

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Dr. S.A. Brooks, DPM,
(NPI: 1235136292/PTAN: 1062730001),

Petitioner,

v.

Centers for Medicare & Medicaid Services

Docket No. C-14-149

Decision No. CR3216

Date: May 2, 2014

DECISION

Petitioner, Dr. S.A. Brook, DPM, met the requirements of 42 C.F.R. § 424.514 (b)(2) and (f)¹ for a hardship exception to the requirement to pay the Medicare enrollment application fee for her Medicare enrollment revalidation application submitted on June 19, 2013.

I. Procedural Background

Petitioner² is a podiatrist and a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) in Belleville, Illinois. Petitioner was enrolled in the

¹ Citations to the Code of Federal Regulations (C.F.R.) are to the version in effect at the time of Petitioner's hardship exception request, unless otherwise stated.

² The evidence shows that Petitioner does business under the name "Arztin Foot Care." Centers for Medicare & Medicaid Services (CMS) exhibit (Ex.) 1 at 8.

Medicare program as a supplier of DMEPOS. In 2013, she was required to revalidate her enrollment as a DMEPOS supplier. On June 19, 2013, Petitioner submitted a revalidation application and a letter requesting a hardship exception to the requirement to pay an application fee. CMS Ex. 1 at 1, 6- 9.

The National Supplier Clearinghouse, (NSC) operated by Palmetto GBA, the Medicare contractor that processes enrollment applications for suppliers of DMEPOS, notified Petitioner by letter dated June 24, 2013, that her request for a hardship exception was denied. NSC advised Petitioner that she could request reconsideration of the denial. CMS Ex. 1 at 10. NSC advised Petitioner by a separate letter dated June 24, 2013, that she had to pay the application fee within 30 days for NSC to process her revalidation application and, if she failed to pay, her application would be denied, or her billing privileges would be deactivated, or her enrollment and billing privileges would be revoked. CMS Ex. 1 at 11-12.

Petitioner requested reconsideration by letters dated July 3 and 22, 2013, which were acknowledged by NSC on August 12, 2013. CMS Ex. 1 at 13-17. Petitioner submitted additional argument and evidence for consideration on reconsideration by letter dated August 22, 2013. CMS Ex. 1 at 18-20. Petitioner was advised by letter dated August 27, 2013, that the hearing officer determined on reconsideration that Petitioner did not meet the requirements for a hardship exception from the application fee. CMS Ex. 1 at 1-5. Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated September 16, 2013.

Notwithstanding her request for ALJ review of her denied request for a hardship exception, the NSC notified Petitioner by letter dated October 30, 2013, that her enrollment and billing privileges were revoked for nonpayment of the application fee and that she was barred from reenrolling for one year. CMS Ex. 3.

On November 5, 2013, the case was assigned to me for hearing and decision and an Acknowledgment and Prehearing Order (Prehearing Order) was issued at my direction.

On December 5, 2013, CMS filed its prehearing exchange, with its prehearing brief and alternative motion for summary judgment (CMS Br.) with CMS Exs. 1 through 3. Petitioner filed her prehearing exchange and response to the CMS motion for summary judgment (P. Br.) with four exhibits (P. Exs. 1 through 4) on January 27, 2014. CMS filed a reply brief on February 10, 2014. Petitioner made no objection to my consideration of CMS Exs. 1, 2, and 3. CMS Exs. 1 and 3 are admitted as evidence. CMS Ex. 2 is not admitted as it is not relevant to any issue that I may decide. CMS objects to P. Exs. 1 through 4, arguing that the exhibits constitute new evidence under 42 C.F.R. § 498.56(e). CMS Reply. P. Exs. 1 through 4 are not admitted as evidence because they are dated after the reconsideration decision or relate to events after the reconsideration decision and, therefore, they are not relevant to whether or not Petitioner

met the requirements for a fee exception as of the time of the adverse initial and reconsideration determinations. 73 Fed. Reg. 36,448, 36,452 (June 24, 2008). Petitioner filed two documents with her request for hearing: an incomplete copy of the August 12, 2013 letter from the NSC hearing officer denying reconsideration; and a September 10, 2013 letter from a banking institution rejecting a loan application for Arztin Foot Care. A complete copy of the August 12, 2013 letter has been admitted as CMS Ex. 1 at 17, therefore it is not necessary to separately admit as a Petitioner's exhibit an incomplete copy of the same letter. The September 10, 2013 letter from the bank is dated after the reconsideration determination. Therefore, the letter is not admitted as it is not relevant to the issue of whether or not Petitioner met the requirements for a fee exception at the time of the adverse initial and reconsideration determinations. 73 Fed. Reg. at 36,452.

