Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

The Orthotic Center, Inc.,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-433

Decision No. CR2627

Date: September 28, 2012

DECISION

I grant the Centers for Medicare & Medicaid Services' (CMS's) motion for summary judgment and uphold the revocation of the Medicare billing privileges of The Orthotic Center, Inc. (Petitioner), based on Petitioner's failure to comply with the supplier standards set out at 42 C.F.R. § 424.57(c)(1), (c)(22), and (c)(25).

I. Background

This matter is before me based on Petitioner's March 8, 2012 Request for Hearing (RFH).[1] Petitioner is a Durable Medical Equipment, Prosthetics, Orthotics and Supplier (DMEPOS) located in Solon, Ohio. By letter dated September 2, 2011, the National Supplier Clearinghouse Supplier Audit Compliance Unit, part of the Medicare contractor Palmetto, GBA (contractor), notified Petitioner that Petitioner's billing privileges were being revoked because of Petitioner's failure to

[1] Along with its request Petitioner filed 15 attachments, identified as Attachments A-N, which included two You Tube videos, instructions linking to a video on the Vimeo website, a CD depicting its product, a CD which includes a slide presentation of the product, and the declaration of Allan Daniel, M.D.

comply with the requirements of DMEPOS supplier standards 1 and 25. Petitioner sought reconsideration of that determination, and on January 11, 2012, Petitioner was advised that the hearing officer had affirmed the contractor's revocation determination. Petitioner timely sought further review before an administrative law judge (ALJ). Petitioner's request was received in the Civil Remedies Division office on March 9, 2012, docketed as No. C-12-433, and assigned to me on March 14, 2012, for hearing and decision. An Acknowledgment and Initial Docketing Order was issued that day at my direction.

On April 26, 2012, CMS filed a motion for summary disposition along with CMS exhibits (CMS Exs.) 1-28, claiming that there are no material issues of fact in dispute and that it is entitled to judgment as a matter of law. In its motion, CMS provided notice that it was amending its initial determination by adding the violation of supplier standard 22 as an additional basis for the revocation of Petitioner's billing privileges. CMS states that the addition of supplier standard 22 is based on Petitioner's failure to obtain accreditation for its durable medical equipment (DME) parts and accessories. CMS maintains that supplier standard 22 is the same as the factual basis and argument as that for supplier standard 25. CMS Motion at 7 n.3. Petitioner resisted summary disposition and filed an Opposition Brief (P. Opp. Br.) with Petitioner Exhibits (P. Exs.) 1-4. Petitioner maintains that there are material factual issues in dispute and that an in-person hearing is necessary. P. Opp. Br. at 1-2.

The resolution of this case rests on whether Petitioner's product, the Total Body Orthotic Management (TBOM), is an orthotic device as Petitioner advocates, or is more properly classified as DME as the contractor and CMS contend. If TBOM is an orthotic device then Petitioner appropriately billed for the product as a Medicare-covered orthotic. Consequently, if this is the case then Petitioner was not in violation of supplier standards 1, 22,[2] and 25. If Petitioner's TBOM product

[2] Relying on 42 C.F.R. § 498.48(c), CMS added a new issue to the pending appeal. Petitioner did not raise any objection in its Opposition Brief to CMS adding supplier standard 22 as a new issue. The Board has generally permitted CMS to amend the legal basis for an adverse administrative action during the appeal process, where the party affected was provided with sufficient notice of the revised basis to permit them to respond. *See, e.g., Fady Fayad, M.D.*, DAB No. 2266, at 10-11 (2009); *Green Hills Enters., LLC*, DAB No. 2199, at 8 (2008). Because CMS has added the new issue during the prehearing proceedings I find Petitioner was provided sufficient notice and is therefore not prejudiced by the addition of this issue. Exercising my authority under section 498.56(a), I permit CMS to add the new issue of Petitioner's noncompliance with supplier standard 22.

is appropriately classified as DME, then I will examine each of the three supplier standards at issue in order to determine if Petitioner was in compliance with the requirements of those standards.

