THE STATE OF SOUTH CAROLINA
In The Court Of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

HONORABLE SHIRLEY C. ROBINSON, ADMINISTATIVE LAW JUDGE

Case No. 12-ALJ-17-0405-CC
Appellate Case No. 2014-001457

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

v.

South Carolina Department of Revenue,.....Appellant.

BRIEF OF APPELLANT

Lauren Acquaviva (Bar No.100528)
Counsel for Litigation
Milton G. Kimpson (Bar No. 7917)
General Counsel for Litigation
PO Box 12265
Columbia, SC 29211
Attorneys for Appellant
South Carolina Department
of Revenue
(803) 898-5110
(803) 896-0171
AcquavL@sctax.org
CourtOrders@sctax.org

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STATEMENT OF THE CASE

This matter came before the Administrative Law Court (ALC) in accordance with the Administrative Procedures Act, S.C. Code Ann. § 1-23-310, et. seq. (2005) for a contested case hearing. CareAlliance Health Services, d/b/a Roper St. Francis Medical Healthcare, Inc. (Respondent or hospital) filed for a contested case hearing with the ALC to challenge a Department Determination issued by the South Carolina Department of Revenue (Department) denying a refund claim for sales and use taxes paid on the hospital's purchases of orthopedic and cardiovascular prosthetic devices (collectively "prosthetic devices" or "medical devices") and blood derivatives between August 1, 2007, and November 30, 2010. (R. pp. 30 – 42; Department Determination.) Specifically, the Department denied the refund claim because a hospital is not required to have a prescription in order to purchase prosthetic devices and because blood derivatives are medicines subject to sales tax. (R. pp. 30 – 42; Id.)

The parties filed cross motions for summary judgment, and the ALC held a motions hearing on October 1, 2013. Just prior to the hearing on September 27, 2013, the parties filed Joint Stipulations of Fact with the Court. (R. pp. 777 – 780; Joint Stipulations of Fact.) In the Joint Stipulations of Fact, the parties divided the items at issue into three basic categories: 1) prescription reconstructive musculoskeletal prosthetic devices (hips, knees, shoulders, mastectomy reconstructive implants, other skeletal implants, and other bone, muscle, and tissue implants) and prescription trauma musculoskeletal prosthetic devices (pins, screws, nails, plates, and other trauma implants) ("Prosthetics A"), 2) prescription cardiac prosthetic devices (pacemakers and implantable cardioverter-defibrillators (ICDs)) ("Prosthetics B"), and 3) blood derivatives. (R. pp. 777

– 778; Joint Stipulations of Fact ¶¶ 1 – 3.) The parties also stipulated that the hips, knees, shoulders, and mastectomy reconstructive implants replace a missing part of the body. (R. p. 779; Id. at ¶ 7.)[1] The ALC issued its order on May 20, 2014 (Initial Order), finding that the sales of prescription reconstructive musculoskeletal prosthetic devices to the hospital are exempt from sales and use tax, but that the sales to the hospital of the prescription trauma musculoskeletal prosthetic devices,[2] the prescription cardiac devices,[3] and the blood derivatives[4] are not exempted from sales and use tax. (R. pp. 17 – 19, 21; Order 12 – 14, 16.) Both parties filed motions for reconsideration, which the ALC granted in part and denied in part. (R. pp. 23 – 26; Order Granting In Part And Denying In Part Mots. For Recons.) In the ALC's Order Granting in Part and Denying in Part Motions for Reconsideration issued on June 27, 2014 (Reconsidered Order), the ALC determined there were questions of fact as to whether the prescription cardiac devices replace a missing part of the body and whether the blood derivatives are subject to sales and use tax and thus ultimately denied summary judgment on these issues. (R. p. 24;

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[1]The question regarding whether the remaining prosthetic devices replace a missing part of the body was a question of fact for the ALC to decide.

[2]The ALC found "it logical to distinguish between a sale related to a particular individual and a bulk sale to a medical provider" and determined that "bulk sales of prescription devices to medical providers are not 'sales by prescription' and are subject to sales tax." (R. p. 17; Order 12.)

[3]The ALC concluded that the cardiac devices replace, enhance, or correct the functioning of the heart, not a missing part of the body; thus, it determined that the cardiac devices are not "prosthetics as defined in [S.C. Code Ann. Regs.] 117-332" and, therefore, are not exempt pursuant to section 12-36-2120(28). (R. p. 18; Order 13.)

[4]The ALC determined that the blood derivatives are subject to sales tax because the Legislature did not enact an express exemption for blood derivatives. (R. p. 21; Order 16.)

Order Granting In Part And Denying In Part Mots. For Recons. 2.) The ALC upheld its Initial Order as it related to the prescription reconstructive musculoskeletal prosthetic devices (including the other bone, muscle, and tissue implants)[5] and prescription trauma musculoskeletal prosthetic devices, concluding that prescription prosthetic devices require a prescription to be sold, (R. p. 25; Id. at 3), that the prescription reconstructive musculoskeletal prosthetic devices were actually sold by prescription, (R. p. 26; Id. at 4), and that the prescription trauma musculoskeletal prosthetic devices were not actually sold by prescription (R. p. 26; Id. at 4, n. 2). The Department filed its appeal of the ALC's decision to the South Carolina Court of Appeals on July 3, 2014.

STATEMENT OF FACTS

The Respondent is a healthcare corporation comprised of Roper and St. Francis hospitals located in Charleston, South Carolina. (R. p. 31; Department Determination 2.) It submitted refund claims for tax periods ending August 1, 2007 through November 30, 2010, totaling $5,014,576.76 for sales and use tax on purchases of medical devices (predominantly joint replacement implants and cardiac pacemakers), bone, tissue, blood products, plasma derivatives, and oncology medicines. (R. p. 31; Id.) Of the total refund claim, $3,055,816.70 was based on the assertion that the prosthetic devices purchased by the hospital are exempt from taxation pursuant to section 12-36-2120(28)(a) as "prosthetic devices sold by prescription." (R. pp. 30, 33; Id. at 1, 4.) Another $435,368.74 of the refund claim relates to the sale of protein-based medicines derived

[5]The ALC stated the "other bone, muscle, and tissue implants" were "presented to the Court as a 'catch-all' category of devices," and it declined to address those items individually. (R. p. 26; Order Granting In Part And Denying In Part Mots. For Recons. 4.)

from human plasma (blood derivatives), which the hospital asserts are exempt from taxation based upon the application of a products liability statute found at S.C. Code Ann. § 44-43-10 (Supp. 2013). (R. pp. 30, 37; Department Determination 1, 8.) The Department denied $3,931,402.31 of the hospital's refund claim by letter dated March 24, 2011, and the hospital timely protested this denial on June 20, 2011. (R. p. 32; Id. at 3.) The Department issued its Determination upholding the denial on August 16, 2012, finding that the prosthetic devices and blood derivatives were not exempt from taxation. (R. pp. 30 – 42; Id.)

ARGUMENTS

In an appeal from the decision of an administrative agency, the Administrative Procedures Act provides the appropriate standard of review. Olson v. S.C. Dep't of Health & Envtl. Control, 379 S.C. 57, 63, 663 S.E.2d 497, 500-501 (Ct. App. 2008); Turner v. S.C. Dep't of Health & Envtl. Control, 377 S.C. 540, 544, 661 S.E.2d 118, 120 (Ct. App. 2008); Clark v. Aiken County Gov't, 366 S.C. 102, 107, 620 S.E.2d 99, 101 (Ct. App. 2005). S.C. Code Ann. § 1-23-610(B) (Supp. 2013) provides the applicable standard:

> (D) The review of the administrative law judge's order must be confined to the record. The reviewing tribunal may affirm the decision or remand the case for further proceedings; or it may reverse or modify the decision if the substantive rights of the Appellant has been prejudiced because of the finding, conclusion, or decision is:
>
> > (a) in violation of constitutional or statutory provisions;
> > (b) in excess of the statutory authority of the agency;
> > (c) made upon unlawful procedure;
> > (d) affected by other error of law;

> (e) clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record; or
> (f) arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

Additionally,

> When reviewing the grant of a summary judgment motion, the appellate court applies the same standard which governs the trial court under Rule 56(c), SCRCP: summary judgment is proper when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law.

