THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

Shirley C. Robinson, Administrative Law Judge

Case No. 12-ALJ-17-0405-AP

Appellate Case No. 2014-001457

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

v.

South Carolina Department of Revenue, ... Appellant.

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TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

STATEMENT OF ISSUES ON APPEAL 6

STATEMENT OF THE CASE 7

STATEMENT OF FACTS 8

STANDARD OF REVIEW 14

RULES OF STATUTORY CONSTRUCTION 15

ARGUMENTS 16

I. THE ALC PROPERLY FOUND THAT FEDERAL REGULATIONS MANDATE THAT SALES TRANSACTIONS BETWEEN A MANUFACTURER AND A HOSPITAL OF FDA REGULATED CLASS II AND CLASS III PRESCRIPTION PROSTHETIC DEVICES REQUIRE LAWFUL PRESCRIPTIONS OR ORDERS. 18

A. Federal Law Requires a Prescription. 18

B. The Factual Conclusions Drawn in Home Medical are Not Applicable Here. 23

C. Roper Agrees that the Transaction at Issue is the Sale between the Manufacturer and the Hospital and that Roper Must Show that a Prescription is Required for that Sale. 24

D. Associated Medical Is Not Relevant to this Matter. 24

E. The SC Pharmacy Act Does Not Alter the FDA Regulations. 26

F. Testimony from Roper Physicians regarding Purchases of Certain Items Does Not Show that the Hospital Can Purchase Prescription Prosthetic Devices Without a Prescription. 27

G. Federal Regulations Require a Prescription for the Sale of Bulk Purchases of Trauma Devices, but Patient Specific Information was Not Available at the Time of Sale. 28

H. Doctors Need Not Write Prescriptions for a Hospital in Order for the Sales Tax Exemption to Apply. 30

I. The ALC's Interpretation of the Exemption in S.C. Code Ann. §12-36-2120(28)(a) Comports with Legislative Intent. 30

II. THE ALC COURT PROPERLY FOUND THAT PHYSICIANS' ORAL ORDERS FOR SPECIFIC PATIENTS, WHICH ARE LATER MEMORIALIZED IN WRITING, CONSTITUTED PRESCRIPTIONS..... 32

III. THE ALC PROPERLY FOUND THAT THE HOSPITAL PURCHASED PATIENT SPECIFIC PROSTHETIC DEVICES BY PRESCRIPTION AS THAT TERM IS USED IN THE SOUTH CAROLINA SALES TAX STATUTE. 37

IV. THE ALC PROPERLY FOUND THAT THE "OTHER BONE, TISSUE AND MUSCLE IMPLANTS" REPLACED MISSING PARTS OF THE BODY 38

CONCLUSION 39

TABLE OF AUTHORITIES

Page(s)

Cases

Associated Medical v. South Carolina Tax Comm'n,
Unpub. Op. No. 97-UP-447 (Aug. 26, 1997) 24, 25, 26

Bovain v. Canal Ins.,
383 S.C. 100, 678 S.E.2d 422 (2009) 15

Boykin v. S.C. Tax Comm'n,
Civil Action No. 89-CP-02-590 ..... 31, 34

Bravis v. Dunbar,
316 S.C. 263, 449 S.E.2d 495 (Ct. App. 1994)..... 15

Hodges v. Rainey,
341 S.C 79, 533 S.E.2d 578 (2000) 15

Home Medical Systems, Inc, v. South Carolina Department of Revenue,
382 S.C. 556, 677 S.E.2d 582 (2009)
..... 16, 17, 18, 21, 22, 23, 24, 25, 28, 31, 33, 34

Madison v. American Home Products,
358 S.C. 449, 595 S.E.2d 493 (1995) 19

McCullouch v. Maryland,
17 U.S. 316 (1819) 26

The Original Blue Ribbon Taxi Corporation v. SCDMV,
380 S.C. 600, 670 S.E.2d 674 (2008) 14, 32