II. Issues

The issues in this case are:

> Whether Petitioner's product is an orthotic device or DME; and, if so,
>
> Whether Petitioner was in compliance with supplier standards 1, 22, and 25.

III. Applicable Law and Regulations

The Social Security Act (Act) requires that a DMEPOS supplier obtain a supplier number from the Secretary of the Department of Health & Human Services in order to establish the supplier's billing privileges within the Medicare program. Act § 1834(j)(1)(A). The Act also requires that DMEPOS suppliers, in relevant part, comply with the applicable state and federal licensure and regulatory requirements and any other requirements the Secretary may specify. Act § 1834(j)(1)(B)(ii)(I) and (IV).

The Secretary has established 30 standards that a DMEPOS supplier must certify it meets and will continue to meet in its application for a supplier number and billing privileges. 42 C.F.R. § 424.57(c)(1)-(30); *Main Street Pharmacy, Inc*., DAB No. 2349, at 2 (2010). If a DMEPOS supplier already enrolled in the Medicare program fails to comply with any of the requirements set forth in section 424.57(c), CMS will revoke that supplier's billing privileges. 42 C.F.R. § 424.57(e); *see also 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.").

DMEPOS suppliers bill Medicare Part B for orthotic devices and DME by using a coding system known as the Healthcare Common Procedure Coding System or HCPCS. Within that system there are certain codes associated with orthotic devices and others designated for DME. The Medicare program covers both orthotic devices and DME under Part A on a per diem payment for beneficiaries residing in a skilled nursing facility (SNF). Orthotic devices and DME are also covered under Part B under certain circumstances. If a beneficiary is not in a Part

A-covered SNF or hospital stay, then Medicare will reimburse orthotic devices for that beneficiary under Part B. 42 U.S.C. § 1395x(s)(9). DME is not covered under Part B if a beneficiary is in a facility that is primarily engaged in providing skilled nursing or rehabilitation services, but Medicare Part B covers both orthotic devices and DME for a beneficiary who is living at home or in a congregate setting such as an assistive living facility that serves as a home. However, a "home" does not include a hospital, critical access hospital, or skilled nursing facility. 42 U.S.C. §§ 1395x(n), 1395i-3(a)(1); 42 C.F.R. § 410.38(a), (b).

IV. Discussion

I make findings of fact and conclusions of law to support this decision. I set them forth below as separate headings in bold type.

A. Summary judge is appropriate in this case as a matter of law.

The Departmental Appeals Board (Board) has, on multiple occasions, discussed the well-settled principles governing summary judgment. Summary judgment is appropriate and no hearing is required where either: there are no disputed issues of material fact and the only questions that must be decide involve application of law to the undisputed facts; or, the moving party must prevail as a matter of law even if all disputed facts are resolved in favor of the party against whom the motion is made. *See White Lake Family Medicine, P.S.*, DAB No. 1951 (2004); *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). A party opposing summary judgment must allege facts which, if true, would refute the facts relied upon by the moving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see for e.g.*, Fed. R. Civ. P. 56(c); *Garden City Medical Clinic*, DAB No. 1763 (2001); *Everett Rehabilitation and Medical Center*, DAB No. 1628, at 3 (1997) (in-person hearing required where non-movant shows that there are material facts in dispute that require testimony); *Thelma Walley*, DAB No. 1367 (1992).

In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Brightview Care Center*, DAB No. 2132, at 2, 9 (2007); *Livingston Care Center*, 388 F.3 at 172 (2003); *Guardian Health Care Center*, DAB No. 1943, at 8 (2004); *but see Brightview*, DAB No. 2132, at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). Moreover, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *cf. Guardian Health Care Center*, DAB No. 1943, at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria

to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.").

Under the applicable substantive law, CMS has the initial burden of coming forward with evidence on any disputed facts showing that the provider was not in substantial compliance with Medicare participation requirements. However, the provider bears the ultimate burden of persuasion that it was in substantial compliance with those requirements. *See South Valley Health Care Center*, DAB No. 1691 (1999), *aff'd, South Valley Health Care Center v. HCFA*, 223 F.3d 1221 (10th Cir. 2000); *see also, Batavia Nursing and Convalescent Center*, DAB No 1904 (2004); *aff'd, Batavia Nursing & Convalescent Center. v. Thompson*, 129 Fed.App'x. 181 (6th Cir. 2005).

