Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Dr. S.A. Brooks, DPM
Docket No. A-14-89
Decision No. 2615
January 15, 2015

REMAND OF ADMINISTRATIVE LAW JUDGE DECISION

The Center for Medicare & Medicaid Services (CMS) requests Board review of the Administrative Law Judge (ALJ) decision in *Dr. S.A. Brooks, DPM*, DAB CR3216 (2014) (ALJ Decision). The ALJ granted summary judgment in favor of Petitioner, Dr. S.A. Brooks, DPM, d/b/a Arztin Foot Care, concluding that Petitioner met the requirements of 42 C.F.R. § 424.514(b)(2) and (f) for a hardship exception to the requirement to pay an application fee for her Medicare enrollment revalidation application submitted on June 19, 2013.

For the reasons stated below, we conclude that the ALJ did not err in determining that a requirement that an institutional provider requesting a hardship exception include, with its enrollment application, documents supporting the request is inconsistent with section 424.514. We further conclude, however, that summary judgment is not appropriate in favor of either party. Accordingly, we remand this case to the ALJ for a decision on the merits of Petitioner's request for a hardship exception consistent with our analysis below.

I. Background

A. Petitioner's request for a hardship exception and the governing regulations

The following facts are not disputed. Petitioner is a podiatrist and the sole proprietor of an Illinois business that was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, and orthotics (DMEPOS) and doing business as Arztin Foot Care. Petitioner submitted a CMS-855S application form to the National Supplier Clearinghouse (NSC), a Medicare contractor, on June 19, 2013 to revalidate her supplier enrollment. With her revalidation application, she submitted a letter requesting a hardship exception to the requirement to pay an application fee (then $532). The fee applies to any "institutional provider" applying for revalidation on or after March 25, 2011. 42 C.F.R. § 424.514 (b). The term "institutional provider" is defined by regulation to include a provider or supplier that submits a CMS-855S or associated Internet-based application. 42 C.F.R. § 424.502.

The Medicare enrollment regulations require that "institutional providers that are subject to CMS revalidation efforts" must, at the time of filing an application, submit either the application fee or a request for a hardship exception, or both. 42 C.F.R. § 424.514(b)(2). The provision at 42 C.F.R. § 424.514(f), titled "*Information needed for submission of a hardship exception request,*" states:

> 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.

Section 424.514(g) permits a contractor to revoke the billing privileges of a currently enrolled institutional provider that (with certain exceptions not relevant here) submits an application that "is not accompanied by the application fee or by a letter requesting a hardship exception from the application fee" but the "contractor must first inform the provider that the application fee was not submitted in accordance with this section."

Section 424.514(h), titled "*Consideration of hardship exception request,*" provides:

> CMS has 60 days in which to approve or disapprove a hardship exception request. If a provider submits a request for a hardship exception to the fee and the provider or supplier has not already submitted the fee . . . and the request for hardship exception is not approved, CMS notifies the provider or supplier that the hardship exception was not approved and allows the provider or supplier 30 days from the date of notification to submit the applicable fee.

This section then goes on to provide that a "Medicare contractor" does not begin processing an application "until CMS has made a decision to approve or disapprove" the request, and that a hardship exception determination made by CMS is appealable.

In her letter requesting a hardship exception, Petitioner stated that she could "not afford the fee." CMS Ex. 1, at 9. As the ALJ found, she "attributed her inability to afford the fee, at least in part, to changes in the Illinois Medicaid program that limited doctors of podiatric medicine to [rendering medical attention only to] individuals under 20, unless diabetic" and explained that "the Medicaid change decreased the number of Medicare/Medicaid patients since July 2012" and "reduced her practice to 'just break even.'" ALJ Decision at 7, citing CMS Ex. 1, at 9. Although the ALJ did not mention it, the letter also stated that, if small suppliers went out of business, that "will only make it difficult for patients to receive devices and other [DMEPOS] products in the comfort of their communities at their doctors' offices" and that there are "patients who are diabetic who cannot go too far to receive the much needed therapeutic shoes and thus such a service . . . is very much appreciated." CMS Ex. 1, at 9.

B. NSC's denial of Petitioner's request

In a letter dated June 24, 2013, NSC denied the request, stating:

> Chapter 15.9.1C of the Program Integrity Manual requires the supplier to present a strong argument to support its request, including providing comprehensive documentation. Based on the NSC's review of the information submitted, there is **not strong enough evidence** to grant a hardship exception.

Id. at 10 (emphasis added). NSC apparently intended to cite to section 15.19.1.C. of the Medicare Program Integrity Manual, which is where the language NSC cited appears. *See* CMS Ex. 1, at 22-24.[1] That section states (in a "Background" subsection): "A provider or supplier requesting a hardship exception from the application fee must include **with its enrollment application a letter (and any supporting documentation)** that describes the hardship and why the hardship justifies an exception." *Id.* at 23 (emphasis added). Under "Criteria for Determination," the manual section states:

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

Id. (emphasis added). The section then goes on to state that "[o]ther factors that **may** suggest that a hardship exception is appropriate include the following" and to list factors including the presence of "substantive partnerships with those who furnish medical care to a disproportionately low-income population." *Id.* at 23-24.