Miller v. Blumenthal Mills, Inc., 365 S.C. 204, 219, 616 S.E.2d 722, 729 (Ct. App. 2005) (internal citation omitted).

Resolution of the issues in this case depends upon the rules of statutory construction and when construing a statute, the cardinal rule is to ascertain the intent of the Legislature. Georgia-Carolina Bail Bonds, Inc. v. County of Aiken, 354 S.C. 18, 22, 579 S.E.2d 334, 336 (Ct. App. 2003). "All rules of statutory construction are subservient to the one that legislative intent must prevail if it can be reasonably discovered in the language used, and that language must be construed in the light of the intended purpose of the statute." Id. at 23, 579 S.E.2d at 336. The words of the statute "must be given their plain and ordinary meaning without resort[ing] to subtle or forced construction to limit or expand [the statute's] operation." Hitachi Data Sys. Corp. v. Leatherman, 309 S.C. 174, 178, 420 S.E.2d 843, 846 (1992) (internal citations omitted). Furthermore, "[t]he language of a tax exemption statute must be given its plain, ordinary meaning and must be 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) (see also Southeastern–

Kusan, Inc. v. S.C. Tax Comm'n, 276 S.C. 487, 489, 280 S.E.2d 57, 58 (1981)). Finally, "[t]he construction of a statute by the agency charged with its administration will be accorded the most respectful consideration and will not be overruled absent compelling reasons." Brown v. S.C. Dep't of Health & Envtl. Control, 348 S.C. 507, 515, 560 S.E.2d 410, 414 (2002) (quoting Dunton v. S.C. Bd. of Examin'rs in Optometry, 291 S.C. 221, 223, 353 S.E.2d 132, 133 (1987)); see also Nucor Steel v. S.C. Pub. Serv. Comm'n, 310 S.C. 539, 543, 426 S.E.2d 319, 321 (1992) (recognizing that where an agency is charged with the execution of a statute, the agency's interpretation should not be overruled without cogent reason).

I. THE ADMINISTRATIVE LAW COURT ERRED IN ITS APPLICATION OF THE FIRST PRONG OF THE TEST PROMULGATED IN HOME MEDICAL SYSTEMS, INC. V. SOUTH CAROLINA DEPARTMENT OF REVENUE, 382 S.C. 556, 677 S.E.2d 582 (2009), BY FINDING THAT THE SALES TRANSACTION BETWEEN A MANUFACTURER AND A HOSPITAL FOR A PROSTHETIC DEVICE REQUIRED A PRESCRIPTION.

The issues in this case all relate to whether the hospital's purchases of prosthetic devices from various device manufacturers/vendors are exempt from sales tax pursuant to Section 12-36-2120(28)(a).[6] In pertinent part, this statute provides:

> Exempted from the taxes imposed by this chapter are the gross proceeds of sales, or sales price of:
>
> * * *
>
> 28)(a) **medicine and prosthetic devices sold by prescription**, prescription medicines used to prevent

[6]It is important to note at the outset that the transactions examined in this case are the sales transactions between the hospital and the device manufacturers/vendors. The hospital is the purchaser of the tangible personal property for use in the delivery of its medical services. The patient in whom the device will eventually be implanted is not a party to the sales transaction between the hospital and manufacturer. The hospital does not make any retail sales of these devices to the patient.

> respiratory syncytial virus, prescription medicines and therapeutic radiopharmaceuticals used in the treatment of rheumatoid arthritis, cancer, lymphoma, leukemia, or related diseases, including prescription medicines used to relieve the effects of any such treatment, free samples of prescription medicine distributed by its manufacturer and any use of these free samples[.]

(emphasis added).

S.C. Code Ann. § 12-36-910 (2014) imposes sales tax upon the retail sale of tangible personal property in this State.[7] Prosthetic devices (and blood derivatives) constitute "tangible personal property."[8] Therefore, if the hospital's purchases of prosthetic devices are retail sales, such are subject to tax unless specifically exempted. S.C. Code Ann. § 12-36-110 (2014) clearly defines the terms "sale at retail" and "retail sale" to include:

> (i) sales of drugs, prosthetic devices, and other supplies to hospitals, infirmaries, sanitariums, nursing homes, and similar institutions, medical doctors, dentists, optometrists, and veterinarians, if furnished to their patients as a part of the service rendered. These institutions, companies, and professionals are deemed to be the users or consumers of the property[.]

Additionally, 10 S.C. Code Ann. Regs. 117-308.8 (2012) states:

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[7]In South Carolina, the seller/vendor making the sale of tangible personal property is liable for the sales tax, but the tax may be passed on to the purchaser. Normally, only the person liable for the tax may make a claim for, and receive, a refund, except that in the case of a purchaser who has paid the sales tax, the seller may assign any right to a refund to a purchaser who has paid the tax. See S.C. Code Ann. § 12-60-470(C)(1)(b) (2014). Here, to the extent the hospital has paid sales taxes to the device manufacturers on its purchases of these items, the hospital has obtained assignments from the manufacturers (the entity liable for the tax) in order to pursue sales tax refunds.

[8]"'Tangible personal property' means personal property which may be seen, weighed, measured, felt, touched, or which is in any other manner perceptible to the senses." S.C. Code Ann. § 12-36-60 (2014).

> Hospitals, infirmaries, sanitariums, nursing homes and like institutions are engaged primarily in the business of rendering services. They are not liable for the sales tax with respect to their gross proceeds or receipts from meals, bandages, dressings, drugs, x-ray photographs and other tangible personal property where such property is used in the rendering of the primary medical service to patients. This is true irrespective of whether or not such tangible items are billed separately to their patients. Hospitals, infirmaries, sanitariums, nursing homes and like institutions are deemed to be the users or consumers of such tangible personal property and the instate [sic] sellers of these items are required to report and remit the tax due on the sale of such property to the hospitals, infirmaries, sanitariums, nursing homes, and like institutions . . . .

Furthermore, 10 S.C. Code Ann. Regs. 117-308.3 (2012) adds: "Doctors 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." When purchasing items such as the prosthetic devices at issue here, which will be used in rendering medical services to patients, the hospital is the end user or consumer of these items. Thus, the hospital's purchases of prosthetic devices are clearly retail sales.

Since sales of prosthetic devices to medical institutions are considered retail sales when the devices are furnished as part of the medical services rendered to patients, those sales are subject to sales tax unless the sale is specifically exempt. Section 12-36-2120(28)(a) provides an exemption from sales and use tax for medical devices, but that exemption only applies to "prosthetic devices sold by prescription." The hospital's sales transactions involving the items at issue do not fall within section 12-36-2120(28)(a) and thus, are subject to sales tax.

Our Supreme Court addressed the exemption found in section 12-36-2120(28)(a) and articulated standards for its proper application. In Home Medical, the Court stated that "[i]n order for this exemption [prosthetic devices sold by prescription] to be applicable . . . the sale must require a prescription and the device must actually be sold by prescription and the device must replace a missing part of the body." 382 S.C. at 564, 677 S.E.2d at 587 (citing S.C. Rev. Rul. #03-02 (2003)). The Court sanctioned the use of the following three pronged test to determine when the prosthetic device exemption applies: 1) the sale must require a prescription, 2) the device must actually be sold pursuant to a prescription, and 3) the device must replace a missing part of the body. At issue in the present matter are prongs one and two of the Home Medical test – whether the sale of prosthetic devices to a hospital requires a prescription, and whether the devices were actually sold to the hospital by prescription. Although the ALC recognized these two prongs of the Home Medical test in its orders, (see R. pp. 10, 24; Order 5; Order Granting In Part And Denying In Part Mots. For Recons. 2), the ALC failed to properly apply those prongs to the transactions at issue here.

