Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

The Orthotic Center, Inc.
Docket No. A-13-16
Decision No. 2531
August 23, 2013

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Petitioner, The Orthotic Center, Inc. (Ortho), a supplier of durable medical equipment, prosthetics, orthotics and supplies (DMEPOS), appeals the September 28, 2012 decision of an Administrative Law Judge (ALJ) upholding on summary judgment the Centers for Medicare and Medicaid Services' (CMS) revocation of its Medicare billing privileges. CMS revoked Ortho's billing privileges for failure to comply with DMEPOS supplier standards at 42 C.F.R. § 424.57(c)(1) (compliance with state licensure requirements), (c)(22) (accreditation for DMEPOS suppliers and specific products and services), and (c)(25) (accreditation for new product lines). The ALJ upheld the revocation after concluding that CMS properly classified Ortho's Total Body Orthotic Management system (TBOM) as durable medical equipment (DME), rather than as an orthotic device as Ortho urges. The ALJ further concluded that based on this classification, Ortho needed to obtain a home medical equipment (HME) license or certificate of registration from the state of Ohio, obtain accreditation from the Healthcare Quality Association on Accreditation (HQAA) in the product category of wheelchair parts and accessories, and disclose the TBOM to HQAA as a new product line consisting of wheelchair parts and accessories. Ortho did not dispute that it took none of these actions but argued that it was not required to do so because the TBOM does not constitute wheelchair parts and accessories but, rather, is an orthotic device, which (it claims) is not required to be licensed or registered as HME in Ohio and is covered by its existing accreditation to sell orthotics supplies. The ALJ rejected this argument.

On appeal, Ortho disputes the ALJ's conclusion that the TBOM is DME. In its Request for Review (RR) and Reply, however, Ortho does not dispute that if the TBOM is properly classified as DME, then supplier standard 1 required it to obtain an Ohio HME license or certificate of registration and that supplier standards 22 and 25 required it to report the TBOM to its accreditation organization and request that it be accredited as a

new product.[1] Accordingly, the only issue we need address on appeal is whether the ALJ properly upheld CMS's classification of the TBOM as DME. As discussed below, we conclude that he did.

Statutory and Regulatory Background

The Social Security Act (Act)[2] requires a DMEPOS supplier to obtain a supplier number from the Secretary of Health & Human Services in order to establish billing privileges within the Medicare program. Act § 1834(j)(1)(A). The Act also requires DMEPOS suppliers to comply with 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); *El Jardin Pharmacy, Inc.*, DAB No. 2438, at 2 (2012). If a DMEPOS supplier already enrolled in the Medicare program fails to comply with even one of the requirements set forth in section 424.57(c), CMS may revoke that supplier's billing privileges. 42 C.F.R. § 424.57(d); *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 13 (2009).

DMEPOS suppliers bill Medicare Part B for orthotic devices and DME by using a coding system known as the Healthcare Common Procedure Coding System (HCPCS), which contains certain codes for orthotic devices and other codes for DME. Medicare covers under Part B both orthotic devices and DME supplied under appropriate conditions to beneficiaries at home or in an institution used as a home, such as an assisted living facility. Act §§ 1832(a), 1861(m), (n), (s)(6) and (9); 42 C.F.R. §§ 410.36, 410.38(a). For beneficiaries residing in a skilled nursing facility (SNF), the SNF must provide necessary DME as part of the prospective payment system without any

[1] As indicated below, failure to comply with even one DMEPOS supplier standard is sufficient for CMS to revoke billing privileges. The applicable Ohio statute provides that "no person shall provide [HME] services or claim to the public to be a [HME] services provider unless either of the following is the case: (1) The person holds a valid license issued under this chapter; (2) The person holds a valid certificate of registration issued under this chapter." Ohio Rev. Code § 4752.02(A) (2013). While Ohio's definition of HME begins with language that closely tracks the federal definition of DME, the scope of HME, as defined, is arguably broader than DME. *Id.* § 4752.01((B). Ortho appears to view Ohio's definition of HME as applying only to DME but does not dispute that it has neither a license nor a certificate to provide HME.

[2] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/ OP_ Home/ssact/ssact.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section.

separate additional payment. Medicare Benefit Policy Manual (MBPM), CMS Pub. 100-02, ch. 8, § 70.[3] Orthotic devices, on the other hand, may be separately paid under Part B for SNF residents. *Id.*

The Act defines DME as including "iron lungs, oxygen tents, hospital beds, and wheelchairs . . . ." Act § 1861(n). The regulations define DME as--

> equipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
> (3) Is primarily and customarily used to serve a medical purpose.
> (4) Generally is not useful to an individual in the absence of an illness or injury.
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202. As relevant here, the statute and regulations define orthotics for purposes of Part B coverage as "leg, arm, back, and neck braces[.]" Act § 1861(s)(9), 1834(h)(4)(C) ; 42 C.F.R. § 414.202; *see also* MBPM, ch. 15, § 130.

Facts[4]

The revocation, reconsideration and appeal

Ortho's DMEPOS business is located in Solon, Ohio. ALJ Decision at 1. In a letter dated September 2, 2011, the National Supplier Clearinghouse Supplier Audit Compliance Unit, part of Palmetto, a Medicare contractor, notified Ortho that its Medicare billing privileges were being revoked because Ortho was not in compliance with DMEPOS supplier standards 1 and 25. *Id.* at 1-2. Palmetto's notice was based on a site visit to Ortho on May 20, 2010, during which the site inspector checked Ortho's inventory and determined that Ortho was selling customized wheelchair seating and parts

[3] The Medicare Benefit Policy Manual is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673.html.