[1] The version of the manual provision that CMS submitted to the ALJ is the version that was not effective until October 8, 2013, after NSC's determination here. CMS Ex. 1, at 21–29. The earlier version, however, was the same in all material effects. See Revision 474 to the manual.

NSC's denial letter informed Petitioner that she had a right to request reconsideration of NSC's determination pursuant to 42 C.F.R. § 405.874. *Id.*[2] NSC also informed Petitioner that she had to pay the fee or her revalidation application would be "denied per 42 CFR 424.525(a)(3)." *Id.* at 11.[3]

C. The reconsideration of Petitioner's request

In a letter dated July 3, 2013, Petitioner stated that she was appealing the denial of a hardship exception. *Id.* at 13. She provided further information, including assertions that she was "not providing much needed diabetic and therapeutic shoes and other medical devices for a profit but as an incidental service of my practice not to mention the conv[enience] this provides to my patients particularly the ones who are homebound," that she "sees mainly poor and elderly" patients, and that many other doctors would not even see patients who have Medicare and Medicaid, but that she would continue to do so if her enrollment were revalidated. *Id.* at 13-14. In a letter dated July 17, 2013, NSC said it was returning this letter because it "does not indicate the request for reconsideration." *Id.* at 15. Petitioner then submitted another letter, dated July 22, 2013, specifically requesting reconsideration of NSC's denial of the hardship exception. *Id.* at 16. In that letter, Petitioner stated, among other things, that she was unable to come up with the fee because she had "so many other [expenses] right now like an office rent of $800 a month." *Id.*

On August 12, 2013, an NSC Hearing Officer informed Petitioner that her request for reconsideration had been received and that the Hearing Officer would "make a new and independent decision based on the evidence in the case file and on any additional evidence you would like to submit." *Id.* at 17. With her response, Petitioner submitted 1099 forms showing her income for 2012 (totaling less than $22,000) from her Medicare and Medicaid patients, whom she said constituted "the majority of the type of patients" she sees, and documentation that some "much needed" payments had been intercepted to pay back taxes she owed to Illinois because she had not been able to pay all of the state taxes she owed for 2011. *Id.* at 18-20. She also identified July 2012 as the effective date of the Illinois Medicaid decision that she said caused her to lose many non-diabetic patients on Medicaid. *Id.* at 18.

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[2] This citation was no longer valid. Section 405.874 was replaced in 2012 by the appeal provisions in sections 405.800 *et seq.* 77 Fed. Reg. 29,002, 29,028–29 (May 16, 2012); *see also* CMS Ex. 1, at 27.

[3] The cited section does not address denials of enrollment, but says that "CMS may reject" an enrollment application if an institutional provider "does not submit the application fee . . . or a hardship waiver request" with the application.

On August 27, 2013, the NSC Hearing Officer determined that Petitioner did not satisfy the requirements for a hardship exception. CMS Ex. 1, at 1-4. The NSC Hearing Officer made the following findings of fact:

1. On June 19, 2013 the supplier submitted a revalidation application and hardship waiver request.
2. On June 24, 2013, the NSC denied the supplier's hardship waiver request.
3. On July 26, 2013 the NSC received a reconsideration request from the supplier.

The NSC Hearing Officer made no findings concerning the facts Petitioner had asserted in support of her request. In the section of her decision giving her rationale for denying Petitioner's request, the NSC Hearing Officer set out the provisions from section 15.19.1.C.2. of the Program Integrity Manual. CMS Ex. 1, at 3. She said that she had reviewed the documents and correspondence submitted by Petitioner and quoted some of Petitioner's statements, stating: "As this can be understood, this does not fulfill the criteria set forth by CMS." *Id.* She then said that she "concurred" that Petitioner "failed to present a strong argument for the hardship exception based upon the criteria set forth by CMS as detailed above, specifically, 'hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship.'" *Id.* The Hearing Officer further stated that the "NSC is deemed appropriate in the denial of the hardship exception fee waiver based upon the information on the record at the time of denial." *Id.* Finally, in a section labeled "Decision," the Hearing Officer stated that her decision was made "in accordance with Medicare guidelines, as outlined in 42 C.F.R. Section 424.514," but she did not cite to any particular guideline in that section. *Id.*

Petitioner requested an ALJ hearing.

II. The ALJ Decision and CMS's Request for Review

The ALJ Decision contains the following conclusions of law:

1. Petitioner has a right to request review and I have jurisdiction.
2. Summary judgment is appropriate.
3. Petitioner met the requirements § 424.514(b)(2) and (f) for a hardship exception to the requirement to pay the Medicare enrollment application fee for her 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. § 424.514(f) for a hardship exception to the requirement to pay an application fee.

ALJ Decision at 5-7. CMS had moved for summary judgment in its favor but Petitioner had not made a motion. The ALJ's grant of summary judgment against CMS was made sua sponte.

