



The Supreme Court of South Carolina

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COLUMBIA, SOUTH CAROLINA
29211
1231 GERVAIS STREET
COLUMBIA, SOUTH CAROLINA 29201
TELEPHONE: (803) 734-1080
FAX: (803) 734-1499
www.sccourts.org

July 14, 2016

The Honorable Jana E. Shealy
Clerk, Administrative Law Court
Edgar A. Brown Building
1205 Pendleton Street, Suite 224
Columbia SC 29201

REMITTITUR

Re: CareAlliance Health Services v. SCDOR
Lower Court Case No. 2012-ALJ-17-0405AP
Appellate Case No. 2014-001457

Dear Clerk of Court:

The above referenced matter is hereby remitted to the lower court or tribunal. A copy of the judgment of this Court is enclosed.

Very truly yours,

Daniel E. Shearouse
DS

CLERK

cc:

John C. Von Lehe, Jr., Esquire
Bryson Moore Geer, Esquire
Lauren Acquaviva, Esquire
Milton Gary Kimpson, Esquire
Raymond P. Carpenter, Esquire

THE STATE OF SOUTH CAROLINA
In The Supreme Court

CareAlliance Health Services d/b/a Roper St. Francis
Healthcare, Respondent,

v.

South Carolina Department of Revenue, Appellant.

Appellate Case No. 2014-001457

Appeal from the Administrative Law Court
The Honorable Shirley C. Robinson, Administrative Law
Judge

Opinion No. 27627
Heard February 9, 2016 – Filed April 20, 2016

REVERSED

Milton G. Kimpson and Lauren Acquaviva, both of the
South Carolina Department of Revenue, of Columbia, for
Appellant.

John C. Von Lehe, Jr. and Bryson M. Geer, both of
Nelson Mullins Riley & Scarborough, LLP, of
Charleston, and Raymond P. Carpenter, of Roswell,
Georgia, for Respondent.

JUSTICE HEARN: The South Carolina Department of Revenue (DOR) appeals
the Administrative Law Court's (ALC) grant of summary judgment in favor of

CareAlliance Health Services (the Hospital) finding (1) orthopaedic prosthetic devices purchased for specific patients are exempt from sales tax and (2) other bone, muscle, and tissue implants replaced a missing part of the body. We reverse.

FACTUAL/PROCEDURAL HISTORY

The Hospital is a health corporation comprised of Roper Hospital and St. Francis Hospital in Charleston, which render customary surgical and emergency services to patients. The Hospital provides orthopaedic prosthetic devices¹ and other implants to patients through either a planned surgical procedure or in response to trauma.

Generally during a scheduled surgery, a prosthetic device vendor is present in the operating room with a portfolio of prosthetic devices from which a surgeon can select the appropriate implant. Upon determining the appropriate device, the surgeon communicates his selection to the vendor. The vendor then provides the chosen device to a circulating nurse for implantation by the surgeon. Subsequently, the vendor fills out a requisition sheet, in which a record of the device is memorialized. The requisition sheet is initialed by the circulating nurse as an acknowledgement the items were consumed. The form is then provided to the Hospital's purchasing department, and a purchase order is generated and submitted to the vendor based on prearranged pricing agreements with the Hospital.

Believing the purchase of orthopaedic prosthetic devices and other implants were eligible for a sales tax exemption, the Hospital sought a refund from DOR.² Specifically, the Hospital asserted under *Home Medical Systems, Inc. v. South Carolina Department of Revenue*, 382 S.C. 556, 564, 677 S.E.2d 582, 587 (2009), the prosthetic devices were "sold by prescription" as required for the tax exemption under section 12-36-2120(28) of the South Carolina Code (2014). Pursuant to

¹ The orthopaedic prosthetic devices in question are Food and Drug Administration (FDA) Class II and Class III prosthetic devices. 21 U.S.C. § 360(a)-(c) (2013).

² The Hospital requested refunds for joint implants, pacemakers, bone, tissue, blood products, plasma derivatives, and oncology medicines. The subject of this appeal is strictly orthopaedic prosthetic devices and other bone, muscle, and tissue implants. The question of exemption as to the remaining items have been stayed pending a decision in this matter.

Home Medical, a device is sold by prescription if (1) the sale requires a prescription; (2) the device is actually sold by prescription; and (3) the device replaces a missing part of the body. 382 S.C. at 564, 677 S.E.2d at 587.

Following an audit, DOR denied the request as to orthopaedic prosthetic devices on the grounds they do not require a prescription to be sold and a prescription was not used in the purchase of the devices.³ DOR also held other bone, muscle, and tissue implants were not exempt because they did not replace a missing part of the body, as required for the exemption.

