Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Nostrand Rx Corp.
(PTAN: 6477000001),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-12-524

Decision No. 2620

Date: September 21, 2012

DECISION

The National Supplier Clearinghouse (NSC), an administrative contractor acting on behalf of the Centers for Medicare and Medicaid Services (CMS), revoked Petitioner's Medicare billing privileges. NSC determined that Petitioner violated Supplier Standard 22, 42 C.F.R. § 424.57(c)(22), when it billed the Medicare program for Durable Medical Equipment (DME) even though Petitioner was not accredited as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). Petitioner appealed. For the reasons stated below, I affirm the determination to revoke Petitioner's billing privileges.

I. Case Background and Procedural History

Elan Katz, Petitioner's owner, completed and signed a Form CMS-855S in May 2010, seeking to enroll Petitioner as a supplier with the Medicare program with direct billing privileges. CMS Ex. 13, at 20. The completed Form CMS-855S indicated that Petitioner: was a "new enrollee"; was a Pharmacy; was not accredited to bill for DME; would not supply DME, including blood glucose monitors and/or supplies; would start conducting business on June 21, 2010; and would be doing business as Care RX

Pharmacy.[1] CMS Ex. 13, at 3, 5, 7, 8, 11, 36. During the enrollment process, NSC conducted a site visit of Petitioner on July 8, 2010. The inspector's report indicates that Petitioner was selling glucose test strips and that Petitioner's manager/pharmacist stated Petitioner would seek accreditation in the near future. CMS Ex. 13, at 49, 68, 70. Subsequently, Petitioner received Medicare billing privileges.

On July 11, 2011, NSC conducted another site inspection of Petitioner. The inspector's report indicates that Petitioner had glucose monitors, and glucose strips and lancets in stock. CMS Ex. 6, at 7, 18-21, 40, 43, 49, 51. By letter dated August 3, 2011, NSC notified Petitioner that it violated Supplier Standard 22 because it had not been accredited. CMS Ex. 7. This letter, sent via certified mail, return receipt requested, notified Petitioner that it had 21 days to: submit an attestation that it was exempt from the accreditation requirement; obtain accreditation; or submit a signed statement that Petitioner would "no longer bill any items other than drugs to Medicare." CMS Exs. 7, at 2; 7A; 19. NSC warned that a failure to comply might lead to the revocation of Petitioner's Medicare supplier number. CMS Ex. 7, at 3. NSC did not receive a response from Petitioner. CMS Ex. 9, at 1.

In an October 21, 2011 letter, NSC notified Petitioner that it was revoking Petitioner's supplier number and billing privileges effective November 20, 2011, and imposing a one-year bar on Petitioner's reenrollment. CMS Ex. 9, at 1. The letter advised Petitioner that it could file a corrective action plan (CAP) and request reconsideration. CMS Ex. 9, at 2.

On November 2, 2011, Petitioner submitted a CAP. P. Ex. C. On November 18, 2011, NSC rejected Petitioner's CAP. CMS Ex. 11. Petitioner then requested reconsideration. P. Ex. E. In its March 21, 2012 determination on reconsideration, NSC concluded that Petitioner did not comply with Supplier Standard 22 and that revocation of Petitioner's billing privileges was appropriate. CMS Ex. 1, at 2-3.

Petitioner timely filed a request for a hearing with the Departmental Appeals Board, Civil Remedies Division. In response to my order requiring a more definite statement of its reasons for requesting a hearing, Petitioner, through counsel, filed an amended request for a hearing (RH). Following the issuance of my April 5, 2012 Acknowledgment and Pre-hearing Order (Pre-hearing Order), CMS filed its pre-hearing brief (CMS Br.), along with 18 proposed exhibits (CMS Exs. 1-18). Petitioner filed the following: a pre-hearing brief (P. Br.); five proposed exhibits (P. Exs. A-E); and the affidavit of Petitioner's general manager, Max Berger. Petitioner did not mark Mr. Berger's affidavit as an