The ALJ stated that 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**." ALJ Decision at 10 (emphasis added). The ALJ then concluded that, because a CMS determination of whether a petitioner is entitled to a hardship exception is subject to de novo review by an ALJ, he needed to consider whether Petitioner had identified a hardship and whether that hardship justifies an exception to the requirement to pay the fee. *Id.* In discussing whether Petitioner's letter satisfied the requirements of section 424.514(f), he stated that the "Act and regulations do not specify that a particular quality or quantity of hardship exist" and that it is "sufficient to identify the hardship and articulate why the hardship justifies the exception." *Id.* at 12. He concluded that "Petitioner met the requirements for a hardship exception to the requirement to pay the application fee." *Id.*

On appeal, CMS asks the Board to review the ALJ's conclusions of law 2, 3, 4, and 7. According to CMS, the ALJ "erred in (1) granting summary judgment in favor of Dr. Brooks, (2) finding that Dr. Brooks met the regulatory requirements for a hardship exception, [and (3)] ruling that CMS cannot rely upon a manual provision that is consistent with the regulation to deny Dr. Brooks' hardship exception." Request for Review (RR) at 1. CMS says it agrees that there are no disputes of material fact in this case that require a hearing, but argues, based on the facts CMS considers material, that the ALJ should have granted summary judgment in its favor. *Id.* at 2, 4. Specifically, CMS argues that the ALJ's conclusion of law 2 (that summary judgment was appropriate in this case) impermissibly shifted the burden of proof to CMS. *Id.* at 4-7.

CMS says that, because the ALJ's legal conclusions are erroneous, the "Board should grant CMS's Request for Review, reverse the ALJ Decision, and uphold CMS's determination that Dr. Brooks does not qualify for a hardship exception." *Id.*

III. Standard of review

Whether summary judgment is appropriate is a legal issue that we address de novo. *Lebanon Nursing & Rehab. Ctr*, DAB No. 1918 (2004). Summary judgment is appropriate if there is no genuine dispute of fact material to the result and the moving party is entitled to judgment as a matter of law. *Everett Rehab. & Medical Center*, DAB No. 1628, at 3 (1997), citing *Travers v. Shalala*, 20 F.3d 993, 998 (9th Cir. 1994). We review disputed conclusions of law for error. Departmental Appeals Board Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html (Guidelines). The Board may modify, reverse, or remand an ALJ decision based on a prejudicial error of procedure. Guidelines at 5.

IV. Analysis

Below, we first address CMS's contentions that its manual provision is consistent with the regulation, and that the ALJ Decision is inconsistent with the statute creating the hardship exception, the regulation, and language in the regulatory preambles, as well as the purpose of the application fee. We then address CMS's arguments that the ALJ erred in granting summary judgment in Petitioner's favor and should have granted summary judgment in CMS's favor.

We conclude that, to the extent the manual is read as requiring that Petitioner have submitted comprehensive documentation supporting her exception request with her revalidation application, that reading is inconsistent with section 424.514(f). We further conclude that, while CMS is not entitled to summary judgment on the grounds it asserts, the ALJ committed procedural error in granting summary judgment sua sponte in favor of Petitioner without affording CMS notice that he might do so based on the facts asserted by Petitioner and without viewing the evidence in the light most favorable to CMS.

A. The ALJ did not err in determining that a requirement that an institutional provider include with its application documents supporting a hardship exception is inconsistent with the regulation.

As CMS points out, section 424.514(f) addresses what information must be submitted **with a request for an exception**. CMS argues that the regulation does not preclude CMS from requiring documentation supporting a request in order to determine whether to grant the request, and therefore the ALJ erred in determining that CMS's manual provision is inconsistent with the regulation. According to CMS, its Program Integrity Manual provision at section 15.19.1 is a permissible interpretation of the regulation, to which the Board should accord deference. RR at 12-18.

The statement in the manual that "[h]ardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship" is interpretative and is consistent with section 424.514(f). That section requires that a supplier requesting a hardship exception both describe the hardship and explain why it justifies an exception, so CMS could reasonably determine that, if an institutional provider does nothing more than assert a financial hardship, the assertion alone would not suffice under the regulation. (Petitioner here, however, met the formal requirement of offering some description of the hardship and of how she thought it justified an exception.) The manual also reasonably provides some guidance regarding factors to be considered in making a case-by-case determination on whether to grant a hardship exception to the requirement for an application fee.[4]

The problem with the Program Integrity Manual provision **as applied** by NSC (and perhaps by the Hearing Officer on reconsideration) is that the provision was read as establishing a requirement that an institutional provider claiming financial hardship include supporting documentation **with the enrollment application.** NSC denied the request on the basis that Petitioner did not meet that requirement. CMS Ex. 1, at 10. Although the NSC Hearing Officer stated in her reconsideration determination that she reviewed the documentation submitted by Petitioner during the reconsideration process, her determination concluded that she "concurred" with the earlier determination by NSC. *Id.* at 3. She also relied specifically on the statement from the Program Integrity Manual that "hardship exceptions should not be granted when the provider simply asserts that the imposition of the application fee represents a financial hardship." *Id.* These two statements created ambiguity about whether the reconsideration was based on a failure to submit supporting documentation with the revalidation application or on the inadequacy of the documents Petitioner submitted to the Hearing Officer, particularly since the Hearing Officer did not identify any specific way in which she considered those documents to be inadequate.

