Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Kreg Therapeutics, Inc.,
(PTAN: 1175460001),

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-553

Decision No. CR2197

Date: July 28, 2010

DECISION

For the reasons set forth below, I grant the Centers for Medicare & Medicaid Services' (CMS's) motion for summary disposition. The undisputed evidence establishes that Petitioner, Kreg Therapeutics, Inc., was not in compliance with Medicare program requirements, and, as a consequence, CMS has the authority to revoke Petitioner's Medicare supplier number.

I. Applicable Law and Regulations

Section 1834(a)(16)(B) of the Social Security Act (Act), 42 U.S.C. § 1395m(a)(16)(B), states that the Secretary of Health and Human Services (Secretary) "shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment for purposes of payment . . . for durable medical equipment furnished by the supplier unless the supplier provides the Secretary on a continuing basis . . . with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000."

CMS's regulations implement these requirements among the "supplier standards" at 42 C.F.R. § 424.57(c), which suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) must meet to maintain Medicare billing privileges. As relevant

here, section 424.57(c) provides:

> (c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier:
>
> * * * *
>
> (26) Must meet the surety bond requirements specified in paragraph (d) of this section.

The surety bond requirements at 42 C.F.R. § 424.57(d), referenced in supplier standard 26, state, as relevant here, that "beginning October 2, 2009, each Medicare-enrolled DMEPOS supplier must meet the requirements of paragraph (d)," which include "a bond that is continuous," which "meet[s] the minimum requirements of liability coverage ($50,000)," and provides that "[t]he surety is liable for unpaid claims, CMPs [civil money penalties], or assessments that occur during the term of the bond." 42 C.F.R. § 424.57(d)(1)(ii), (4), (5). "The term of the initial surety bond must be effective on the date that the application is submitted to the NSC [National Supplier Clearinghouse, a Medicare contractor]." 42 C.F.R. § 424.57(d)(2).

The regulations provide that failure to submit a surety bond as required is grounds for revocation of a supplier's billing privileges. *See* 42 C.F.R. § 424.57(d)(4)(ii)(B); *see also* 42 C.F.R. § 424.57(d)(11) ("CMS revokes the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions."). The regulations also provide more generally that CMS "will revoke a supplier's billing privileges if it is found not to meet" the supplier standards or other requirements in section 424.57(c). 42 C.F.R. § 424.57(e) (formerly § 424.57(d)).[1]

A supplier that has had its billing privileges revoked is "barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation." 42 C.F.R. § 424.535(c).

CMS may at any time require a DMEPOS supplier to show compliance with the surety bond requirement. 42 C.F.R. § 424.57(d)(12).

---

[1] Paragraph (e) of section 424.57 was previously designated paragraph (d) and was redesignated by the rulemaking that imposed the surety bond requirements at paragraph (d); however, the redesignations have not yet been incorporated into the Code of Federal Regulations. *See* 42 C.F.R. Ch. IV § 424.57, Editorial Note (Oct. 1, 2009). References are to the regulation as redesignated.

II. Background

Petitioner, Kreg Therapeutics, Inc., is a Medicare DMEPOS supplier. The CMS contractor, Palmetto GBA National Supplier Clearinghouse, determined that Petitioner was not in compliance with 42 C.F.R. § 424.57(c)(26) (supplier standard 26) and revoked Petitioner's Medicare supplier number by notice letter dated November 9, 2009.

The notice letter stated that the revocation was effective 30 days from the date of postmark and that Petitioner was barred from re-enrolling in the Medicare program for one year from the effective date of the revocation. CMS Ex. 4; *see* 42 C.F.R. § 405.874(b)(2) (revocation effective 30 days after CMS or the CMS contractor mails the notice of its determination). The letter informed Petitioner that it could appeal the decision by requesting reconsideration within 60 days of the date of postmark, and/or it could submit a corrective action plan within 30 days. CMS Ex. 4.

