Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

R.B. Hughes Drug, Inc.
d/b/a Halifax Pharmacy,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-1070

Decision No. CR3108

Date: February 11, 2014

DECISION

The National Supplier Clearinghouse (NSC) of Palmetto GBA, a contractor for the Centers for Medicare & Medicaid Services (CMS), revoked the Medicare enrollment and billing privileges of R.B. Hughes Drug, Inc., doing business as Halifax Pharmacy (Petitioner), for not providing information to NSC upon request and not complying with the accreditation requirements for suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Petitioner requested a hearing, arguing that it is exempt from the accreditation requirement, and CMS moved for summary judgment.

For the reasons explained below, I find that the undisputed material facts show that Petitioner did not comply with at least one supplier standard for suppliers of DMEPOS that required the production of statutorily-required information upon CMS's request. 42 C.F.R. § 424.57(c)(21). NSC, acting on behalf of CMS, was therefore authorized to revoke Petitioner's billing privileges. Accordingly, I grant summary judgment in favor of CMS.

I. Case Background and Procedural History

Petitioner is a licensed pharmacy in South Boston, Virginia, that had been enrolled in the Medicare program as a supplier of DMEPOS. In December 2010, Petitioner requested exemption from the general requirement that all suppliers of DMEPOS enrolled in the Medicare program be accredited by an approved accrediting organization. *See* CMS Exhibit (Ex.) 6, at 7; *see also* 42 C.F.R. § 424.57(c)(22). At that time, Petitioner did not submit evidence demonstrating its eligibility for the exemption, nor did it have to; rather, Petitioner was merely required to mail a completed exemption request form titled "Attestation for Exemption from Accreditation." CMS Ex. 6, at 7. The attestations on the form that Petitioner's president signed included, among others, that the "total billing by the pharmacy for DMEPOS to Medicare are less than 5 percent of total pharmacy sales, as determined based on the average total pharmacy sales for the previous 3 years" and that "the pharmacy agrees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually . . . ." CMS Ex. 6, at 7. Based on Petitioner's completed attestation form, NSC exempted Petitioner from the accreditation requirement and notified Petitioner of its exemption in a letter dated January 5, 2011. CMS Ex. 6, at 9.

By letter dated December 19, 2012, NSC notified Petitioner that it was "conducting an audit to verify the validity of [Petitioner's] attestation statement" in Petitioner's 2010 exemption request form. CMS Ex. 6, at 11. Specifically, NSC required that, within 30 days of receipt of the request, Petitioner had to "submit materials that verify you meet the requirement that your billings to Medicare for [DMEPOS] for the previous three calendar years or fiscal years were less than 5% of your total pharmacy sales." CMS Ex. 6, at 11.

Three months later, on March 19, 2013, NSC notified Petitioner that it was revoking Petitioner's Medicare billing privileges "pursuant to 42 [C.F.R.] §§ 405.800, 424.57(e), 424.535(a)(1), and 424.535(g)" effective 30 days after the date of the notice letter, or April 18, 2013. CMS Ex. 5, at 1. NSC also imposed a one year reenrollment bar against Petitioner. CMS Ex. 5, at 1. NSC determined that Petitioner did not comply with two supplier standards stated in 42 C.F.R. § 424.57(c)(21) and (22). Specifically, NSC stated that Petitioner "failed to provide the certification statement and signed tax returns requested in a letter dated December 19, 2012[,] to prove [Petitioner's] pharmacy meets the exemption from accreditation" and that Petitioner's pharmacy "is not currently accredited." CMS Ex. 5, at 1. The notice provided Petitioner with two options: either correct the stated deficiencies and submit a corrective action plan (CAP) within 30 days of the notice, or challenge the stated deficiencies and submit a request for reconsideration within 60 days of the revocation notice. CMS Ex. 5, at 2.

On April 8, 2013, NSC received several documents from Petitioner, but NSC notified Petitioner that its submission did "not indicate the submission of a CAP or request reconsideration." CMS Ex. 4, at 10. Petitioner's president then submitted a letter to NSC on April 16, 2013, which stated:

> I would like to request a reconsideration of your decision not to re-enroll our pharmacy in the Medicare program. This is a corrective action plan to give you any and all information you request so you can determine we are eligible to continue billing [M]edicare without going through the accreditation process . . . .

CMS Ex. 4, at 1.[1] Petitioner also submitted "income reports" for 2011 and 2012, as well as its corporate tax return for 2011. CMS Ex. 4, at 3-9.