As the ALJ concluded, imposing on Petitioner an obligation to have submitted all supporting documentation with her application would be inconsistent with section 424.514(f). That section requires a requester to submit with the application only a letter describing the hardship and stating why it justifies an exception. As applied in this case, the manual provision effectively imposed on Petitioner an obligation to have submitted comprehensive supporting documentation **with her application** in addition to the letter required by the regulation. A manual provision that imposes a new obligation is not merely interpretative, contrary to what CMS argues.

[4] We note, however, that the statement regarding "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.)" is not clear. To the extent that the provision refers to "comprehensive" documentation, we would view it as unreasonable to apply it in such a way as to require providers to submit documentation not related to, or disproportionately burdensome in light of, the nature of the hardship being argued.

Moreover, Petitioner did not have timely notice of any obligation to include supporting documentation **with her application** – the manual on its face is directed at CMS contractors, not at providers and suppliers, and CMS does not claim that it issued the manual as guidance to the public. Petitioner certainly could reasonably think based on the regulatory wording that she need submit with her application only a letter describing the hardship and why it justified an exception.

We agree with CMS that section 424.514(f) addresses merely what is required for **submission** of an exception request and does not address procedures for CMS **review** of such a request pursuant to section 424.514(h). While CMS could reasonably ask an institutional provider to support assertions in a hardship exception request as part of its case-by-case review of the request, CMS may not reasonably reject a request without some notice to the provider regarding what documentation CMS found lacking and an opportunity to submit it. We note that, elsewhere, the manual provides instructions about what to do if an application submission does not include required supporting documents and directs CMS's contractors to list what additional documents are needed and to give the provider/supplier 30 days to provide the documents. MPIM § 15.7. While the Hearing Officer did provide Petitioner an opportunity to present "additional evidence," neither NSC nor the Hearing Officer gave Petitioner any timely notice that additional documentation was needed to support the hardship claims.

CMS argues that the ALJ Decision is inconsistent with the statute creating the hardship exception, the regulation itself, and language in the preambles to the proposed and final rules, all of which, CMS asserts, "support that Dr. Brooks did not satisfy the requirements for a hardship fee waiver." RR at 8. Section 1869(j)(2)(C)(ii) of the Social Security Act (Act) provides:

> The Secretary may, **on a case-by-case basis**, exempt a provider of medical or other items or services or a supplier from the imposition of an application fee under this paragraph if the Secretary determines that the imposition of the application fee would result in a hardship.

(Emphasis added.) CMS points out that the preambles also state that hardship exception requests "will be considered **on a case-by-case basis**." 75 Fed. Reg. 58,204, 58,219 (Sept. 23, 2010); 76 Fed. Reg. 5862, 5909 (Feb. 2, 2011) (emphasis added). According to CMS, the "ALJ Decision, by placing dispositive weight on the supplier's letter claiming hardship, inappropriately strips the Secretary of her discretion, which Congress gave to her, to determine if a hardship exception is warranted." RR at 8. CMS also points out that the preamble to the proposed rule solicited comments "on the appropriate objective criteria that should be used in making a hardship determination" and "on the kinds of documents to be submitted to CMS or its contractor to exhibit hardship, including any comments on the financial or legal records that might be needed to make a determination of hardship." *Id.* at 11, citing 75 Fed. Reg. at 58,219. CMS says that,

although it appears that no comments were received, the lack of comments "does not establish that CMS disavowed any need for documentation concerning the hardship waiver, where the invitation for comments expressly shows that such was in fact contemplated." RR at 11. Indeed, the preamble to the final rule explains that CMS was not providing a form or checklist for requesting an exception because "there could be many situations that justify exception from the fee" and CMS did not wish to "limit the basis for fee exceptions for providers and suppliers to a pre-established list of circumstances," and therefore CMS chose not to list "options for providers and suppliers to request hardship exceptions" but rather to proceed with considering each request "on its own merit on a case-by-case basis." 76 Fed. Reg. at 5910.

CMS argues that the ALJ Decision would undercut this approach:

> While the regulation requires a letter describing the hardship and the reasons for an exception, the regulation nowhere states, as the ALJ Decision concludes, that CMS must automatically grant a hardship application fee waiver to any supplier submitting such a letter.

Id. at 9.

We agree that CMS is not obliged to automatically approve any hardship exception request that meets the requirements of section 424.514(f). We do not read the ALJ Decision to require this result. When discussing whether Petitioner's letter satisfied the requirements of sections 424.514(b)(2) and (f), the ALJ did state that it "is sufficient to identify the hardship and articulate why the hardship justifies the exception for the particular provider or supplier." ALJ Decision at 12. In determining that a hardship exception was warranted, however, the ALJ pointed out that the "determination of whether or not a provider or supplier is entitled to a hardship exception" is "specifically reviewable by an ALJ and the Board" and that his review was de novo. *Id.* at 11. He then reviewed the facts asserted by Petitioner in her letter to determine whether she identified a hardship and whether the hardship she identified "justifies an exception to the requirement to pay the fee." *Id.* We therefore do not think that the ALJ intended to impose an automatic approval requirement, and we do not do so here.