The Hospital filed for a contested case hearing. After discovery, both parties filed motions for summary judgment. Following a hearing on the motions, the ALC granted summary judgment in favor of the Hospital, finding orthopaedic prosthetic devices qualified for the exemption and other bone, muscle, and tissue implants replaced a missing part of the body.

DOR filed a motion for reconsideration, which was denied, and thereafter filed a notice of appeal. This Court certified the case for review pursuant to Rule 204(b), SCACR.

ISSUES PRESENTED

- I. Did the ALC err in finding the sales tax exemption applies to orthopaedic prosthetic devices and granting summary judgment in favor of the Hospital?
- II. Did the ALC err in finding other bone, muscle, and tissue implants replaced a missing part of the body?

STANDARD OF REVIEW

In an appeal from an ALC decision, the Administrative Procedures Act provides the appropriate standard of review. S.C. Code Ann. § 1-23-610(B) (Supp. 2015); *Kiawah Dev. Partners, II v. S. C. Dep't of Health & Envtl. Control*, 411 S.C. 16, 28, 766 S.E.2d 707, 715 (2014). While an appellate court will not substitute its judgment for that of the ALC as to findings of fact, we may reverse or

³ The requested refund covered the Hospital's sales from August 1, 2007, through November 30, 2010, and amounted to \$5,014,576.76.

modify decisions that are controlled by an error of law or are clearly erroneous in view of the substantial evidence on the record as a whole. *S.C. Dep't of Corr. v. Mitchell*, 377 S.C. 256, 259, 659 S.E.2d 233, 235 (Ct. App. 2008). Substantial evidence is evidence which, considering the record as a whole, would allow reasonable minds to reach the conclusion that the administrative agency reached or must have reached in order to justify its action. *Lark v. Bi-Lo, Inc.*, 276 S.C. 130, 135, 276 S.E.2d 304, 306 (1981). Ordinarily, tax exemption statutes are strictly construed against the claimed exemption. *TNS Mills, Inc. v. S.C. Dep't of Revenue*, 331 S.C. 611, 620, 503 S.E.2d 471, 476 (1998).

LAW/ANALYSIS

I. APPLICATION OF THE SALES AND USE TAX EXEMPTION

DOR challenges the ALC's holding the Hospital is entitled to the sales tax exemption for orthopaedic prosthetic devices. Specifically, DOR contends the ALC erred in finding a prescription is required for the sale of an orthopaedic device between the Hospital and vendor because of federal regulations. We agree.

Generally, the retail sale of a prosthetic device to a hospital or doctor is a taxable sale if the prosthetic device is furnished to a patient as part of a service being rendered by a hospital. S.C. Code Ann. § 12-36-110(1)(i) (2014). As noted above, the sales tax exemption enumerated in section 12-36-2120(28) is for prosthetic devices sold by prescription. S.C. Code Ann. § 12-36-2120(28); *see also* 10 S.C. Reg. 117-308 (2012) (explaining when a prosthetic device is furnished to a patient by a hospital as part of the services a patient is receiving, the hospital will be deemed a user or consumer of the prosthetic and subject to the sales and use tax); S.C. Rev. Ruling #98-9 (stating that once it is established that a sale to a hospital is a retail sale, then one must determine whether the item in question comes within an exemption). Although the tax code does not define the term *sold by prescription*, this Court in *Home Medical* enunciated a three-part test to determine whether an item is sold by prescription. 382 S.C. at 564, 677 S.E.2d at 587. A device is sold by prescription if (1) the sale requires a prescription; (2) the device is actually sold by prescription; and (3) the device replaces a missing part of the body. *Id.*

DOR applied *Home Medical* and found the exemption inapplicable for orthopaedic prosthetic devices because a prescription is not required for the transaction between the Hospital and vendor. Relying on Regulation 117-308.3

and Regulation 117-308.8, DOR argues the purchase of an orthopaedic prosthetic device is equivalent to the purchase of traditional medical supplies like bandages. Under 117-308.3, "[d]octors are the consumers of the supplies, medicines, office furniture and fixtures and special tools and equipment they use in the practice of their profession. Sales of such supplies and equipment to doctors *are retail sales and subject to the sales tax.*" 10 S.C. Reg. 117-308.3 (2011)(emphasis added). Similarly, hospitals are considered the consumers "[w]here drugs, prosthetic devices and other supplies are furnished to their patients as a part of the medical service rendered." 10 S.C. Reg. 117-308.8 (2011). DOR accordingly asserted the Hospital was not required to have a prescription to acquire supplies, be they prosthetic devices or bandages. Moreover, DOR suggested the exemption was intended for individual patients who purchase a prosthetic device with a prescription from a brace and boot shop, not for a hospital or doctor rendering services by implanting prosthetic devices.

