Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Oakes Family Care, LLC d/b/a The Doctor's Office,[1]

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1974

Decision Number CR3617

Date: February 4, 2015

DECISION

Oakes Family Care, LLC (Petitioner), submitted an application to enroll in the Medicare program as a Federally Qualified Health Center (FQHC). With its application, Petitioner requested a hardship exception from paying the required application fee. The Centers for Medicare & Medicaid Services (CMS) denied Petitioner's request for a hardship exception. Petitioner requested a hearing to dispute CMS's determination. For the reasons stated below, I conclude that Petitioner has not sufficiently substantiated its claim of hardship. Accordingly, I affirm CMS's determination to deny Petitioner's request for a hardship exception.

[1] The Civil Remedies Division originally captioned this case with Luther Brandon Oakes, M.D., as Petitioner. However, both parties have noted in their briefs that Dr. Oakes is not properly the Petitioner in this case. Although Dr. Oaks is the owner of Oakes Family Care, LLC (Petitioner's Brief at 1 n.1), the relevant enrollment application filed in this case is a CMS-855A, which is for an institutional provider, i.e., Oakes Family Care, LLC d/b/a The Doctor's Office, and not an individual, i.e., Dr. Oaks. Centers for Medicare & Medicaid Services Exhibit 1. Because Oakes Family Care, LLC, is the actual Petitioner in this case, I amend the caption as indicated above.

I. Background and Procedural History

On May 8, 2014, Petitioner filed an application to enroll in Medicare as a FQHC. CMS Exhibit (Ex.) 1. Petitioner submitted a letter with its application asking CMS for a hardship exception from paying the required application fee because "Oakes Family Care, LLC is operating in its initial year and would have difficulty paying the application fee of $542.00." CMS Ex. 1 at 1. Petitioner attached a profit and loss statement from October 1, 2013 (the business start date) through May 8, 2014 (the date the enrollment application was signed), which Petitioner stated "reflects the company's financial losses of $5,145.30." CMS Ex. 1 at 1-2.

On July 30, 2014, CMS denied Petitioner's request for a hardship exception due to "[i]nsufficient documentation demonstrating financial hardship." CMS Ex. 2. On August 5, 2014, Petitioner requested reconsideration, enclosing a 2013 tax document (Form 1040, Schedule C Profit and Loss from Business) showing a loss of $28,582. Petitioner stated that "our clinic cannot afford a $542 fee at this time since Oakes Family Care is in its infancy with our opening date of October 1, 2013 less than one year ago." CMS Ex. 3.

On August 25, 2014, CMS denied Petitioner's request for reconsideration. CMS Ex. 4. CMS stated the following:

> All of the documentation in the file for this case has been reviewed and the decision has been made in accordance with Medicare guidelines as outlined in this letter. The 2013 Form 1040 Schedule C does not include any financial information for the current year, 2014, when your Medicare CMS-855A application was submitted. Without current financial information we are unable to determine if Oakes Family Care meets the conditions for a hardship exception to the application fee requirement.

CMS Ex. 4 at 1.

On September 22, 2014, the Civil Remedies Division received Petitioner's request for hearing (RFH). In the RFH, Petitioner asserted that:

> The $542 application fee is excessive for our clinic to afford. As you may know, we are located and serve the residents in Greenville, Mississippi, a rural area of the country in dire need of Physician aid. In addition, we are in our initial phase of operations. To be deemed a Rural Health Clinic would be

> greatly beneficial in further assisting the surrounding Delta communities, but we *cannot* afford the $542 application fee.

RFH (emphasis in original). Enclosed with the RFH was Petitioner's profit and loss statement as of September 12, 2014, showing a loss of $17,252.73.

The case was assigned to me for hearing and decision. In response to my October 6, 2014 Acknowledgment and Pre-Hearing Order (Pre-Hearing Order), on November 10, 2014, CMS filed a motion for summary judgment (CMS Mot.) and four proposed exhibits (CMS Exs. 1-4). On December 8, 2014, Petitioner filed a motion for summary judgment (P. Mot.) and three proposed exhibits (P. Exs. 1-3). CMS filed objections to Petitioner's exhibits and a response to Petitioner's motion (CMS Resp.).

II. Evidentiary Ruling

Petitioner did not object to CMS Exs. 1-4 and CMS did not object to P. Ex. 2. Therefore, I admit those exhibits into the record.