Contrary to what CMS argues, however, a conclusion that a hardship request would not be denied based solely on the failure to include supporting documentation with the request is not inconsistent with the preambles to the application fee rule. An automatic denial of an application for lack of comprehensive documentation would indeed be inconsistent with the description of a case-by-case evaluation of individual applications on the merits as set out in preambles. The preamble to the final rule also discussed the provision in section 424.514(f) for a hardship exception request as a collection of information under the Paperwork Reduction Act, concluding that the resulting information collection would impose only a minimal burden, specifically, one hour to

develop a letter to justify a hardship exception request. 76 Fed. Reg. at 5949. Had the Secretary intended to impose an additional obligation for submitting comprehensive supporting documentation **with every application**, the analysis under the Paperwork Reduction Act would likely have been different. On the other hand, the preamble recognizes that the basis for a hardship exception might vary according to the particular situation giving rise to the request. Thus, we do not read the preamble as ruling out the possibility that a determination about whether to grant an exception might include consideration of whether the provider failed to provide adequate, appropriate supporting documents even after being provided notice of the need to do so. In this case, however, given the reasons for initial denial of the request and the ambiguity in the reconsideration determination, it is not clear that any case-by-case review of Petitioner's claims was made.

CMS also argues that the ALJ ignored the purpose of the application fee, which is to fund program integrity efforts. RR at 11. According to CMS, under the ALJ Decision, "waivers will have to be routinely, rather than rarely, granted" and this "will thwart the legislative purpose behind the application fee and could compromise provider enrollment program integrity efforts." *Id.* CMS also says that the ALJ Decision "overlooks completely" statements in the preambles to the proposed and final rules "in which CMS estimated that only 2.5 percent of providers and suppliers would be granted a hardship exception because such exceptions would be infrequently approved." RR at 11, citing 75 Fed. Reg. at 58,233-34; 76 Fed. Reg. at 5955-56. According to CMS, "under the conclusory letter criteria set forth in the ALJ Decision, there is no doubt that CMS would be granting significantly more hardship exceptions than originally estimated." RR at 11.

Since we do not read the ALJ Decision as requiring (or ourselves require) automatic approval of a request complying with section 424.514(f), we reject CMS's argument that the ALJ Decision is inconsistent with the purpose of the fee. While Congress clearly intended to increase funding for program integrity efforts with income from the application fee, Congress also specifically provided for a hardship exception from the fee requirement. Consideration of the matters raised by Petitioner to justify an exception to the fee requirement, such as ensuring easy access to supplies necessary for diabetic beneficiaries with foot problems and retaining physicians in the Medicare program who are willing to serve low-income beneficiaries, is consistent with the purpose of the fee. Indeed, the preamble to the final rule referred to the need to "balance the necessity to eliminate fraud, waste, and abuse with reducing the burden on legitimate providers, suppliers, and beneficiaries." 76 Fed. Reg. at 5948; *see also* Act, § 1869(j)(2)(C)(ii) ("Secretary may waive the application fee . . . for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care.") .

B. Summary judgment is not appropriate under the particular circumstances of this case.

As noted above, whether summary judgment is appropriate is a legal issue that we address de novo.

1. The ALJ committed a procedural error by granting summary judgment sua sponte without affording CMS notice that he might do so based on the facts asserted by Petitioner and without viewing the evidence in the light most favorable to CMS.

In this case, the ALJ granted summary judgment sua sponte in favor of Petitioner even though Petitioner had not moved for summary judgment, without giving CMS notice that he might do so. Rule 56(c) of the Federal Rules of Civil Procedure permits courts to grant summary judgment sua sponte in limited circumstances, but requires the court to notify the party against whom it intends to enter summary judgment at least ten days before doing so.[5] Some courts strictly enforce this procedural requirement. *Powell v. U.S.*, 849 F.2d 1576, 1579 (5th Cir. 1988); *Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit*, 28 F.3d 1388 (5th Cir. 1994). As the Board has recognized, however, in some particular cases, courts have declined to find reversible error where such notice was not given. *Community Home Health*, DAB No. 2134 (2007), at 9, citing *Goldstein v. Fidelity and Guaranty Insurance Underwriters*, 86 F.3d 749 (7th Cir. 1996); *Bridgeway Corp. v. Citibank*, 201 F.3d 134 (2d Cir. 2000); *Exxon Corp. v. St. Paul Fire and Marine Ins. Co.*, 129 F.3d 781, 786-87 (5th Cir. 1997); *Cool Fuel, Inc. v. Connett*, 685 F.2d 309, 311-12 (9th Cir. 1982); *see, also, Oklahoma Heart Hospital*, DAB No. 2183 (2008). Moreover, even in cases where the appellant itself had not moved for summary judgment (or neither party had moved on the issue on which summary judgment was granted), courts have declined to reverse sua sponte entries of summary judgment where an appellant cannot show any prejudice. *See, e.g., Tranzact Technologies, Ltd. v. Evergreen Partners, Ltd.*, 366 F.3d 542 (7th Cir. 2004) (upholding a sua sponte grant of summary judgment where the complaining party could not show on appeal that it was deprived of a chance to present a viable claim); *Oppenheimer v. Morton Hotel Corp.*, 324 F.2d 766 (6th Cir. 1963) (per curiam) (upholding a sua sponte grant of summary judgment where essential facts in the record were undisputed and there was no claim on appeal that counsel had further evidence to submit).