Rosmer v. Pfizer,
263 F.3d 263 (4th Cir. 2001) 30

State v. Leopard,
349 S.C. 467, 563 S.E.2d 342 (Ct. App. 2002)..... 15, 30

Talley v. Danek Med., Inc.,
179 F.3d 154 (4th Cir. 1999) 20

Wigfall v. Tideland Utilities, Inc.,
354 S.C. 100, 580 S.E.2d 100 (2003) 15

Rules

South Carolina Rules of Civil Procedure 29(D) 8

South Carolina Rules of Civil Procedure 56 15

South Carolina Rules of Civil Procedure 59(E) 8

South Carolina Rules of Civil Procedure 68 8

Statutes

21 U.S.C. § 352 19

21 U.S.C. § 360j (e)(1) 18, 32, 35

South Carolina Code Ann. § 1-23-610 (Supp. 2009) 14, 17

South Carolina Code Ann. § 1-23-610(B) 14

South Carolina Code Ann. § 12-6-2320(28) 31

South Carolina Code Ann. § 12-36-110 16

South Carolina Code Ann. § 12-36-2120(28) 16, 22, 24, 30

South Carolina Code Ann. § 12-36-2120(28)(a) 30

South Carolina Code Ann. § 12-36-2120(63) 31

South Carolina Code Ann. § 12-36-2120(80) 31

South Carolina Code Ann. § 40-43-10 et. seq. 25

South Carolina Code Ann. § 40-43-30 ..... 19, 33, 34

South Carolina Code Ann. § 40-43-30(5) 37

South Carolina Code Ann. § 40-43-30(7) 35, 36

South Carolina Code Ann. § 40-43-30(45) 26

South Carolina Code Ann. § 40-43-60(H) 26

South Carolina Code Ann. § 40-43-86(7)(h) 29

South Carolina Code Ann. § 40-43-86(E) 36

South Carolina Code Ann. § 40-43-86(EE) 19

South Carolina Code Ann. § 40-43-86(F)(6) 33

Other Authorities

21 C.F.R. § 801.109(a) 18, 19, 22

21 C.F.R. § 801.109(a)(1)(i) 19

21 C.F.R. § 801.109(a)(1)(i) and (2) 19

21 C.F.R. § 801.109(a)(2) 19, 20

21 C.F.R. § 801.109(b)(1) 13

S.C. Private Rev. Op. # 01-4 19

S.C. Rev. Ruling #03-2 16

S.C. Rev. Ruling #11-3 16

South Carolina Code Regulations § 117-332 16

STATEMENT OF ISSUES ON APPEAL

I. DID THE ADMINISTRATIVE LAW COURT PROPERLY FIND THAT FEDERAL REGULATIONS MANDATE THAT SALES TRANSACTIONS BETWEEN A MANUFACTURER AND A HOSPITAL OF FDA REGULATED CLASS II AND CLASS III PRESCRIPTION PROSTHETIC DEVICES REQUIRE LAWFUL PRESCRIPTIONS OR ORDERS?

II. DID THE ADMINISTRATIVE LAW COURT PROPERLY FIND THAT PHYSICIANS' ORAL ORDERS FOR SPECIFIC PATIENTS, WHICH ARE MEMORIALIZED, CONSTITUTE PRESCRIPTIONS?

III. DID THE ADMINISTRATIVE LAW COURT PROPERLY FIND THAT THE HOSPITAL PURCHASED PATIENT SPECIFIC PROSTHETIC DEVICES BY PRESCRIPTION AS THAT TERM IS USED IN THE SOUTH CAROLINA SALES TAX STATUTE?

IV. DID THE ADMINISTRATIVE LAW COURT PROPERLY FIND THAT THE OTHER BONE, TISSUE AND MUSCLE IMPLANTS REPLACED MISSING PARTS OF THE BODY?

STATEMENT OF THE CASE

This matter involves a contested case hearing brought by Respondent CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Roper") challenging a Department Determination of Appellant South Carolina Department of Revenue ("SCDOR") that denied Roper a refund claim of sales and use taxes for the period of August 1, 2007 - November 30, 2010. (Department Determination, R. at ___.) Roper filed a request for a contested case hearing with the Administrative Law Court ("ALC") on September 7, 2012 on the basis that (1) it was entitled to an exemption from sales and use tax for certain orthopedic, cardiac and trauma prescription prosthetic devices that were purchased by prescription; and (2) that certain blood derivatives were excluded from sales and use tax because they were not sales of tangible personal property but rather were sales of services.

The parties filed cross motions for summary judgment, and the ALC held a hearing on October 1, 2013. (Roper's Motion for Summary Judgment and Memorandum in Support of Same ("Roper's MSJ"), R. at ____; Roper's Amended Motion for Summary Judgment and Memorandum in Support of Same ("Roper's Am. MSJ"), R. at ___; and SCDOR's Motion for Summary Judgment and Memorandum in Support ("SCDOR's MSJ"), R. at ____.) The ALC issued an order on May 20, 2014 granting in part and denying in part the cross motions for summary judgment (Order dated May 20, 2014 ("MSJ Order"), R. at ____.) More specifically, the ALC granted Roper's Am. MSJ (and denied SCDOR's MSJ) as to the orthopedic prosthetic devices finding that they were exempt from sales tax as prosthetic devices sold by prescription. The ALC granted SCDOR's MSJ (and denied Roper's Am. MSJ) as to the cardiac

prosthetic devices finding that, unlike the orthopedic prosthetic devices (which she had found replaced a missing part of the body), these devices replaced a missing function and further finding that the blood derivatives were not excluded from sales tax. Both parties filed motions for reconsideration (Roper's Motion for Reconsideration under ALC Rule 29(D) and/or to Alter or Amend under SCRCP Rule 59(E) ("Roper's Motion for Reconsideration"), R. at _____; SCDOR's Notice of Motion and Motion for Reconsideration Pursuant to ALC Rule 29(D), ALC Rule 68, and to Alter or Amend Pursuant to Rule 59(e), SCRCP ("SCDOR's Motion for Reconsideration"), R. at ___.)

The ALC granted in part and denied in part these motions for reconsideration on June 27, 2014. (Order Granting in Part and Denying in Part Motions for Reconsideration ("Reconsideration Order"), R. at ____.) In this order, the ALC affirmed its prior ruling in favor of Roper on the orthopedic prosthetic devices while clarifying several issues related to its ruling on those devices. The ALC also granted Roper's request that it reconsider the granting of summary judgment to SCDOR on the cardiac prosthetic devices and the blood derivatives issues and altered its ruling to find that factual disputes existed that precluded summary judgment. SCDOR filed this appeal on July 3, 2014. Thereafter, the ALC issued an order staying the cardiac prosthetic device and blood derivative issues pending determination of this appeal. (Order Denying Motion to Proceed dated July 29, 2014, R. at ____.)

STATEMENT OF FACTS

The prescription prosthetic devices at issue in this appeal are primarily orthopedic reconstructive implants (such as artificial hips, knees and shoulders) and other bone, muscle and tissue implants (collectively referred to herein as "orthopedic

prosthetic devices").[1] (Joint Stipulations of Fact at ¶1, R. at ___.) Both parties agree that all of the prosthetic devices at issue both in the underlying case and this appeal are Federal Food and Drug Administration ("FDA") regulated Class II and Class III prescription prosthetic devices. (Id. at ¶6, R. at ___.)