CMS timely objected to P. Exs. 1 and 3. P. Ex. 1 is an email exchange between Dr. Oakes and a CMS employee concerning the type of evidence that could be used to prove financial hardship for an exception to the enrollment application fee and Petitioner's profit and loss statement as of September 12, 2014, showing a loss of $17,252.73. P. Ex. 3 is an "Aging Report By Patient" that shows Petitioner has $31,197.06 in accounts receivables that were more than 120 days old as of December 3, 2014. *See* P. Mot. at 3. CMS argues that Petitioner failed to show good cause in order for me to admit evidence at this stage of the appeal process and the exhibits are irrelevant because they are dated after CMS rendered the reconsidered determination in this matter. CMS Resp. at 3. For the reasons stated below, I find good cause for Petitioner's submission of evidence at the administrative law judge level (ALJ) of appeal and conclude that the evidence is relevant to this case.

A provider or supplier may appeal CMS's determination concerning a hardship exception to an enrollment application fee in the same manner as they would appeal the denial or enrollment or the revocation of Medicare billing privileges.[2] 42 C.F.R. § 424.514(h)(2). Such appeals must follow the procedures in 42 C.F.R. Part 498. 42 C.F.R. § 405.803(a). The regulations also direct providers and suppliers to submit all evidence they want CMS to consider at the time they file their request for reconsideration. 42 C.F.R. § 405.803(c).

[2] The regulation at 42 C.F.R. § 424.514(h)(2) indicates providers and suppliers have appeal rights in hardship exception cases as provided in 42 C.F.R. § 405.874. However, in 2012, the Department of Health and Human Services re-codified the provisions in 42 C.F.R. § 405.874 as 42 C.F.R. §§ 405.800-405.818 but did not update the cross-reference in 42 C.F.R. § 424.514(h)(2). 77 Fed. Reg. 29,001 (Mar. 16, 2012).

If a provider or supplier does not submit supporting evidence with the reconsideration request, then CMS must contact the provider or supplier to obtain the evidence. 42 C.F.R. § 405.803(d). If the provider or supplier fails to submit the evidence before CMS renders the reconsidered determination, the provider or supplier cannot introduce evidence at the ALJ level of appeal unless good cause exists. 42 C.F.R. §§ 405.803(e); 498.56(e).

In the context of hardship exceptions, the regulations only require providers and suppliers to "include with its enrollment application a letter that describes the hardship and why the hardship justifies an exception." 42 C.F.R. § 424.514(f). However, CMS, in its Medicare Program Integrity Manual (MPIM), requires that the providers and suppliers provide "comprehensive documentation" of their financial situation. MPIM § 15.19.1(C)(2). Although CMS may require a provider or supplier to provide evidence to support the hardship request, it must first notify the provider or supplier of this requirement and the MPIM is not sufficient to provide this notice. *Dr. S.A. Brooks, DPM*, DAB No. 2615 at 9 (2015).

> While the NSC Hearing Officer gave Petitioner an opportunity to submit "additional evidence" to support her request for reconsideration, moreover, neither NSC nor the Hearing Officer prior to issuing the reconsideration decision informed her about the kind of documentation that might be needed to support her arguments or clarified the manual provision and where it could be found. The Hearing Officer's reconsideration determination did quote the part of section 15.19.l.C.2. of the Program Integrity Manual that refers to "comprehensive documentation (which **may include, without limitation**, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.)." *Id*. at 2 (emphasis added). This statement, as noted above, is not entirely clear about what documentation was required in any particular circumstance. But, in any event, the Hearing Officer's determination contained no analysis of why the tax forms and other documents Petitioner had already submitted were not sufficient to meet this description.

Dr. S.A. Brooks, DPM, DAB No. 2615 at 15 (2015).

The present case has similarities to *Brooks*. The initial determination denying the hardship waiver request merely stated that Petitioner provided insufficient documentation demonstrating financial hardship. Although the initial determination indicated that Petitioner could submit a reconsideration request and quoted the same portion of the

MPIM concerning comprehensive documentation as noted above in the *Brooks* case (CMS Ex. 2 at 1), *Brooks* indicates that this quotation is not entirely clear as to what documents ought to be submitted.