Petitioner submitted to Palmetto both a corrective action plan and a request for reconsideration and enclosed what it identified as its surety bond.[2] CMS Ex. 5.

A Medicare hearing officer denied the request for reconsideration in a decision dated February 11, 2010, on the ground that Petitioner "has not shown compliance [with] supplier standard 26." CMS Ex. 7, at 2. The hearing officer gave the following rationale for the decision:

> [The] reconsideration request of November 17, 2009 stated in pertinent part, "We failed to meet the October 1, 2009 deadline due to changes in Medicare personnel. The task of assigning new staff distracted our attention from administrative duties. As a result we are now submitting the surety bond along with this request and Corrective Action Plan (CAP)." Kreg Therapeutics Inc has passed the allotted time to satisfy the requirement for a surety bond, which was October 2, 2009, and there is no time extension as noted in the terms set forth for the bond as mandated by 42CFR 424.57(c) and 42CFR 424.57(d). The date of the bond of November 17, 2009 is after the deadline. The supplier, Kreg Therapeutics, Inc, failed to obtain their surety bond in the time frame allotted; consequently the NSC revoked the billing privileges appropriately.

[2] The disposition of the corrective action plan is not before me. The Departmental Appeals Board has held that a contractor has discretion as to whether to accept such later correction and reverse a revocation. *DMS Imaging, Inc.*, DAB No. 2313, at 5 (2010). During the reconsideration and appeal process, the issue is whether a basis for revocation legally sufficient to support CMS's action existed at the time of the revocation notice, not whether the basis was later eliminated pursuant to a corrective action plan.

> Regarding the hearing officer's (HO) scope of review, according to the CMS Program Integrity Manual (PIM), it states in pertinent part, "In reviewing an initial enrollment decision or a revocation, a Medicare contractor, including the NSC, should limit the scope of its review to the contractor's reason for imposing a denial or revocation at the time it issued the action and whether the contractor made the correct decision (i.e., denial/revocation). If a provider or supplier provides evidence that demonstrates or proves that they met or maintained compliance **after** the date of denial or revocation, the contractor shall exclude this information from the scope of the review."

Id., quoting Medicare PIM, ch. 10, § 19.A (emphasis added).

Petitioner timely requested a hearing before an Administrative Law Judge (ALJ). This case was assigned to me for hearing and decision pursuant to 42 C.F.R. § 498.44, which permits designation of a member of the Departmental Appeals Board (Board) to hear appeals taken under part 498. I issued an initial order on March 25, 2010.

On April 26, 2010, pursuant to the briefing schedule, CMS filed a motion for summary disposition and supporting memorandum (CMS Br.). CMS accompanied its April 26, 2010 motion and supporting memorandum with CMS Exhibits (Exs.) 1-7, which I admit into evidence.

Petitioner filed a response to CMS's motion dated May 25, 2010 (P. Br.). Petitioner accompanied its response with several documents, which it did not mark with exhibit numbers. Two of them were duplicates of CMS exhibits, namely CMS Exhibits 4 and 5, and others included the surety bond and other materials attached to the hearing request. I have marked the documents with Petitioner's exhibit numbers for ease of reference as follows: (1) correspondence from the surety to Petitioner dated November 17, 2009, indicating the surety bond is enclosed; (2) a copy of the November 17, 2009 surety bond, (3) copies of the invoices from the surety; (4) a copy of Petitioner's hearing request letter dated March 17, 2010; (5) the duplicate copy of CMS Exhibit 4; and (6) the duplicate copy of CMS Exhibit 5. In its motion, CMS argues that the November 17, 2009 surety bond materials submitted with Petitioner's reconsideration request and hearing request (and with its response brief attachments, which I have marked as Petitioner Exhibits 1-3) should not be admitted as new evidence, because they are not relevant to determine whether the initial decision of revocation was correct when made. CMS Br. at 7-8. I address below CMS's objection.