Roper purchases all of the orthopedic prosthetic devices only upon the prescription or order of physicians who are board certified and authorized to prescribe such devices in their practices. (Affidavit of Charles Trescott Ferguson ("Ferguson Aff.") at ¶3(b), R. at __; Affidavit of John McCrosson, M.D. ("McCrosson Aff.") at ¶4, R. at ___.) Dr. John McCrosson, a board certified orthopedic surgeon who is authorized to implant orthopedic hips and knees into his patients who require hip and knee joint replacements, testified that these devices are prescription devices and can only be sold by prescription. (Deposition of John McCrosson, M.D. dated June 13, 2013 ("McCrosson Dep. II") at 7:19- 8:6; 34:5-9 and 40:6-42:15, R. at ____.)

The sales transactions at issue here take place in Roper hospital operating rooms. (Id. at 13:2-17 and 44:1- 45:10, R. at ___; Deposition of Brett M. Baker, M.D. dated 7/2/13 ("Baker Dep.") at 15:20- 17:12, R. at ___.) More specifically, Dr. McCrosson stated that he issues an oral order for the orthopedic prosthetic devices he

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[1] Prescription prosthetic cardiac devices were also involved in the underlying case but as previously stated, the ALC denied both parties' motions for summary judgment on those devices and, thus, no final decision has been issued on them. (Reconsideration Order at 2, R. at __.) Additionally, certain trauma devices, such as pins, plates and screws, were also at issue. The ALC ruled against Roper on those items; however, Roper has chosen not to appeal that decision as it believes the ALC's ruling provides a rational, bright-line test for determining when prosthetic devices qualify for the exemption at issue, which will be discussed in more depth below, that can be understood and applied by both SCDOR and taxpayers thus bringing clarity to this area of sales tax law, and Roper's trauma devices do not meet the elements of that test.

implants during surgery, which is when he finally determines exactly what size and type of device the patient needs. (McCrosson Dep. II at 25:7-24, R. at ____.) When the manufacturer's representative brings a device to the operating room for Dr. McCrosson or any other physician, it is owned by and in the possession of the manufacturer's representative (Deposition of Charles Trescott Ferguson ("Ferguson Dep.") at 11:15- 12:5, R. at ___; Baker Dep. at 15:20- 17:12, R. at ___), who is regularly and lawfully engaged in the manufacture of such devices. The manufacturer's representative then hands the device over for sale to the hospital upon the oral order or prescription of a physician such as Dr. McCrosson. (McCrosson Dep. II at 13:2-17 and 44:1- 45:10, R. at ___; and Baker Dep. at 15:20- 17:12, R. at ___.) The physician then implants the device into the patient (McCrosson Dep. II at 40:19- 41:12. R. at ___.) Dr. McCrosson further testified that his order for an orthopedic device is a prescription as required by law. (Id. at 28:22- 29:11, R. at ____.) This prescription is then memorialized in writing in a number of ways, including, in the hospital's computer system, on stickers on the boxes of the implants used, in the patient's chart, on a requisition sheet, in a hospital log and in the operative report. (Id. at 25:25- 26:20, R. at ___; see also McCrosson Aff. at ¶5, R. at ___; Baker Aff. at ¶6, R. at ___.)[2] As both Dr. McCrosson and Dr. Brett Baker, a cardiovascular electrophysiologist, testified, their oral orders constitute prescriptions. (McCrosson Aff. at ¶4, R. at ___; Baker Aff. at ¶4, R. at ___.; McCrosson Dep. II at 44:1- 45:10, R. at ___.)

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[2] The hospital does not own any inventory of orthopedic devices; however, it does purchase and maintain an inventory of certain trauma devices for use on patients treated in the hospital as these items are needed on an emergency basis. (Ferguson Aff. at ¶3(c), R. at ____.) Even these trauma devices kept in inventory, however, are ordered only upon the order or prescription of a physician. (Id., R. at ____.)

Roper is required to maintain and if requested provide sufficient documentation to the hospital accrediting agency and to the FDA to document the proper purchase practices for prescription only devices. (Ferguson Aff. at ¶3(a) and (d), R. at ___.) Roper is, and was during the time periods at issue, in full compliance with the FDA mandates that (a) all sales be made by or on the order of a physician, and (b) all physicians' orders be properly memorialized. (Ferguson Aff. at ¶3(e), R. at ___.) The hospital has never been held in violation of laws or regulations of the state or federal government or the hospital accrediting agency with regard to the purchase or documentation of prescription prosthetic devices during the past ten years, if not longer. (Id. at 3(f), R. at ___.)

Mary Pendergast, former Deputy Commissioner and Senior Advisor to the Commissioner of the FDA, provided testimony (both by affidavit and deposition) regarding the relevant FDA statutes and regulations. She stated that the FDA is the only governmental agency, federal or state, with legal authority to regulate the labeling, distribution, and restrictions regarding the use of prosthetic devices implanted in human beings. (Affidavit of Mary K. Pendergast ("Pendergast Aff.") at ¶6(a), R. at ___.) She further stated that the State of South Carolina has no authority to modify, limit or expand restrictions placed on these prosthetic devices without specific authority from the FDA. (Id. at ¶6(b), R. at ___.) FDA regulations provide an appeal process for states to request exemptions from such restrictions, but South Carolina has not requested such an exemption. (Id. at ¶6(d), R. at ___.) Prosthetic devices that can cause harm in their use are restricted by FDA regulations to sale only by "prescription or other order" of a physician licensed to use such devices in their medical practice.

(Id. at ¶6(e), R. at ___.) Hospitals can only purchase such restricted prosthetic devices upon the lawful "prescription or other order" of a physician licensed to use such devices in his medical practice. (Id. at ¶6(f), R. at __.) These orders may be oral, electronic or written, but oral orders must be memorialized in writing. (Deposition of Mary K. Pendergast dated May 1, 2013 ("Pendergast Dep.") at 49:7-14, R. at ___.) Hospitals that purchase such devices without the lawful prescription or order of a physician are subject to prosecution under federal law for "misbranding" of prescription devices. (Pendergast Aff. at ¶6(g), R. at ___.)