A. The Sale Of A Prosthetic Device From A Manufacturer To A Hospital Does Not Require A Prescription.

The transactions at issue in this matter involve the sale of a prosthetic device by a manufacturer to a hospital. In order to qualify for the exemption set forth in section 12-36-2120(28)(a), the hospital must first establish that the sales transaction *requires* a prescription. The record is replete with evidence that for sales of the prosthetic devices from the manufacturer/vendor to the hospital, no prescriptions are required. The hospital's claimed refund must therefore be denied.

The question here is not whether the prosthetic device is a regulated item of the type that requires a prescription in order to possess,[9] but whether the particular sales transaction between the manufacturer and hospital requires a prescription in order to complete the sale.[10] The Court in Home Medical addressed this same language – "the sale must require a prescription – in the context of section 12-36-2120(28)(a)'s companion exemption for "medicines sold by prescription." The Court held that "[i]n order for this exemption to be applicable, the medicine must be of a type that requires a prescription, the sale must require a prescription, and must actually be sold by prescription." 382 S.C. at 564, 677 S.E.2d at 587. The issue in Home Medical was whether or not the sale of over-the-counter medicines could ever qualify for the exemption such that the Court focused on the prong "the medicine must be of a type that requires a prescription." Significantly, this means that the second prong "the sale must require a prescription" focuses not on the type of item purchased but instead on whether a prescription must be produced in order to effectuate the sale of the item between the seller and purchaser. Given Home Medical, it is reasonable that this same language – the sale must require a prescription – should be given the same meaning when interpreting two contextually identical clauses of the same statute. There are no "over-the-counter" surgically implantable prosthetic devices such that all of the prosthetics here are

[9]The parties stipulated that the prosthetic devices at issue are FDA regulated Type II and Type III prescription prosthetic devices. (R. p. 779; Joint Stipulations of Fact ¶ 6.) This stipulation that these devices are of the type which require a prescription does not then obviate the Home Medical prong that the "sale must require a prescription."

[10]To phrase this question in another way – does the hospital need to produce a prescription in order to purchase the prosthetic devices? The answer to this question is no.

"prescription" prosthetic devices. Thus, this case should turn on whether or not a *hospital* must produce a prescription before making the purchases at issue here. Because a hospital is not required to produce a prescription to purchase a prescription prosthetic device, the claimed exemptions under section 12-36-2120(28)(a) should be denied.

The Court of Appeals actually examined the "sale requires a prescription" element of the exemption statute in the context of "medicines sold by prescription" in Associated Medical v. South Carolina Tax Commission, Unpub. Op. No. 97-UP-447 (Aug. 26, 1997). While this decision is unpublished and therefore lacks formal precedential value, the Department incorporated the rationale of Associated Medical in its policy document, S.C. Rev. Rul. #03-02 (2003).[11] This same rationale was subsequently sanctioned in Home Medical when the Supreme Court adopted the respective tests for "medicines and prosthetic devices sold by prescription" laid out in S.C. Rev. Rul. #03-02.

In Associated Medical, this Court decided that a professional medical association (an institution similar to the Respondent) was the user and consumer of the drugs it administered to patients as part of its professional services. This Court recognized that the exemption "does not exempt 'prescription medicine' but instead exempts 'medicine . . . sold by prescription.' Therefore, we believe the plain, ordinary meaning of this exemption supports Department's argument and requires a transaction in which a prescription is used to purchase the medicine." Assoc. Med., Op. No. 97-UP-447

[11]S.C. Revenue Ruling #03-02 has been superseded by S.C. Revenue Ruling #10-02 (2010) and then S.C. Revenue Ruling #11-03 (2011). Except for the references to the Home Medical decision supporting the Department's longstanding position regarding the proper application of section 12-36-2120(28)(a), no significant changes have been made to the relevant portions of these revenue rulings.

(emphasis in original). This Court further determined that the sale of such drugs to the doctors did not qualify for the exemption for "medicine . . . sold by prescription" because the purchases by the doctors did not actually require a prescription. Rather, this Court recognized that doctors have the ability to purchase medicines without a prescription, regardless of whether one is written. In doing so, this Court stated:

> While it may appear curious that the exemption does not apply to Appellant in this case but would apply if Appellant's patients simply took a prescription to a pharmacist, purchased the . . . medicine, and returned to Appellant for administering of the drug, we believe the exemption's plain language, its legislative history, and Department's interpretation of the exemption clearly demonstrate the legislature's intent that the **transaction** be the focus of the tax.

Assoc. Med., Op. No. 97-UP-447 (emphasis added). In the present matter the transaction at issue is the sale between the manufacturer/vendor and the hospital. Therefore, when deciding whether the sale of a prosthetic device *requires* a prescription, the ALC should have looked solely at this sales transaction, and not the transaction, or any parts thereof, between the hospital and the patient or the doctor and the patient.[12]

It is statutorily established that the sales transaction between the hospital and the device manufacturers does not require a prescription. Pursuant to S.C. Code Ann. section 40-43-60(H) (2011) – part of the South Carolina Pharmacy Practice Act (Pharmacy Act)

[12]It should be reiterated that the transaction between the hospital and its patient is not a sales transaction involving the retail sale of tangible personal property. Instead, the hospital provides medical services to its patients. The retail sale occurs between the hospital and the device manufacturers. See Regulation 117-308.8. While the Department disputes that prescriptions were written for any of these items, even if it is determined that there were valid prescriptions, a physician cannot write a prescription for a patient that would exempt the sale between the hospital and the manufacturer/vendor.

– a licensed practitioner does not need a prescription in order to possess or administer drugs or devices.[13] Specifically, section 40-43-60(H) provides:

> Nothing in this chapter shall be construed to require a permit of or to prevent a licensed practitioner as defined under Section 40-43-30(45) from possessing or administering drugs or devices, or compounding drugs used for administration in the regular course of professional practice.

By virtue of the medical license to practice, doctors, medical professionals, and hospitals (which carry a facility license, see S.C. Code Ann. § 44-7-260 (Supp. 2013)), all have the legal authority to purchase regulated devices that are necessary to practice medicine without prescriptions. As a result it is clear that a prescription is not required for a physician or hospital to purchase prosthetic devices.

The fact that a hospital does not need a prescription to purchase a regulated device is further evinced by the deposition testimony of two of the hospital's physician witnesses – Dr. Daud Nawabi, an oncologist and hematologist, (R. p. 269, lines 4 – 5; Nawabi Dep. 5:4 – 5) and Dr. John McCrosson, an orthopedic surgeon (R. p. 221, lines 23 – 25; McCrosson Dep. 5:23 – 25). Dr. Nawabi testified how medical supplies, including regulated items such as prescription-type drugs, are purchased in his practice. His testimony clearly indicates that a prescription is not required for his office to purchase regulated items. Specifically, Dr. Nawabi stated that some regulated items are kept in inventory, prior to any patients' needs being involved. (See R. p. 270 line 19 – p. 271, line 23; Nawabi Dep. 7:19 – 8:23.) He also stated that no patient-specific

[13] "Practitioner" means a physician, dentist, optometrist, podiatrist, veterinarian, or other health care provider authorized by law to diagnose and prescribe drugs and devices. S.C. Code Ann. § 40-43-30(45) (2011).

information is provided to the vendor prior to ordering the regulated items that are kept in inventory. (See R. p. 272, line 13 – p. 273, line 19; Nawabi Dep. 11:13 – 12:19.) Since a prescription requires patient specific information,[14] a prescription could not have been required in order for Dr. Nawabi's office to purchase the regulated items kept in inventory because at the time of purchase those items were not being purchased for a specific patient. Therefore, the clear testimony of the hospital's own witness evidences that regulated, prescription-type items can be purchased by licensed physicians and by extension, licensed hospitals, at will, without prescriptions.