On May 23, 2013, NSC issued a reconsidered determination that upheld the revocation of Petitioner's Medicare billing privileges. CMS Ex. 2. The hearing officer found that the documentation Petitioner submitted on April 18, 2013, "does not provide evidence of compliance with supplier standard 21 [42 C.F.R. § 424.57(c)(21)] within the required timeframe." CMS Ex. 2, at 2. The hearing officer also found that Petitioner did not submit materials to support its prior attestation that it was exempt from accreditation and that Petitioner "does not satisfy the requirements for accreditation as mandated by 42 [C.F.R.] 424.57(c)." CMS Ex. 2, at 2-3.

On July 22, 2013, Petitioner filed a request for hearing with the Civil Remedies Division along with several supporting documents, including:

- Petitioner's Medicare claim totals for 2010, 2011 and 2012;
- Petitioner's "Income Reports" for 2010, 2011, and 2012; and
- Petitioner's corporate tax returns for 2010, 2011, and 2012.

On July 26, 2013, I issued an Acknowledgment and Pre-Hearing Order (Pre-Hearing Order) directing the parties to develop the record for a hearing, if necessary, or decision on the written record. CMS filed a motion for summary judgment and supporting brief (CMS Br.) as well as six proposed exhibits (CMS Ex. 1-6). For clarity, CMS reprinted Petitioner's hearing request and supporting documents in CMS Ex. 1. Petitioner filed a one-page letter as its written argument (P. Resp.), as well as three exhibits (P. Exs. 1-3).

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[1] While Petitioner described the initial determination for which it was requesting reconsideration as one "not to re-enroll our pharmacy in the Medicare program," it is apparent, based on its timing and content, that Petitioner was requesting reconsideration of NSC's March 19, 2013 initial determination to revoke Petitioner's billing privileges. There is no evidence that NSC issued a separate initial determination related to Petitioner's enrollment in the Medicare program other than that of March 19, 2013.

Petitioner did not object to the admission of any of CMS's proposed exhibits. Therefore, I admit CMS Ex. 1-6 into the record, with the limited exception of reprinted material in CMS Ex. 1, as explained below.

CMS objects to the admission of the supporting documents that Petitioner submitted with its request for hearing (reprinted in CMS Ex. 1, at 6-10, 12-13, 15, and 20-23) as well as three of Petitioner's proposed exhibits: P. Ex. 1, at 1, 6-9 (Petitioner's 2010 tax return); P. Ex. 2, at 2 (Petitioner's 2010 "Profit & Loss" statement); and P. Ex. 3 in its entirety (Petitioner's Medicare claims information for 2010, 2011, and 2012). CMS Br. at 8 n.4. CMS argues that these documents were not previously submitted to CMS, and Petitioner has not shown good cause for failing to present them earlier, as required by 42 C.F.R. § 498.56(e). CMS Br. at 8 n.4; *see also* Pre-Hearing Order at 2, ¶ 3. Petitioner did not respond to CMS's objections.

I must exclude any evidence presented for the first time at this level, unless I find good cause for Petitioner's failure to submit it earlier. 42 C.F.R. § 498.56(e). Here, Petitioner has implied that it was too busy to respond to NSC, although Petitioner does not expressly claim this as "good cause" to admit these documents. P. Resp. at 1. In any event, being busy is not an acceptable basis to excuse the untimely submission of these documents and certainly not good cause to admit these documents nearly six months after they were due and three months after Petitioner had another opportunity to submit them to NSC with its CAP and request for reconsideration. I therefore decline to admit or consider the supporting documents that Petitioner submitted with its hearing request (reprinted in CMS Ex. 1, at 6-10, 12-13, 15, and 20-23), as well as P. Ex 1, at 1, 6-9; P. Ex. 2, at 2; and P. Ex. 3. I admit P. Ex. 1, at 2-5 and P. Ex. 2, at 1, 3-4 as those documents were produced during the reconsideration level of review and CMS has not objected to their admission.

Neither party filed direct witnesses testimony in the form of affidavits, so there is no need for an in-person hearing. *See* Pre-Hearing Order at 6, ¶ 10.

II. Statutory and Regulatory Framework

The Social Security Act (Act) requires a supplier of DMEPOS to comply with quality standards, "applied by recognized independent accreditation organizations," in order for the supplier to furnish any item for which Medicare will make payment and to receive or retain a supplier number used to obtain reimbursement. 42 U.S.C. § 1395m(a)(20)(A); *see also* 42 C.F.R. § 424.57(c)(22). The Act also requires pharmacies selling DMEPOS to obtain the necessary accreditation by January 1, 2010, although the Act clarifies that evidence of accreditation need not to be submitted until January 1, 2011. 42 U.S.C. §§ 1395m(a)(20)(F).