On the eve of the hearing on this matter, SCDOR presented a new witness, Steven Silverman with the FDA, via affidavit in opposition to Ms. Pendergast's testimony and to Roper's Amended Motion for Summary Judgment. Mr. Silverman did not provide any deposition testimony, and SCDOR conceded that he would likely be unavailable to do so even if the case went to trial. Without clarifying testimony, the affidavit is unclear, overly broad and ambiguous and does not appear to provide testimony that directly relates to any factual issues in dispute in this matter. Because of the procedural and substantive defects with the affidavit, Roper moved to exclude it.[3] Although at the start of the hearing, the ALC denied this motion at least in so far as SCDOR was submitting it in response to Roper's Amended Motion for Summary Judgment (see 10/1/13 Hearing Tr. at 6-7, R. at ___), she later expressed concern

[3] More specifically, the basis for Roper's Motion to Exclude was that SCDOR had not named Mr. Silverman as a witness in the case, did not file his affidavit with its motion for summary judgment, did not file it at all until one week before the hearing and had acknowledged that he was most likely unavailable for cross examination even if the case went to trial. As a result, Roper argued that the admission of this affidavit (which was unclear and ambiguous at best) would be highly prejudicial to Roper and would violate its due process rights. (Roper's Motion to Exclude Silverman, R. at ___.)

about SCDOR's heavy reliance on the affidavit and the fact that Roper had not been permitted to cross-examine him. In response to these concerns, SCDOR stated that the ALC could "remove his affidavit from the record," that it was "immaterial," and that the Court need only consider the law. (Id. at 84-85, R. at ___.) Roper agrees that the Silverman affidavit should be removed from the record, that it is immaterial and that the ALC as well as this Court should not consider it but rather need only consider the law.

To the extent this Court wishes to consider the Silverman affidavit, Roper would submit that it does not even purport to address or relate to the exact facts of this case, and its conclusions are unclear and ambiguous. Chiefly, the affidavit is overbroad. Mr. Silverman does not define the term "prescription devices," and he does not specify that he is addressing only prescription prosthetic devices that are implanted into the body and the federal mandates requisite for a lawful order thereof.[4] Roper's case is distinct to FDA regulated Class II and Class III prescription *prosthetic* devices implanted into the musculoskeletal system and does not contemplate other devices that may be categorized as "prescription devices." However, the affidavit does highlight that *"The Secretary may by regulation require that a device be restricted to sale, distribution or use only upon a written or oral authorization of a practitioner licensed by law to administer or use such devices*" and that "*the device"[i]s to be sold only to or on the order of such practitioner . . . .*" (Silverman Aff. at ¶5-6, R. at ___.) Roper purchases all of the orthopedic prosthetic devices only upon the prescription or order of

[4] More specifically, for example, a review of 21 C.F.R. §801.109(b)(1) reveals that the term "prescription devices" includes surgical instruments, which obviously are not implanted into the body nor do they require memorialized patient specific information.

physicians who are board certified and authorized to prescribe such devices in their practices. (Ferguson Aff. at ¶3(b), R. at ___.)

Both parties agree that the orthopedic prosthetic devices, which are all implanted into the musculoskeletal system, all replace a missing part of the body. (Joint Stipulations of Fact at ¶7, R. at ___.) However, SCDOR did not concede that a portion of the orthopedic devices including other bone, muscle and tissue implants, which are also implanted into the musculoskeletal system, replace a missing part of the body. However, the evidence in the record and common sense indicate that they do.

STANDARD OF REVIEW

The Administrative Procedures Act provides the appropriate standard of review in an appeal of a decision of an administrative agency. S.C. Code Ann. § 1-23-610 (Supp. 2009); see also The Original Blue Ribbon Taxi Corporation v. SCDMV, 380 S.C. 600, 604, 670 S.E.2d 674, 676 (2008). Under S.C. Code Ann. § 1-23-610(B), the Court of Appeals 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 petitioner have been prejudiced because 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 light 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." S.C. Code Ann. § 1-23-610 (Supp. 2009); Original Blue Ribbon Taxi, 380 S.C. at 604, 670 S.E.2d at 676 (addressing subsection (C) of the 2007 version of this code section, which is substantially similar to the current subsection (B)).

In addition, when reviewing a summary judgment decision of a trial court, this Court applies the standard under Rule 56 of the South Carolina Rules of Civil Procedure, which provides that summary judgment is appropriate where there is "no genuine issue as to any material fact," and the moving party shows that it is entitled to judgment as a matter of law. S.C. R. Civ. P, Rule 56. The moving party has the burden to establish that, based on the pleadings, affidavits and discovery on file, it is entitled to judgment as a matter of law. Bovain v. Canal Ins., 383 S.C. 100, 678 S.E.2d 422, 424 (2009); Bravis v. Dunbar, 316 S.C. 263, 449 S.E.2d 495, 496 (Ct. App. 1994).

RULES OF STATUTORY CONSTRUCTION

Both state and federal statutes are applicable to this matter. When interpreting a statute, the sole function of the Court is to determine and give effect to the intent of the legislature. Hodges v. Rainey, 341 S.C 79, 85, 533 S.E.2d 578, 581 (2000). The starting point in doing so should always be the text of the statute itself. Id. (holding that "[w]hat a legislature says in the text of a statute is considered the best evidence of the legislative intent or will"); Wigfall v. Tideland Utilities, Inc., 354 S.C. 100, 580 S.E.2d 100 (2003). In interpreting the text, the plain meaning rule requires that "words must be given their plain and ordinary meaning without resort to subtle or forced construction to limit or expand that statute's operation." State v. Leopard, 349 S.C. 467, 471, 563 S.E.2d 342, 344 (Ct. App. 2002). As discussed more fully below, Roper submits that the sales tax exemption statute at issue is not ambiguous, and the Court should simply apply it in accordance with the clear and plain meaning of the language therein.