Similarly, Dr. McCrosson discussed regulated items that are kept in his office. Specifically, he testified that cortisone and local anesthetic are kept in inventory, but that the artificial joint fluid is not. (R. p. 225, line 18 – p. 226, line 4; McCrosson Dep. 61:18 – 62:4.) Regarding the artificial joint fluid, Dr. McCrosson explained that he "wrote a prescription and the patient would go get it filled and bring it back, because we lost money if we kept it in inventory." (R. p. 225, lines 4 – 7; Id. at 62:4 – 7.) When asked about purchasing cortisone, a regulated item that was kept in inventory, Dr. McCrosson said the following: "All I know is the medical assistants just took inventory and did monthly orders or something like that. But I don't know what was involved with doing that. I don't remember ever signing anything as part of that." (R. p. 225, lines 7 – 23; Id. at 62:7 – 23.) Dr. McCrosson did not indicate that any patient specific information was

[14]Section 40-43-30(47) defines "prescription drug order" as "a lawful order from a practitioner for a drug or device for a **specific patient** . . . ." (emphasis added); S.C. Code Ann. section 44-117-310(7) (Supp. 2013) of the Prescription Information Privacy Act uses similar language when defining "prescription" or "prescription drug order" as it relates to electronic prescription processing.

transmitted prior to the purchasing of the cortisone. Furthermore, no patient specific information would have been available since the cortisone was purchased prior to any specific patient being identified. Clearly, doctors are able to purchase regulated items without a prescription.

The hospital proffered Mary Pendergast, a former official with the United States Food and Drug Administration (FDA), to testify as an expert to support its position. When asked "[i]f selling it to a physician is the same thing as a sale by prescription, why would there be the distinction then in [21 C.F.R. section 801.109(a)(2)][15] for it to be sold only to **or** on the order of," (R. p. 281, lines 11 – 14; Pendergast Dep. 55:11 – 14) (emphasis added), Ms. Pendergrast responded as follows:

> Well, I mean, it's very practical. If you're a -- if you are handing a device to a doctor because the doctor has asked you to sell the doctor the device, that is an implicit -- the sale is an implicit order saying, give me this. And so **you only need a prescription or other order if it *isn't* being sold directly to the doctor** because then you have to memorialize that that's what the doctor is asking for, is prescribing, is wanting.

(R. p. 281, line 15 – p. 282, line 1; Id. at 55:15 – 56:1) (emphasis added). Accordingly, the hospital's own proposed expert witness recognized that a prescription is not required for a doctor or a hospital to purchase regulated items. This testimony further demonstrates that the hospital's purchases of regulated devices from manufacturers do not require a prescription.

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[15]The full text of subsection (a) appears on page 23 of this brief.

Finally, Steven D. Silverman, the current Director of the Office of Compliance, Center for Devices and Radiological Health, United States Food and Drug Administration, submitted an affidavit in which he stated that under 21 C.F.R. section 801.109(a) "properly-licensed healthcare facilities, such as hospitals, may purchase and store prescription devices . . . ." (R. p. 772; Silverman Aff. ¶ 6.) He also stated that there is nothing in the Federal Food, Drug, and Cosmetic Act or its regulations that prohibits device manufacturers from selling regulated devices to properly-licensed healthcare facilities even though those facilities do not have patient-specific physician orders for such devices at the time of purchase. (R. p. 773; Id. at ¶ 7.) Director Silverman's statements further evidence that the sale of a prosthetic device by the device manufacturers to the hospital – the transaction at issue in this case – does not require a prescription. Therefore, the sale of a prosthetic device from a manufacturer to a hospital does not require a prescription, and the ALC erred in finding that it did.

B. The ALC's Holding That The Sale Of Prosthetic Devices To A Hospital Requires A Prescription Is Contradicted By The ALC's Own Finding That Hospitals Can Purchase These Items In Bulk Without A Prescription.

In its orders, the ALC held that the hospital's purchases of prescription items in bulk were not exempt from sales tax under section 12-36-2120(28)(a) because the items were not purchased with a specific patient in mind. (R. pp. 17, 26; Order 12; Order Granting In Part And Denying In Part Mots. For Recons. 4.) This conclusion explicitly recognizes that prosthetic devices *can* be purchased by the hospital without the need for a prescription. It necessarily follows that the hospital's claimed exemption must be denied as the first prong of Home Medical– the sale must require a prescription – has not been

satisfied. Nevertheless, the ALC then contradicts itself by allowing the exemption in those instances where the purchase was made with a specific patient in mind. If a hospital is legally allowed to purchase regulated devices in bulk without prescriptions, it is illogical and inconsistent to conclude that when a specific patient is in mind the *hospital* is *required* to have a prescription. The ALC's orders fail to explain how the bulk purchases did not require a prescription but the patient-specific purchases did. To the contrary, the ALC clearly misapplied the "sale must require a prescription" analysis and instead appears to have applied a "prescription could be possible" analysis. Such misapplication of the holding in Home Medical is an error of law that must be overturned.

Regarding the bulk purchases, Mr. Scott Ferguson, the hospital procurement director for medical and surgical supplies, stated that the hospital does keep an inventory of certain "prescription only" items. Specifically, he stated that the hospital has "some inventories of plates and screws," (R. p. 171, lines 4 – 11; Ferguson Dep. 21:4 – 11), and "a few heart valves in inventory," (R. p. 187, lines 9 – 21; Id. at 37:9 – 21). Heart valves are regulated under the exact same laws as joint replacements, yet the hospital purchases heart valves in bulk without prescriptions for trauma inventory. Further, when asked what documentation the hospital sends to the device manufacturers when purchasing a prosthetic device, Mr. Ferguson said that the hospital only sends a purchase order, (see R. p. 163, line 13 – p. 164, line 10; Id. at 13:13 – 14:10), which does not contain any patient-specific information. The hospital's business decision to purchase some items in bulk to keep in inventory and some on a patient-by-patient basis is ostensibly for economic reasons. (See R. p. 160, line 14 – p. 161, line 7; Id. at 10:14 – 11:7.) The exemption for

the sale of prosthetic devices by prescription is not dependent upon the hospital's business decision, but rather whether sales of the devices to the hospital require a prescription. The hospital's choice to purchase some items as they are needed for a patient does not create a sales transaction that *requires* a prescription. Because a prescription is not required for the sales transactions at issue, these purchases by the hospital are not exempt from sales tax under section 12-36-2120(28)(a).

The fact that the hospital purchased some of the prosthetic devices at issue in bulk without a specific patient in mind further establishes that a hospital is not required to have a prescription in order to purchase regulated items. The ALC recognized that the hospital purchased some of the prosthetic devices in bulk, and correctly held that the purchases of those devices were not exempt from sales and use tax. (R. p. 17, Order 12.) The ability of the hospital to purchase regulated devices in bulk demonstrates that the hospital is not required to have a prescription before it purchases prosthetic devices. Clearly, a hospital can purchase any regulated device it needs, whether for a specific patient or not, without a prescription. Since the prosthetic devices can be purchased without a prescription, such sales are not exempt from sales and use tax. Here again, the ALC misinterpreted the exemption and the holding in Home Medical. The ALC's application of a "prescription could be possible" analysis is incorrect. The analysis must be whether a prescription is required, not simply possible. The admitted bulk sales without a prescription demonstrate that a prescription is not required; therefore the ALC's conclusion is an error of law.