The Act permits pharmacies selling DMEPOS to be exempted from the accreditation requirement if they meet four criteria: (1) the total billing of the items or services for which accreditation was required were less than five percent of the pharmacy's total sales during the last three years; (2) the pharmacy was enrolled as a DMEPOS supplier in the Medicare program for at least five years and has not been subject to an adverse action in the past five years; (3) the pharmacy attests that it meets the first two criteria; and (4) the pharmacy agrees to submit documentation to the Secretary that demonstrates the pharmacy meets the first and second criteria. *Id.* § 1395m(a)(20)(G)(ii)(I)-(IV). The Act leaves alternative accreditation requirements of exempt pharmacies to the Secretary's discretion. *Id.* § 1395m(a)(20)(G)(i)(II).

The Act also authorizes the Secretary to establish by regulation various requirements for suppliers of DMEPOS to maintain enrollment in the Medicare program. *Id.* § 1834(a). A supplier of DMEPOS must, among other things, certify that it meets and will continue to meet the standards at 42 C.F.R. § 424.57(c). These standards include, in relevant part, that a supplier will provide "to CMS, upon request, any information required by the Medicare statute and implementing regulations." 42 C.F.R. § 424.57(c)(21). In addition:

> All suppliers of DMEPOS and other items and services must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must include the specific products and services, for which the supplier is accredited in order to receive payment for those specific products and services.

Id. § 424.57(c)(22). If a DMEPOS supplier does not comply with any of the standards set forth in section 424.57(c), CMS "will revoke" the supplier's billing privileges. *Id.* § 424.57(e).[2] A provider or supplier that does not comply with applicable enrollment requirements is also subject to revocation pursuant to section 424.535(a)(1) and an enrollment bar from one to three years. 42 C.F.R. § 424.535(a)(1), (c).

[2] Subsection (e) of section 424.57 was previously designated as subsection (d) and was redesignated by the rulemaking that imposed the surety bond requirements at subsection (d). The redesignations, however, were not officially incorporated in the C.F.R. volumes issued October 1, 2009, 2010, 2011, or 2012 "due to inaccurate amendatory instruction," and the text added by revised paragraph (d) appears in those volumes as an "Editorial Note" to section 424.57. *See Complete Home Care, Inc.*, DAB No. 2525, at 2 n.2 (2013). Consistent with the Board's practice in similar cases, references here are to the regulation as redesignated.

III. Discussion

a. Issue Presented

The issue in this case is whether CMS is entitled to summary judgment that NSC, acting on behalf of CMS, was authorized to revoke Petitioner's Medicare enrollment and billing privileges.

b. Findings of Fact and Conclusions of Law

1. *Summary judgment is appropriate*.

Summary judgment is appropriate if "the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law." *Senior Rehab. & Skilled Nursing Ctr.*, DAB No. 2300, at 3 (2010) (citations omitted). The moving party must show that there are no genuine issues of material fact requiring an evidentiary hearing and that it is entitled to judgment as a matter of law. *Id.* If the moving party meets its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial . . . .'" *Matsushita Elec. Indus. Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986). "To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact — a fact that, if proven, would affect the outcome of the case under governing law." *Senior Rehab.*, DAB No. 2300, at 3. To determine whether there are genuine issues of material fact for hearing, an ALJ must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. *Id.*

Here, CMS moved for summary disposition and provided documentary evidence that sufficiently establishes the material facts of the case. CMS Br. at 1; CMS Exs. 1-6. Petitioner has not disputed the documentary evidence that CMS submitted, nor has Petitioner established a genuine dispute of material fact that would preclude summary judgment. Even though Petitioner has submitted additional documentation that may have supported its overall position that it was exempt from the accreditation requirement applicable to suppliers of DMEPOS, that issue, and therefore those documents, are not material to the outcome here. A conclusion that CMS was authorized to revoke Petitioner's billing privileges because Petitioner did not comply with at least one supplier standard for suppliers of DMEPOS is a sufficient basis to decide this case through summary judgment without consideration of Petitioner's compliance with other supplier standards. *See 1866ICPayday.com, L.L.C.*, DAB No. 2289, at 13 (2009) ("[F]ailure to

comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges."). Therefore, while there may be facts in dispute with regard to Petitioner's compliance with some supplier standards, those facts are ultimately not material here because there are undisputed facts establishing Petitioner's noncompliance with 42 C.F.R. § 424.57(c)(21).