This case is appropriate for summary judgment. There is no genuine dispute as to any material fact and I have drawn all favorable inferences in favor of Petitioner, the non-movant, for purposes of summary judgment. This decision turns upon the interpretation of regulatory provisions and interpretive agency rulings and their application to the undisputed material facts.

B. Petitioner's TBOM product (braces-connected-to-braces) is appropriately classified by CMS as DME.

CMS claims that Petitioner is a supplier of DME accessories and is required to comply with the relevant standards for DME suppliers. CMS states that during a site visit of Petitioner's facility on May 20, 2010, the site inspector determined that Petitioner was selling customized wheelchair seating and parts and not the customized orthotics which it was billing Medicare for. CMS Ex. 2, at 1. Petitioner had been billing Medicare for lower limb orthoses, upper limb orthoses, and spinal orthoses. CMS Ex. 2, at 8.

Petitioner maintains that the allegations are incorrect, stating that its inventory consists of orthotic components and from these components it custom fabricates and custom fits an array of braces-connected-to-braces for each of its patients. Petitioner states that no part of its inventory consists of DME or wheelchair accessories and that no part of its inventory is attached to, or acts as accessories to a wheelchair. RFH at 1; P. Opp. Br. at 1.

Petitioner explains that its TBOM product is orthotics and is designed for "catastrophically disabled patients, who suffer from extreme contractures of their limbs and bodies." CMS Ex. 4, at 4. Petitioner describes its braces as forming an external skeleton (exoskeleton) of anchor and fulcrum points to brace the patient's

weakened or diseased body parts. Petitioner further states that although not required the –

> Array-of-braces-connected-to-braces are typically outfitted with wheels attached to several of the lower braces in the array to facilitate emergency evacuation of the array-of-braces-connected-to-braces. The presence of wheels connected to a brace does not mean that a [its] array-of-braces-connected-to-braces is a wheelchair or that the braces interconnected to a wheeled brace are accessories to a wheelchair.

CMS Ex. 4 at 5. Petitioner admits that there can be a potential for visual confusion between its braces and wheelchairs with accessories, claiming that its product is "sometimes mistaken by uninformed observers to be wheelchairs or accessories to wheelchairs." CMS Ex. 4, at 3. However, Petitioner argues that CMS's reliance on HCFA Ruling 96.1, the United States Court of Appeals for the First Circuit's decision in *Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998), and a 2002 GAO report is misplaced because the ruling, the court's decision, and the GAO report are based on what Petitioner describes as "obsolete factual assumptions" and therefore CMS cannot now classify its TBOM product based on those documents.

1. HCFA Ruling 96.1

In 1996, HCFA, now known as CMS, issued an interpretive ruling that provided guidance on how to classify braces attached to DME equipment. The ruling clarified the conditions under which certain devices would be classified as orthotics or as DME under Medicare Part B payment, and classified medical or nonmedical items attached to equipment such as DME. The ruling provided that attached devices that brace individuals, which include devices that attach to wheelchairs, would not be paid under Medicare's orthotics benefit. HCFAR 96.1 (Sept. 18, 1996); P. Ex. 1. The ruling clarified that the "orthotics benefit" as to braces, are "limited to leg, arm, back and next braces that are stand-alone devices used independently of other kinds of medical equipment." HCFAR 96-1-7, 9-10; P. Ex. 1, at 1-5, 6.

HCFA Ruling 96-1 in effect limited Medicare coverage for orthotics to those braces "used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment." *See* HCFAR 96-1-1; P. Ex. 1, at 1-2. The ruling clarified that attached bracing devices are DME and not to be billed as orthotics, and consequently, that Part B would no longer pay claims for attached

bracing devices for beneficiaries in institutions that are primarily engaged in providing skilled nursing care because DME is not covered in these settings.