[4] The facts stated herein are all undisputed facts from the ALJ decision or exhibits in the record and are recited as background for our decision, not as findings of fact made by the Board. We note that Ortho attached to its reply brief four numbered exhibits (all of them witness declarations). Ortho has not moved to admit these exhibits, so no ruling on admissibility is required. In any event, these exhibits appear to be the same in all material respects as documents that were submitted by the parties in support of, or opposition to, the motion for summary judgment and were thus already part of the record for decision in this appeal. *See* ALJ Decision at 2; P. Exs. 2 (Greene Decl.), 3 (Malas Decl.), and 4 (Rhodes Decl.); CMS Ex. 16, at 4-6 (Daniel Decl.).

rather than the customized orthotics for which Ortho was billing Medicare – lower limb orthoses, upper limb orthoses and spinal orthoses. ALJ Decision at 5, *citing* CMS Ex. 2, at 1, 8; *see also* CMS Ex. 3 (Palmetto letter of June 22, 2010). Ortho sought reconsideration, and the hearing officer affirmed the contractor decision. ALJ Decision at 2. Ortho timely filed a notice of appeal before an ALJ. *Id*. After the appeal was filed, CMS added a new issue, alleging noncompliance with supplier standard 22 in addition to supplier standards 1 and 25. *Id*. at 2 n.2. CMS moved for summary judgment. *Id*. at 2. Ortho opposed the motion on the ground there were material factual issues in dispute that required an in-person hearing. *Id*.

The resolution of the revocation issue, the ALJ stated, depended on "whether Petitioner's product [the TBOM] is an orthotic device as Petitioner advocates, or is more properly classified as DME as the contractor and CMS contend." *Id*. at 2. If the TBOM was an orthotic device, the ALJ continued, then Ortho "appropriately billed for the product as a Medicare-covered orthotic . . . [and] [c]onsequently . . . was not in violation of supplier standards 1, 22, and 25." *Id*. (footnote omitted). If he concluded that the TBOM was properly classified as DME, the ALJ continued, he would then determine whether Ortho complied with the cited supplier standards. *Id.* at 2-3. The ALJ found the case "appropriate for summary judgment." *Id*. at 5. He rejected Ortho's assertion that there were material facts in dispute because, the ALJ said, "This decision turns upon the interpretation of regulatory provisions and interpretive agency rulings and their application to the undisputed material facts." *Id*. The ALJ granted summary judgment for CMS, concluding that the TBOM was DME, not an orthotic device, and that Ortho had not complied with the cited supplier standards. *Id*. at 1, 10, 14. Ortho timely filed this appeal to the Board. *Id.*

The TBOM and the predecessor "OrthoConcepts Seating System"

Ortho denied that its inventory consisted of wheelchair accessories or was attached to, or acted as accessories to, a wheelchair, or otherwise constituted DME. ALJ Decision at 5. Instead, Ortho contended that its inventory consisted of orthotic components, that from these components it custom fabricates and fits an array of braces-connected-to-braces, and that its "TBOM product is orthotics designed for 'catastrophically disabled patients, who suffer from extreme contractures of their limbs and bodies.'" *Id*., *citing* CMS Ex. 4, at 4. Ortho described the braces in the TBOM "as forming an external skeleton (exoskeleton) of anchor and fulcrum points to brace the patient's weakened or diseased body parts." *Id*.

Ortho is part of the same corporate family as OrthoConcepts, the manufacturer of the TBOM. *Id.* at 7 n.3, *citing* CMS Ex. 2, at 35. OrthoConcepts previously manufactured a product that it marketed as the "Seating System." *Id.* In 1996, CMS issued an interpretive ruling, HCFAR 96-1 (Sept. 18, 1996) (Ruling),[5] providing guidance on how to classify braces attached to DME equipment. *Id*. at 6. Based on the Ruling, the Seating System was classified as DME, and two Medicare beneficiaries for whom the product was prescribed and several suppliers of the product sued in federal court to challenge the Ruling and its application to the Seating System. *Id*. at 7. The First Circuit Court of Appeals upheld the Ruling and its application to classify the Seating System as DME, concluding that the "Ruling was an interpretation of Medicare policy and that HCFA [the acronym for the Health Care Financing Administration, CMS's predecessor] had followed appropriate procedures when it issued the [Ruling], that the [Ruling] was supportable, and that HCFA's treatment of [the Seating System] as DME was consistent with Congressional intent." *Id*., *citing Warder v. Shalala*, 149 F.3d 73 (1st Cir. 1998), *cert. denied,* 526 U.S. 1064 (1998). The First Circuit described the Seating System as follows:

> 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 prevent contractures.

Warder, 149 F.3d at 77. In 2002, the General Accounting Office (GAO)[6] published a report entitled "Orthotics Ruling Has Implications for Beneficiary Access and Federal and State Costs." CMS Ex. 21 (GAO Report) (GAO-02-330 May 2002). The report addressed HCFA's concern about the inconsistency in how suppliers were billing Medicare for certain items attached to wheelchairs or other equipment – as between orthotic braces and DME – and HCFA's particular concern about the Seating System and HCFA's issuance of the Ruling to "explain the agency's long-standing policy of considering devices that attach to DME or other equipment as DME and not as orthotics." ALJ Decision at 8, *citing* CMS Ex. 21, at 4, 5.

Ortho claims that the "new or 'Modern Braces' in its TBOM product [are] not the same as the 'Obsolete Items' in its prior Seating System[.]" ALJ Decision at 9. Thus, Ortho contends, the TBOM is not the same as the product covered by the Ruling or the *Warder* decision or described in the GAO report, and those authorities cannot be relied on to classify the TBOM as DME. *Id*.

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[5] The ruling is CMS Exhibit 20 and Petitioner's Exhibit 1.