III. Issue

The issue in this case is whether CMS is entitled to summary disposition on the ground that the undisputed facts demonstrate that the revocation of Petitioner's Medicare billing privileges was legally authorized.

IV. Applicable Standard

CMS's motion made clear that the disposition it sought was in the nature of summary judgment. CMS Br. at 1, 4-5. The Board stated the standard for summary judgment as follows.

> Summary judgment is appropriate when 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. . . . The party moving for summary judgment bears the initial burden of showing that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. . . . 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. . . . In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.

Senior Rehab. & Skilled Nursing Ctr., DAB No. 2300, at 3 (2010) (citations omitted). The role of an ALJ in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the weight of conflicting evidence. *Holy Cross Vill. at Notre Dame, Inc*, DAB No. 2291, at 5 (2009).

V. Findings of Fact, Conclusions of Law, and Discussion

I make a single finding and conclusion set out below and followed by my supporting discussion:

> ***CMS was authorized to revoke Petitioner's billing privileges based on undisputed evidence that Petitioner had not obtained a surety bond as required by 42 C.F.R. § 424.57(c)(26) and (d).***

As noted above, the statute states that the Secretary shall not issue or renew a DMEPOS supplier number "unless the supplier provides the Secretary **on a continuing basis** . . . with a surety bond . . . ." 42 U.S.C. § 1395m(a)(16)(B) (emphasis added).

This requirement for continuous compliance is implemented in the regulations that the Secretary issued. The introductory language of 42 C.F.R. § 424.57(c) states, in pertinent part, "[t]he supplier must meet and must certify in its application for billing privileges that it meets **and will continue to meet**" the supplier standards listed within. (Emphasis added). Those standards include section 424.57(c)(26) (supplier standard 26), which states that a supplier "[m]ust meet the surety bond requirements specified in paragraph

(d) of this section." It follows that a supplier must meet the surety bond requirements specified in paragraph (d) on a continuing basis.

Consistent with this, the preamble to the final rule on appeals of CMS determinations, when a provider or supplier fails to meet the requirements for Medicare billing privileges, states "we believe all providers and suppliers must meet and maintain all Federal and State requirements for their provider or supplier type to enroll or maintain their enrollment in the Medicare Program." 73 Fed. Reg. 36,448, 36,452 (June 27, 2008).

Petitioner admits that it was not in compliance with the surety bond requirement. P. Br. at 2. However, Petitioner argues that "in accordance with the November 9, 2009 letter from NSC Supplier Audit and Compliance Unit[, warning Petitioner that its supplier number will be revoked in 30 days,] Kreg Therapeutics, Inc., has successfully submitted a Corrective Action Plan providing sufficient evidence that it is in full compliance with all Medicare requirements with the submission of its Reconsideration Request on November 17, 2009." *Id.* With its February 11, 2010 reconsideration request, Petitioner submitted a surety bond dated November 17, 2009. P. Ex. 2.

As noted, CMS objects to the admission of an invoice with the November 17, 2009 surety bond, which I have marked as Petitioner Exhibit 2 and related documents in Petitioner Exhibits 1 and 3, on the grounds that this was new evidence that did not bear on the question of whether the initial decision of revocation was correct when made. CMS Br. at 7-8. CMS contends that the documents were "presumably to establish that the bond, although dated November 17, 2009, was considered by the surety to be effective as of October 2, 2009." *Id*. This presumption is apparently based on the invoice identifying the "effective date" as October 1, 2009 and the "policy period" as October 1, 2009 to October 1, 2010. P. Ex. 4, at 4.