Petitioner submitted a 2013 Form 1040 Schedule C with its reconsideration request. CMS Ex. 3. However, the reconsidered determination disregarded this evidence because CMS stated that it was not from the then current year, 2014, and informed Petitioner that CMS could not determine if Petitioner met the conditions for a hardship exception without current financial information. CMS Ex. 4 at 1. Dr. Oakes emailed the CMS employee who rendered the reconsidered determination and informed him that "I have received varying information when calling CMS as to the documents desired and needed for review . . . . Can I submit additional documents to support my case?" P. Ex. 1 at 2. The CMS employee responded on September 12, 2014, stating that Petitioner may submit evidence to the Departmental Appeals Board and that "it is recommended to include information available to you that support the need for the [hardship] exception (this includes current tax information, bank statements, budget information)." P. Ex. 1 at 2. Dr. Oakes responded to the CMS employee asking if a profit and loss sheet generated on September 12, 2014, which was attached to the email, was sufficient documentation to submit. P. Ex. 1 at 1, 4-5. The CMS employee replied on September 15, 2014 and stated that "this is information that would be useful when determining a hardship decision"; the employee then provided Petitioner with a link to the MPIM. P. Ex. 1 at 1.

Consistent with these emails, Petitioner's RFH specifically references its inclusion of the September 12, 2014 profit and loss sheet Dr. Oaks provided to the CMS employee by email because "my previous requests lack 2014 financial data." Also, apparently utilizing information from the MPIM, Petitioner submitted as an exhibit with its prehearing exchange a document concerning what Petitioner has termed as its "bad debts." P. Mot. at 3; P. Ex. 2 at 4; P. Ex. 3.

Although *Brooks* involves a different issue related to notice of the requirement to submit documentation to support a hardship exception request, I cannot overlook the concerns raised in *Brooks.* As a result, I must conclude that Petitioner has shown good cause for filing additional evidence at the ALJ level of review.

I also find P Exs. 1 and 3 to be relevant to this case. As described above, P. Ex. 1 includes email exchanges that directly related to whether Petitioner has good cause for submitting its documents late. Further, as discussed below in more detail, I agree with the CMS employee who conducted the reconsidered determination that the September 12, 2014 profit and loss sheet is useful in considering whether Petitioner should receive a hardship exception to the enrollment application fee. Further, Petitioner's "bad debt" documentation is potentially useful because it includes debts 120 days and older, thus providing information concerning much of 2014. Therefore, I admit P. Exs. 1 and 3 into the record. 42 C.F.R. §§ 498.56(e)(2), 498.60(b).

III. Decision on the Record

Neither party indicated that they sought to introduce testimony from witnesses. My Order advised the parties that they must submit written direct testimony for each proposed witness and that an in-person hearing would be necessary only if the opposing party requested an opportunity to cross-examine a witness. Pre-Hearing Order ¶¶ 8-10. Because neither party submitted written direct testimony, I issue a decision on the written record. Pre-Hearing Order ¶ 11; *Marcus Singel, D.P.M.*, DAB No. 2609, at 5-6 (2014). Because I am deciding this case on the written record, it is unnecessary for me to consider whether summary judgment is appropriate.

IV. Issue

The only issue in this case is whether Petitioner is entitled to a hardship exception from paying the $542 Medicare enrollment application fee.

V. Jurisdiction

I have jurisdiction to decide this issue. As discussed earlier, the regulations at 42 C.F.R. § 404.803(a) state that provider and supplier enrollment appeals are governed by the procedures in 42 C.F.R. Part 498. Under those procedures, a provider or supplier who is dissatisfied with a reconsidered determination related to enrollment may request a hearing before an ALJ. 42 C.F.R. § 498.5(l), 498.40.

VI. Discussion

CMS properly exercised its discretion to deny Petitioner's request for hardship exception because Petitioner has failed to meet its burden to prove hardship to pay the $542 application fee.[3]

Section 6401(a) of the Affordable Care Act requires the Secretary of Health and Human Services (Secretary) to "include screening of providers and suppliers" as part of the Medicare enrollment process. 42 U.S.C. § 1395cc(j)(1)(A). The Secretary "shall impose a fee on each institutional provider of medical or other items or services or supplier . . . with respect to which screening is conducted . . ." 42 U.S.C. § 1395cc(j)(2)(C)(i). An applicant seeking enrollment in the Medicare program as a FQHC is subject to the application fee. 76 Fed. Reg. 5861, 5910-11 (Feb. 2, 2011). The application fee is used "for program integrity efforts, including to cover the cost of conducting screening . . ." 42 U.S.C. § 1395cc(j)(2)((C)(iii). The application fee is adjusted annually based on

[3] I make this one finding of fact/conclusion of law.

changes in the consumer price index. 42 U.S.C. § 1395cc(j)(2)(C)(i); 42 C.F.R. § 424.514(d)(2). The application fee for Medicare enrollment in 2014 was $542. MPIM § 15.19.1.B.