[5] Although the federal rules do not bind ALJs or the Board, it is appropriate to look to them for guidance (*see, e.g.,White Lake Family Medicine, P.C.*, DAB No. 1951, at 12-14 (2004)). In the instant case, the ALJ's Acknowledgment and Pre-Hearing Order informed the parties that he would apply the standards developed under Rule 56 of the Federal Rules of Civil Procedure and applicable case law in ruling on any motion for summary judgment.

In granting summary judgment sua sponte here, the ALJ said he found "no prejudice to CMS as CMS had the opportunity to brief the legal issues in this case" and there "are no disputes as to material facts in this case that require a hearing." ALJ Decision at 6. In concluding that no material facts were in dispute, the ALJ apparently was relying on CMS's motion for summary judgment. In context, though, CMS's assertion in its motion that no material facts were in dispute could not reasonably be read as conceding the facts asserted by Petitioner in support of her hardship exception request. First, CMS's brief relied on the CMS manual as requiring Petitioner to have submitted comprehensive documentation with her request or (at the very least) during the reconsideration process. Thus, CMS was evaluating materiality in terms of what it considered to be the applicable legal standard, and its position was therefore based on the premise that the only facts material to determining whether to grant an exception were that Petitioner had claimed a financial hardship, but had not submitted what CMS considered to be a strong argument, including comprehensive supporting documentation.

Second, although CMS's motion for summary judgment relied on its general contention (in the heading of section II of its motion) that the undisputed facts establish that Dr. Brooks failed to present evidence that she qualifies for a hardship exception and its contention that "the regulation and CMS manual make it clear that hardship exception should not be granted when the provider simply asserts that the application fee represents a financial hardship," CMS's motion also contained some analysis of what CMS considered to be flaws in Petitioner's argument and evidence. CMS's Pre-hearing Br. and Motion for Summary Judgment at 8-9. CMS argued that Petitioner's arguments and documents intermingled information about the financial and business condition of Dr. Brook's podiatry practice with Petitioner's DME business; that Petitioner's claims about her patient mix were conclusory and lacked any specifics; and that her allegations of bias by the state and federal government were irrelevant. In evaluating whether a genuine dispute of fact exists, an ALJ must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party's favor. For purposes of considering whether to grant summary judgment in Petitioner's favor, the ALJ should have treated CMS as the non-moving party. Yet, the ALJ Decision contains no discussion of whether, viewing the evidence in the light most favorable to CMS, a rational trier of fact could find in CMS's favor.[6]

[6] On appeal, CMS states that "[a]s noted in the ALJ Decision, the relevant facts are not in dispute," and that "the ALJ Decision is correct in finding that '[t]here are no disputes as to material fact in this case that require a hearing' . . . ." RR at 2, 4. CMS, however, again premises this statement on its view of what facts are material, so we do not read it as conceding the facts asserted by Petitioner.

Thus, we conclude that the ALJ committed procedural error by granting summary judgment in favor of Petitioner without affording CMS notice that he might do so and without viewing the evidence in the light most favorable to CMS. We next turn to CMS's arguments in support of its position that the ALJ should have granted summary judgment in favor of CMS, explaining why we reject those arguments.

2. Petitioner did not concede that she submitted no documentation to support her request, nor did she have timely notice of what documentation CMS would have considered adequate.

CMS suggests that the ALJ should have granted summary judgment in its favor because "there is no dispute that Dr. Brooks did not submit any related documentation" to support her assertions. RR at 5. CMS quotes from a statement by Petitioner giving her reasons why she should not have to submit "more proof" about how financially devastated she is. *Id.*, quoting Petitioner's Hearing Request. If CMS intends to imply that Petitioner's statement constitutes a concession that she never submitted any proof related to her request, that would not be accurate. The record shows that, in addition to her application, Petitioner did submit some documents to the NSC Hearing Officer to support her assertions, including 1099 forms showing her Medicare and Medicaid income for 2012, the last year for which she would have received those forms at the time. CMS Ex. 1, at 19-20. Contrary to what CMS argues, this documentation is not unrelated, given that Petitioner's revalidation application (to which Dr. Brooks certified) identified Dr. Brooks as the sole proprietor of the supplier entity. The certified application also identified Petitioner as doing business as Arztin Foot Care and represented that Petitioner qualified for an exception to the requirement in 42 C.F.R. § 424.57(c)(30) that a DMEPOS supplier be open for business for at least 30 hours a week. CMS Ex. 1, at 7.[7] This certified information is at least relevant to Petitioner's representation in the hardship exception request that she was supplying orthotics to her diabetic patients as an incidental service of her podiatry practice and a convenience to them, rather than seeking to compete as a general medical supply business (which, as CMS points out, is a highly competitive business that, if adequately capitalized, could generally pay the application fee without it being a significant burden). Given the relationship of Dr. Brooks to Petitioner, her income from Medicare and Medicaid is not, in our view, inappropriate to consider in evaluating whether it would be a hardship for Petitioner to pay the application fee relating to the DME business.