II. Discussion

A. Applicable Law

Section 1831 of the Social Security Act (Act) establishes the supplementary medical insurance benefits program for the aged and disabled known as Medicare Part B. (42 U.S.C. § 1395(j)). Administration of the Part B program is through contractors, such as NSC and Palmetto. Act § 1842(a) (42 U.S.C. § 1395u(a)). Payment under the program for services rendered to Medicare-eligible beneficiaries may only be made to eligible providers of services and suppliers.³ Act §§ 1835(a), 1842(h)(1) (42 U.S.C. §§ 1395n(a), 1395u(h)(1)).

The Act requires the Secretary of Health and Human Services (the Secretary) to issue regulations that establish a process for the enrollment of providers and suppliers, including the right to a hearing and judicial review of certain enrollment determinations. Act § 1866(j) (42 U.S.C. § 1395cc). Once enrolled, the supplier receives billing privileges and is issued a billing number that is required to receive payment for services

³ A "supplier" furnishes services under Medicare. The term supplier applies to physicians or other practitioners and facilities that are not included within the definition of the phrase "provider of services." Act § 1861(d) (42 U.S.C. § 1395x(d)). A "provider of services," commonly shortened to "provider," includes hospitals, critical access hospitals, skilled nursing facilities, comprehensive outpatient rehabilitation facilities, home health agencies, hospice programs, and a fund as described in sections 1814(g) and 1835(e) of the Act. Act § 1861(u) (42 C.F.R. § 1395x(u)). The distinction between providers and suppliers is important because they are treated differently under the Act for some purposes.

rendered to a Medicare beneficiary. 42 C.F.R. § 424.505. Petitioner is a DMEPOS supplier and to receive direct-billing privileges, a DMEPOS supplier must meet and maintain the Medicare application certification standards set forth in 42 C.F.R. § 424.57(c). After being granted billing privileges a DMEPOS supplier is required to revalidate the information in its application for billing privileges every three years or as directed by CMS, by completing a new application. 42 C.F.R. §§ 424.57(e); 424.515(d), (e).

Section 1866(j)(2) (42 U.S.C. § 1395cc(j)(2)) of the Act requires that the Secretary establish screening procedures and application fees for providers and suppliers. The Act establishes an application fee for individual and institutional providers and suppliers who are submitting an initial enrollment application or currently enrolled providers who are revalidating their Medicare enrollment beginning in 2010. Act § 1866(j)(2)(C)(i); 42 C.F.R. § 424.514. Congress authorized the Secretary to use fees collected for program integrity efforts and to cover the cost of screening providers and suppliers. Act § 1866(j)(2)(C)(iii). Congress also authorized the Secretary to exempt a provider or supplier from the imposition of an application fee. Act § 1866(j)(2)(c)(ii). The Secretary imposed an application fee for revalidating institutional providers effective March 25, 2011. Institutional providers that are filing an application to revalidate must submit the application with the application fee or a request for a hardship exception to the application fee. 42 C.F.R. § 424.514(b). Petitioner is an “institutional provider” as defined by 42 C.F.R. § 424.502 because she is required to revalidate using a CMS-855S form as a DMEPOS supplier. 76 Fed. Reg. 5861, 5911 (Feb. 2, 2011). The application fee was \$532 in 2013. CMS Ex. 1 at 22.

Section 1866(j)(2)(C) of the Act does not establish a procedure for requesting an exemption from the requirement to pay an application fee. The Act does provide that the Secretary may grant the exemption on a case-by-case basis, “if the Secretary determines that the imposition of the application fee would result in a hardship.” Act § 1866(j)(2)(C)(iii). The quantity or quality of the hardship that justifies an exemption is not specified. The Secretary has delegated authority to CMS to grant a hardship exception to the requirement to pay the application fee. 42 C.F.R. § 424.514(h). The regulation provides that a “provider or supplier requesting an exception from the application fee must 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); 76 Fed. Reg. at 5909. Denial of a hardship exception is subject to reconsideration and ALJ and Departmental Appeals Board (Board) review using the procedures of 42 C.F.R. pt. 498. 42 C.F.R. §§ 405.800, 424.514(h)(2); 76 Fed. Reg. at 5909. A hearing on the record, also known as an oral hearing, is required under the Act. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 748-51 (6th Cir. 2004).

B. Issues

Whether summary judgment is appropriate; and

Whether Petitioner met the requirements for a hardship exception to the requirement to pay a Medicare enrollment application fee.

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis.