The Secretary is authorized to except an institutional provider or supplier from imposition of the application fee on a case-by-case basis if the Secretary "determines that the imposition of the application fee would result in a hardship." 42 U.S.C. § 1395cc(j)(2)(C)(ii). The Secretary delegated to CMS the authority to grant a hardship exception. 42 C.F.R. § 424.514(h). The regulations allow an applicant to request a hardship exception to the application fee at the time of filing a Medicare enrollment application. 42 C.F.R. § 424.514(b)(2). CMS has 60 days from receipt of the application for a hardship exception to approve or disapprove the exception.[4]

The most basic requirement for a hardship exception is that providers or suppliers must provide a letter with the enrollment application "that describes the hardship and why the hardship justifies an exception." 42 C.F.R. § 424.514(f). In the present case, Petitioner's letter stated that it could not afford the $542 application fee because Petitioner "is operating in its initial year" and that Petitioner's financial loss from the day it opened until the date of the request was $5,145.30. CMS Ex. 1 at 1. As support, Petitioner submitted a profit and loss statement. CMS Ex. 1 at 2.

Petitioner's reconsideration request stated merely that a hardship exception is necessary because Petitioner is a new medical practice. CMS Ex. 3 at 1. As support, Petitioner submitted a 1040 Schedule C (Profit or Loss from Business) form showing a $28,582 loss in 2013. CMS Ex. 3 at 2.

In its RFH, Petitioner, for the first time, indicates that it serves a rural area "in dire need of Physician aid" and that Petitioner meets the requirements to be deemed a rural health clinic, and that such a designation would permit Petitioner to further its efforts in the community. However, it was not until Petitioner's motion for summary judgment that there was some explanation of Petitioner's service to low income individuals and an explanation of alleged bad debts that have accumulated. P. Mot. at 3-4.

MPIM § 15.19.1.C.2 sets forth the criteria it considers when making a hardship determination.

> The application fee generally should not present a significant burden for an adequately capitalized provider or supplier.

[4] Petitioner notes that CMS "failed to adhere to their standard of reply within 60 days, exceeding this mandate by 23 days." P. Br. at 3. However, the regulations do not provide a remedy for a provider or supplier who receives a late determination. Therefore, this issue does not impact this decision.

> Hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship. The provider must instead make a strong argument to support its request, including providing comprehensive documentation (which may include, without limitation, historical cost reports, recent financial reports such as balance sheets and income statements, cash flow statements, tax returns, etc.).
>
> Other factors that may suggest that a hardship exception is appropriate include the following:
>
> (a) Considerable bad debt expenses,
>
> (b) Significant amount of charity care/financial assistance furnished to patients,
>
> (c) Presence of substantive partnerships (whereby clinical, financial integration are present) with those who furnish medical care to a disproportionately low-income population;
>
> (d) Whether an institutional provider receives considerable amounts of funding through disproportionate share hospital payments, or
>
> (e) Whether the provider is enrolling in a geographic area that is a Presidentially-declared disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121-5206 (Stafford Act).

When reviewing the non-exhaustive list of factors above that may suggest hardship, I agree with the view that "[p]lainly CMS anticipated granting exceptions in ways that would benefit disadvantaged program beneficiaries." *Earl Braunlin, M.D.*, DAB CR3499, at 4 (2014). Therefore, I believe that CMS is correct when it argues that Petitioner's initial reason for needing a hardship exception, i.e., that Petitioner is a new medical practice, is insufficient because it is likely that many new providers would experience financial constraints when starting their businesses. CMS Mot. at 5 ("If Congress intended for CMS to waive the enrollment fee for providers and suppliers in their first year of business, it would have provided such waiver in the statute."). Petitioner's asserted losses appear to be consistent with a new practice, with Petitioner incurring a $28,582 loss by the end of 2013, but only having a total loss of $5,145.30 by May 8, 2014. Another profit and loss sheet from Petitioner indicates that "All

Transactions" as of September 12, 2014 resulted in a net income of "-17,252.873." P. Ex. 1 at 4-5. The amounts Petitioner posits as its losses in the first year of operation appear insufficient to show financial hardship would occur if forced to pay the $542 application fee. These would not affect an adequately capitalized provider or supplier.

