Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Franklin Avenue Pharmacy,
(PTAN: 1220500001),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-635

Decision No. CR2231

Date: August 31, 2010

DECISION

For the reasons set forth below, I grant the Centers for Medicare & Medicaid Services' (CMS's) motion for summary judgment. The undisputed evidence establishes that Petitioner, Franklin Avenue Pharmacy, 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).

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[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 is a Medicare DMEPOS supplier. NSC determined that Petitioner was not in compliance with supplier standard 26 and revoked Petitioner's Medicare supplier number by notice letter dated November 12, 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. 2; *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 of the revocation notice, and/or submit a corrective action plan within 30 days. CMS Ex. 2, at 2.

Petitioner submitted to NSC a request for reconsideration on December 4, 2009 stating that "[w]e are in the process of correcting non compliance standards in order meet Medicare requirements. We have contacted our Accredidation company with the updated changes and schedule an appoint to be resurveyed before December 31st, 2009." CMS Ex. 3.

On March 10, 2010, a Medicare hearing officer issued an unfavorable reconsideration decision on the ground that Petitioner "has not shown compliance with supplier standard #26." CMS Ex. 4, at 2. The hearing officer gave the following rationale for the decision:

> The information on file with the NSC did not show that the supplier submitted a valid surety bond for this location. . . . Franklin Ave Pharmacy has surpassed the allotted time frame to obtain a surety bond which was October 2, 2009. Franklin Ave Pharmacy is required to have a surety bond as mandated by 42CFR 424.57(c) and 42CFR 424.57(d). There was no surety bond for review or submitted as additional documentation for review; therefore the NSC appropriately revoked their billing privileges. Based upon detailed review of the case file, Franklin Ave Pharmacy, is found to be non-compliant with supplier standard #26.

CMS Ex. 4, at 2.

Petitioner timely requested a hearing before an Administrative Law Judge (ALJ). Petitioner submitted a hearing request dated March 17, 2010 (HR) and a copy of the March 10, 2010 Medicare hearing officer reconsideration decision. This case was assigned to me 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 Acknowledgment and Pre-Hearing Order on April 26, 2010.

On July 19, 2010, CMS filed a motion for summary judgment and incorporated memorandum of law (CMS Br.). CMS accompanied its July 19, 2010 motion and memorandum with CMS Exhibits 1-4, which I admit into evidence without objection. On August 23, 2010, Petitioner filed a letter in response to the CMS motion.

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

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 did not obtain 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). 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. 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 that "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 at the time CMS revoked its supplier number. *See* HR. In its response to the CMS Motion for Summary Judgment dated August 23, 2010 Petitioner states that –

> [t]he enactment of suppliers standard 26 of 42 C.F.R. 424.57(c) created uncertainty in making compliance. I had no idea as how bonding worked or who could issue me a surety bond. I called my General Counsel Mr. Ken Jones after 4 months of attempting to find a company that issued surety bonds. Mr. Jones in turn explained how bonding works and referred me to Noah Lewis Insurance Agency. Mr. Lewis is currently working to obtain a bond that makes full compliance with sub section 26 of the C.F.R. I will forward this information as soon as I receive the binder.

On its face, this letter discloses that Petitioner had not successfully obtained a compliant surety bond, nor has Petitioner even at this late date alleged that it has complied with the requirements of 42 C.F.R. § 424.57(d).

The issue before me, in any case, is not whether Petitioner can belatedly achieve compliance with the surety bond requirements, but whether CMS correctly found that, at the time of the revocation, Petitioner was not in compliance. If CMS correctly found that Petitioner was not in compliance with the regulatory requirements, CMS had authority to revoke Petitioner's supplier number.

Petitioner admits it did not have a compliant surety bond at the time of the revocation. HR; P. Response dated August 23, 2010. Even if a surety is now willing to undertake retroactive coverage for Petitioner, CMS has not been protected from fraud or billing errors by Petitioner during the period since the surety bond requirements took effect. Furthermore, it is unlikely that a surety would undertake retroactive coverage for a supplier had fraud or abuse been discovered during the past period when no coverage was in place. Thus, a belated retroactive surety bond would 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.

Moreover, 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, not simply to later obtain retroactive *coverage* to that date. 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. Section 424.535 provides that a supplier's billing privileges are revoked when the 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.

42 C.F.R. § 424.57(d)(11); *see also* 42 C.F.R. § 424.57(c)(26). In addition, a supplier that has 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 and the re-enrollment bar is a minimum of 1 year. 42 C.F.R. § 424.535(c).

The regulatory language is plain. A supplier must comply with all standards, or CMS will revoke its billing privileges. I am bound by applicable laws and have no authority to invalidate or change an existing regulation or grant Petitioner an exemption from compliance with regulatory requirements. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 14 (2009). I must sustain CMS's determination where the facts establish noncompliance with one or more of the regulatory standards.

I 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. I therefore uphold the revocation of Petitioner's Medicare billing privileges and supplier number and the one-year bar on re-enrollment.

VI. Conclusion

For the reasons explained above, I grant summary judgment in favor of CMS and uphold the revocation of Petitioner's Medicare supplier number.

/s/
Leslie A. Sussan
Board Member