The only issue to be resolved in this case is a matter of law, which, as discussed below, must be decided in CMS's favor. Accordingly, summary judgment is appropriate.

2. *The undisputed evidence shows that Petitioner did not provide required information to NSC.*

Suppliers of DMEPOS must "[provide] to CMS, upon request, any information required by the Medicare statute and implementing regulations." 42 C.F.R. § 424.57(c)(21). The Act (Title XVIII of which establishes the Medicare program) requires pharmacies to meet four criteria to be exempt from the requirement that suppliers of DMEPOS be accredited, including, as relevant here, that the exempt pharmacy:

> [A]grees to submit materials as requested by the Secretary, or during the course of an audit conducted on a random sample of pharmacies selected annually, to verify that the pharmacy meets the criteria described in subclauses (I) and (II). Materials submitted under the preceding sentence shall include a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods, as requested by the Secretary.

42 U.S.C. § 1395m(a)(20)(G)(IV). "Subclauses I and II" state that the amount of a pharmacy's total Medicare claims for DMEPOS must be less than five percent of its overall total sales for it to be exempt from accreditation, and the pharmacy must have been enrolled in the Medicare program for the preceding five years. 42 U.S.C. § 1395m(a)(20)(G)(I)-(II).

By letter dated December 19, 2012, in order to conduct an "audit to verify the validity of [Petitioner's] attestation statement," NSC required Petitioner to submit:

- A certification statement signed by an accountant that verifies that you meet the requirement that your billings to Medicare for [DMEPOS] for the previous three calendar years or fiscal years were less than 5% of your total pharmacy sales; or

- Copies of signed tax returns that verify that you meet the requirement that your billings to Medicare for DMEPOS for the previous three calendar years or fiscal years were less than 5% of your total pharmacy sales.

CMS Ex. 6, at 11. The material that NSC requested from Petitioner tracks the Act's description of the material that is required to verify a pharmacy's exemption from the accreditation requirement. *Compare* CMS Ex. 6, at 11 (requesting a certification of income by an accountant or the pharmacy's tax returns for three preceding years) *with* 42 U.S.C. § 1395m(a)(20)(G)(IV) (requiring either "a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods"). Therefore, the December 16, 2012 letter from NSC requested "information required by the Medicare statute." 42 C.F.R. 424.57(c)(21). The letter directed Petitioner to provide that information within 30 days of the receipt of the request letter. CMS Ex. 6, at 11.

It is undisputed that Petitioner did not respond in any way to the request for information that verified its exemption from accreditation within the 30-day timeframe that NSC specified. *See* CMS Ex. 5, at 1; P. Resp. at 1 (acknowledging that it did not timely provide information to NSC). Even after receiving NSC's initial notice of revocation, Petitioner still did not properly respond to the request. Instead, with its CAP and request for reconsideration, Petitioner provided an accountant's certification of income for 2011 and 2012, a tax return for 2011, and Form 1099-MISC for 2012. CMS Ex. 4, at 4-9. These income verifications, however, covered only two years, not three years as required by statute as well as NSC's December 19, 2012 letter. It was only with its request for hearing that Petitioner finally included a certification of income for three calendar years as well as tax returns for those years.

While neither the Act nor the regulations specify a period in which a pharmacy must respond to a request for income-related information, 30 days, which NSC provided Petitioner in this case, is certainly reasonable. Indeed, Petitioner has not disputed the reasonableness of the length of time to respond to NSC's request. The requested documents were not complex, and the certified income statement that Petitioner finally submitted had only three columns and was about one quarter of a page long. *See* CMS Ex. 4, at 4. In addition, if Petitioner had opted to send tax returns as a means of verifying its income, the documents should have already been created and accessible.

In its response letter, Petitioner implies for the first time that it was too busy to comply with NSC's request in a timely fashion. Petitioner states that it "had to complete a full count of all control drugs plus take an inventory for tax purposes to end out the year."

P. Resp. at 1. Petitioner also explains that it took significant time to receive claim-related information from CGS Administrators, another CMS contractor, which helped explain the total claims that Petitioner submitted to CMS for DMEPOS.[3] P. Resp. at 1.