1. Petitioner has a right to request review and I have jurisdiction.

There is no dispute that Petitioner timely requested a hearing and I have jurisdiction. Pursuant to 42 C.F.R. § 424.514(h)(2) a CMS hardship exception determination is subject to my review pursuant to “42 C.F.R. § 405.874.” In 2012, 42 C.F.R. § 405.874 was recodified as 42 C.F.R. §§ 405.800 - .818. 77 Fed. Reg. 29,001, 29,016-17 (May 16, 2012) but 42 C.F.R. § 424.514(h)(2) was not amended to reflect the change. CMS has not objected to my jurisdiction. CMS Br.; CMS Reply.

2. Summary judgment is appropriate.

A party may waive appearance at an oral hearing, but must do so affirmatively in writing. 42 C.F.R. § 498.66. In this case, Petitioner has not waived the right to oral hearing or otherwise consented to decision based only upon the documentary evidence or pleadings. Accordingly, disposition on the written record alone is not permissible, unless the motion for summary judgment filed by CMS in this case has merit.

Summary judgment is not automatic upon request but is limited to certain specific conditions. The procedures established by 42 C.F.R. pt. 498 related to ALJ hearings applicable in this case do not include a summary judgment procedure. However, the Board has long recognized the availability of summary judgment in cases subject to 42 C.F.R. pt. 498 and the Board’s interpretative rule has been recognized by the federal courts. *See, e.g., Crestview Parke Care Ctr. v. Thompson*, 373 F.3d at 749-50. Furthermore, a summary judgment procedure was adopted as a matter of judicial economy within my authority to regulate the course of proceedings and made available to the parties in the litigation of this case by my Prehearing Order. Prehearing Order §§ II.D and II.G.

Summary judgment is appropriate when there is no genuine dispute as to any issue of material fact for adjudication or the moving party is entitled to judgment as a matter of law. In determining whether there are genuine issues of material fact for trial, the

reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. The party requesting summary judgment bears the burden of showing that there are no genuine issues of material fact for trial or that it is entitled to judgment as a matter of law. Generally, the non-movant may not defeat an adequately supported summary judgment motion by relying on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact, i.e., a fact that would affect the outcome of the case if proven. *Mission Hosp. Reg'l Med. Ctr.*, DAB No. 2459 at 4 (2012) (and cases cited therein); *Experts Are Us, Inc.*, DAB No. 2452 at 4 (2012) (and cases cited therein); *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300 at 3 (2010) (and cases cited therein); see also *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

The standard for deciding a case on summary judgment and an ALJ's decision-making in deciding a summary judgment motion differ from resolving a case after a hearing. On summary judgment, the ALJ does not make credibility determinations, weigh the evidence, or decide which inferences to draw from the evidence, as would be done when finding facts after a hearing on the record. Rather, on summary judgment the ALJ construes the evidence in a light most favorable to the non-movant and avoids deciding which version of the facts is more likely true. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291 at 5 (2009). The Board has also recognized that on summary judgment it is appropriate for the ALJ to consider whether a rational trier of fact could find that the parties' evidence would be sufficient to meet that party's evidentiary burden. *Dumas Nursing & Rehab., L.P.*, DAB No. 2347 at 5 (2010). The Secretary has not provided for the allocation of the burden of persuasion or the quantum of evidence in 42 C.F.R. pt. 498. The Board, however, has provided some persuasive analysis regarding the allocation of the burden of persuasion in cases subject to 42 C.F.R. pt. 498. *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 Fed. App'x 181 (6th Cir. 2005).

There are no disputes as to material facts in this case that require a hearing. Summary judgment is appropriate as the issues that require resolution are issues of law related to the interpretation and application of the regulation that authorizes a hardship exception to the requirement to pay an application fee and the application of the regulation to the undisputed facts. A correct construction of 42 C.F.R. § 424.514(f) and application of the regulation to the undisputed facts requires that this case be resolved against CMS. Accordingly, I conclude summary judgment is appropriate as this case must be resolved against CMS as a matter of law. Although, Petitioner did not specifically move for summary judgment, I find no prejudice to CMS as CMS had the opportunity to fully brief the legal issues in this case.

3. Petitioner met the requirements of 42 C.F.R. § 424.514 (b)(2) and (f) for a hardship exception to the requirement to pay the Medicare enrollment application fee for her Medicare enrollment revalidation application submitted on June 19, 2013.

4. NSC cannot rely upon a policy statement of CMS that is inconsistent with 42 C.F.R. § 424.514(f) to deny Petitioner's application for a hardship exception to the requirement to pay a Medicare enrollment application fee.

