Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Beata Kwiatkowska, M.D.,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-17-174

ALJ Ruling No. 2017-8

Date: February 1, 2017

RULING

I deny the request for an extension of time to file a request for hearing filed by Petitioner, Beata Kwiatkowska, M.D., because Petitioner did not establish good cause to extend the time for filing. 42 C.F.R. §§ 498.40(a)(2), (c); 498.70(c).

I. Background and Procedural History

Petitioner is a pathologist who served as the laboratory director of Quick Biodiagnostic Laboratory (QBL) in Las Vegas, Nevada. QBL participated in the Medicare program and held a CLIA certificate under the provisions of the Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a *et seq*.

On May 4, 2016, surveyors from the State of Nevada Department of Health and Human Services, Division of Public and Behavioral Health (state agency), conducted a survey of QBL and found that it was not in substantial compliance with four conditions of participation for the CLIA program. The state agency also found that QBL was out of compliance with various standard-level CLIA requirements. Petitioner Exhibit (P. Ex.) B. In a letter dated June 14, 2016, the state agency notified QBL of the deficiencies and provided it with a Form CMS-2567 (Statement of Deficiencies), which listed all of the

deficiencies. The state agency advised QBL that the seriousness of the deficiencies warranted a finding of immediate jeopardy to patient health and safety, and requested that QBL take immediate action to abate the immediate jeopardy, bring any unmet condition-level requirements into compliance, and submit a credible allegation of compliance and acceptable evidence of correction within 10 days of receipt of the notification letter. *See* P. Ex. C. QBL requested, and received, two extensions of the deadline to submit a response to the state agency's June 14, 2016 letter, and it submitted a response to the state agency on July 7, 2016. The state agency, QBL's general supervisor (Balbir S. Bhogal), and Petitioner participated in a telephonic conference call on July 11, 2016, at which time the state agency provided notice that QBL's submission did not constitute a credible allegation of compliance and acceptable evidence of correction, and did not demonstrate that the immediate jeopardy had been abated. Petitioner requested that QBL be given another opportunity to submit a plan of correction and evidence of correction, and the state agency granted the request. On July 13, 2016, QBL submitted its second plan of correction and allegation of compliance, which the state agency again deemed to be inadequate. The state agency notified QBL of its determination by letter dated July 20, 2016, and referred the case to the Centers for Medicare & Medicaid Services (CMS), recommending sanctions against QBL's CLIA certificate. P. Ex. C.

On July 19, 2016, Petitioner informed QBL, through an email message to Mr. Bhogal, that she would be resigning as QBL's laboratory director, effective September 1, 2016. P. Ex. D.

In a letter dated July 25, 2016, CMS notified Petitioner that it concurred with the state agency's findings and had proposed sanctions that included revocation of QBL's CLIA certificate, suspension of its certificate, a civil money penalty (CMP), and cancellation of QBL's approval to receive Medicare payments. CMS's letter also notified Petitioner of the following:

> Also, under revocation, 42 U.S.C. § 263a(i)(3) and 42 C.F.R. § 493.1840(a)(8) prohibit the owners or operator(s) (including the laboratory director – see 42 C.F.R. § 493.2) from owning or operating (or directing) a laboratory for at least two years from the date of the revocation. *This prohibition applies to the owner(s) as well as the laboratory director at the time the deficiencies were found which led to the current sanction actions.*

P. Ex. F at 4 (emphasis added). CMS informed Petitioner that QBL had until August 4, 2016, to submit, in writing, any evidence or information as to why the sanctions should not be imposed. Petitioner submitted responses on August 2 and 11, 2016, both of which were signed by Petitioner and Mr. Bhogal. P. Exs. G, H.

In a letter dated August 15, 2016, Petitioner informed the state agency that she would resign as QBL's laboratory director, effective September 1, 2016. P. Ex. I.

On September 16, 2016, CMS sent a letter addressed to both Petitioner and Varinder Singh, QBL's owner, in which it informed them that QBL's previous submission did not constitute a credible allegation of compliance and acceptable evidence of correction. The letter further stated that QBL did not demonstrate that the immediate jeopardy had been abated.[1] P. Ex. J. CMS advised that it was imposing the following sanctions against QBL: revocation of its CLIA certificate; suspension of its CLIA certificate; a CMP; a directed portion of a plan of correction; and cancellation of the laboratory's approval to receive Medicare and Medicaid payments for all laboratory services.[2] CMS's notice letter again advised, as had been included in the July 25, 2016 notice of proposed sanctions, that if a laboratory's CLIA certificate is revoked, the laboratory owner and operator, to include the laboratory director, would be prohibited from owning or operating another laboratory for a two-year period. P. Ex. J at 11. The notice further stated:

> By letter dated August 15, 2016, the State agency received notice from Dr. Kwiatkowska that as of September 1, 2016, she would no longer be the laboratory director. Because she was the laboratory director at the time of the May 4, 2016 CLIA recertification survey, Dr. Kwiatkowska, as well as the laboratory's owner, Varinder Singh, will be subject to the two-year prohibition.