Petitioner maintains that since its braces are not connected to equipment but rather are connected to braces, HCFA Ruling 96-1 does not serve to reclassify its product as either DME or as accessories to wheelchairs. CMS Ex. 4.

Agency rulings are decisions of the agency's administrator and are final opinions and statements as to agency's policy and interpretation. Agency rulings serve to clarify and interpret ambiguous provisions of the statute or regulation in order to ensure consistency in the application. These ruling are final upon issuance.

HCFA Ruling 96.1 is a final opinion of the CMS Administrator: it is precedential and thus binding on the Departmental Appeals Board and ALJs to ensure consistency in the interpretation of agency policy and the adjudication of Medicare appeals. 42 C.F.R. §§ 401.108(c); 405.1063. The regulation is clear that these agency rulings "are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS …" Moreover, the Board and ALJs are required to follow published guidance of CMS that is not inconsistent with applicable statutes and regulations. HCFA Ruling 96.1 affords me no discretion, and I am bound by the ruling in determining whether Petitioner's TBOM product is properly classified as DME.

2. The First Circuit's ruling in *Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998)

The validity of HCFA Ruling 96.1 was challenged in 1997 by OrthoConcepts [3] whose product was affected by the Ruling, two beneficiaries who were prescribed the product, and several suppliers of the OrthoConcepts attached bracing device product. The plaintiffs' claim was that CMS should have promulgated its decision as a regulation after public notice and comment. The First Circuit Court of Appeals concluded that the ruling was an interpretation of Medicare policy and that HCFA had followed appropriate procedures when it issued the rule, that the ruling was supportable, and that HCFA's treatment of OrthoConcept's seating systems product as DME was consistent with congressional intent. The Court's decision is clear that HCFA Ruling 96.1 is binding on all agency officials, "including its Administrative Law Judges . . ." *Id.* at 73. The United States

[3] Petitioner here, The Orthotic Center, Inc., is part of the same corporate family as OrthoConcepts. The TBOM product is manufactured by OrthoConcepts. CMS Ex. 2, at 35.

Supreme Court denied plaintiffs' request that it review the First Circuit's decision. *Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998), *cert. denied*, 526 U.S. 1064 (1999).

It should be obvious that I am bound by HCFA Ruling 96.1, as it was validated by the First Circuit's decision in *Warder*.

3. May 2002 GAO Report

Concerned over Medicare program integrity issues and whether HCFA Ruling 96.1 would adversely impact Medicare beneficiaries, Congress directed the General Accounting Office (GAO) to study the ruling and its impact. In 2002, GAO published a report entitled "Orthotics Ruling Has Implications for Beneficiary Access and Federal and State Costs." *See* CMS Ex. 21 (GAO-02-330 (May 2002)). The GAO report noted that an inconsistency existed as to how suppliers were billing Medicare for certain items that attached to wheelchairs and other equipment. Some suppliers were billing these attachments as orthotic devices and other suppliers were billing the attachments as DME. The GAO report also noted that the suppliers were billing Medicare "for each support as a separate orthotic brace, using multiple orthotics billing codes that described braces expected to be used independently of other medical equipment." CMS Ex. 21, at 7. The GAO report stated that HCFA was particularly concerned by the way suppliers of a product manufactured by OrthtoConcepts were billing Medicare. The report observed that:

> The OrthoConcepts systems consisted of leg, arm, neck, and back supports that attached to a base that could be put on wheels. OrthoConcepts said that its adjustable system of multiple supports provided orthotic support to the body, which would be particularly helpful to individuals with severe neurological problems who needed to be properly positioned. Suppliers of its system were billing each attached support as a separate orthotic brace, using multiple orthotics billing codes that described braces expected to be used independently of other medical equipment.

CMS Ex. 21, at 14. The GAO report noted that in order to address this inconsistency in billing practices, and to clarify its payment policy for orthotics, HCFA issued Ruling 96-1 to explain the agency's long-standing policy of considering devices that attach to DME or other equipment as DME and not as orthotics. CMS Ex. 21, at 4, 5.