ARGUMENTS

The central issue in this appeal is whether Roper's purchases of certain prescription orthopedic prosthetic devices from various manufacturers are exempt from sales and use tax. South Carolina sales and use tax law defines the sale of prescription prosthetic devices to hospitals as retail sales. See S.C. Code Ann. § 12-36-110 (stating that the hospital is deemed to be the consumer or user of the devices). However, the law provides an exemption for medicines and prosthetic devices "sold by prescription." S.C. Code Ann. § 12-36-2120(28).

The sales tax exemption statute does not elaborate further on the term "sold by prescription;" however, case law (as well as Department revenue rulings cited therein) provides that in order to qualify as a prosthetic device that is "sold by prescription," (1) the sale must require a prescription; (2) the device must actually be sold by prescription; and (3) the device must replace a missing part of the body. See Home Medical Systems, Inc, v. South Carolina Department of Revenue, 382 S.C. 556, 677 S.E.2d 582 (2009); S.C. Rev. Ruling #03-2; S.C. Rev. Ruling #11-3; S.C. Code Reg. § 117-332. SCDOR and Roper stipulated that the orthopedic prosthetic devices at issue replace a missing part of the body (except as to the items discussed in section IV herein), so the primary contested issues in this appeal are whether Roper meets the first two requirements, i.e. that the sales required a prescription and that the devices were actually sold by prescription.

As the ALC noted, "[t]he first two prongs of Home Medical overlap in that they both intimate the same requirement: the sale of the device must require and be made with a prescription for the tax exemption to apply." (Reconsideration Order at 2, R. at

___.) However, the use of the word "actually" in the second prong implies a distinction between the two prongs, i.e. the second prong "implies that there are situations in which a prescription is required for sale, but the sale is not actually accomplished by a prescription." (Id.) The South Carolina tax code does not define the term "prescription," and SCDOR has issued no regulations, private letter rulings or other guidance to taxpayers that would indicate that it means anything other than the plain and ordinary meaning that it is the lawful order of a physician. (See McCrosson Dep. II at 80:22- 83:4, R. at ___ for discussion of several dictionaries defining prescription as lawful order of physician or something similar.)

Beyond the three requirements set forth in Home Medical, no case law, statute or regulation controls the exact facts in this case; therefore, this is a case of first impression for the courts of South Carolina. As the ALC found, and as is discussed in more detail below, Roper meets all three prongs of Home Medical and thus qualifies for the sales tax exemption at issue. SCDOR fails to specifically identify which of the bases under S.C. Code Ann. § 1-23-610 (Supp. 2009) would support this Court reversing the ALC's decision in this matter, but it argues that the ALC's decision was in error and thus appears to be arguing under subsection (d) that the decision was affected by an error of law. Roper submits that the ALC made no such error of law.

I. THE ALC PROPERLY FOUND THAT FEDERAL REGULATIONS MANDATE THAT SALES TRANSACTIONS BETWEEN A MANUFACTURER AND A HOSPITAL OF FDA REGULATED CLASS II AND CLASS III PRESCRIPTION PROSTHETIC DEVICES REQUIRE LAWFUL PRESCRIPTIONS OR ORDERS.

A. Federal Law Requires a Prescription.

SCDOR asserts that Roper does not meet the first element of the 3-prong test that the sale must require a prescription. As the ALC determined in her Reconsideration Order, the applicable federal law says otherwise. (Reconsideration Order at 2-3, R. at ___ (finding "the prosthetic prescription devices at issue require a prescription to be sold, and they satisfy the first prong of Home Medical").)

The Food, Drug and Cosmetics Act of 1976, under the authority of the Commerce Clause, empowers the Secretary of the Federal Department of Health and Human Services Development to require by regulation that a device be restricted to sale, distribution or use:

> (A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or,
>
> (B) upon such other conditions as the Secretary may prescribe in such regulation.

21 U.S.C. § 360j (e)(1).

The Secretary has exercised the authority above in 21 C.F.R. § 801.109(a), which provides, *inter alia,* that a device that may be harmful if not used under the supervision of a physician is only exempt from federal labeling requirements (which would require adequate directions for use), 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;

. . . ; 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.

21 C.F.R. § 801.109(a)(emphasis added); see also Pendergast Aff. at ¶6(e), R. at ___.[5]

Thus, as long as a regulated device is in the hands of a manufacturer (per 21 C.F.R. § 801.109(a)(1)(i)) and is being sold to a hospital on the prescription or order of a physician (per 21 C.F.R. § 801.109(a)(2)), then the device need not be labeled. Conversely, a manufacturer selling a prescription prosthetic device that does not contain adequate instructions for use to a hospital requires a prescription or order of a physician. 21 C.F.R. § 801.109(a)(1)(i) and (2).[6]

These federal regulations are consistent with the legal doctrine known as the "learned intermediary rule," which provides that manufacturers of prescription drugs and devices discharge their duty of care to patients by providing warnings to the prescribing physicians and need not provide warnings directly to the patients of the prescribing physicians. See Madison v. American Home Products, 358 S.C. 449, 595

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[5] The South Carolina Pharmacy Code even adopts this federal law on at least two occasions: (1) the definition of a device in S.C. Code Ann. § 40-43-30: "Federal law restricts this device for sale by or on the order of a physician" and (2) the restriction on the sale of devices set forth in S.C. Code Ann. § 40-43-86(EE), which states: "Caution: Federal law restricts devices for sale by or on the order of a physician." Indeed, S.C. Private Rev. Op. # 01-4 adopts the federal law in determining whether a sale of total parenteral nutrition *("TPN")* solutions by a retail home health care business qualify for the sales tax exemption for prescription medicines: "It is the opinion of the department that *sales of ... TPN ... solutions* by XYZ to individuals *are exempt from sales tax ... as medicines sold by prescription* ***since federal law requires that*** *... TPN solutions be sold by prescription* when sold to the patient."