[6] In 2004, GAO was renamed the Government Accountability Office.

Discussion

A. *The disputed facts alleged by Ortho are not material and, therefore, do not preclude summary judgment.*

Summary judgment is appropriate only if there is no genuine dispute about a fact or facts material to the outcome and the moving party is entitled to judgment as a matter of law. *See, e.g., Livingston Care Center*, DAB No. 1871 at 5 (2003*), aff'd, Livingston Care Center v. U.S. Dep't of Health & Human Servs.*, 388 F.3d, 168, 172-73 (6th Cir. 2004). The Board has described the parties' respective burdens as follows:

> The party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law. *Celotex* [*Corp. v. Catrett*, 477 U.S. 317, 323 (1986)]. If a moving party carries its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Industrial Co. v. Zenith Radio*, 475 U.S. 574, 587 (1986) (quoting FRCP 56(e)). 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. *Id.* at 586, n.11; *Celotex*, 477 U.S. at 322. In order to demonstrate a genuine issue, the opposing party must do more than show that there is "some metaphysical doubt as to the material facts. Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita*, 474 U.S. at 587. In making this determination, 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. *See, e.g., U.S. v. Diebold, Inc.*, 369 U.S. 654, 655 (1962).

Kingsville Nursing and Rehab. Center, DAB No. 2234, at 3-4 (2009); *accord, e.g., 1866ICPayday.com, L.L.C.* at 2-3; *Livingston Care Center*, DAB No. 1871, at 5.

Ortho sets out (RR at 5) what it alleges are "disputed issues of material fact" precluding summary judgment for CMS on the issue of whether CMS properly classified the TBOM as DME. We summarize these as follows:

- whether Ortho "redesigned [the] TBOM so as to not be covered by Ruling 96-1";
- whether the TBOM is so materially different from the Seating System as to not be covered by the Ruling;
- whether "the mere presence of wheels on a brace . . . make the brace a wheelchair or part of a wheelchair, if the wheels are only connected to other 'braces'";
- whether "Modern Braces are not factually what was deemed DME 16 years . . . ago in Ruling 96-1;
- whether orthotists and DME specialists refer to braces as "equipment";
- whether CMS Ruling 96-1's "reference to 'medical or non-medical equipment payable as durable medical equipment' . . . include[s] 'braces', even when 'braces' are connected to other braces";
- whether a "multi-brace brace" (such as a Shoulder, Elbow, Wrist, Hand orthosis . . . which braces shoulder, elbow, wrist and hand) is a "freestanding orthotic device" and therefore not subject to the Ruling; and
- whether any "part of a TBOM array of braces-connected-to-braces "would properly be deemed connected to 'medical or non-medical equipment payable as DME.'"

We reject Ortho's arguments that these alleged factual disputes preclude summary judgment. Many of the assertions on which Ortho relies to show factual disputes are not material to the issue before the ALJ. Others are not even factual in nature but, rather, address the appropriate interpretation and application of legal standards to facts which are not themselves in dispute. Where there are factual differences, we accept Ortho's evidence and the reasonable inferences from it, but find that the result is not altered. Where the question is one of interpreting and applying Medicare coverage standards, however, it is appropriate to defer to CMS's expertise to resolve any ambiguities.

For example, declarations submitted by Ortho state that orthotists do not consider braces to be "equipment" and assert that "Ortho redesigned its items so that they would be braces-connected-to-braces ('Modern Braces') rather than items which [the] Ruling . . . characterized as 'attachments to wheelchairs,' 'customized wheelchairs,' or 'connected to medical or non-medical equipment.'" *See, e.g.*, P. Ex. 2, at 2 ¶ 5. It is not clear that CMS disputed either assertion. In any case, that Ortho's motivation in its redesign of the prior seating system to create TBOM was precisely to avoid the application of the Ruling and court decision that the prior system constituted DME, even accepting it as true, tells us nothing about whether that attempt succeeded in its purpose. Similarly, whether orthotists or other equipment suppliers opine that TBOM is a system of braces or that braces are not DME does not determine whether TBOM meets the applicable federal legal definition of DME. As the *Warder* court effectively concluded, whatever terminology may be used by such suppliers, braces may, in certain circumstances,

become part of or take on the character of DME. The issue before us is whether TBOM is an example of such circumstances. Whether braces connected to other braces can be considered to be connected to equipment within the meaning of the Ruling may thus be characterized as an issue of law involving whether the TBOM, accepting Ortho's factual assertions about its composition, construction and function, fits the legal definition of DME.

Even accepting Ortho's factual statements about the TBOM, there is ambiguity regarding its classification, and, as the ALJ noted, "'there was nothing precluding HCFA from resolving the ambiguity in favor of DME.'" ALJ Decision at 10, *quoting Warder*, 149 F.3d at 84. In upholding CMS's classification of the earlier Seating System as DME, the *Warder* court concluded:

> Even assuming that the entire device [the Seating System] could alternatively be reasonably construed to satisfy the definition of a brace (which includes only examples of individual braces), there was nothing precluding HCFA from resolving the ambiguity in favor of DME. The district court concluded that equipment that could be categorized as both DME and an orthotic must be treated as an orthotic based on a portion of the MCM's definition of DME that provides that "[t]here are other items which, although durable in nature, may [sic] fall into other coverage categories such as braces [and other categories]." MCM § 2000.1. We do not read this language as establishing DME as a category of last resort; it does not say, for instance, that *any* equipment that could be classified as a brace is necessarily not DME. Instead, it uses the term "may," suggesting that the classification of equipment that is both brace-like and durable is left to HCFA. Accordingly, we do not accept OrthoConcepts' argument that HCFA had bound itself to resolve cases of ambiguity on the side of braces.