The choice the hospital made in buying some prosthetic devices in bulk and some on a patient-by-patient basis does not alter its legal ability to buy any prosthetic device it

needs in bulk and without patient-specific prescriptions. This point was validated by Ms. Melanie Hutcherson, a national sales manager for Zimmer, Inc. (one of the manufacturers often used by the hospital), who explained that hospitals could keep an inventory of the reconstructive prosthetic devices if they so choose, but because the sales representatives are so accommodating many hospitals do not. (R. p. 201, line 18 – p. 203, line 15; Hutcherson Dep. 15:18 – 17:15.) The distinction made by the ALC between "a sale related to a particular individual and a bulk sale to a medical provider" is without substance for purposes of the Home Medical sales tax exemption analysis and inherently confirms the Department's position that the sale of a regulated device to a hospital does not require a prescription. (R. p. 17; Order 12.) The trauma devices purchased in bulk for trauma patients are governed by the exact same laws as the reconstructive devices purchased with specific patient information. Nothing under those laws requires the hospital to purchase reconstructive devices with prescriptions while lifting that requirement for trauma devices. There is absolutely no appreciable legal difference between a knee replacement and a heart valve as it relates to the ability of a hospital to purchase these items, and the hospital failed to provide one statute, regulation, or case that would suggest otherwise. Thus, the ALC's error in finding that a sale of a prosthetic device with a specific patient in mind requires a prescription and is therefore exempt under section 12-36-2120(28)(a), but a bulk sale of prosthetic devices does not require a prescription and is therefore subject to tax dictates that this Court reverse the ALC's ruling on this issue.[16]

[16]The inconsistency in the ALC's ruling between its treatment of the hospital's

C. A Doctor Cannot Write A Prescription For A Corporate Entity Operating As A Hospital, Therefore Sales To A Hospital Cannot Require A Prescription.

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bulk sales transactions and "specific patient intended" sales transactions suggests that the ALC was persuaded that where a prescription-like writing such as a chart order or requisition sheet was provided (which the ALC erroneously concluded constituted prescriptions), the prosthetic device was "sold by prescription" within the meaning of section 12-36-2120(28)(a). This is not correct. Even if the writings *do* qualify as prescriptions, a sales transaction which does not *require* a prescription does not transform into one qualifying for the sales tax exemption simply because a prescription is provided. Again, referring to the Home Medical test, even if the second prong – a prescription is used in the transaction – is met, the first prong – the sale must require a prescription – remains an independent element that must be satisfied. In Home Medical, when the Court considered whether over-the counter medicines are exempt if sold by prescription, the Court dismissed a similar argument proffered by the taxpayer:

> As discussed above, the DOR has set forth a definition for "medicine by prescription" – the medicine must be of a type that requires a prescription, the sale must require a prescription, and it must actually be sold by prescription. Taxpayer argues that a prior legislative version (a 1970 reimbursement statute) more explicitly stated the requirement – "medicines required by law to be sold only by prescription" – and therefore, the current language is not **exclusively** for medicines that require a prescription. In our opinion, however, the current statutory language – "medicine ... sold by prescription" – clearly evidences a legislative intent that the exemption be only for those medicines requiring a prescription.

382 S.C. at 566, 677 S.E.2d at 588. (internal citations omitted) (emphasis in original). Although the Court found the Certificate of Medical Necessity used by the taxpayer therein did not qualify as a prescription, the import of the Court's ruling is that even if the taxpayer had written a prescription for over-the counter medicines, that circumstance could not have exempted a transaction the Legislature intended to tax. The same logic applies here inasmuch as even if a prescription is written for the prosthetic devices, this would not thwart the legislature's intent to tax the retail sale between the hospital and the device manufacturer/vendor because the sales transaction between these parties does not require a prescription. Further, the opposite result would lead to the potential for widespread manipulation of the tax base at the discretion of the hospital/purchaser.

In order to uphold the ALC's decision, this Court would have to find that licensed medical practitioners, the only people licensed to prescribe medicine or devices, can write a prescription for a hospital, which is a corporate entity, so that the hospital may purchase the devices 'by prescription."[17] However, as will be explained, such a conclusion would violate South Carolina law, and our Supreme Court has stated that it "will reject an interpretation when such an interpretation leads to an absurd result that could not have been intended by the legislature." Lancaster Cnty. Bar Ass'n v. S.C. Comm'n on Indigent Def., 380 S.C. 219, 222, 670 S.E.2d 371, 373 (2008). Since interpreting a statute in a way that would violate South Carolina law is clearly absurd, this Court must reject such an interpretation.

Pursuant to South Carolina law, a licensed medical practitioner cannot write a prescription for a hospital. Specifically, S.C. Code Ann. section 40-47-113(A) (2011)[18] states that "[i]t is unprofessional conduct for a licensee initially to prescribe drugs to an individual without first establishing a proper physician-patient relationship." A doctor simply cannot create a doctor-patient relationship with a corporate entity; thus, it naturally follows that a doctor could never write a prescription for a hospital. To that end, purchases made by a hospital can *never* be transactions that require a prescription.

When questioned regarding for whom he was authorized to prescribe something, Dr. McCrosson stated that "as long as I establish a physician/patient relationship and

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[17]As stated earlier, it is important to note that the transaction at issue is the sale of a prosthetic device between the manufacturer/vendor and the hospital. The transaction between the hospital or doctor and the patient is not relevant for purposes of this analysis.

[18]Chapter 47 of Title 40 is entitled "Physicians and Miscellaneous Health Care Professionals."

document that in a chart, I can prescribe most things to most people, but I cannot prescribe certain controlled substances to family members or inappropriate relationships, where it would be foggy whether I had a proper therapeutic relationship." (R. p. 222, lines 6 – 12; McCrosson Dep. 34:6 – 12.) Moreover, another physician witness for the hospital, Dr. Brett Baker, a licensed cardiologist, stated that a doctor-patient relationship could not be formed with a hospital, nor could he write a prescription to a hospital. (R. p. 133, lines 6 – 15; Baker Dep. 30:6 – 15.) As previously stated, the exemption applies only to sales transactions in which the purchaser is required to use a prescription in order to obtain the device. The hospital is the purchaser in this case, and the hospital can never actually obtain a prescription because a doctor cannot write one for it; consequently, it would be illogical and impossible for a prescription to be required in the sales transaction between the device manufacturer and the hospital.

D. The ALC's Interpretation Of 21 C.F.R. Section 801.109(a)(2) To Mean That Prescription Prosthetic Devices Will Always Require A Prescription To Be Sold Is An Error Of Law.

In the ALC's Initial Order, the ALC properly rejected the hospital's contention that section 801.109(a)(2) somehow restricts all sales of the devices at issue to a transaction requiring a prescription. (R. p. 11; Order 6.) 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.

(emphasis added). Generally, section 801.109 provides that adequate directions for use of a device are not necessary if certain conditions are met. One of those conditions is that the device is in the possession of a practitioner, such as a physician, licensed by law to use or order the use of the device. Another condition is that the device can be sold (1) only to, (2) on the prescription of, or (3) by order of such practitioner for use in the course of his or her professional practice. If section 801.109 required a prescription for all transactions, then the distinction between such devices being "sold only to" or "on the prescription of" would be unnecessary. Thus, this section does not create a legal requirement that doctors, or hospitals, must have a prescription in order to purchase prescription devices. On the contrary, section 801.109 suggests that doctors, just like manufacturers and distributors, can legally possess prescription devices without a prescription, and, in that situation, the FDA labeling and branding requirements for these devices are exempted.

The ALC recognized that section 801.109 only applies to federal labeling requirements and does not mean that a hospital is required to have a prescription in order to purchase prescription devices. (R. p. 11; Order 6.) The ALC further recognized that the purpose of section 801.109 is to protect consumers through the use of labeling requirements that ensure "the devices pass through a physician gatekeeper before reaching the consumer." Id. Specifically, the ALC noted the use of the word "or" in the regulation and stated that the word "or" must have been used for a reason. (R. pp. 11, 24; Order 6; see also Order Granting In Part And Denying In Part Mots. For Recons. 2.) The

use of the word "or" demonstrates that a prescription is not required for the transaction at issue in this case since the device can be sold directly to a physician or directly to a patient after the physician writes the patient a prescription for the device. See 21 C.F.R. § 801.109(a)(2). Based on that, the ALC went on to say that "a sale to a hospital is not *de facto* a 'sale by prescription.'" (R. p. 11; Order 6.)