[1] Prior to purchase by the current owner on June 20, 2010, a pharmacy existed at Petitioner's location named Care Pharmacy. P. Ex. C. Care Pharmacy's accreditation as a DMEPOS supplier was valid from September 14, 2009 through September 13, 2012. P. Ex. B.

exhibit; therefore, I mark it as Petitioner's Exhibit F. CMS later filed a motion to supplement its exhibit list and provided two additional proposed exhibits (CMS Exs. 19-20). Petitioner filed a reply brief (P. Reply Br.) and did not oppose the admission of CMS Exs. 19 and 20. Because neither party has objected to any of the proposed exhibits, I admit CMS Exhibits 1-20 and Petitioner's Exhibits A-F into the record.

The Pre-hearing Order advised the parties that they must submit written direct testimony for each proposed witness and that an in-person hearing would only be necessary if the opposing party requested an opportunity to cross-examine a witness. Pre-hearing Order ¶¶ 7, 9; *Vandalia Park*, DAB No. 1940 (2004); *Pacific Regency Arvin*, DAB No. 1823, at 8 (2002) (holding that the use of written direct testimony for witnesses is permissible so long as the opposing party has the opportunity to cross-examine those witnesses). CMS did not offer any witnesses that Petitioner could request to cross-examine. Petitioner offered the written direct testimony of Max Berger (P. Ex. F); however, CMS did not request to cross-examine this witness.[2] *See* Pre-hearing Order ¶ 8. Consequently, I will not hold an in-person hearing in this matter. *See Kate E. Paylo, D.O.*, DAB CR2232, at 9 (2010). Accordingly, the record is closed and I will evaluate the submitted documentary evidence and Mr. Berger's written direct testimony. *See* Pre-hearing Order ¶ 10.

II. Discussion

A. Issues

The issues in this case are:

1. whether Petitioner was in compliance with 42 C.F.R. § 424.57(c)(22); and

2. if Petitioner was not in compliance with 42 C.F.R. § 424.57(c)(22), whether CMS had the authority to revoke Petitioner's billing privileges.

[2] Petitioner's list of proposed witnesses identifies both Mr. Berger and Elan Katz. However, Petitioner did not submit written direct testimony for Elan Katz as required by paragraph 7 of the Pre-hearing Order. Further, Petitioner did not object to the written direct testimony requirement in the Pre-hearing Order, nor did it request that I waive the requirement. *See Golden Living Center – Frankfort*, DAB No. 2296, at 4 (2009) (noting that the petitioner had not "made any request below to require particular witnesses to present their direct testimony in person"); *The Laurels at Forest Glenn*, DAB No. 2182, at 10 (2008) (noting that a party failed to object to the pre-hearing order's direct testimony requirement "at the time").

B. Findings of Fact, Conclusions of Law, and Analysis[3]

In order to participate in the Medicare program as a supplier, individuals and entities must meet certain criteria to enroll and receive billing privileges. 42 C.F.R. §§ 424.505, 424.510. Further, CMS may revoke those privileges if the supplier fails to comply with regulatory requirements. 42 C.F.R. § 424.57(d) (2011). In this case, CMS determined that Petitioner violated 42 C.F.R. § 424.57(c)(22), which provides that a supplier 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.

Therefore, in order for Petitioner to be in compliance with 42 C.F.R. § 424.57(c)(22), I must determine whether Petitioner billed (i.e., sought to receive payment from) the Medicare program for DME, and if so, whether Petitioner was accredited to bill the Medicare program for that DME.

1. Petitioner billed the Medicare program for blood glucose monitors without the proper accreditation.

NSC determined that Petitioner improperly billed the Medicare program for DME. CMS Ex. 1. CMS provided as evidence for this conclusion the NSC's inspection reports that show Petitioner was selling glucose testing strips and monitors, and a summary of CMS's billing records that shows Petitioner billed the Medicare program for $6,335.50 for glucose monitors and $4,440.51 for nebulizers and related drugs from August 2011 through October 2011. CMS Exs. 6, at 7, 18-21; 8; 13, at 49, 68.