[7] To qualify for such an exception, a practice location must be one where a specified type of physician or physical or occupational therapist furnishes items to his or her own patients as part of his or her professional service or be a DMEPOS supplier working with custom made orthotics and prosthetics. 42 C.F.R. § 424.57(c)(30)(ii).

Moreover, CMS's argument is premised on its position that Petitioner had notice of the "comprehensive documentation" required because, "in its initial determination letter dated June 24, 2013, CMS notified Dr. Brooks that it had relied on the criteria set forth in § 15.19.1.C.2" of the manual. RR at 17. NSC's initial determination letter, however, cited to "Chapter 15.9.1C of the Program Integrity Manual," the wrong section. CMS Ex. 1, at 10. 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 15.19.1.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.

Thus, we reject as unfounded CMS's assertion that the ALJ should have granted summary judgment to CMS on the basis that Petitioner conceded that she submitted no supporting documents despite having notice of what she needed to submit.

3. CMS's argument that the ALJ erred because Petitioner's letters were not in the form of affidavits has no merit.

CMS asserts that the ALJ's reasoning in support of summary judgment in favor of Petitioner is erroneous because Petitioner's letters "were not sworn or submitted under oath and were entirely conclusory" and therefore "were insufficient as a matter of law to furnish a basis for entry of summary judgment in her favor." RR at 6. In support, CMS cites the following statement from the Board's decision in *Guardian Health Care Ctr.*, DAB No. 1943 at 7 (2004): "General allegations or conclusory statements that are unsubstantiated by evidence of specific facts are insufficient to create a genuine factual dispute." *Id.*

The quoted statement from *Guardian* refers to the burden on a **non-moving** party to defeat an adequately supported summary judgment motion. Here, CMS did move for summary judgment, arguing that there was no dispute as to a material fact, so that summary judgment in its favor was warranted. The ALJ Decision, however, was not evaluating whether Petitioner showed in response to CMS's motion that a genuine

dispute of material fact existed that would preclude summary judgment in CMS's favor. Instead, the ALJ concluded (albeit without proper procedures) that the undisputed facts entitled Petitioner to judgment in her favor as a matter of law, rather than entitling CMS to judgment as a matter of law.

We also note that all enrollment applications must include a signature on a certification statement that "attests that the information submitted is accurate." 42 C.F.R. § 424.510(d)(3). This requirement does not distinguish between information submitted on the application and information submitted with the application.

4. The ALJ's decision is consistent with Board decisions on burden of proof.

CMS argues that the ALJ erred in granting summary judgment in Petitioner's favor because he wrongly placed the burden of proof on CMS. According to CMS, the ALJ correctly cited to the Board's decision in *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005), which CMS says places the ultimate burden of persuasion on Petitioner. CMS argues, however, that the ALJ Decision "through its reasoning, wrongly places the burden of proof on CMS." RR at 5. In support of this argument, CMS points out that the ALJ Decision states that "CMS has not rebutted the assertions made by Petitioner in her June 14, 2013 letter," that "Petitioner's assertions are unrebutted," and that CMS does "not deny or dispute Petitioner's assertions in her letter regarding the hardship and that it should justify an exception." *Id.* quoting ALJ Decision at 7, 12, and 10. We agree that such statements were inconsistent with the grant of summary judgment, because, as noted in our earlier discussion, the ALJ failed to treat CMS as the non-movant in weighing whether to grant summary judgment against CMS. They do not, however, demonstrate an error in articulating the burden of proof in provider enrollment cases.

The *Batavia* decision involved a CMS determination different from the matter at issue here, so the rationale in that decision would not necessarily apply.[8] Even assuming that the burden of proof analysis in *Batavia* and related cases applies, however, we would conclude that CMS's argument has no merit.

The ALJ's use of the term "unrebutted" in two of the statements CMS quotes is troublesome, particularly since CMS had no notice of what the ALJ considered to be the material facts or that he might grant summary judgment to Petitioner. After reading his

[8] In that case, CMS had imposed a remedy on a long-term care facility for its failure to comply substantially with Medicare participation requirements. The Board held that CMS had the burden of going forward to make a prima facie showing with respect to any disputed fact, but that the nursing home had the ultimate burden of persuasion.

decision as a whole (including the fact that he cited to the *Batavia* decision), however, we do not think the ALJ intended to place the ultimate burden of proof on CMS. In context, the ALJ's statements are best read as meaning merely that CMS did not dispute Petitioner's assertions of fact regarding the hardship that would be associated with her paying the fee. Indeed, this is basically the wording the ALJ used in the third statement quoted by CMS. ALJ Decision at 10.