Id. The CMS notice letter also contained a separate section which explicitly advised Petitioner of the right to request a hearing:

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[1] CMS sent the notice letter via facsimile and by first class mail. Petitioner acknowledges that she received the letter on September 16, 2016. P. Mot. at 4 ¶ 11.

[2] CMS's notice letter discussed the effective dates of the sanctions; however, I do not mention them because they are not relevant to the issues I must decide.

> **Appeal Rights**
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> If Quick Biodiagnostic Laboratory does not believe that the determination upon which imposition of the sanction is based is correct, the laboratory may request a hearing before an administrative law judge (ALJ) of the Departmental Appeals Board (DAB) in accordance with 42 C.F.R. §§ 493.1844 and 498.40-.78.
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> A request for hearing must be filed **electronically** no later than **sixty (60) calendar days** after the date this letter is received . . . . You should file your request for an appeal (accompanied by a copy of this letter) via the DAB Electronic Filing System website . . .
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> * * *
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> As noted above, if a timely request for hearing is filed, i.e., by **November 15, 2016**, CMS will not revoke the CLIA certificate until after an ALJ hearing that upholds the sanction determination.

P. Ex. J. at 11 (emphasis in original).

Petitioner sent a letter to CMS, dated September 24, 2016, in which she acknowledged CMS's September 16, 2016 notice letter and stated that she had resigned as the laboratory's director. Petitioner reported that she "was relieved from all of [her] responsibilities as of 9/1/2016" and that she resigned "primarily due to the total lack of honesty and cooperation on the part of [laboratory supervisor] Dr. Balbir S. Bhogal." Petitioner stated that she would forward CMS's notice of imposition of sanctions to QBL and asserted that she "never jeopardized any patient knowingly or unknowingly." P. Ex. K. In email correspondence to the state agency dated October 13, 2016, Petitioner stated that she would be willing "to take full responsibility for the deficiencies committed under [her] directorship" and asked for an opportunity to submit a revised plan of correction. Petitioner also explained that Mr. Bhogal did not want her to be involved in any laboratory activities with QBL. P. Ex. L.

On November 18, 2016, CMS issued a notice letter to Petitioner and Mr. Singh, advising that the deadline for filing an appeal had expired without the filing of an appeal, and as a result, the sanctions imposed in the September 16, 2016 notice were final. Among other things, the notice reiterated that the two-year mandatory prohibition regarding owning or

operating (or directing) any laboratory would commence on November 15, 2016, and conclude on November 14, 2018. The notice also directed Petitioner to resign from any other laboratory directorships and set a deadline of December 5, 2016, to provide evidence of the resignation(s). P. Ex. M. At Petitioner's request, CMS extended this deadline to December 31, 2016. P. Ex. N.[3]

On December 6, 2016, Petitioner, through counsel, filed a motion requesting an extension of time to file a substantive appeal (P. Mot.) with supporting documents labeled as P Exs. A-N. Petitioner conceded that her request was untimely filed and requested an extension until February 1, 2017, to file a substantive appeal, claiming that good cause existed for an extension. I issued an order on December 15, 2016, acknowledging receipt of Petitioner's December 6, 2016 request and directing CMS, by January 13, 2017, to file a response to Petitioner's request for an extension of the filing deadline.

On January 13, 2017, CMS filed its opposition to Petitioner's request (CMS Br). Petitioner filed a reply on January 17, 2017, at which time she requested "until March 1, 2017 to file her substantive appeal." [4]

II. Issues

The general issue here is whether I should grant Petitioner's request for an extension of time to file a request for hearing. The specific issues that I must decide are whether Petitioner has filed a timely request for hearing, and if not, whether Petitioner has good cause to file a late request for hearing.