However, the Hospital argued that because the devices are Class II and Class III federal prescription prosthetics, inquiry into the nature of the transaction was unnecessary—the implants are prescription devices by federal mandate. *See* 21 C.F.R. § 801.109(a) (2011) (exempting prescription devices from certain labeling requirements, including when devices "[are] to be sold only to or on the prescription or other order of such practitioner").⁴ Consequently, the Hospital

⁴ Section 801.109(a) states, in part, that a device is exempt from certain labeling requirements if:

The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

suggested these prosthetics will always satisfy *Home Medical*, and the Hospital was therefore entitled to the exemption. DOR argued the federal regulation relied on by the Hospital merely dictates labeling requirements for when the device is allowed in the stream of commerce and therefore provided no insight into the state's taxation of the devices. *See* 21 C.F.R. § 801.109(a). It therefore gave no weight to the devices' classification as Class II or Class III in formulating its position.

The ALC rejected DOR's construction of federal regulations, finding *Home Medical* was satisfied because FDA regulation requires a prescription for orthopaedic prosthetic devices. *See* 21 C.F.R. § 801.109(a); *see also* 21 U.S.C. § 360j(e)(1)(A) (2006) (explaining the Secretary of the FDA sets forth the sale, distribution, or use of restricted devices and requires restricted devices only be available "upon the written or oral authorization of a practitioner licensed by law to administer"). While the ALC acknowledged a prescription is not necessary for all sales under section 801.109, it found DOR interpreted the regulation too strictly and as a result defeated the statutory purpose to allow for an exemption as applied by *Home Medical*. The ALC concluded "if a distinction is made between 'prescription' and 'order' in the federal regulation, then no device would *ever* require a prescription for sale—an order could always suffice. Consequently the first prong of *Home Medical* would never be satisfied and no devices would ever be tax exempt." The ALC acknowledged Class II and Class III devices will always require a prescription to be sold and as a result, the first prong of *Home Medical* will always be satisfied.

At the outset, we agree with DOR that section 801.109(a) addresses the labeling requirements for Class II and Class III devices and does not always require a prescription. Federal regulation restricts the access of Class II and Class III surgical devices because the FDA has determined such devices are unsafe for public consumption without medical supervision. 21 C.F.R. § 801.109 (explaining such devices are "not safe except under the supervision of a practitioner licensed by law to direct the use of such device"). Due to the public's restricted access to these devices, the FDA exempts these devices from standard warnings and labeling requirements because they "[are] to be sold only to or on the prescription or other

21 C.F.R. § 801.109(a) (emphasis added).

order of such practitioner for use in the course of his professional practice."⁵ 21 C.F.R. § 801.109(a)(2).

By its terms, this regulation allows Class II or Class III prescription prosthetic devices to be sold directly to a practitioner, on the order of a practitioner, or on the prescription of a practitioner. *Id.* Thus, it envisions a sale can occur directly to a practitioner, with no prescription or order requirement. We therefore reject the Hospital's assertion and the ALC's finding the devices at issue can *only* be sold by prescription. Instead, the regulation allows for a sale directly between a vendor and practitioner, as an agent of the Hospital.

The ALC's broad interpretation of the federal regulation is fundamentally at odds with the plain reading of the regulation and the strict construction afforded a tax exemption. Accordingly, we hold the ALC erred in finding section 801.109(a) satisfies the first prong of *Home Medical*. The statute expressly allows a practitioner to be in possession of a prosthetic device without a prescription or order. We therefore reverse the ALC because these devices do not require a prescription for the purpose of qualifying for a tax exemption. Because we find the Hospital is unable to satisfy the first prong, we need not reach the second prong. *See Futch v. McAllister Towing of Georgetown, Inc.*, 335 S.C. 598, 613, 518 S.E.2d 591, 598 (1999) (stating that if an appellate court's ruling on a particular issue is dispositive of an appeal, rulings on remaining issues are unnecessary).

II. OTHER BONE, MUSCLE, AND TISSUE IMPLANTS

DOR next argues the ALC erred in finding that the other bone, muscle, and tissue implants replace a missing part of the body because the Hospital did not present evidence to support this finding. We agree. The record is devoid of any evidence to support the ALC's finding that other bone, muscle, and tissue implants replaced missing parts of the body. No evidence provides any details regarding the bone, muscle, and tissue implants that were being ruled on by the ALC; therefore the record plainly does not contain the level of substantial evidence necessary to uphold the finding.

⁵ The provision indicates that practitioners are individuals "such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device." 21 C.F.R. § 801.109(a)(1)(ii).

CONCLUSION

Based on the foregoing, we reverse the ALC and find the Hospital is not entitled to a tax exemption for the sale of orthopaedic prosthetic devices. Further, we reverse the ALC's finding that other bone, muscle and tissue implants replace a missing body part because it is not supported by substantial evidence in the record.

BEATTY, KITTREDGE, JJ., and Acting Justice Alison Renee Lee, concur.
PLEICONES, C.J., concurring in result only.