5. The ALJ did not place an impossible burden on CMS.

In a related vein, CMS argues that "[u]nder the rationale of the ALJ Decision, in order to deny Dr. Brooks a hardship exception, CMS would be required to investigate her allegations and produce evidence in response to her letter of June 14, 2013, regarding the changes in the Illinois Medicaid program coverage of podiatry services, the number of Medicare and Medicaid patients treated by Dr. Brooks, and financial information about Dr. Brooks' practice." RR at 5. According to CMS, "absent resort to traditional discovery methods, which are not available in proceedings under 42 C.F.R. Part 498, CMS cannot obtain documents about a supplier's financial condition or practice trends unless a supplier provides it as part of the record." *Id.* Furthermore, CMS argues, "given the ALJ's reasoning, as long as a supplier writes a letter explaining why its business is struggling to stay even, without any evidence to substantiate such assertion, CMS would have to grant a hardship exception because it would be unable to refute the claim." *Id.* at 5-6.

We disagree with CMS because we do not read the ALJ Decision as relying on such a rationale. In any case, we 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. Under section 424.514(f), CMS could deny a request for an exception if the letter submitted with the application did not, in fact, describe "the hardship and why the hardship justifies an exception" or if CMS had a reason for determining that the described facts did not exist or did not, in fact, constitute a hardship justifying an exception. CMS or NSC may also request that a provider support its assertions with reasonable documentation and may apply reasonable guidance to make a case-by-case evaluation of the claimed justifications for a request.[9]

[9] We note, however, that CMS's claim that it had **no** way of evaluating the validity of Petitioner's assertions is inconsistent with what CMS has said elsewhere about the information available to it. *See, e.g.,Capitol Hill Comm. Rehab. & Specialty Care Ctr.*, DAB CR469 (1997) (declarant's explanation of how CMS's predecessor agency could evaluate a provider's financial condition by obtaining information from sources such as a Medicare contractor and a Medicaid agency), *aff'd* DAB No. 1629 (1997). Petitioner was already enrolled in the Medicare program at the time Petitioner submitted the revalidation application, and her evidence shows she was also participating in Medicaid. Moreover, while it is true that traditional discovery procedures are not available in a Part 498 proceeding, a party in such a proceeding may request a subpoena identifying documents to be produced. 42 C.F.R. § 498.58.

CMS also asserts that the ALJ failed to consider that the "Board and numerous ALJs have consistently rejected claims concerning financial condition and inability to pay that are completely bereft of documentary support," quoting from several ALJ and Board decisions. RR at 6-7. As CMS acknowledges, however, those decisions were each addressing whether a nursing facility had shown that its financial condition warranted a reduction of the amount of a civil money penalty (CMP) imposed on the facility for a failure to comply substantially with Medicare participation requirements. In that context, the Board had long held that an ALJ could reasonably determine that CMS did not need to establish that a nursing facility's financial condition enabled it to pay the CMP amount imposed, but, instead, the burden was on a facility advocating a reduction in the CMP amount to show that paying that amount would cause it to go out of business or compromise resident health or safety. *See, e.g., Oceanside Nursing & Rehab. Ctr.*, DAB No. 2382, at 22-23 (2011), citing *Gilman Care Ctr.*, DAB No. 2357, at 7 (2010). That holding was based in part on the preamble to the relevant regulation, which specifically said that it was the facility's responsibility to "furnish the information it believes appropriately represents its financial status" if it wished CMS to consider financial condition in setting the amount of the penalty. 59 Fed. Reg. 56,116, 56,204.[10]

While CMS may reasonably require documentation of the assertions on which a particular hardship exemption is requested, and reasonably presume that the provider has access to information about its own business and finance, it would not be reasonable to expect that a provider would need to submit the same level of documentation to support a hardship request as to reduce a CMP. For one thing, paying an application fee could represent a "hardship" for a provider, even if it would not cause the provider to go out of business or to compromise patient health and safety. Moreover, the amount of the fee is relatively low compared to many CMPs, which may range up to $10,000 per day of noncompliance. At some point, the cost of providing supporting documentation could become as expensive as paying the application fee, and Congress clearly could not have intended that. Instead, any documentation requirement must represent a balance between the need for program integrity and the burden on providers.

C. We remand this case to the ALJ.

Having concluded that summary judgment is not appropriate in either party's favor, we remand this case to the ALJ to issue a decision on the merits consistent with our analysis above. Because neither party has requested further record development in this case, the ALJ may issue a new decision based on the existing record, unless he determines that further record development is needed.

[10] CMS erroneously suggests that it is only the State Operations Manual that indicates that information provided by the facility will be used to evaluate a nursing facility's financial condition. RR at 16.

Conclusion

For the reasons stated above, we conclude that summary judgment is not appropriate and therefore reverse the ALJ Decision and remand this case to the ALJ.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Judith A. Ballard
Presiding Board Member