III. Analysis

Administrative hearings in cases involving challenges to determinations to impose sanctions pursuant to CLIA, including revocation of a CLIA certificate, are governed by regulations at 42 C.F.R. Part 498; *see* 42 C.F.R. § 493.1844(a), (b). Under these

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[3] On December 16, 2016, Petitioner filed a motion seeking a stay of the requirement that she resign from any laboratory directorships she currently held, by December 31, 2016. On December 22, 2016, I issued an order denying Petitioner's motion for a stay and directed CMS, no later than December 29, 2016, to review Petitioner's request and provide notice whether it would grant an extension of the deadline for this requirement. On December 27, 2016, CMS filed a notice denying Petitioner's request for a further extension of time to resign from any laboratory directorship(s) that she currently held.

[4] In my December 15, 2016 Order, I did not offer Petitioner an opportunity to submit a reply. As I see no prejudice to CMS by accepting the reply, I will accept the reply.

regulations, a party affected by an adverse determination must file its request for hearing no later than 60 days from the date that it receives notice from CMS. 42 C.F.R. § 498.40(a)(2). Receipt of the notice is presumed to be five days after the date of notice unless shown otherwise. 42 C.F.R. § 498.40(a)(2); 42 C.F.R. § 498.22(b)(3). An affected party may request that an ALJ extend the date to file a hearing request; however, the affected party must show good cause in order for the ALJ to grant such a request. 42 C.F.R. § 498.40(c). If a hearing request is untimely and there is no good cause to extend the filing date, then an ALJ may dismiss the hearing request. 42 C.F.R. § 498.70(c).

A. Petitioner did not file a timely hearing request.

CMS's notice letter imposing sanctions against QBL is dated September 16, 2016. Petitioner acknowledges that she received CMS's notice on September 16, 2016. P. Mot. at 4, ¶ 11. Petitioner thus had 60 days from receipt of the notice, until November 15, 2016, to file a hearing request. 42 C.F.R. § 498.40(a)(2). Petitioner filed her request for an extension of time to file a request for hearing on December 6, 2016, which is 21 days after the filing deadline. Petitioner concedes that she did not file a timely hearing request, but argues that good cause exists to extend the filing deadline. As Petitioner did not file a hearing request prior to the November 15, 2016 deadline, I find that Petitioner has not timely filed a request for hearing.

B. Petitioner did not establish good cause for an extension of the regulatory deadline for filing a hearing request.

If an affected party establishes that there is good cause to extend the filing date for a hearing request, then an ALJ may accept an otherwise untimely hearing request. 42 C.F.R. § 498.40(c). The regulations do not define what constitutes "good cause" to extend the filing deadline, and the Departmental Appeals Board (Board) "has never attempted to provide an authoritative or complete definition of the term 'good cause' in section 498.40(c)(2)." *Brookside Rehab. & Care Ctr.*, DAB No. 2094 at 7 n.7 (2007) (citing *Glen Rose Med. Ctr. Nursing Home*, DAB No. 1852 at 7 n.5 (2002)). Rather, an adjudicator must consider the relevant circumstances of each case to determine whether there is "good cause" to extend the filing deadline. *See NBM Healthcare, Inc.*, DAB No. 2477 at 3-4 (2012) ("[T]he facts of this case do not show good cause under 'any reasonable definition of that term.'").

Petitioner makes several arguments that good cause exists to justify extending the time for filing. She contends that after she resigned as QBL's laboratory director, she was denied access to QBL's records, and was also instructed by Mr. Bhogal not to respond to

CMS's notice letter. P. Mot. at 5, 7. Petitioner further argues that she was "[u]nrepresented, unsophisticated to the administrative process, and unaware of the exacting personal consequences she faced" if the laboratory did not file a hearing request. P. Mot. at 7.

I conclude that Petitioner's reasons for failing to file a timely hearing request do not constitute good cause to extend the filing deadline. Dismissal of a hearing request is appropriate where the determination clearly explained the filing requirements and deadlines to the petitioner.[5] *Waterfront Terrace*, DAB No. 2320, at 6, 8 (2010) (holding that no good cause existed to justify extending the filing deadline where the notice letter reasonably informed the petitioner of its appeal rights.)

Here, CMS's September 16, 2016 notice letter clearly notified both Petitioner and QBL's owner of appeal rights, and explained that a hearing request needed to be filed no later than 60 days from the receipt of the notice. Further, it explicitly advised that the deadline for filing a timely hearing request was November 15, 2016. Petitioner does not deny that she was provided clear notice of the right to appeal and detailed instructions for submitting her request. Nor does she contend that she did not understand those instructions.