However, in the ALC's Reconsidered Order, the ALC reversed itself on this issue and instead stated that "parsing out the language [sic] defeats the statute's purpose," and that doing so would mean that a regulated device would never require a prescription to be sold. (R. pp. 24 – 25; Order Granting In Part And Denying In Part Mots. For Recons. 2 – 3.) The ALC then stated that even though the effect of the Reconsidered Order is that the sale of regulated prosthetic devices will always require a prescription, thus always satisfying the first prong of Home Medical, that is a less absurd result than the alternative. (R. p. 25; Id. at 3.) The ALC's misapplication of the exemption statute renders the first prong of the Home Medical test meaningless. If a prong is always satisfied it is not really a prong at all. Such interpretation is clearly incorrect, for our Supreme Court would not have included this prong in its analysis if such prong is always satisfied. Furthermore, the language of the regulation clearly shows the FDA's intent to distinguish between a sale directly to a doctor and a sale to a patient on the order or prescription of a doctor. The ALC's analysis demonstrates that it is confusing the transaction at issue in this case – the retail sale of a prosthetic device to a hospital for use in patient treatment. A close reading of the federal regulation means that *a physician or hospital* will never be required to have a prescription to purchase regulated devices, not that a regulated device will never require a prescription to be sold in other sales

transactions such as when a patient purchases an item from a pharmacy or a brace and boot shop. The ALC failed to focus solely on the sales transaction between the manufacturer and the hospital. While there is a second transaction between the hospital and its patient, that transaction is not a retail sale of any prosthetic devices for sales tax purposes and is not at issue in this matter. When focusing on the retail sales transaction between the hospital and manufacturer/vendor, finding that a hospital will never be required to have a prescription in order to purchase regulated devices is not absurd inasmuch as it is a correct statement of the law that the sale of such a regulated device to a licensed hospital does not require any prescription. Therefore, in the context of this case where the only sales at issue are sales to hospitals, the ALC erred in interpreting section 801.109(a)(2) to mean that prescription prosthetic devices will always require a prescription to be sold.

E. The ALC's Interpretation Of The Exemption Set Forth In Section 12-36-2120(28)(a) Does Not Comport With Legislative Intent.

The ALC's interpretation of section 12-36-2120(28)(a) exempting the prosthetic devices purchased with a specific patient in mind would essentially mean that all prescription-type items purchased by doctors, hospitals or similar institutions for the benefit of a patient would be exempt from sales tax. This result does not comport with legislative intent as expressed in the sales tax exemption statutes themselves. Not only does the ALC's interpretation create an internal inconsistency within 12-36-2120(28)(a) itself, at least two more recent statutes enacted by the Legislature would become superfluous if the ALC's decision is upheld. Such a result would be improper, as our Supreme Court has clearly held, "[a] statute should be so construed that no word, clause,

sentence, provision or part shall be rendered surplusage, or superfluous." In re Decker, 322 S.C. 215, 219, 471 S.E.2d 462, 463 (1995).

First, S.C. Code Ann. section 12-36-2120(80)(a) (2014) would become superfluous if the ALC's interpretation was correct. Subsection (80)(a) exempts "injectable medications and injectable biologics, so long as the medication or biologic is **administered by or pursuant to the supervision of a physician in an office** which is under the supervision of a physician . . . ." (emphasis added). Inasmuch as this subsection allows physicians to purchase these injectables free from sales taxes provided they are to be used under the specified conditions, the exemption statute is an explicit recognition by the Legislature that unless excepted, sales of prescription-type medications to physicians are retail sales subject to sales taxes. The "administered by or pursuant to the supervision of a physician in an office" portion of subsection (80)(a) would be rendered unnecessary and superfluous if all prescription medications purchased by physicians for specific patients were already exempted by subsection (28)(a).

Second, S.C. Code Ann. section 12-36-2120(63) (2014) would also be rendered superfluous if the ALC's interpretation was correct. Subsection (63) exempts "**prescription** and over-the-counter **medicines** and medical supplies, including diabetic supplies, diabetic diagnostic equipment, and diabetic testing equipment, **sold to a health care clinic** that provides medical and dental care without charge to all of its patients" (emphasis added). This statute allows tax exempt sales of prescription-type medicines to health care clinics (which are akin to hospitals) as long as those clinics provide free medical care to all of their patients. Subsection (63) would be unnecessary and superfluous if subsection (28)(a) exempted all prescription medicines purchased by doctors

or hospitals or similar institutions for the benefit of specific patients Enactment of subsection (63) is further evidence that the Legislature cannot have intended to provide the exemption under subsection (28)(a) that the hospital is seeking here. The ALC's interpretation of subsection (28)(a) allowing the exemption does not comport with legislative intent.

Finally and most importantly, the Legislature has amended subsection (28) itself several times over the years and has always retained the "sold by prescription" limitation contained in "medicines and prosthetic devices sold by prescription." In latter portions of subsection (28), the Legislature inserted the language "prescription medicines used to prevent respiratory syncytial virus" and "prescription medicines and therapeutic radiopharmaceuticals used in the treatment of rheumatoid arthritis, cancer, lymphoma, leukemia, or related diseases, including prescription medicines to relieve the effects of any such treatment." This language allows sales of the enumerated categories of prescription-type items to be made to physicians and hospitals free of sales taxes. As with subsections (63) and (80)(a), the more recent exemptions in (28)(a) become unnecessary and superfluous under the ALC's decision. Significantly, the distinction between the phrase "prescription medicines" (an exemption for a type of item) and "medicine and prosthetic devices sold by prescription" (an exemption for a type of transaction) clearly evinces the Legislature's intent to limit the "sold by prescription" part of the exemption to a specific type of *transaction* – a transaction where the sale of an item from its manufacturer/vendor to a purchaser requires a prescription and the item is

actually sold by prescription.[19] If the Legislature wanted to exempt all prescription items, regardless of the circumstances surrounding the sale of the item and the parties to the sales transaction, it could have done so. In fact, the Legislature did just that when it amended subsection (28)(a) and added the two aforementioned exemptions for prescription medicines. If the Legislature intended for the "medicine sold by prescription" language to exempt all prescription medicines regardless of how they are sold, it would not have needed to add the newer language exempting those types of prescription items used under those specific circumstances.

Furthermore, by adopting the taxpayer's arguments, the ALC's decision has broadly expanded the "medicines and prosthetic devices sold by prescription" exemption and its impact. The potential revenue impact alone is staggering. This case involves only a limited number of prescription-type items purchased by *one* hospital during a three year period and results in a refund claim in excess of $3,000,000.00. Under the ALC's application of the exemption statute, the purchase of every prescription item by any physician, physician's office, hospital, health care clinic, or other similar medical institution for the benefit of a patient would be exempt. If the ALC decision is upheld, the number of refund claims on this issue may rise exponentially and the dollars sought on appeal could reach astronomical levels. It is illogical to think that the Legislature intended such a result, especially given the Home Medical decision and the Department's

[19]It necessarily follows that, without more, any sale of an item to a purchaser who does not *need* a prescription in order to purchase the item is not within the intended scope of the sales tax benefit afforded under the exemption.

longstanding policy on the application of the exemption.[20] Nevertheless, the ALC's interpretation of the exemption far exceeds the intent of the Legislature, which specifically limited the exemption to a certain type of transaction.

II. THE ADMINISTRATIVE LAW COURT ERRED IN BROADLY INTERPRETING THE TERM "PRESCRIPTION" AND FINDING THAT A "CHART ORDER" AND A REQUISITION SHEET CAN CONSTITUTE A PRESCRIPTION.

The ALC's interpretation of the definition of "prescription" is inconsistent with the Home Medical decision's limitation of the term. See 382 S.C. at 566, 677 S.E.2d at 588. In Home Medical, our Supreme Court found that a Certificate of Medical Necessity (CMN),[21] a standard form used by Medicaid and Medicare that contains patient specific information was not equivalent to a prescription, despite such a document containing patient specific information and even an order from a doctor for a specific treatment. 382 S.C. at 559, 566, 677 S.E.2d at 584, 588. That holding clearly evinces that not all documents from a physician constitute a prescription.