Petitioner argues that CMS has not provided any evidence that it billed the Medicare program for items requiring accreditation and that the claims that Petitioner billed for nebulizer equipment is incorrect; Petitioner asserts it only billed for nebulizer drugs, which do not require accreditation. P. Br. at 4-5; P. Exs. A, B, F at ¶¶ 5-7, 14. Petitioner also states that it could sell items requiring accreditation so long as Petitioner did not bill Medicare for those items, apparently asserting that Petitioner did not bill Medicare for those items. P. Br. at 5, 8.

In response, CMS argued that Petitioner's general manager did not deny that Petitioner sold glucose monitors, which CMS stated was clearly DME under 42 U.S.C. § 1395x(n). CMS Motion to Supplement Exhibit List at 2 n.1. CMS did not respond to Petitioner's evidence that it only billed the Medicare program for nebulizer drugs, P. Ex. A, and

[3] My findings of fact and conclusions of law are set forth in italics and bold font.

CMS's summary of billing indicates Petitioner may have billed for nebulizer drugs. CMS Ex. 8.

I find that CMS has sufficient evidence to conclude that Petitioner billed the Medicare program for glucose monitors, and that Petitioner failed to prove that it had not billed for those items. It is well established that CMS only has the burden of production to show non-compliance. *Hillman Rehabilitation Center*, DAB No. 1611 (1997) ("The burden remains on the provider to show that it continues to qualify under the Act and the regulations"), *aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). As explained in *Hillman*: "[The petitioner] here is the proponent of an order certifying it as qualified to participate in the program and to receive Medicare payment for services rendered, so it is fair to place the burden on [the petitioner]." *Id.* This principal has been repeatedly reaffirmed for cases adjudicated under 42 C.F.R. Part 498. *See, e.g., Tri-County Extended Care Center*, DAB No. 2060 (2007); *Sanctuary at Whispering Meadows*, DAB No. 1925 (2004); *Fairfax Nursing Home, Inc.*, DAB No. 1794 (2001).

Although Petitioner has provided evidence to dispute that it billed for nebulizers, Petitioner has not met its burden regarding CMS's determination that it billed for glucose monitors. To the contrary, Petitioner has admitted to selling and billing for DME. P. Ex. C (stating in CAP that "[t]he only Durable Medical Equipment dispensed by our pharmacy during this time was diabetic strips and diabetic monitors"); RH at 2-3 ("the amount of billing for the products required accreditation was *de minimus*."). Therefore, I find that Petitioner billed the Medicare program for glucose monitors, items for which it needed accreditation.

2. Petitioner has never been accredited to bill Medicare for blood glucose monitors.

NSC revoked Petitioner's Medicare billing privileges because Petitioner was billing for items for which Petitioner needed accreditation. CMS Exs. 1, at 2; 6, at 7, 16-18, 20-21, 40, 43, 49, 51. The Social Security Act (Act) requires a DMEPOS supplier to be subject to 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). The definition of DME includes "blood-testing strips and blood glucose monitors for individuals with diabetes without regard to whether the individual has Type I or Type II diabetes." 42 U.S.C. §§ 1395m(a)(13); 1395m(a)(20)(D); 1395x(n). Pharmacies furnishing DME needed to obtain accreditation by January 1, 2010, but were not required to submit evidence of accreditation until January 1, 2011. 42 U.S.C. §§ 1395m(a)(20)(F). Pharmacies furnishing DME could be exempted from the accreditation requirement if they met all four of the following criteria: 1) the total billing of the items or services for which accreditation was required was 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 its tax records. 42 U.S.C. § 1395m(a)(20)(G)(ii)(I)-(IV).