[6] Furthermore, if Roper purchased, or a manufacturer sold, prescription prosthetic devices without an order or prescription, such transactions would violate the law. 21 U.S.C. §352; Pendergast Aff. at ¶6(g), R. at ___.

S.E.2d 493 (1995); Talley v. Danek Med., Inc., 179 F.3d 154, 163 (4th Cir. 1999). In the context of prescription prosthetic devices, the policy considerations behind the learned intermediary rule and the federal regulations requiring a prescription for sale are the same and serve a similar purpose: physicians are in the best position to know what prescription prosthetic devices are needed by their patients and to adequately advise and warn their patients of any benefits and risks associated with such devices. Thus, the law requires that these devices only be sold upon the order of a prescribing physician, upon whom the law places this legal burden to adequately advise and, where appropriate, warn his or her patient.[7] As the ALC noted, the "overarching purpose of the regulation is to require a gate-keeper to protect consumers from purchasing potentially dangerous products." (Reconsideration Order at 2, R. at ___.)

SCDOR's primary argument against this clear reading of the federal law is based on the language in 21 C.F.R. § 801.109(a)(2), which provides that a prescription device must be sold "only to or on the prescription or other order of such practitioner." (SCDOR Brief at 16 and 23-24.) SCDOR interprets this language to mean that a prescription device may be sold to both physicians and hospitals without a prescription or order. (Id.) It then claims that Roper's expert, Mary Pendergast, supported this interpretation. (Id.) This conclusion is a misreading of both the law and the expert's testimony. What the law provides, which Ms. Pendergast confirmed, is that a manufacturer may sell a restricted device (a) to a physician, or (b) on a physician's order. 21 C.F.R. §801.109(a)(2). Thus, if a physician is directly purchasing the device

[7] The law is also consistent with the testimony of Mary Pendergast, former Deputy Commissioner and Senior Advisor to the Commissioner of the FDA, which is summarized above. See supra, Statement of Facts, at 5-6.

him or herself, then a prescription is not required because the device is being sold ***to a physician*** (thus, it is clearly understood to be a doctor's order). On the other hand, if the hospital is making the purchase, then the device must be sold ***on the order of a physician***. (Pendergast Dep. at 55:15- 56:1, R. at ___) (stating that "you only need a prescription or 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."). Here, because the hospital (and not a physician) is making the purchases at issue, a prescription or order is required.

SCDOR also argues that because the language in the federal regulation says prescription **or** order, a prescription is not required because an order could be used. This argument flies in the face of common sense and the interchangeable and synonymous nature of the terms "prescription" and "order." As the ALC explained in her ruling on the motions for reconsideration:

> 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. Presumably our legislature did not craft the exemption with the intent that it would never apply.

(Reconsideration Order at 3, R. at ___.)

SCDOR also complains that interpreting prescription and order synonymously would mean that federal regulations always require a prescription for the sale of regulated prosthetic devices and that would render the first element of the test meaningless as it would always be satisfied. SCDOR Brief at 24. This critique has no

merit. The statute speaks to exempting a "prosthetic device" where it is "sold by prescription." S.C. Code Ann. § 12-36-2120(28). Home Medical then defines what constitutes "sold by prescription." Home Medical, 382 S.C. at 563-564, 677 S.E.2d at 586-587. The first element of that test provides that in order to qualify, a prosthetic device must require a prescription to be sold. It is established here that federal regulations are precisely why the first element of the test exists. If the FDA does not designate a prosthetic device as a *prescription* device, one that requires a prescription to be sold, then the first prong of the test would not be met. Thus, where an external prosthetic device for a knee or ankle may be a "Class I, which means that only general controls are necessary for the sale of the product" (Pendergast Dep. at 31:10-12, R. at ____) such that no prescription is required for its sale, then that prosthetic device would not qualify for this exemption. However, because federal law mandates that FDA regulated Class II and Class III prescription prosthetic devices require a lawful order of a doctor for the sale of such devices, then such transactions could not lawfully take place otherwise. SCDOR fails to recognize that the FDA is the only regulatory body that can mandate controls upon the sale of a device such that it "is to be sold only to or on the prescription or order of such practitioner for use in the course of his professional practice" per 21 C.F.R § 801.109(a), as are all the devices in question here. Furthermore, as the ALC noted, it is actually SCDOR's interpretation that leads to absurd results as under its view, no prescription prosthetic device would ever qualify for the exemption. (Reconsideration Order at 3, R. at ___.)

SCDOR asserts a plethora of other arguments as to why this very clear federal requirement should not be accepted as such. Roper will address these arguments below.

B. The Factual Conclusions Drawn in Home Medical are Not Applicable Here.

SCDOR claims that Home Medical dictates that the items at issue here cannot meet the 3-part test. However, that is not the case. Home Medical involved sales of various prescription devices (such as ventilator devices) and a non-prescription or over-the-counter medicine (enteral nutritional formula). Home Medical, 382 S.C. at 558-559, 677 S.E.2d at 583-84. The Court determined that none of the prescription devices at issue were *prosthetic* devices (i.e. they were not implanted into the body and did not replace a missing part of the body), and, thus, they could not qualify for the exemption. Home Medical, 382 S.C. at 565, 677 S.E.2d at 587. The Court also stated that a Certificate of Medical Necessity ("CMN"), which is a standard form used by Medicare and Medicaid for reimbursement of over-the-counter medicines, was not equivalent to a prescription. The Court did not explain why a CMN is not equivalent to a prescription, but the focus of its holding was that a CMN cannot convert a non-prescription item into a prescription item. Home Medical, 382 S.C. at 565-66, 677 S.E.2d at 587-88. Unlike Home Medical, the parties in this case agree that the orthopedic devices at issue are prescription prosthetic devices that replace a missing part of the body. Roper is not attempting to convert non-prescription items into prescription items via the physician's orders in this case. In addition, neither prescription medicines nor CMNs are at issue here. Therefore, the factual conclusions drawn in Home Medical are not applicable to this case.

