appeal. F CMS Ex. 6, at 1. In any case, before Ms. Pearson emailed Dr. Mussaji on April 25, 2016, that is, by April 5, 2016 at the latest (the last CMS fax notice to Fairway), Dr. Mussaji was put on actual notice that CMS had no record of appeal in either case and that both of his laboratories' certificates had been revoked. But neither laboratory filed its hearing request until October 14, 2016.

Petitioners' complaint and explanation about retaining an attorney do, however, come close to being a concession that the reason they did not act sooner after the last fax on April 5, 2016 is that Petitioners failed to obtain legal counsel sooner. It is Petitioners' right to obtain legal representation at any stage of the revocation proceedings and for appeal of revocation. As early as April 8, 2015 (fax to Shadow Creek), Dr. Mussaji was informed, "You may be represented by counsel at a hearing at your own expense." SC CMS Ex. 1, at 57. The right to counsel, however, does not entitle Petitioners to sit on their appeal rights indefinitely without seeking or receiving an extension. Nothing in the record suggests that either Petitioner even claimed that it was delayed in appealing because Dr. Mussaji was seeking legal advice, let alone that Dr. Mussaji asked the ALJ at any time to allow more time to appeal so that he could retain an attorney.

We also note Petitioners' argument in support of good cause that, by its October 30, 2015 fax to Shadow Creek stating that there was "nothing CMS can do to reactivate your CLIA number" (SC CMS Ex. 8), CMS "wrongly instructed" the laboratories to "take no action." SC Br. at 21; F Br. at 19-20. Shadow Creek made this argument below, in its response to CMS's motion to dismiss, at 16. It is evident that CMS's October 30, 2015 fax to Shadow Creek was sent in response to Dr. Mussaji's September 29, 2015 email and his October 20, 2015 letter reporting that corrective actions were made and requesting a site visit to Shadow Creek. SC CMS Ex. 7, at 1; SC P. Ex. 3, at 1. CMS's statement that there was "nothing CMS can do to reactivate" was intended only to convey that Shadow Creek had not appealed and revocation already had taken effect.

Lastly, Petitioners allege that the ALJ erred by not finding good cause given that CMS failed to file objections to Petitioners' request for extension of time to appeal (based on non-receipt of CMS's notices) as the ALJ instructed CMS to do in his October 28, 2016 Acknowledgment and Order. According to Petitioners, CMS's failure to file objections should have been reason enough for the ALJ to grant the extension. SC Br. at 17; F Br. at 15-16. But Petitioners disregard that, by moving to dismiss both hearing requests for untimeliness, CMS effectively communicated its position – that CMS did indeed object to extension of time. The ALJ had discretion to accept CMS's motions as responsive to his Order (and he apparently did), but, more importantly, it was within his discretionary authority to conclude, ultimately, that dismissal is proper for untimely appeal and for lack of credible explanation of good cause for late filing.

Conclusion

The Board sustains the ALJ's Ruling dismissing Petitioners' requests for hearing.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Susan S. Yim
Presiding Board Member