149 F.3d at 84 (italics in original).

Ortho does not challenge before us the ALJ's reliance on this *Warder* court statement. Nor does Ortho dispute (or address in any fashion) CMS's authority to resolve ambiguity and determine to classify a product as DME. We conclude that there is ambiguity regarding the proper classification of the TBOM and that CMS has the authority to resolve that ambiguity in favor of classifying it as DME.

B. *Whether the TBOM constitutes DME under HCFA Ruling 96.1 is ambiguous.*

1. **The evidence Ortho relies on to show that the TBOM is materially different from the Seating System covered by the Ruling does not demonstrate that CMS could not reasonably construe the Ruling as nevertheless extending to the TBOM.**

As noted above, the ALJ based his conclusion that the TBOM was appropriately classified as DME in large part on HCFA Ruling 96.1, which states in relevant part:

> The "orthotics" benefit described in section 1861(s)(9) of the [Act], insofar as braces are concerned, is limited to leg, arm, back, and neck braces that are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment. It is also held that leg, arm, back, and neck braces used in conjunction with, and necessary for the full functioning of, durable medical equipment are accessories to the durable medical equipment and, hence, subject to the requirements of section 1861(n) of the [Act].

CMS Ex. 20, at 2. The ALJ noted that GAO found that the Ruling had been formulated in response to inconsistent Medicare billing by various suppliers of the Seating System (as between orthotics and DME, and of the component braces as if used independently of each other). ALJ Decision at 8, *citing* CMS Ex. 21. He quoted the GAO Report description of the system about which HCFA (now CMS) was concerned in developing the Ruling as consisting of "leg, arm, neck, and back supports that attached to a base that could be put on wheels." *Id., quoting* CMS Ex. 21, at 14. We observe that the concerns and description expressed in the GAO Report review of the Ruling extend to multiple interconnected braces mounted on a wheeled base rather than being limited to braces connected to a preexisting wheelchair.

The ALJ further noted the *Warder* court found the Ruling to be an interpretive rule for determining whether certain products were to be classified as orthotics or DME for Medicare billing purposes and upheld CMS's application of the Ruling to classify the Seating System as DME. ALJ Decision at 7-8. The ALJ then rejected Ortho's assertions 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, therefore, was not properly classified as TBOM under the Ruling. *Id.* at 9. The ALJ stated:

> 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.

Id.

Ortho takes exception to this statement on appeal. Ortho says that the TBOM is "sufficiently differentiated from Seating Systems so as not to be subject to CMS Ruling 96-1."[7] RR at 11. Ortho relies on the following statement by two of its witnesses:

> A patient in a TBOM is not sitting. Instead such patient's hips and legs are being braced to counteract torque and other contractive forces without concentrated point pressure. Unlike wheelchairs, TBOM is specially designed and customized for each patient to suspend the patient's legs, lower spine and hip joints with orthotic redirection or countering of contractive forces. . . .

P. Ex. 3, at 2 ¶ 9; P. Ex. 4, at 2 ¶ 9.

Other evidence submitted by Ortho is not consistent with this assertion. In at least some of Ortho's promotional photos, the TBOM is positioned as if for sitting, even accepting the witness's assertion that the patient's positioning in the TBOM would be such that the full force of sitting would not be experienced by the patient. *See e.g.*, P. Ex. 4, at 11. We also note, as did the ALJ, that the above product description of the TBOM is not unlike the product description for its predecessor product which, as previously noted, was expressly called a "Seating System":

> 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.

[7] Ortho also argues that the ALJ misstated its burden on summary judgment which, Ortho says, "was not to prove conclusively that TBOM should be classified as an orthotic device rather than DME . . . [but] only to adduce evidence or averment of one or more disputed material facts which, if construed in favor of Ortho, would preclude summary judgment in favor of CMS." RR at 6. We need not decide whether the ALJ's statement was appropriate under summary judgment principles because we find summary judgment appropriate based on our own de novo review of the record as explained herein. In so doing, we do not place any burden on Ortho to present affirmative proof of TBOM's correct classification but rather conclude that Ortho has not shown any dispute of a fact material to CMS's determination about TBOM's qualification as DME. Thus, any alleged error by the ALJ in phrasing the summary judgment standard would be harmless.

ALJ Decision at 9, *quoting Warder*, 149 F.3d at 77. While Ortho's witnesses may not consider the positioning to amount to sitting, their testimony does not thereby distinguish TBOM from the predecessor Seating System in any relevant respect. Ortho's own evidence on the issue of whether the TBOM is a seating system, even accepted as truthful, does not create a material dispute of fact. Furthermore, while the Ruling was created in response to the Seating System (and hence contains descriptions related to the then-existing version of the product), that does not mean that the Ruling's effects are limited to that single product, such that any alteration to the product automatically removed it from the scope of the Ruling. Thus, as the GAO Report recognized, the target of the Ruling extended not only to wheelchairs with attached braces but to systems of braces holding the body in a seated posture and made mobile by mounting on a wheeled base. The TBOM as depicted in Ortho's evidence can reasonably be viewed as still falling within this domain and thus within the scope of the Ruling.