5. Whether or not a provider or supplier meets the requirements for a hardship exception under 42 C.F.R. § 424.514 is not a matter within the sole discretion of CMS as 42 C.F.R. § 424.514(h)(2) specifically makes the determination reviewable by an ALJ and the Board using the procedures of 42 C.F.R. pt. 498.

6. My review of the denial of a hardship exception is de novo.

7. Petitioner satisfied the regulatory requirements of 42 C.F.R. § 424.54(f) for a hardship exception to the requirement to pay an application fee.

Petitioner requests review of the denial of her request for a hardship exception to the requirement to pay a \$532 application fee for her Medicare enrollment revalidation application. Request for Hearing; P. Br. CMS claims that Petitioner failed to present evidence "in support of a strong argument" showing that she, operating as Arztin Foot Care, qualified for the hardship exception. CMS Br. at 1, 8-9; CMS Reply at 2. The facts are not disputed.

a. Facts

On June 19, 2013, Petitioner submitted her revalidation application, a CMS-855S form, with a letter dated June 14, 2013 requesting a hardship exception to the requirement to pay an application fee. CMS Ex. 1 at 1, 6-9. Petitioner stated in her letter that: she could not "afford the fee demanded of all revalidators [sic];" she attributed her inability to afford the fee, at least in part, to changes in Illinois Medicaid that limited doctors of podiatric medicine to individuals under 20, unless diabetic; the Medicaid change decreased the number of Medicare/Medicaid patients since July 2012; and reduced her practice to "just break even." CMS Ex. 1 at 9. CMS has not rebutted the assertions made by Petitioner in her June 14, 2013 letter.

Five days after she filed her revalidation application, NSC notified Petitioner by letter dated June 24, 2013, that her request for a hardship exception was denied. NSC cited the

Medicare Provider Integrity Manual (MPIM), ch. 15, § 9.1.C (§15.9.1.C), as requiring that a supplier present a strong argument to support a request for a hardship exception, including providing “comprehensive documentation.” CMS Ex. 1 at 10. The NSC letter stated that “there is not strong enough evidence to grant a hardship exception to the application fee.” CMS Ex. 1 at 10.

Petitioner requested reconsideration by letter dated July 3, 2013. CMS Ex. 1 at 13-14. . Petitioner argued that as a doctor of podiatric medicine, she did not provide her patients “diabetic therapeutic shoes and other medical devices for a profit but as an incidental service” and convenience for her patients, particularly the homebound. CMS Ex. 1 at 13. She also argued that Medicaid limited her to seeing diabetic patients and that she saw mostly the poor, black, and elderly. CMS Ex. 1 at 13-14. On July 17, 2013, NSC returned Petitioner’s July 3, 2013 reconsideration request stating that “[a]s the documentation provided does not indicate the request for reconsideration, it is being returned to you.” CMS Ex. 1 at 15. On July 22, 2013, Petitioner resubmitted her reconsideration request. CMS Ex. 1 at 16. On August 12, 2013, the reconsideration hearing officer acknowledged receipt of Petitioner’s reconsideration request and invited Petitioner to submit additional documentation. CMS Ex. 1 at 17. Petitioner responded to the hearing officer by letter dated August 22, 2013. Petitioner continued her argument that changes in Illinois Medicaid significantly limited her practice income from Medicare and Medicaid. She added that Medicaid payments were being taken by the state to pay state taxes for 2011. She also submitted some documents showing that a payment had been involuntarily withheld by the State of Illinois and her payments from Medicare and Medicaid in 2012. CMS Ex. 1 at 16-20.

On August 27, 2013, a reconsideration decision was issued upholding the denial of Petitioner’s hardship exception request. The reconsideration hearing officer, citing section 19.1.C.2 of the MPIM, concluded that Petitioner failed to present a strong argument for a hardship exception. In a paragraph titled “Decision” the hearing office stated that her decision was made “in accordance with Medicare guidelines, as outlined in 42 C.F.R. Section 424.514.” CMS Ex. 1 at 3.

b. Analysis

Beginning March 25, 2011, the Secretary required that a revalidating institutional provider such as Petitioner submit with an application for revalidation either the application fee or a request for hardship exception to the fee requirement. 42 C.F.R. § 424.514(b). The regulation establishes the following requirements for a hardship exception request.

(f) Information needed for submission of a hardship exception request. A provider or supplier requesting an exception from the application fee must 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). The regulation is clear that all that is required to request a hardship exception is a letter submitted with the revalidation application that describes the hardship and why the hardship justifies an exception to the requirement to pay the application fee.