4. Petitioner's current TBOM product and Petitioner's Prior Seating System product.

Petitioner claims that the GAO Report is "out of date" because it addresses "Ortho's TBOM prior to 2002," and that the Report does not address its "new designs of the Ortho's TBOM." Petitioner states further that CMS is relying on "obsolete factual assumptions" when it relies on CMS Ruling 96-1, the First Circuit's ruling in *Warder*, and the May 2002 GAO Report. RFH at 5; P. Opp. Br. at 1. Petitioner asserts that the new or "Modern Braces" in its TBOM product is not the same as the "Obsolete Items" in its prior Seating System, and that its current TBOM product has been misclassified by the Medicare contractor as a wheelchair when in fact the product fits within the orthotic definition and should be reimbursed under Medicare Part B as an orthotic device. P. Opp. Br. at 2.

Petitioner's assertions are unsupported by the evidence before me. Petitioner has not met its burden of showing that its current TBOM bracing system is significantly different in function and design from Petitioner's prior Seating System product to warrant the product to be classified as an orthotic device rather than a DME. Like the Seating System product at issue in HCFA Ruling 96.1 and in the *Warder* decision, the TBOM bracing system product at issue here is designed to treat patients with complete or severe musculoskeletal failures that render the patient immobile. *Compare Warder* at 3 *with* CMS Ex. 4 at 3, 4 and CMS Ex. 15 at 6, 14. The Seating System product's design is described in the *Warder* decision as:

> The Seating System consists of a set of connected braces – the number and type depending on the patient's condition – attached to a wheeled base. The patient sits, or reclines, on the Seating System, and the component braces maintain the patient in a position designed to reduce the weight borne by weaker extremities and to prevent contractures.

Warder at 78. The Seating System consisted of several individual braces that were attached to an external frame. The TBOM bracing system is described as an "array-of-braces-connected-to-braces [which] link together to form external anchor points for the braces." CMS Ex. 4, at 5. Both bracing systems are composed of multiple braces connected to either an external frame or to a "bracing device." As with the Seating System at issue in *Warder*, the individual braces Petitioner billed Medicare for under its current TBOM system design cannot be used independent of other equipment. Photos of these individual braces show that each brace is designed to be connected to another brace, thus to another piece of equipment. The photos show also that the brace system component is connected

to a base. *See* CMS Ex. 11, at 24, 27-31, 42-47, 55-58, 61-66; CMS Ex. 15 at 120-26. Petitioner does not advance any argument that each brace can function independent of the other braces. Rather, it is fundamental to Petitioner's product that braces connect to other braces in order to form the TBOM arrays-of-braces-connected-to-braces. A photo of the assembled TBOM product establishes that each brace is not a stand-alone device and cannot be used independent of other equipment. The photo also establishes that the TBOM product, once assembled, is attached to a base with a wheel. CMS Ex. 11, at 22.

Both the statute and regulations list four criteria in classifying a device as DME. Equipment is DME if it: (1) can withstand repeated use; (2) is primarily and customarily used to serve a medical purpose; and (3) generally is not useful to an individual in the absence of an illness or injury; and (4) is appropriate for use in the home. 42 U.S.C. § 1395x(n); 42 C.F.R. § 414.202. These criteria are repeated in the Medicare Carrier's Manual (MCM) § 2000; *see also* MCM § 2100.5 (explaining that DME includes "supplies and accessories" that are "necessary for the effective use of [DME].") The evidence before establishes that Petitioner's product meets these criteria, and I find that Petitioner has not advanced any supportable argument to the contrary.

I note that the First Circuit in *Warder* also noted that even if the Seating System could be reasonably construed to meet the definition of a brace, "there was nothing precluding HCFA from resolving the ambiguity in favor of DME." *Warder* at 85.

Accordingly, I conclude that Petitioner's TBOM product is appropriately classified by CMS as DME. Having resolved that Petitioner's product is properly classified as DME, I now address whether Petitioner was in compliance with supplier Standards 1, 22, and 25 at the time of the .