Furthermore, even if the patient in a TBOM is not "sitting," Ortho's evidence indicates that the patient is still positioned in some way. *See* P. Ex. 4, at 11 (photo depicting the TBOM in a position in which the patient would be partially reclining). Indeed, the witness statement quoted above and other witness statements (and photos) indicate that positioning patients to reduce pressure on various points of the body is a principal function of the TBOM. In a declaration submitted by Ortho to Palmetto, Allan Daniel, M.D. made a number of such representations. These include, for example, statements that the TBOM can "slow the progression of contractures by maintaining a stable joint position through improved range of motion and support of weak muscle groups"; "improv[e] spinal alignment and support"; "reduce the risk of aspiration pneumonia by improving vertical posture through enhanced lumbar support and postural alignment"; "help maintain vertical posture while elevating the legs"; "minimize friction" and "avoid and arrest forces of shear" during a change in position. CMS Ex. 16, at 20-22; *see also* P. Ex. 4, at 2 ¶ 12 (referring to TBOM bracing as being "designed to provide different angles of orthosis support"); P. Ex. 4, at 11 (promotional document stating that the TBOM is appropriate for treating pressure ulcers). Products specifically identified as appropriate for DME classification (certain types of wheelchairs and hospital beds, for example) include products designed to put or maintain patients in positions other than or additional to sitting, such as reclining. Act §1861(n). Thus, a finding that the TBOM is not a seating system would not necessarily preclude classifying it as DME even if it were reasonable to read the Ruling itself as limited to seating systems, as Ortho seems to do.

2. Ortho's evidence that the TBOM is not a wheelchair or an accessory connected to medical or non-medical equipment, even accepted as true, similarly fails to establish that the TBOM is outside the scope of the Ruling.

In another attempt to distinguish the TBOM from the Seating System, Ortho argues that the Ruling does not cover the TBOM because that product, unlike the Seating System, consists of "braces-connected-to-braces" not braces "connected to medical or non-medical equipment . . . ." RR at 11. More specifically, Ortho argues, citing witness declarations, that the TBOM is not a wheelchair or an attachment to a wheelchair or other "equipment." *Id.*; Reply at 1. Ortho does not dispute that the TBOM, at least when fully assembled, is on wheels and also has a handle for pushing the device. However, Ortho asserts that the wheels are attached to one of the braces, not to a "base" and that the "mere presence of wheels on a brace do not make the brace a wheelchair or part of a wheelchair, if the wheels are only connected to other 'braces.'" RR at 5. Ortho also asserts that while the TBOM is mobile, wheelchair-like mobility is not its principal function.[8] One of Ortho's witnesses states:

> Certain braces within TBOM brace arrays, often the hip, pelvic or femur braces, have small wheels (much, much smaller than, and different from, wheelchair wheels) as an integral component of the brace. An Ortho brace with the small wheels is not a "base." It is a brace itself, most often a hip or pelvic brace. The wheels allow the brace to be moved short distances. These wheels are in no way used for self-propulsion or longer primary transportation as are the wheels in regular or customized "wheelchairs." By virtue of the rich tapestry of interacting orthotic forces provided by braces-connected-to-braces, TBOM braces together are redesigned to approximate all or portions of the internal skeleton of the human body and to resist or redirect associated benign or pathologic forces.

P. Ex. 3, at 2-3 ¶ 13.

Ortho uses the quoted declaration statement (among others) to try to minimize the extent to which the TBOM functions to increase mobility. However, Ortho's own promotional literature for the TBOM touts it as "[a]ppropriate for [t]reating . . . disabling conditions resulting from immobility," and these "disabling conditions" include "immobility" itself. P. Ex. 3, at 15. Presumably treating immobility, at least given the limitations of the

[8] Ortho told Palmetto that the purpose of the wheeled base was to facilitate emergency evacuation. CMS Ex. 4, at 5. Ortho does not repeat that argument here.

patients using the TBOM, involves enhancing mobility by using the wheeled equipment to permit their movement. Ortho does not acknowledge or attempt to explain this contradiction. We also note that the witness's statement stops short of saying that the wheels on the TBOM are not used for transportation at all, but only says they are not used for "longer primary transportation." This attempt to distinguish the TBOM from wheelchairs fails to account for the fact that regular or customized wheelchairs can be and regularly are used for short or secondary transportation as well as for "longer, primary transportation." Indeed, Medicare generally covers wheelchairs as DME only when they are needed for completing mobility-related activities of daily living within the home, not when they are primarily for transportation within the community. Medicare National Coverage Determinations Manual, CMS Pub. 100-03, ch. 1, pt. 4, § 280.3.[9] We also note, as did the ALJ, Ortho's acknowledgement that the TBOM is "'sometimes mistaken by uninformed observers to be wheelchairs or accessories to wheelchairs.'" ALJ Decision at 6, *citing* CMS Ex. 4, at 3; *see also* CMS Ex. 16, at 1 (statement to Palmetto hearing officer that the TBOM can mistakenly be perceived as a wheelchair or an attachment to a wheelchair or other equipment). This acknowledged perception, despite Ortho's position that such a perception is erroneous, tends to further support CMS's position that the distinctions Ortho draws between its new product and wheelchair-like equipment are not material to the scope of the Ruling.

Ortho's assertion that the product element with the attached wheels is not a "base" but merely an "integral component" of one of the braces is not so much a dispute of fact as a conclusion about how to characterize a construction that can be viewed directly in the photos of the product itself. It is obvious from the pictures of the TBOM presented by Ortho that even assuming the "base" is an "integral component" of a hip, pelvic or femur brace as Ortho contends, the supposed "integral component" functions as a support for the fully assembled TBOM as a whole not simply as part of a single brace. Ortho makes no claim that the TBOM can function as a total body orthotic management device without the wheeled component regardless of whether is called a "base," and it seems obvious from Ortho's own promotional photo of the TBOM that it cannot. We also note the witness's phrasing that the hip, pelvic, or femur brace "within TBOM brace arrays" has wheels. The witness does not state, and Ortho does not contend, that wheels or a base would be an integral part of a hip, pelvic, or femur brace that is used independently of the TBOM. The photos of the braces submitted with the declaration quoted above do not include a photo of any brace identified as a "hip, pelvic or femur" brace. The photos do include a picture captioned as a "hip femoral knee" brace which appears to be attached to a frame similar to the frame depicted in the picture of the fully assembled TBOM to

[9] The Medicare National Coverage Determinations Manual is available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS014961.html.

which the wheeled base is attached. P. Ex. 3, at 21. However, in contrast to the pictures of the other component braces depicted alone (that is, not as components within the assembled TBOM), the caption for this brace does not represent that it is an orthosis. *Compare, e.g.*, P. Ex. 3, at 21 *with* P. Ex. 3, at 17-20. This may suggest that the photo does not represent what this brace used independent of the TBOM looks like and at least leaves open the question of whether the frame on the fully assembled TBOM (and the wheeled base attached to it) is an integral component of a brace as opposed to an addition to a brace when it is used as a component of the TBOM.