In the present matter, Petitioner does not dispute that it has never been accredited and, therefore, cannot bill Medicare for the sale of certain DME items. *See* P. Br. at 7-9. Further, Petitioner has not shown, nor has it argued, that it is exempt from the accreditation requirement. Indeed, Petitioner's CMS-855S application (CMS Ex. 13) dated May 27, 2010, shows that Petitioner was not enrolled as a DMEPOS supplier for at least five years, as required for an exemption. 42 U.S.C. § 1395m(a)(20)(G)(ii)(II). Moreover, the Act places the burden of showing accreditation on the supplier: "the Secretary shall require suppliers furnishing [DME] items and services . . . directly or as a subcontractor for another entity, *to have submitted to the Secretary evidence of accreditation* . . . ." 42 U.S.C. § 1395m(a)(20)(F)(i) (emphasis added). Petitioner has not provided such proof.

Rather than assert it received accreditation, Petitioner argues that it believed that the accreditation from the pharmacy it bought, Care Pharmacy, would automatically transfer to Petitioner upon sale of the former to the latter. RH at 2; P. Exs. B; F at ¶ 14. Petitioner also argued that it did not indicate on the Form CMS-855S that it would sell items requiring accreditation because the accreditation requirement did not apply to Petitioner until January 1, 2011. P. Br. at 4-5.

The testimony of Petitioner's general manager that Petitioner believed that the accreditation from Care Pharmacy was transferred to Petitioner does not absolve it of correctly obtaining accreditation. As argued by CMS, its stated policy is that accreditation is not transferable to a new owner (CMS Exs. 16, at 3; 17, at 8), and Petitioner provides no basis in law that accreditation is transferable.

Further, the evidence of record contradicts Petitioner's claim that it truly believed that the accreditation transferred. On its May 2010 Form CMS-855S, Petitioner stated that it was not accredited. CMS Ex. 13, at 8. However, had Petitioner expected the accreditation to transfer, Petitioner would not have simply provided a negative response. Further, NSC's first inspector recorded that Petitioner's manager/pharmacist stated that the previous pharmacy had been accredited but that Petitioner was "going to go through accreditation again in the near future." CMS Ex. 13, at 70. Because the previous pharmacy's accreditation was valid until 2012 (P. Ex. B), there would not have been any reason for Petitioner to seek accreditation "in the near future" had Petitioner thought the previous pharmacy's accreditation transferred.

Perhaps as an explanation, Petitioner claims that it did not indicate on the May 2010 Form CMS-855S that it would sell items requiring accreditation because it was not required to be accredited until January 2011. P. Br. at 4. However, this argument does not explain why Petitioner would fail to assert it if the accreditation from Care Pharmacy had transferred. Further, Petitioner is incorrect in stating that it did not need to be accredited until January 1, 2011. Pharmacies were required to obtain accreditation by January 2010; however, they did not need to provide proof of the accreditation until January 2011. 42 U.S.C. § 1395m(a)(20)(F). Therefore, by the May 2010 enrollment application, Petitioner should have been accredited to furnish DME and disclosed its intention to sell DME on the Form CMS-855S.

3. Petitioner did not comply with DMEPOS Supplier Standard 22.

Because I find that Petitioner was not accredited to bill the Medicare program for DME and Petitioner billed Medicare for DME, Petitioner violated 42 C.F.R. § 424.57(c)(22).

4. ***The regulations authorize CMS to revoke Petitioner's billing privileges and impose a one-year reenrollment bar.***

If a supplier does not continue to meet the DMEPOS supplier standards, CMS will revoke that supplier's billing privileges. 42 C.F.R. § 424.57(d) (2011). In the present matter, Petitioner's failure to comply with 42 C.F.R. § 424.57(c)(22) is sufficient to uphold the revocation of Petitioner's billing privileges. *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.").

Petitioner suggests in its hearing request that I consider the *de minimus* nature of the DME items for which Petitioner billed Medicare. RH at ¶ 2. Petitioner also argued that a one-year bar from reenrollment was unduly harsh.