In determining what a prescription is for purposes of the sales and use tax exemption, the ALC referenced the Pharmacy Act's definition of "prescription drug order," which defines the term as "a lawful order from a practitioner for a drug or device for a specific patient, issued for a legitimate medical purpose within the prescriber's

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[20]Before an exemption is enacted, the Legislature examines its potential financial impact. In doing so for section 12-36-2120(28)(a), the Legislature would only have factored the financial impact of exempting sales of prescription-type items required to be sold by prescription and actually sold by prescription, and not every prescription item purchased by doctors or hospitals or similar institutions for the benefit of a patient.

[21]See R. p. 394; Exhibit A to Department's Mot. For Sum. J.

course of legitimate practice and including orders derived from collaborative pharmacy practice." (R. p. 25; Order Granting In Part And Denying In Part Mots. For Recons. 3.) (citing S.C. Code Ann. § 40-43-30(47)).[22] The ALC then went on to hold that a "chart order" and a requisition sheet can constitute a prescription. The ALC misapplied the definition of prescription drug order when it found that a chart order and a requisition sheet constitute a prescription.

A "chart order" is defined as follows:

> [A] lawful order from a practitioner for a drug or device **for patients of a hospital or extended care facility**, or such an order prepared by another person and signed by a practitioner either immediately or at another time, issued for a legitimate medical purpose within the practitioner's course of legitimate practice and including orders derived on behalf of a practitioner from a practitioner approved drug therapy management.

S.C. Code Ann. § 40-43-30(5) (emphasis added). There is a difference between a "prescription drug order" and a "chart order." If the Legislature intended for a "chart order" to constitute a prescription, it would not have provided a separate definition for the former term. Here again, the ALC's interpretation renders the legislative meaning of "chart order" superfluous as under such interpretation chart order and prescription are the same thing. Additionally, if the definition of prescription is broad enough to include any physician's order – as the ALC suggests it is – the Legislature would not have had to

[22]The wholesale transfer of statutory definitions of terms from other parts of the Code for use in tax exemption statutes is often fraught with the potential for inconsistencies. Nevertheless, for the limited purposes here, the Department submits that given that there is no statutory or regulatory definition of "prescription" for tax purposes, the definitions used in the Pharmacy Act provide the best evidence of the Legislature's intended meaning of the word "prescription."

define "medical order" as "a lawful order of a practitioner which **may or may not include a prescription drug order**." Section 40-43-30(31) (emphasis added). Clearly there is a distinction between medical order and prescription. While a medical order may at times be a prescription, the definition of medical order demonstrates that this is not automatically the case. Because a medical order is not per se a prescription, a chart order, which is a type of medical order, is also not per se a prescription. Finally, after Dr. McCrosson was shown the various definitions in the Pharmacy Practice Act, he admitted that a chart order does not constitute a prescription under South Carolina law. (See R. p. 258, lines 13 – 15; McCrosson Video Dep. 63:13 – 15.) Nevertheless, the ALC erroneously failed to recognize this distinction and instead rendered this distinction superfluous.

Furthermore, the ALC stated the following regarding what constitutes a prescription:

> [A]lthough the sales presented like a chart order because the physician signed off on the requisition sheet, it is important to note that at all times the device was procured for a specific patient. A physician initially contacted the vendor for a specific patient, the physician lawfully ordered the device for the specific patient in the operating room, patient-specific information followed the device on the requisition sheet, and the device was issued for a legitimate medical purpose. This process meets the definition of prescription.

(R. p. 26; Order Granting In Part And Denying In Part Mots. For Recons. 4.)[23] This finding is clearly erroneous in light of the Home Medical decision. As previously stated,

[23]No evidence exists in the record stating that the physician signed the requisition sheet. (R. p. 238, line 11 – p. 249, line 5, p. 250, line 10 – p. 251, line 21, p. 138, line 2 –

the Court in Home Medical found that a CMN did not constitute a prescription. 382 S.C. at 566, 677 S.E.2d at 588. The ALC did not explain in its orders how a requisition sheet could constitute a prescription when a CMN, which contains much more information than a requisition sheet, (see R. p. 394; Exhibit A to Department's Mot. For Sum. J.), does not constitute a prescription. To that end, the ALC's interpretation of the term "prescription" to include a "chart order" and a requisition sheet is clearly erroneous and an error of law.[24]

III. THE ADMINISTRATIVE LAW COURT ERRED IN ITS APPLICATION OF THE SECOND PRONG OF THE HOME MEDICAL TEST BY FINDING THAT A PRESCRIPTION WAS ACTUALLY USED BY THE HOSPITAL TO PURCHASE THE PROSTHETIC DEVICES AT ISSUE FROM A MANUFACTURER/VENDOR.

In order to satisfy the second prong of the Home Medical test, the hospital had to prove that it actually used a prescription to purchase the devices at issue, meaning the hospital must actually submit a prescription to the manufacturer. The hospital cannot satisfy this requirement because a doctor cannot write a prescription for a hospital. The ALC erroneously found that the doctor asking for a device while in the operating room

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p. 143, line 7, p. 144, line 24 – p. 148, line 1; McCrosson Video Deposition 16:11 – 27:5; 34:10 – 35:21; Baker Video Deposition 13:2 – 18:7; 40:24 – 44:1.) Ms. Hutcherson testified only that the operating room nurse *reviews* the requisition sheet. (R. p. 196; Hutcherson Dep. 10:1 – 25.)

[24]Moreover, this excerpt from the ALC order highlights its improper focus on the transaction between the hospital/doctor and the patient. That transaction is not a retail sales transaction for the purchase of tangible personal property. Whatever the hospital's method of communicating the need for the prosthetic device – whether chart order, requisition sheet or even prescription – the only retail sales transaction at issue is the sale between the manufacturer/vendor and the hospital. The physician cannot write any order for a patient for a prosthetic device that may be used to exempt the retail sales transaction between the manufacturer/vendor and the hospital for the purchase of that device from sales taxes.

with a specific patient constituted a prescription and the fact that a requisition sheet is submitted to the device manufacturer meant that the hospital purchased the prosthetic devices by prescription. (R. p. 26; Order Granting In Part And Denying In Part Mots. For Recons. 4.) However, the transaction at issue in this case is the transaction between the hospital and the manufacturer, not the doctor and the patient. If a prescription was in fact used in the abovementioned scenario, which the Department maintains one was not, the prescription was for the patient, not the hospital.

The fact that the hospital did not use prescriptions to purchase the devices from the manufacturers is evidenced by the deposition of Mr. Ferguson, the actual hospital employee who completes the purchase of these devices, and Ms. Hutcherson, a national sales manager for a device manufacturer. Mr. Ferguson stated that with regard to the purchase of joint replacements he has "not seen a written prescription." (R. p. 167, lines 5 – 9; Ferguson Dep. 17:5 – 9.) Additionally, when asked if any of the information that is statutorily required to be on a prescription drug order[25] is incorporated into any of the

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[25]A prescription drug order shall contain at a minimum, the:

> (1) full name and address of the patient;
> (2) name, address, telephone number, and degree classification of the prescriber; license number, and Drug Enforcement Agency registration number of the prescribing practitioner where required by law;
> (3) date of issuance;
> (4) name, strength, dosage form, and quantity of drug prescribed;
> (5) directions for use;
> (6) number of refills authorized. No prescription marked "PRN" or any other nonspecified number of refills may be refilled more than two years beyond the date it was originally written. Nothing in this subsection abridges the

documentation that the hospital sends to the manufacturer, Mr. Ferguson said that it is not. (See R. p. 185, lines 4 – 15; Ferguson Dep. 35:4 – 15.) The only documentation Mr. Ferguson sends to the manufacturer is a purchase order. (R. p. 163, line 13 – p. 164, line 10; Id. at 13:13 – 14:10). Furthermore, Ms. Hutcherson testified about the procedure that is generally followed when a hospital purchases a device from Zimmer, Inc.:

> **Once the case has been completed**, so the implant has been implanted into the patient, there is a requisition sheet that has the patient sticker put on it, identifies information about the patient, produced by the hospital, put on the requisition sheet, and then the rep will take the bar code stickers from each of the products that were consumed and put that on the sticker sheet, along with the pricing.
>
> At that point in time they'll review that document with the OR nurse or the circulating nurse **to make sure that both parties are in agreement to the product that was implanted into the patient**, and then that requisition sheet then typically goes to a buyer to input the requisition into the system to create the purchase order.
>
> At the same time our rep will scan . . . the stickers on the sticker sheet, and that will go into our system, so we

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> right of a pharmacist to refuse to fill or refill a prescription; and
> (7) a written order signed by the prescriber, which shall bear the name of the patient; name, strength, and quantity of the drug or device prescribed; directions for use; date of issue; and, either rubber stamped, typed, printed by hand, or typeset, the name, address, telephone number, and degree classification of the prescriber; and, if a controlled substance is prescribed, the prescriber's federal registration number;
> (8) only one drug and set of instructions for each blank, if preprinted;
> (9) a chart order is exempt from the requirements of this subsection.

S.C. Code Ann. § 40-43-86(E) (2011).

> recognize what products have been consumed or used in the patient.
>
> And at that point in time **we'll wait for the purchase order to reconcile between what the rep sent in and what the purchase order presented to make sure that both are intact**. And then we will go ahead and add the purchase order so that we can generate the invoice.

(R. p. 196; Hutcherson Dep. 10:1 – 25.) (emphasis added). The manufacturers do not ask for a prescription prior to selling the prosthetic devices to the hospital. (R. p. 195, line 8 – p. 206, line 24; Id. at 9:8 – 20:24). Furthermore, Ms. Hutcherson testified that the only two documents Zimmer, Inc. receives from hospitals like the Respondent are a requisition sheet and a purchase order. (R. p. 196, p. 200, line 9 – p. 201, line 2; Id. at 10:1 – 25, 14:9 – 15:2.) In situations where a hospital purchases numerous devices to be kept in inventory, the only document the manufacturer receives is a purchase order. (R. p. 203, lines 10 – 13, p. 206, lines 9 – 24; Id. at 17:10 – 13, 20:9 – 24.) In addition, Mr. Ferguson never mentioned that the manufacturers ask the hospital for a prescription prior to selling the prosthetic devices to the hospital. (See R. pp. 154 – 190; Ferguson Dep., specifically 13:13 – 14:10.)

If a prescription is used in the transaction between the hospital and the manufacturer as the Respondent maintains, the hospital would have to send a prescription to the manufacturer *prior* to the transaction occurring. Here, the hospital never sent anything remotely resembling a prescription to the manufacturer, and the manufacturer does not receive any documentation from the hospital until after "the case has been completed." (R. p. 196; Hutcherson Dep. 10:1 – 25.) Additionally, the documentation that the manufacturer does receive is clearly for billing purposes, as evidenced by Ms.

Hutcherson's testimony. (R. p. 196; Id.) Thus, based on the testimony of Ms. Hutcherson and Mr. Ferguson, the prosthetic devices are not actually sold to the hospital by prescription. Therefore, the ALC's finding that a prescription was actually used is clearly erroneous in view of the evidence.

IV. THE ADMINISTRATIVE LAW COURT ERRED IN FINDING THAT THE HOSPITAL'S "OTHER BONE, MUSCLE, AND TISSUE IMPLANTS" WERE PROSTHETIC DEVICES WHEN THE HOSPITAL FAILED TO PRODUCE ANY EVIDENCE THAT THESE ITEMS REPLACED MISSING PARTS OF THE BODY.

It is well settled law that a tax exemption "must be strictly construed against the claimed exemption." Home Med., 382 S.C. at 564, 677 S.E.2d at 587; see also Southeastern-Kusan, 276 S.C. at 489, 280 S.E.2d at 58 ("As a general rule, tax exemption statutes are strictly construed against the taxpayer."). More importantly, our case law dictates that the burden is on claimants to prove their rights to an exemption by bringing themselves clearly within the conditions imposed by the statute. TNS Mills, 331 S.C. at 618, 503 S.E.2d at 475 (citing York County Fair Assoc. v. S.C. Tax Comm'n, 249 S.C. 337, 341, 154 S.E.2d 361, 363 (1967)); see also Asmer v. Livingston, 225 S.C. 341, 82 S.E.2d 465, 466 (1954) (a refund of taxes is solely a matter of governmental grace, and taxpayers seeking such relief must bring themselves clearly within the terms of the statute authorizing a refund). Due to the lack of evidence presented by the hospital, the hospital did not bring itself squarely within the conditions imposed by the statute, and thus failed to meet its burden of proof. Because the hospital did not meet its burden, the ALC's finding that the "other bone, muscle, and tissue implants" replace a missing part of the body is clearly erroneous.

The hospital presented no evidence to establish that the "other bone, muscle, and

tissue implants" fell within the definitional parameters of the sales tax exemption. In fact, even now, the Department is without sufficient facts to articulate what these broad "catch all" categories of devices would include. The ALC recognized that the Department took issue with these "other" devices in its Conclusions of Fact, but took no notice of the complete absence of evidence presented to describe them. (R. p. 7; Order 2.) It is unclear whether these devices replace a part of the body or simply aid failing body functions, and, therefore, such devices cannot be said to fit squarely into the exemption at issue. In a *sua sponte* conclusory sentence, the ALC held that the "other bone, muscle, and tissue implants replace missing parts of the body." (R. p. 18; Order 13.) This conclusion is erroneous as not one fact was presented by the hospital to support it. Then, in its Reconsidered Order, the ALC denied the Department's motion concerning the "other bone, muscle, and tissue implants" because it "was presented to the Court as a 'catch-all' category of devices, and the Court declines to now address the items individually." (R. p. 26; Order Granting In Part And Denying In Part Mots. To Recons. 4.) However, the ALC did not need to address the items individually because no evidence was presented that would demonstrate any of those devices replace a missing part of the body. The ALC decided on its own volition that these other items "replace missing parts of the body just like a man-made hip replacement replaces a human hip that is removed from a patient." (R. p. 18; Order 13.) No evidence exists in the record to support the ALC's conclusion. Therefore, the hospital failed to meet its burden as to these "catch all" categories of devices, and, as such, the ALC's finding that these other devices are exempt from sales tax is clearly erroneous.

CONCLUSION

The Administrative Law Court erred in determining that the hospital's purchases of prescription prosthetic devices are exempt from sales tax pursuant to section 12-36-2120(28)(a) and improperly applied our Supreme Court's holding in Home Medical.

Respectfully Submitted,

Lauren Acquaviva (Bar No.100528)
Counsel for Litigation
Milton G. Kimpson (Bar No. 7917)
General Counsel for Litigation
PO Box 12265
Columbia, SC 29211
Attorneys for Appellant
South Carolina Department of Revenue
AcquavL@sctax.org
CourtOrders@sctax.org

March 16, 2015

STATE OF SOUTH CAROLINA
In the Court of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

HONORABLE SHIRLEY C. ROBINSON, ADMINISTRATIVE LAW JUDGE

Case No. 12-ALJ-17-0405-CC
Appellate Case No. 2014-001457

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

v.

South Carolina Department of Revenue,.....Appellant.

CERTIFICATE OF COUNSEL

The undersigned certifies that this Final Brief complies with Rule 211(b), SCACR.

Lauren Acquaviva (Bar No. 100528)
Counsel for Litigation
Milton G. Kimpson (Bar No. 7917)
General Counsel for Litigation
P.O. Box 12265
Columbia, SC 29211
(803) 898-5110
Attorneys for Appellant

March 16, 2015