It should be apparent from the foregoing that the evidence relied on by Ortho for its position that the TBOM is not a wheelchair, even accepted as true for summary judgment purposes, does not resolve that question. But even if we assume the contrary, such facts would not unequivocally take the TBOM outside the scope of the Ruling. Although, as noted above, HCFA adopted the Ruling to address the TBOM's predecessor Seating System, the language in the Ruling is not by its own terms limited to wheelchairs or other seating systems or attachments to same. Neither the word "wheelchair" nor the phrases "attachment to wheelchair" or "seating system" appears in the Ruling. One of the examples of products covered by the Ruling does refer to "'orthotic braces' require[d] . . . to be attached to the chair frame," and states "the 'orthotic braces' cannot function and be used apart from the chair to which they are attached." CMS Ex. 20, at 5, *cited in* CMS Response to Petitioner's Request for Review (Response) at 6. This example appears to have been intended to describe the Seating System. However, the Ruling's holding is broader and covers leg, arm, back and neck braces that are used "in conjunction with, or as components of, other medical or non-medical equipment." The "Background" section of the Ruling states as follows:

> The Medicare program's long-standing policy has been to limit payment for "orthotics" under Medicare Part B to leg, arm, back, and neck braces that are stand-alone devices used independently of other kinds of medical equipment. Recent decisions issued by administrative law judges and Medicare carrier hearing officers have, however, diverged from this policy and have interpreted section 1861(s)(9) of the Act, insofar as braces are concerned, as encompassing all devices that serve to support or restrict motion in a part of the body, even if the devices may not reasonably be used on their own and are primarily intended to be used with other equipment. The purpose of this Ruling is to provide clarification and guidance regarding the scope and meaning of the statutory benefits for "orthotics" and "durable medical equipment."

CMS Ex. 20, at 2. Ortho states that the braces comprising its TBOM, unlike those in its Seating System, are not connected to medical or non-medical equipment but only to other braces. RR at 11.

CMS asserts that it is immaterial whether the TBOM braces attach to braces or equipment "because under either scenario, there is no assertion that the TBOM components can function independently. HCFA Ruling 96-1 stresses that bracing systems comprised of component pieces that cannot function independently are not orthotics." Response at 7-8. CMS notes that "the ALJ's ultimate decision that TBOM is DME rested on the fact that the individual component parts cannot function independently." *Id.* at 9. Indeed, the ALJ stated:

> 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.

ALJ Decision at 10, *citing* CMS Ex. 11, at 22.

Ortho replies as follows:

> The [Medicare billing code] system is replete with reimbursable compound "non-independently functioning" braces. These braces consist of braces-attached-to-braces in which each component brace requires connection to other component braces for their collective functioning. Examples of these include: . . . L-2000, Knee-Ankle-Foot Orthosis . . . ; L-3805, Shoulder-Elbow-Wrist-Hand Orthosis . . . . In the world of braces, unlike the world of DME described in CMS Ruling 96-1, "independent functioning" is not a relevant concept. If no part of the TBOM is DME or attached to DME, then CMS Ruling 96-1's notion of "function independently" is not applicable to reimbursement for pure braces.

Reply at 3 (emphasis in original). CMS does not dispute here that certain combinations of braces can be billed as orthotic devices. However, in our view, the issue is not whether every combination of braces must be viewed as DME under the Ruling. The issue is whether CMS may reasonably view the TBOM as within the scope of the Ruling. We conclude that such a view is reasonable because when the braces that comprise the TBOM are used in the TBOM, they no longer function as individual braces (or braces that would be billable as compound braces) for body parts but rather as part of a total system that manages the positioning of the whole body. As the ALJ noted, Ortho itself does not claim that each brace, or even each compound brace, functions independently as part of the TBOM but, rather, that the braces function, as the name itself indicates, as a total body management system.

Ortho appears to argue that this is not enough to qualify the device as DME under the Ruling, but rather that, in order to come within the Ruling, the "array of braces" must at some point be attached to separate medical or non-medical equipment, and, in its view, the array of braces is not attached to anything that itself qualifies as equipment. As discussed above, there may be ambiguity about whether the wheeled "base" to which the braces in a fully assembled TBOM are attached is, in fact, a base or would constitute "equipment." However, at a minimum, in our view, it is not unreasonable to regard the wheeled base as non-medical "equipment," or even medical equipment to the extent it is used to facilitate mobility, thereby functioning as do wheelchairs, which are specifically included in the equipment category, even if not constituting a wheelchair. Similarly, CMS could reasonably consider the fully assembled TBOM a form of medical equipment based on its function and usage, regardless of whether it would qualify as a wheelchair. We note in this regard that the regulations define DME as a subset of "equipment," 42 C.F.R. § 414.202, whereas the Ruling uses the word "equipment" more generically.