The bond itself was presented to the hearing officer and therefore is not "new evidence" under 42 C.F.R. § 498.56(e) (requiring a showing of good cause for submission of documentary evidence "for the first time at the ALJ level"). It is not clear whether the invoice was also submitted to the hearing officer, although it is not included in CMS Exhibit 5, which CMS describes as "Petitioner's Reconsideration Request and Corrective Action Plan (CAP) with supporting documentation, dated November 17, 2009." The reconsideration decision, however, states that Petitioner submitted additional surety bond information in response to the hearing officer's December 8, 2009 acknowledgment (without identifying what specific information was submitted or reviewed). Regardless of whether the November 17, 2009 surety bond and the relating invoice and correspondence are admissible, however, they are irrelevant.

First, the issue before me is not whether Petitioner has belatedly achieved compliance with the surety bond requirement, but whether CMS correctly found that, at the time of the revocation, Petitioner was not in compliance and that CMS therefore had authority to revoke. Petitioner admits it did not have a compliant surety bond at the time of the

revocation. That a surety was willing to undertake to cover Petitioner's potential overpayments after the fact does not mean that CMS was protected at the relevant time from fraud or billing errors by Petitioner. Furthermore, it is unlikely that a surety would undertake such retroactive coverage for a supplier had fraud or abuse been discovered during the past period when no coverage was in place. Therefore, a belated retroactive surety bond does not satisfy the statutory and regulatory purpose of providing continuous protection to the Medicare program from the risk of loss due to a supplier's fraud or abuse.

Secondly, I must apply the regulations as they are stated. The applicable regulations clearly required Petitioner to have *in place* a compliant surety bond by October 2, 2009. Petitioner points to no source of authority for me to waive the compliance requirement or grant an exemption on equitable grounds. Moreover, I have no authority to declare the statute or the regulation invalid or ultra vires. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 (2009) ("An ALJ is bound by applicable laws and regulations and may not invalidate either a law or regulation on any ground."). Even if I did have such authority, there would be no basis where, as here, the regulation does what the statute grants the Secretary the authority to do, that is, to require DMEPOS suppliers to demonstrate that they have obtained a surety bond "in a form specified by the Secretary" and maintain such coverage "on a continuing basis." 42 U.S.C. § 1395m(a)(16)(B).

The regulation at 42 C.F.R. § 424.535 plainly authorizes CMS to revoke a supplier's Medicare enrollment whenever the supplier fails to maintain compliance with enrollment requirements. Thus, section 424.535 provides:

> **Revocation of enrollment and billing privileges in the Medicare program.**
>
> (a) *Reasons for revocation.* CMS may revoke a currently enrolled provider or supplier's Medicare billing privileges and any corresponding provider agreement or supplier agreement for the following reasons:
> (1) *Noncompliance.* The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. . . .

It is an enrollment requirement that "[t]he supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet" the supplier standards in 42 C.F.R. § 424.57(c), which includes the surety bond requirement of section 424.57(c)(26). CMS may revoke the supplier's Medicare billing privileges if the supplier fails to meet any of these standards. 42 C.F.R. § 424.57(e); *1866ICPayday.com*, DAB No. 2289, at 13 ("[F]ailure to comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges.").

Section 424.57(d)(11) further makes abundantly clear the consequences of a failure to maintain a compliant surety bond:

> CMS revokes the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions. Notwithstanding paragraph (e) of this section, the revocation is effective the date the bond lapsed and any payments for items furnished on or after that date must be repaid to CMS by the DMEPOS supplier.

See 42 C.F.R. § 424.57(d)(11); *see also* 42 C.F.R. § 424.57(c)(26).

The regulatory language is plain. A supplier must comply with all standards, or CMS will revoke its billing privileges. And I must sustain CMS's determination where the facts establish noncompliance with one or more of the regulatory standards.

I therefore conclude that CMS acted within its regulatory authority to revoke Petitioner's Medicare supplier number, because Petitioner was not compliant with the surety bond requirements of 42 C.F.R. § 424.57(c)(26) and (d) by October 2, 2009.

VI. Conclusion

For the reasons explained above, I grant summary judgment in favor of CMS.

/s/
Leslie A. Sussan
Board Member