C. Petitioner was not in compliance with all supplier standards.

CMS claims that Petitioner was out of compliance with three supplier standards – 42 C.F.R. § 424.57(c)(1), (c)(22), (c)(25). CMS maintains that Petitioner was cited because it failed to obtain a state license or certificate of registration and accreditation which is required of DME accessory suppliers; failed to obtain accreditation from a CMS-approved accreditation organization; and failed to inform the Medicare contractor that it was selling DME accessories instead of orthotics. CMS Ex. 2, at 4; CMS Motion at 7 n.3.

1. Supplier Standard 1 (42 C.F.R. § 424.57(c)(1))

Supplier standard 1 requires that a supplier "[o]perates its business and furnishes

Medicare-covered items in compliance with . . . State licensure and regulatory requirements." 42 C.F.R. § 424.57(c)(1)(ii). CMS maintains that as a supplier of DME parts and accessories Petitioner was required to obtain an Ohio Home Medical Equipment Services Provider (HME) License or Certificate of Registration, but failed to do so. CMS Ex. 12, at 1-2.

Petitioner does not dispute that it has neither an Ohio HME license nor a certificate of registration. Instead, Petitioner argues that is an orthotics supplier and it does not provide its products to patients in non-institutional homes. According to Petitioner, under Ohio Revised Code Section 4752.02(B)(8), it is not required to obtain an Ohio HME license. Petitioner also maintains that the State of Ohio does not require companies that provide orthotics to be licensed by the state. RFH at 2, 5; CMS Ex. 4, at 2.

CMS asserts that OHIO REV. CODE ANN. § 4752.02(A) requires a license or certificate of registration for home medical equipment services. The statute defines HME as:

> Equipment that can stand repeated use, is primarily and customarily used to serve a medical purposes, is not useful to a person in the absence of illness or injury, is appropriate for use in the home, and is one or more of the following:
>
> * * * *
>
> (2) Technologically sophisticated medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by a home medical equipment services provider to maintain a patient's health care condition or the effectiveness of the equipment.

OHIO REV. CODE ANN § 4752.01(B). The Ohio Administrative Code states that "custom seating or positioning systems" are technologically sophisticated medical equipment which also includes "[i]individually sized or customized accessories that are an integral part of equipment defined." OHIO ADMIN. CODE 4761:1-3-02(B)(14) and 4761:1-3-02(C)(7). CMS argues that since the custom seating of positioning system is integral to the TBOM system, these devices qualify as HME under Ohio law. CMS Motion at 13-14.

As to Petitioner's argument that its product is only provided institutional settings and not "homes," I agree with CMS that the definition of HME equipment in OHIO REV. CODE ANN. § 4752.01(B) is not limited to the setting in which the product is provided. Rather, Ohio defines HME equipment in terms of equipment

that "is appropriate for use in the home." Although Petitioner prefers to supply its current TBOM product to beneficiaries in institutional settings and has asserted that it currently only provides its product to individuals residing in nursing homes, Petitioner has provided no evidence that its TBOM cannot be used in the home setting.

Because the products Petitioner supplies are classified as DME, those DME products must meet the applicable state requirements as required by supplier standard 1. The Ohio statue allows for an exception to the license or certificate of registration requirement for an individual who holds a valid license to practice orthotics. However, I agree with CMS that the statute is ambiguous as to whether it applies only to individual practitioners or to a corporate entity such as petitioner. OHIO REV. CODE ANN. § 4752.02 (B)(8); CMS Ex. 4, at 10. Petitioner did present evidence that its President, Kenneth Greene, is licensed by the Ohio State Board of Orthotics, Prosthetics & Pedorthics as an Orthotist. CMS Ex. 2, at 19, 36; CMS Ex. 11, at 8. To address this ambiguity, the Ohio Respiratory Care Board directs providers who believe they are exempt from the licensure or certificate requirement of section 475.01 (B)(8) to file an Affidavit of Exception with the Board. CMS Ex. 26, at 1, 3, 5-8. A review of the record before me confirms that Petitioner has not provided a copy of an Affidavit of Exception. Consequently, Petitioner has not met its burden in showing that it was in compliance with the state licensure and certification requirements or exempt from them.