However, Petitioner's submission of documents at this level of review, which should have been submitted to NSC six months ago, does not absolve Petitioner's prior noncompliance with 42 C.F.R. § 424.57(c)(21), which requires a response "upon request," not when it was apparently most convenient for Petitioner. In its December 2010 attestation form, Petitioner attested that it would "submit materials as requested by the Secretary . . . [including] a certification by an accountant on behalf of the pharmacy or the submission of tax returns filed by the pharmacy during the relevant periods[.]" Petitioner, therefore, certainly knew the requirements for exemption from accreditation, and that it was required to provide NSC or CMS with information verifying its exemption upon request. *See* CMS Ex. 6, at 7. But Petitioner did not comply with the statutory and regulatory requirements with which it attested it would. Moreover, if Petitioner would not or could not provide the required information upon request (as it now implies), then it was not exempt from the accreditation requirement from the outset. *See* 42 U.S.C. § 1395m(a)(20)(G)(IV); CMS Ex. 6, at 7.

The undisputed evidence shows that Petitioner did not comply with the regulation requiring it to provide CMS, upon request, with material required by the Medicare statute and the implementing regulations. *See* 42 C.F.R. § 424.57(c)(21).[4]

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[3] It is unclear why Petitioner sought to obtain its own billing information from a CMS contractor when neither the Act nor NSC's December 16, 2012 request letter required such a breakdown of Petitioner's Medicare claims. Moreover, Petitioner apparently made the request in May or June of 2013, well after NSC requested the information and the deadline for supplying that material had passed. *See* P. Resp. at 1 (stating that it was "over a month" before receiving a response from CGS, which, in turn, was dated July 15, 2013). Therefore, I reject as unreasonable any inference that Petitioner sought the information from CGS as part of its response to NSC's original December 16, 2012 request for information. *See Brightview Care Ctr.*, DAB No. 2132, at 10 (2007) (rejecting inferences that were not reasonable on review of summary judgment).

[4] I do not reach the issue of whether Petitioner complied with 42 C.F.R. § 424.57(c)(22) because, even if I accepted Petitioner's income-related documents submitted with its request for hearing, and Petitioner cured that alleged deficiency with those documents, there is a basis to revoke Petitioner's billing privileges because it did not comply with at least one other supplier standard in section 424.57(c).

3. *NSC, acting for CMS, was authorized to revoke Petitioner's billing privileges because Petitioner was not in compliance with the Medicare enrollment requirements for suppliers of DMEPOS.*

CMS "will revoke" the Medicare billing privileges of a supplier of DMEPOS that does not comply with the requirements in 42 C.F.R. § 424.57(b)-(c). 42 C.F.R. § 424.57(e). Also, CMS "may revoke" the Medicare enrollment billing privileges of any provider or supplier that does not comply with enrollment requirements applicable for its provider or supplier type. 42 C.F.R. § 424.535(a)(1). The enrollment requirements for suppliers of DMEPOS are stated in 42 C.F.R. § 424.57(c), thus noncompliance with any of those standards permits CMS to revoke a supplier's billing privileges under both of these regulatory provisions. *See Main St. Pharmacy, LLC*, DAB No. 2349, at 7 n.4 (2010).

Here, NSC cited both section 424.57(e) and section 424.535(a)(1) as a basis for revoking Petitioner's billing privileges. CMS Ex. 5, at 1. However, NSC stated that the revocation of Petitioner's billing privileges would be effective 30 days after the notice and also provided Petitioner an opportunity to correct its noncompliance through a CAP, both of which are only stated in 42 C.F.R. § 424.535(a)(1), (g).[5] CMS Ex. 5, at 1-2; *see also Conchita Jackson, M.D.*, at 1 (2013) ("[T]he CAP process gives a supplier an opportunity to correct deficiencies that resulted in the denial of its application or the revocation of its billing privileges."). Thus, while NSC cited both sections 424.57(e) and 424.535(a)(1), it is apparent that it revoked Petitioner's billing privileges pursuant to 42 C.F.R. § 424.535(a)(1).

The supplier standards in 42 C.F.R. § 424.57(c) are requirements that suppliers of DMEPOS must meet to maintain enrollment. *See A to Z DME, LLC*, DAB No. 2303, at 3 (2010). Here, Petitioner's noncompliance with 42 C.F.R. § 424.57(c)(21) means that it was no longer in compliance with the enrollment requirements applicable to its supplier type, and revocation was authorized under 42 C.F.R. § 424.535(a)(1).

IV. Conclusion

For the reasons explained, I find that CMS is entitled to summary judgment that it was authorized to revoke Petitioner's Medicare enrollment and billing privileges effective April 18, 2013.

/s/
Joseph Grow
Administrative Law Judge

[5] Revocations under 42 C.F.R. § 424.57(e) are effective 15 days after the notice is sent and there is no opportunity to correct any deficiencies.