For all of the reasons stated above, we conclude that, even viewing Ortho's own evidence about the construction and use of the TBOM in the light most favorable to Ortho, the applicability of the Ruling to the TBOM is at least arguably reasonable, and whether the TBOM is properly classified as DME remains at least ambiguous. In the next section, we explain why, in resolving ambiguity in relation to the scope and applicability of the coverage authorities (as opposed to any actual disputes of material fact), we defer to the authority and expertise of CMS.

C. *CMS has the authority to resolve this ambiguity in favor of DME.*

As we noted earlier, the *Warder* court and the ALJ concluded that even if the TBOM could alternatively be classified as an orthotic device, "there was nothing precluding HCFA from resolving the ambiguity in favor of DME." *Warder*, 149 F.3d at 84; ALJ Decision at 10. Ortho does not address or dispute that conclusion before us, and, for the following reasons, we agree with it.

1. **The TBOM meets the statutory and regulatory criteria for classifying products as DME.**

Section 1861(n) of the Act does not define DME but merely provides, in relevant part, that the term "includes iron lungs, oxygen tents, hospital beds, and wheelchairs . . . used in the patient's home . . . ." The Secretary has interpreted the word "includes" in the DME definition as meaning that the items listed in the statute are not exclusive and that the Secretary (through CMS) has discretion to designate other equipment as DME. *NCD Complaint – Durable Medical Equipment Reference List (Air Cleaners) § 280.1*, DAB No. 1999, at 2 (2005). Notably, Ortho has not disputed this interpretation, and it is

consistent with settled rules of statutory construction. *See Puerto Rico Maritime Shipping Auth. v. ICC*, 645 F.2d 1102, 1112 n. 26 (D.C. Cir. 1981) ("It is hornbook law that the use of the word 'including' indicates that the specified list . . . that follows is illustrative, not exclusive"), *cited in Fady Fayad, M.D.*, DAB No. 2266, at 8 (2009). Even if the meaning of the word "includes" were ambiguous, the Secretary's construction would be permissible and, therefore, entitled to deference under principles enunciated by the Supreme Court in *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984).

To assist in exercising her statutory discretion to designate additional items as DME, the Secretary promulgated the following criteria (inter alia) for classifying a product as DME:

> [E]quipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
> (3) Is primarily and customarily used to serve a medical purpose.
> (4) Generally is not useful to an individual in the absence of an illness or injury.
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202. Although Ortho denies that the TBOM is DME, it quite conspicuously does not address this definition of DME or dispute the ALJ's conclusion that the TBOM meets it. We also note that, although Ortho seeks to have Medicare Part B pay for use of the TBOM in SNFs, as Medicare cannot do if it is classified as DME, Ortho does not deny that the TBOM is appropriate for use in the home, were a patient with the disabilities for which it is designed to be cared for at home.

We find no error in the ALJ's conclusion that the TBOM meets the regulatory definition of DME. This is true regardless of whether the Ruling directly applies to TBOM or not. Accordingly, CMS's designation of the TBOM as DME is consistent with the Medicare statute and implementing regulations applicable to DME.

2. CMS's classification of the TBOM as DME is not precluded by the statutory or regulatory definition of braces.

The statute defines braces, in relevant part, as "leg, arm, back, and neck braces . . . ." *See* Act §§ 1861(s)(9) . The regulation tracks this language. 42 C.F.R. § 414.202. The *Warder* court read this definition as "includ[ing] only examples of individual braces . . . ." 149 F.3d at 84. The Ruling, as previously discussed, interprets the definition as covering the listed braces only if they "are used independently, rather than in conjunction with, or as components of, other medical or non-medical equipment." CMS Ex. 20, at 2. As discussed above, Ortho denies that the TBOM is connected to or used in conjunction with other medical or non-medical equipment and also asserts that certain compound braces qualify for Medicare payment. However, Ortho does not argue that CMS is not authorized to resolve any ambiguity as to whether a particular product meets the definition of braces or that the terms of the Ruling exhaust CMS's discretion in doing so. We find nothing in the legal definition of "braces" restricting CMS's authority to resolve ambiguity as to whether a particular product meets that definition. We also agree with the First Circuit that the Medicare Manual definition of DME does not make DME a classification of last resort and, therefore, reflects no intent on the part of CMS to bind itself to resolve any ambiguities in favor of braces. *See* 149 F.3d at 84, *citing* MCM § 2000.1.[10]

3. It is appropriate to defer to CMS's expertise to resolve the ambiguity surrounding the TBOM.

As previously discussed, the Secretary's interpretation of an ambiguous statute is entitled to deference. Similarly, federal courts are required to give an agency's view of its own regulations "controlling weight unless [that view] is plainly erroneous or inconsistent with the regulations." *Bowles v. Seminole Rock & Sand Co*., 325 U.S. 410, 414 (1945). The federal courts have recognized the special importance of that deference where the Secretary's interpretation of the complex Medicare regulations is concerned:

> [D]eference to the Secretary's interpretations of Medicare regulations is "all the more warranted," because Medicare "'is a complex and highly technical regulatory program,' in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'"

[10] When the MCM was in use, the definition was actually located at MCM § 2100.1. The MCM, a paper-based manual, has been discontinued and its contents transferred to various internet-based manuals. The language quoted by the court now appears in Chapter 15, section 110.1 of the Medicare Benefit Policy Manual.