Accordingly, I conclude that Petitioner was not in compliance with supplier standard 1 during the May 2010 site visit of Petitioner's facility.

2. Supplier Standards 22 (42 C.F.R. § 424.57(c)(22)) and 25 (42 C.F.R. § 424.57(c)(25)).

CMS charges that because Petitioner did not obtain accreditation for its DME parts and accessories, it was not in compliance with supplier standard 22. CMS also charges that Petitioner was not in compliance with supplier standard 25 because it failed to obtain accreditation for its product line of wheelchair accessories. CMS Ex. 12, at 2; CMS Motion 7 n.3. Petitioner maintains that the products it supplies are not wheelchair accessories and that it has not added a new product line. According to Petitioner, it is not required to obtain accreditation for wheelchair accessories. RFH at 3.

Supplier standard 22 requires that "[a]ll 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," and that the "accreditation

must indicate the specific products and services for which the supplier is accredited in order for the supplier to receive payment for those specific products and services." 42 C.F.R. § 424.57(c)(22). Although Petitioner is accredited by the Healthcare Quality Association on Accreditation in the product category code of orthoses, it is not accredited by that association for wheelchair parts and accessories.

Supplier standard 25 requires that "[a]ll DMEPOS suppliers must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation. If a new product line is added after enrollment, the DMEPOS supplier will be responsible for notifying the accrediting body of the new product so that the DMEPOS supplier can be re-surveyed and accredited for these new products." 42 C.F.R. § 424.57(c)(25). CMS claims that in Petitioner's February 2010 Medicare revalidation enrollment application Petitioner failed to disclose that it was supplying wheelchair parts and accessories. CMS Motion at 16 *citing* CMS Ex. 27, at 11. Petitioner maintains that it has not added any new product lines since its April 9, 2010 accreditation. Given this, Petitioner maintains that it is not required to obtain accreditation for wheelchair accessories. CMS Ex. 4.

A review of section 2 of Petitioner's enrollment application reveals that Petitioner listed that it was supplying "orthoses; custom fabricated; orthoses; prefabricated (non-custom fabricated); and orthoses: off-the-shelf. CMS Ex. 27, at 11. Petitioner's sole defense is that its TBOM array-of-braces-connected-to-braces are orthotics and not DME and therefore it is not required to obtain accreditation for wheelchair parts and accessories. However, for the reasons discussed above, Petitioner's TBOM system is classified by CMS as DME and Petitioner must adhere to the supplier standards applicable to the classification of its product.

A supplier must comply with all required standards. I am bound by applicable laws and regulations and lack any authority to invalidate or change an existing regulation or grant Petitioner an exemption from compliance with regulatory requirements. *1866ICPayday.com*, DAB No. 2289, at 14 (2009). I must sustain CMS's determination where the undisputed facts establish noncompliance with one or more of the regulatory standards. Here, the undisputed facts show that during the May 2010 site visit, Petitioner was not in compliance with supplier standards 1, 22, and 25.

Petitioner's assertion that HCFA Ruling 96-1 is invalid because public notice and opportunity to comment was not provided was addressed in the *Warder* decision. I need not repeat that discussion here, since I am bound by *Warder*. As for Petitioner's constitutional arguments regarding HCFA Ruling 96-1, those

arguments are beyond my authority to entertain. It is "well established that administrative forums, such as [the] Board and the Department's ALJs, do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional." *Sentinel Med. Labs., Inc.*, DAB No. 1762, at 9 (2001), *aff'd, Teitelbaum v. Health Care Fin. Admin.*, 32 F. App'x 865 (9th Cir. 2002).

V. Conclusion

After reviewing the evidence in the light most favorable to Petitioner, I conclude that CMS is entitled to summary judgment as a matter of law. Petitioner was not in compliance with Medicare supplier standards 1, 22, 25. I therefore GRANT summary judgment to CMS because CMS acted within its regulatory authority to revoke Petitioner's Medicare billing privileges. By this Decision I AFFIRM that revocation.

/s/
Richard J. Smith
Administrative Law Judge