I am bound by the regulations and have no equitable authority to reverse a revocation or reduce a reenrollment bar based on the magnitude of Petitioner's noncompliance with DMEPOS supplier standards. *See Letantia Bussell, M.D.*, DAB No. 2196, at 13 (2008). Revocation of Petitioner's billing privileges was not premised on the amount Petitioner billed Medicare for DME items but on Petitioner's failure to be accredited. CMS Ex. 1.

5. Petitioner received an opportunity to correct its deficient compliance and Petitioner does not have a right to administrative law judge review of the decision to reject Petitioner's CAP.

Petitioner argued that it never received NSC's August 3, 2011 letter and, as a consequence, "Petitioner was not given the opportunity to correct the deficient compliance requirement [under 42 C.F.R. § 424.535(a)(1)] before a final determination to revoke billing privileges" and "therefore was forced to submit a CAP that was improperly considered." P. Br. at 8. Further, in its amended hearing request, Petitioner argued that I should review NSC's rejection of Petitioner's CAP. *See* RH at ¶ 2. However, Petitioner received an opportunity to correct its deficiencies and Petitioner has no right to seek further review of its CAP.

While it is true that CMS must afford a supplier the opportunity to correct deficiencies before a final determination to revoke is made, 42 C.F.R. § 424.535(a)(1), such an opportunity can be provided through the submission of a CAP. *DMS Imaging, Inc.*, DAB No. 2313, at 7 (2010). Because there is no dispute that the initial determination to revoke informed Petitioner of the opportunity to submit a CAP (CMS Ex. 9, at 2) and Petitioner submitted a CAP in response to the initial determination (P. Ex. C), Petitioner received an opportunity to correct as required by the regulations. *DMS Imaging, Inc.*, DAB No. 2313, at 4 ("[Petitioner] does not deny that it received an opportunity to correct through the submission of a CAP. Therefore, we need not reach the question of whether the scope of review by an [administrative law judge] of a revocation under section 424.535(a)(1) includes determining whether CMS granted a supplier an opportunity to correct.").

Moreover, I find that NSC provided that opportunity through the issuance of its August 3, 2011 letter. CMS Ex. 7. Although Petitioner asserts that it never received that letter, *see* P. Br. at 6, NSC sent the letter by certified mail, return receipt requested, and the United States Postal Service (USPS) delivered it to Petitioner's address on August 6, 2011. The certified mail receipt indicates the same item number as the signed return receipt card, and a USPS internet printout showing delivery also indicates the same item number. CMS Exs. 7, 7A, 19. Such evidence creates "a strong presumption that Petitioner received the notice," *Sunil R. Lahiri, M.D.*, DAB CR296, at 17 (1993), a presumption that Petitioner did not rebut through Mr. Berger's simple denial of receipt. P. Ex. F, at ¶¶ 9-11. I find that the signed USPS certified mail return receipt and corroborating USPS printout, which show delivery of the letter to Petitioner's address and receipt of the letter from the signatory, significantly outweigh the affidavit. This is especially so because Petitioner did not object to CMS's Exhibit 19 or deny the validity of the return receipt card or the signature on it.

Finally, Petitioner argues that CMS erred in rejecting its CAP and seeks review of that decision. However, CMS's decision to reject a CAP is not an initial determination under 42 C.F.R. Part 498, *see* 42 C.F.R. § 405.874(e) (2011); therefore, Petitioner has no right to seek administrative law judge review of that decision. *See* 42 C.F.R. §§ 498.5, 498.40; *DMS Imaging*, DAB No. 2313, at 8, 10-11.

IV. Conclusion

Upon weighing the evidence in this case, I find that Petitioner was not in compliance with DMEPOS Supplier Standard 22 when it furnished and billed the Medicare program for DME items requiring accreditation. Therefore, CMS's determination to revoke Petitioner's Medicare billing privileges is affirmed.

/s/
Scott Anderson
Administrative Law Judge