The drafters of the regulation explained the process for requesting a hardship exception as follows:

We proposed that a provider or supplier that believes it is entitled to a hardship exception from the application fee enclose a letter with the enrollment application or, if using Internet-based PECOS, with the Certification Statement, explaining the nature of the hardship.

76 Fed. Reg. at 5909.

During the comment period, CMS received the following suggestion:

Comment: A commenter suggested that CMS develop and issue a standard enrollment fee “hardship exception form” that a provider can use when requesting an exception to the fee.

Response: Whereas a standard form might be useful, there could be many situations that justify exception from the fee. **We do not want to limit the basis for fee exceptions for providers and suppliers to a pre-established list of circumstances.** Accordingly we have not listed options for providers and suppliers to request hardship exceptions from application fees. As indicated in the preamble to the proposed rule, **each request will be considered on its own merit on a case-by-case basis.**

76 Fed. Reg. at 5909 (emphasis added). The drafters assessed the information collection requirements for providers and suppliers and estimated that it should require no more than one hour to prepare the letter requesting an exception. The drafters did not discuss

or analyze any requirement to submit any supporting documentation to prove that a hardship existed. The drafters did not attempt to describe or limit the hardships that might qualify for an exception to the requirement to pay a fee. 76 Fed. Reg. at 5949.

In this case the NSC and CMS did not deny Petitioner's request for a hardship exception because she failed to comply with 42 C.F.R. § 424.514(b) and (f) or because she failed to explain in the required letter the hardship or why it justified an exception. The NSC and CMS do not deny or dispute Petitioner's assertions in her letter regarding the hardship and that it should justify an exception. Rather, the NSC decided initially and on reconsideration to deny Petitioner's request for exception because she failed to meet the requirement of the MPIM §15.19.1.C to make a strong argument with comprehensive documentation. CMS Ex. 1 at 2, 10. CMS also urges me to apply MPIM §15.19.1.C to deny Petitioner a hardship exception. CMS Br. at 8-9; CMS Reply at 2.

Section 15.19.1.C.2 of the MPIM provides:

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 received 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).

MPIM, §15.19.1.C.2 (rev. 474, Jul. 23, 2011) (emphasis added); CMS Ex. 1 at 23-24. This provision of the MPIM is clearly at odds with the plan language of 42 C.F.R. § 424.514(f) and the intent of the drafters of that regulation. Due to the inconsistency, the requirements of the MPIM cannot be enforced against Petitioner as the regulation controls. The MPIM sets forth CMS policy and instructions for its contractors. The Board has had many occasions to address the relationship among the Act and the regulations and the policy statements of CMS.

Unlike the Medicare statute and regulations . . . CMS's instructions to contractors do not have the force and effect of law and are not binding on the Board. *See Fady Fayad, M.D.*, DAB No. 2266, at 9 n.6 (2009), *citing Massachusetts Executive Office of Health and Human Services*, DAB No. 2218, at 12 (2008); *Foxwood Springs Living Center*, DAB No. 2294, at 8-9 (2009). In section 1866(j) of the Act, Congress specifically directed the Secretary to establish *by regulation* the procedures for actions on applications, rather than relying merely on instruction manuals.

Tri-Valley Family Medicine, Inc., DAB No. 2358 at 7 (2010) (emphasis in original).

The MPIM is CMS policy and does not have the force and effect of law. MPIM § 15.19.1.C.2 creates significant obstacles to requesting a hardship exception by imposing substantial requirements not found in the Act or regulations. The MPIM provisions cited by the NSC and CMS may not be used as a basis to deny Petitioner a hardship exception to the extent they are inconsistent with the plain language of the regulations and the stated intent of the drafters. I conclude that the application of the provisions of the MPIM by NSC and CMS rather than the regulation was an error. The fact that Petitioner failed to satisfy the requirements of the MPIM § 15.19.1.C.2 was not a proper basis for the denial of her request for a hardship exception that otherwise met the requirements of 42 C.F.R. § 424.514 (b) and (f).

The determination of whether or not a provider or supplier is entitled to a hardship exception is not a matter solely within the discretion of CMS, because that determination is specifically reviewable by an ALJ and the Board. 42 C.F.R. § 424.514(h)(2). Review by an ALJ applying the procedures of 42 C.F.R. pt. 498 is *de novo*. Therefore, I must consider Petitioner's letter requesting a hardship exception that was submitted with her revalidation application, to determine whether she identified a hardship and whether that hardship justifies an exception to the requirement to pay the application fee. Petitioner's June 14, 2013 letter submitted with her revalidation application requested a hardship exception. In that letter Petitioner described her hardship stating: "I cannot afford the fee demanded of all revalidators [sic]." She also explained why the hardship justified the