Petitioner's contention that she lacked access to QBL's records after she resigned as laboratory director does not constitute good cause to extend the time for filing a hearing request. While a lack of access to records may have ultimately necessitated the issuance of a subpoena to procure testimony and certain records if a timely hearing request had been filed, Petitioner has not demonstrated that a lack of access to records prevented her from meeting the basic requirements for filing a request for hearing. As the Board has previously explained, "[a] request for hearing must identify 'the specific issues, and the findings of fact and conclusions of law with which the affected party disagrees,' and specify 'the basis for contending that the findings and conclusions are incorrect.'" *Kids Med (Delta Medical Branch)*, DAB No. 2471 at 1 (2012), *citing* 42 C.F.R. § 498.40(b).

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[5] Petitioner's motion was accepted as a request for hearing by the Civil Remedies Division. Civil Remedies Division Procedures, § 2.(d.) (stating that "[c]ases are docketed upon receipt of a request for an ALJ hearing"). Petitioner's uploaded its motion as a "request for hearing" in DAB E-File, and it is identified on DAB E-File, under the first docket entry, as a "Request for Hearing." Further, CMS has not disputed the docketing of Petitioner's motion as a request for hearing (arguing that Petitioner's "request for hearing should be dismissed pursuant to 42 C.F.R. § 498.70(c)"). CMS Br. at 8. For purposes of this discussion, I am ruling on Petitioner's motion for an extension of time to file a request for hearing, as well as considering and ruling on whether Petitioner's construed request for hearing is timely.

By her own admission, and, as evidenced by the exhibits she filed with her request for an extension of time, Petitioner was actively involved in preparing QBL's responses to the state agency and CMS after the survey. She prepared the plans of correction following the May 4, 2016 survey, and she also assisted with preparing further submissions to CMS in response to CMS's July 25, 2016 notice of proposed sanctions. P. Mot.; P. Exs. F, G, H; *see* P. Ex. C. Given the extensive detail in those submissions, it is evident that Petitioner was well acquainted with the deficiencies cited by CMS and with QBL's records regarding those deficiencies. Even if Petitioner did not have access to specific documents pertaining to QBL's laboratory activities, she had enough firsthand knowledge to submit a request for hearing in which she could identify the basis for her disagreement with the September 16, 2016 determination. *See* 42 C.F.R. § 498.40(b). Moreover, Petitioner has not argued that she unsuccessfully sought access to specific documentation during the 60-day regulatory time period that would be necessary for her to file a request for hearing, nor has she identified any specific documents in the custody or control of QBL that she needed to prepare a hearing request. Furthermore, if there were any documents in the custody or control of QBL that Petitioner needed in order to submit a hearing request that met the requirements of 42 C.F.R. § 498.40(b), Petitioner could have requested an extension of time for filing her hearing request, prior to the 60-day deadline, to allow her time to obtain these records. 42 C.F.R. § 498.40(c). However, at no time prior to the expiration of the deadline to file a timely request for hearing did Petitioner act to preserve her right to a hearing.

Petitioner also contends that Mr. Bhogal instructed her not to respond to the September 16, 2016 letter or otherwise misled her into believing that QBL would file a hearing request on her behalf. These contentions, even if true, do not constitute good cause to extend the time for filing a hearing request. CMS addressed its notice letters to both Petitioner and QBL's owner, Mr. Singh, and clearly advised Petitioner of the adverse consequences that she personally faced as a result of the revocation of QBL's CLIA certificate. CMS's July 25, 2016 notice of proposed sanctions put Petitioner on notice that she, as the laboratory director, would be subject to a two-year prohibition on serving in a similar position at any other laboratory from the date of revocation. Further, CMS's September 16, 2016 notice not only reiterated this information, but explicitly advised Petitioner that she was subject to this prohibition because she was the laboratory director at the time of the May 4, 2016 CLIA survey. Petitioner was provided with a detailed

explanation of appeal rights and instructions on filing an appeal in CMS's letter. Thus, Petitioner had notice of the adverse consequences that she personally faced, and she failed to timely take the measures necessary to preserve her hearing rights, regardless of Mr. Bhogal's preferences.[6] Her failure to timely act does not establish good cause.