C. Roper Agrees that the Transaction at Issue is the Sale between the Manufacturer and the Hospital and that Roper Must Show that a Prescription is Required for that Sale.

SCDOR spends substantial time in its brief arguing that the transaction at issue is the one between the manufacturer and the hospital. SCDOR Brief at 11-14. Roper agrees and has never argued otherwise. SCDOR then argues that "this case should turn on whether or not a hospital must produce a prescription." Id. at 12. As the language "must produce a prescription" does not appear anywhere in the relevant statute, Department rulings or any case cited by SCDOR in its brief, it is unclear exactly what requirements SCDOR is trying to add to the statutory requirements and the 3-part test from Home Medical that govern this case. Under that test, Roper must only show that a prescription is required for that sale between the manufacturer and the hospital to take place; there is no requirement that a prescription be "produced." S.C. Code Ann. § 12-36-2120(28); Home Medical, 382 S.C. at 563-564, 677 S.E.2d at 586-587. As set forth above, the law is clear that a prescription is required for the devices at issue here. See supra, I(A).

D. Associated Medical Is Not Relevant to this Matter.

SCDOR also argues that Associated Medical v. South Carolina Tax Comm'n, Unpub. Op. No. 97-UP-447 (Aug. 26, 1997), which SCDOR correctly notes is unpublished, should control the result in this matter. SCDOR asserts that the holding in that case was that the sale of drugs or medicines to physicians did not qualify for the exemption because "the purchases by the doctors did not actually require a prescription. Rather, the Court recognized that doctors have the ability to purchase medicines

without a prescription, regardless of whether one is written." SCDOR Brief at 13. Roper disagrees with SCDOR's interpretation of the Court's decision.

First, no medicines are at issue in this case, and the test applied in Associated Medical for medicines is simply not applicable here. Even if they were, Roper would note that the test for prescription medicines is different from the test for prescription devices in that the former has a separate and distinct prong, which requires proof that the medicine is of a type that requires a prescription. See Home Medical, 382 S.C. at 564, 677 S.E.2d at 587 (citing S.C. Rev. Rul. #03-02 (2003)). This requirement is not necessary for devices but is relevant to medicines because of the role pharmacists play in the compounding and sale of medicines. More specifically, a pharmacist is allowed to lawfully purchase both prescription and over-the-counter ("OTC") drugs for inventory without a doctor's order; however, the dispensation of such medicines is distinctly regulated. S.C. Code Ann. 40-43-10 et. seq. On the other hand, pharmacists do not purchase or sell prescription prosthetic devices. Thus, the test discussed in Associated Medical regarding prescription medicines is not relevant to the prescription devices at issue here.

Associated Medical does, however, discuss one prong of the test for medicines that is the same for devices, i.e. the prong that a prescription must be used for the sale of the medicine. The Court's example of a drug prescription prepared for a specific patient concludes that that is the type of transaction that would be exempt. Associated Medical at 5. Roper's purchases of the prescription prosthetic devices in question here are patient specific. See supra, Statement of Facts, at 4-5; Reconsideration Order at 4, R. at ___ (finding that "at all times the device was procured for a specific patient").

The Court in Associated Medical simply did not address the question of whether federal regulations required sales of prescription prosthetic devices to be only on the order or prescription of a doctor, nor did it examine whether patient specific prescriptions were actually used for sales of prescription prosthetic device within a hospital. Consequently, Associated Medical is not applicable to the facts of this case.

E. The SC Pharmacy Act Does Not Alter the FDA Regulations.

SCDOR argues that a section of the South Carolina Pharmacy Act (S.C. Code Ann. § 40-43-60(H) (2011))[8] establishes that a sales transaction between a manufacturer and a hospital does not require a prescription. (SCDOR Brief at 13-14.) However, this section only addresses what a *licensed practitioner* may *possess* and *administer* without a permit; it has nothing to do with and does not address in any way, shape or form, the federal requirements imposed on *hospitals purchasing* prescription prosthetic devices, nor could it given the FDA regulations to the contrary. McCullouch v. Maryland, 17 U.S. 316 (1819). SCDOR seems to be confusing requirements regarding possessing and administering by physicians versus requirements for purchasing by hospitals. (Roper's Am. MSJ at 9-11, R. at ___; and Roper's Opposition to SCDOR's MSJ at 4-6, R. at ___.)

[8] The provision reads in full as follows: "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." S.C. Code Ann. §40-43-60(H).

F. Testimony from Roper Physicians regarding Purchases of Certain Items Does Not Show that the Hospital Can Purchase Prescription Prosthetic Devices Without a Prescription.

SCDOR points to testimony from two Roper physicians as support for its position that the hospital does not need a prescription to purchase prosthetic devices. More specifically, it cites testimony of Dr. Daud Nawabi, an oncologist and hematologist, regarding purchases by his medical practice's pharmacy of certain medical supplies and prescription drugs, and testimony of Dr. John McCrosson, an orthopedic surgeon, related to purchases of certain prescription drugs made by his prior orthopedic practice.[9]

First, as stated previously, medicine and prosthetic devices have separate and distinct requirements under which an exempt transaction takes place. None of the purchases discussed in the testimony cited by SCDOR involved purchases made by a hospital like Roper, and none involved prescription prosthetic devices. To disregard the legal requirements imposed by the FDA upon a hospital for the purchase of prescription prosthetic devices by examining a physician or pharmacy's purchase transaction of medicine, is simply misplaced.