Dist. Mem'l Hosp. of Southwestern N.C., Inc. v. Thompson, 364 F.3d 513, 518 (4th Cir. 2004) (*quoting Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994)). In *Almy v. Sebelius*, 679 F.3d 297, 302-04, 306-07 (4th Cir. 2012), *cert. denied*, 133 S.Ct. 841 (2013), the First Circuit applied this principle to uphold the Secretary's interpretation of regulations implementing the Medicare Act's "reasonable and necessary" standard for Part B coverage. In M*acKenzie Medical Supply, Inc. v. Leavitt*, 506 F.3d 341 (4th Cir. 2007), the Fourth Circuit applied *Chevron* deference principles to uphold CMS's interpretation that the certificate of medical necessity required by section 1834(j)(2)(A)(i) and (2)(B) of the Act was not the only documentation CMS could require for payment of DME claims involving power wheelchairs. The court further stated that *Chevron* deference was "especially" appropriate "given that 42 U.S.C. § 1395ff(a) affords the Secretary discretion to make determinations with respect to DME claims under Part B of the Medicare Act, and 42 U.S.C. §§ 1395u(p)(4) and 1395ddd afford the Secretary (or the fiscal agent of the Secretary) auditing powers with respect to such claims under Part B." 506 F.3d at 348.

Here, CMS has found the TBOM to qualify as DME under the statute and regulations, and, as discussed above, we find no error in its doing so. For that reason, and applying settled principles of deference, we conclude that it is lawful and appropriate to defer to CMS's judgment to resolve the ambiguities concerning the TBOM in favor of classifying the TBOM as DME.

Determining how to classify medical devices for purposes of Part B payment involves complex and highly technical issues, with a medical component, that make these determinations comparable to those addressed by the courts in such cases as *Almy* and *MacKenzie*. DME classification decisions, like other Part B decisions, involve "[t]he identification and classification of medical eligibility criteria [that] necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns." *Almy*, 679 F.3d at 304 (*quoting Pauley v. BethEnergy Mines, Inc*., 501 U.S. 680, 697 (1991)). In this case, the Secretary has delegated the authority to make those determinations to CMS, which, as the agency responsible for administering the Medicare program, has the expertise to make them. We see no material distinction between deferring to CMS's judgment regarding the medical necessity of a product for which Medicare payment is claimed and deferring to CMS's judgment whether to classify a product as DME rather than braces. Certainly, Ortho has not argued there is such a distinction. Such exercises of judgment are the keystone of agency discretion. Ortho has pointed to no statutory or other legal authority that would justify substituting our judgment for that of CMS in this matter.

Nor has Ortho cited any legal requirement for CMS to issue a ruling particular to the TBOM rather than either relying on the extant Ruling for determining that the TBOM must be billed as DME rather than braces under Part B or making that assessment apart from the development of a ruling. Indeed, although Ortho asserts that the TBOM is not

covered by the Ruling, it has not specifically argued that CMS would need to issue another ruling to cover the TBOM. We conclude that CMS has the flexibility to determine whether or not a new ruling is needed to cover the TBOM before it can deny payment for the device when it is billed as orthotics. While the Ruling was not developed specifically for the TBOM, as we have discussed, it also does not unequivocally exclude application to the TBOM. Ortho points to nothing that would justify our denying CMS the flexibility it needs with respect to classifying this product in a manner CMS, in its expertise, deems necessary to implement the statute and regulations relating to classification of DMEPOS products for purposes of Part B payment. *Cf. Almy*, 679 F.3d at 303-04 (*citing* the court's history of refusing to limit the Secretary's flexibility in implementing Part B's "reasonable and necessary" requirement for coverage of DME.)

In *Almy*, the Fourth Circuit upheld the District Court's rejection of a DME supplier's argument that the Secretary's final decisions denying coverage for its product (the Bionicare Stimulator System, Model 1000 (BIO-1000) – used to treat osteoarthritis of the knee by delivering electronic impulses) were not entitled to the deference traditionally accorded such decisions because they were not preceded by any statute, regulation or policy addressing that particular product. The Fourth Circuit agreed with the District Court's conclusion that to accept that theory "would be to 'effectively requir[e] the Secretary to issue item-specific coverage rules for each and every item of DME before issuing case adjudications.'" 679 F.3d at 304 (*quoting Almy v. Sebelius*, 749 F.Supp. 2d 315, 324 n.2 (D. Md. 2010)). In doing so, the court noted that "[t]he Supreme Court has long warned about the unsuitability of precisely the kind of rule BioniCare urges us to adopt: 'To hold that the [Secretary] had no alternative in this proceeding but to approve the proposed transaction, while formulating any general rules it might desire for use in future cases of this nature, would be to stultify the administrative process.'" *Id*. (*quoting SEC v. Chenery Corp.*, 332 U.S. 194, 202 (1947)).

We recognize that the case before us arose from a revocation of billing privileges for noncompliance with DMEPOS supplier standards not, as in *Almy*, denials of payment for individual Part B claims. However, we do not find that distinction material. As indicated above, Ortho does not dispute that the revocation action was authorized if the Secretary properly classified the TBOM as DME. Thus, the material issue before us is whether CMS's classification was proper in light of the statute and regulations, the Ruling and application of generally accepted principles of deference to administrative decision making in matters of Medicare policy. For purposes of resolving that issue, we conclude that cases such as *Almy* and *Chenery* support our conclusion that CMS did not need to issue a new ruling in order to lawfully classify the TBOM as DME. This is particularly so since Ortho freely acknowledges that it designed the TBOM precisely to try to avoid coverage under the extant Ruling. While it might be "cleaner" for CMS to issue an item-specific coverage determination for the TBOM, requiring CMS to do so under these circumstances would be inconsistent with the settled principles of deference discussed

above which recognize the importance of administrative flexibility, especially for agencies charged by Congress with administering complex programs like Medicare. Congress has left to the Secretary the task of classifying medical devices for purposes of Part B payment, and we will not unduly impede that task by requiring CMS to issue a TBOM-specific ruling under these circumstances.

/s/
Constance B. Tobias

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member