Finally, I am unpersuaded by Petitioner's claim that she was "unrepresented, unsophisticated to the administrative process, and unaware of the exacting personal consequences" of failing to file a request for hearing. P. Mot. at 7. As the laboratory director of other laboratories besides QBL, Petitioner would presumably have been involved with other surveys, and, as such, cannot claim to be so unfamiliar with CLIA regulations or the administrative process. Petitioner has not identified anything that prevented her from hiring counsel other than her own lack of diligence. In fact, Petitioner eventually did retain counsel, and that counsel filed the untimely request for an extension of time to file the hearing request.[7] Indeed, if Petitioner had difficulty in retaining representation, she could have simply filed a timely hearing request on her own, accompanied by a request for an extension of the 60-day filing deadline in order to supplement it once she obtained counsel. Petitioner, however, failed to take any action to preserve her hearing rights.

Furthermore, as discussed above, I reject Petitioner's claim that she was unaware of the "personal consequences" that would result if she failed to timely file a hearing request. CMS clearly informed Petitioner of the personal and adverse consequences that she faced if QBL's CLIA certificate was revoked. At the time CMS issued its July 25, 2016 notice of proposed sanctions, CMS warned Petitioner that the owners, operators, and director of a laboratory with a revoked CLIA certificate are prohibited from owning, operating, or directing another CLIA laboratory for a period of two years. Moreover, if Petitioner was uncertain if she would be the subject of the aforementioned prohibition, CMS's September 16, 2016 notice letter left no doubt that she would face a two-year prohibition

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[6] As CMS notes, Petitioner's claim that she believed that QBL would file a request for hearing on her behalf is inconsistent with her statement that she resigned as laboratory director due to Mr. Bhogal's "lack of honesty and cooperation." CMS Br. at 6 n.4; P. Ex. K.

[7] In the motion requesting an extension of the time to file a request for hearing, Petitioner's counsel states: "Naively, [Petitioner] did not retain counsel until November 28, 2016, after the sanctions became final." P. Mot. at 5 n.3. Petitioner is a physician who was advised, on more than one occasion, that she could be subject to a prohibition of serving as a laboratory director for two years. The evidence does not support that Petitioner is naïve or that, in the absence of counsel, she was ignorant of the potential repercussions of her failure to timely file a request for hearing.

because she was the laboratory director at the time of the May 4, 2016 CLIA survey. Despite Petitioner's claim of ignorance, she cannot deny that she was clearly warned by CMS of the "personal consequences" that would result from the revocation of QBL's CLIA certificate. If Petitioner was unaware that she faced such a two-year prohibition, it is because she did not read CMS's letters in their entirety.

Although Petitioner did not explicitly argue that her September 24, 2016 letter to CMS should be accepted as a timely request for hearing, I have nonetheless considered whether Petitioner's letter could constitute a request for a hearing. This letter does not express a desire for a hearing pursuant 42 C.F.R. § 498.40(b), nor does it support Petitioner's argument that the deadline to file a request for hearing should be extended based on good cause. In her letter, Petitioner acknowledged receipt of CMS's September 16, 2016 notice letter and informed CMS, for a second time, that she had resigned as the laboratory director. Among other things, Petitioner stated that she will forward CMS's letter to QBL and discussed that she never jeopardized patient care. P. Ex. K. Nowhere in this letter does Petitioner directly challenge any of the deficiencies cited by CMS. Moreover, there is nothing in her letter that expresses any wish or intention to request a hearing, nor does the letter comply with the requirements for a hearing request that were addressed in CMS's September 16, 2016 letter. Petitioner's September 24, 2016 letter thus cannot be reasonably construed to be a hearing request. *See Kids Med,* DAB No. 2471 at 4-5.

I conclude that Petitioner's explanations for the untimely filing of a hearing request do not fall within any reasonable definition of the term "good cause" as set out in 42 C.F.R. § 498.40(c)(2). The Board has consistently ruled that where, as here, a party consciously chooses for reasons of its own not to request a hearing, it must accept the consequences of its inaction. *Hammonds Lane Ctr.,* DAB No. 1853, at 1 (2002); *Hillcrest Healthcare, L.L.C.,* DAB No. 1879 (2003). Because Petitioner has made no showing of good cause for filing her request for an extension of the filing deadline 21 days after the expiration of the 60-day deadline for filing a request for hearing, I cannot extend the filing deadline for the hearing request based on good cause.

IV. Conclusion

Petitioner has not shown that an extension of the filing deadline is warranted based on good cause. Therefore, I deny Petitioner's motion for an extension of the filing deadline. To the extent Petitioner's submission may be construed as a request for hearing, I dismiss Petitioner's hearing request pursuant to 42 C.F.R. § 498.70(c).

_______/s/________________
Leslie C. Rogall
Administrative Law Judge