As indicated above, Petitioner did not have the benefit of knowing the contents of MPIM § 15.19.1.C.2 until Dr. Oakes' email exchange with CMS following the issuance of the reconsidered determination. P. Ex. 1 at 1. Therefore, it is understandable that Petitioner, upon review of the manual provision, would indicate in the RFH that its practice involves providing medical care in an underserved, rural area, and would include information about alleged bad debts. Consistent with Petitioner's assertion that its practice is meant to help an underserved area, Petitioner indicates in various documents that it seeks enrollment in the Medicare program as a rural health clinic and that Petitioner meets the requirements to be enrolled as a rural health clinic.[5] RFH; P. Mot. at 2, 4; P. Ex. 1 at 2. However, Petitioner provided no documentary or testimonial support for these assertions.

A review of Petitioner's enrollment application shows that Petitioner requests enrollment as a FQHC and not a rural health clinic.[6] CMS Ex. 1 at 8. A review of the enrollment application also shows Petitioner is a proprietary business (i.e., not non-profit) and does not include information that expressly shows that Petitioner serves an underserved, rural area. CMS Ex. 1 at 28. While it may be true that Petitioner's enrollment in the Medicare program might benefit individuals in an underserved area, there is no evidence in the record to support this.

Petitioner asserts that it has accumulated "bad debts" because its patients are often uninsured and unable to pay for the medical services it provides. P. Mot. at 3-4. Petitioner submitted a document purporting to show the accumulated bad debts incurred by Petitioner through December 3, 2014. P. Ex. 3. However, aside from a limited explanation of this somewhat ambiguous document in Petitioner's motion for summary judgment (the document title indicates that it is "Aging Report By Patient," but the document simply lists the "Grand Total" for each column displayed), there is nothing in the record that supports Petitioner's claim concerning bad debts or explains how or who generated the figures in the document. Rather, the document shows that Petitioner has accounts receivables that are aged but there is no evidence provided that Petitioner has written off these receivables as "bad debts." P. Ex. 3. Generally, a bad debt is "[a] debt

[5] A rural health clinic is a clinic that is in a rural area designated as a shortage area and is not a rehabilitation agency or a clinic that primarily treats mental disease. 42 C.F.R. § 491.2 (definition of *Rural health clinic*).

[6] A FQHC is an entity that meets the requirements to receive or is receiving a Public Health Service Act grant, or is a health facility operated by an Indian tribe. 42 C.F.R. § 405.2401(b) (definition of *Federally qualified health center*).

that is uncollectible; a permissive deduction for tax purposes in arriving at taxable income. I.R.C. § 166." Black's Law Dictionary 139 (6th ed. 1990).

My Pre-Hearing Order explained in detail the process by which a party could submit written direct testimony through affidavit or declaration, which could have been used to explain the "Aging Report By Patient." *See* Pre-Hearing Order ¶ 8. A proceeding before an ALJ is a formal administrative proceeding and an ALJ's "decision is based on the evidence of record . . . ." 42 C.F.R. § 498.74(a). Although I am not implying that Dr. Oakes or Petitioner's representative have dissembled, I am nevertheless required to have record support for any finding I make that is material to the outcome of the case. Although CMS does not provide evidence disproving Petitioner's assertions, CMS is not obligated to do so. *See Brooks*, DAB No. 2615 at 17 ("[W]e do not adopt a rule requiring CMS to investigate the allegations in a hardship exception request or to produce evidence contravening the allegations in the request in order to support a denial of the request."). It is sufficient that CMS disputes Petitioner's evidence and that the evidence is not clear so that I can accord it significant weight in my decision. As a result, I cannot find that the evidence submitted proves the existence of bad debts.

VII. Conclusion

Based on the written record, I affirm CMS's determination to deny Petitioner's request for a hardship exception from paying the Medicare enrollment application fee.

/s/
Scott Anderson
Administrative Law Judge