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[9] Roper would note that Dr. McCrosson explained that he did not know how the drugs in his practice were purchased, that the medical assistants were involved but that he did not know what was involved in doing that, and thus there is no evidence in the record from someone with first hand knowledge as to how those items were ordered and whether or not other physicians within his practice ordered these drugs using prescriptions. (Deposition of John McCrosson, M.D. dated April 25, 2013 ("McCrosson Dep. I") at 62:17-23, R. at ___.)

G. Federal Regulations Require a Prescription for the Sale of Bulk Purchases of Trauma Devices, but Patient Specific Information was Not Available at the Time of Sale.

The parties stipulated that all prescription trauma items, such as screws, plates, and pins, are FDA regulated Class II and Class III prescription prosthetic devices (see Joint Stipulation of Fact at ¶ 6, R. at ___), and Roper asserts that federal law requires a prescription for their purchase of these devices. Roper presented the testimony of Scott Ferguson, the materials handling manager for Roper, in support of this. In his affidavit, Ferguson stated that the hospital purchases and maintains an inventory of trauma devices for use on patients treated in the hospital as these items are needed on an emergency basis, and even these trauma devices "are purchased by the hospital only upon the order or prescription of a physician." (Ferguson Aff. at ¶ 3(c), R. at ___.) Thus, by their nature, these bulk purchases are made before a specific patient is known.

The ALC held that sales transactions for patient specific prescription prosthetic devices differ from sales transactions for prescription prosthetic devices sold in bulk. (MSJ Order at 12, R. at ___.) She found that all devices at issue met the "sale must ***require*** a prescription" prong (prong 1), but determined that the bulk sales of prescription prosthetic devices did not qualify as to the "actually sold ***by*** prescription" prong (prong 2), because a specific patient was not identified at the time of the transaction. (Id.; Reconsideration Order at 3, R. at ___ (finding that the "prescription prosthetic devices at issue require a prescription to be sold, and they satisfy the first prong of Home Medical").) More specifically, she found that in order to qualify as a sale by prescription for tax exemption purposes under South Carolina sales tax law, the prescription must be "a *written* order prescribing a certain medicine or prosthetic for a

particular patient," and she found that the oral orders for specific patients at issue here, which were later memorialized in writing, qualified as written orders (MSJ Order at 11, R. at ___(emphasis in original).)

SCDOR now argues in this appeal that because the ALC found that hospitals could purchase certain items in bulk, it should have also found that no prescription prosthetic devices can require prescriptions. (SCDOR's Brief at 17-20.) This conclusion simply does not follow. First, federal law is clear that a prescription or order is required, and the law makes no exception for items purchased in bulk. See supra Arguments, § I(A). Roper presented evidence that all trauma items are purchased only upon a physician's order. (Ferguson Aff. at ¶ 3(c), R. at ___.) Additionally, federal law does not require that a particular patient be identified when the order is made. See supra I(A).[10]

Because patient specific information is not known at the time of the bulk sales of trauma devices to Roper, the ALC found that Roper could not satisfy the requirement under South Carolina sales tax law that a prescription was actually used (prong 2). Thus, under the ALC's bright-line test, the trauma devices do not qualify as prosthetic devices "sold by prescription." However, the remaining prescription prosthetic devices

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[10] In fact, taxpayers in South Carolina may claim exemptions for certain diagnostic or therapeutic radiopharmaceuticals even though under South Carolina law, no patient name must be known at the time the prescription is made. (See S.C. Rev. Ruling #96-4; McCormack Dep. at 90:25–92:4, R. at ___) (testimony of Senior Administrator for Policy in the Office of General Counsel, Tax and Regulatory Services at SCDOR agreeing that Revenue Ruling 96-4 allows diagnostic radioactive isotopes to qualify as sold by prescription); S.C. Code Ann. § 40-43-86(7)(h) (stating that "[w]here the patient's name is not available at the time of dispensing, a seventy-two hour exemption is allowed to obtain the name of the patient.").

at issue where a patient is known at the time of sale do qualify as prosthetic devices "sold by prescription."

H. Doctors Need Not Write Prescriptions for a Hospital in Order for the Sales Tax Exemption to Apply.

SCDOR asserts that in order to qualify for the sales tax exemption, the prescription would have to be written for the hospital or that the purchaser must be the patient into whom the device is implanted. (SCDOR Brief at 21-23.) This suggestion is non-sensical, and neither the statute nor the case law contains any such requirement. To read the statute in this way, the Court would need to add additional language requiring that the device be sold by prescription "to the patient into whom the device is implanted." Instead, the statute requires only that the device be "sold by prescription." S.C. Code Ann. 12-36-2120(28). This Court should not re-write the statute to add a requirement that the Legislature did not see fit to add. State v. Leopard, 349 S.C. 467, 471, 563 S.E.2d 342, 344 (Ct. App. 2002) (holding that when the language of the statute is clear, "a court cannot rewrite the statute and inject matters into it which are not in the legislature's language. . . ."); Rosmer v. Pfizer, 263 F.3d 263 (4th Cir. 2001) (holding that when a statute is plain on its face, the court's inquiry is at an end).

I. The ALC's Interpretation of the Exemption in S.C. Code Ann. §12-36-2120(28)(a) Comports with Legislative Intent.

SCDOR argues that the ALC's interpretation of this statute will 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" and that "this result does not comport with legislative intent as expressed in the sales tax exemption statutes

themselves." (SCDOR Brief at 26.) It then argues that two recently enacted statutes would be superfluous if the statute is interpreted as the ALC did.

On the contrary, the ALC's ruling provides a rational, bright-line test for determining when prosthetic devices qualify for the exemption at issue that can be understood and applied by both SCDOR and taxpayers thus bringing transparency to the exemption provided within the South Carolina sales tax code. The ALC's ruling does not alter the 3-prong test for prosthetic devices but rather conforms to Home Medical. Furthermore, medicines were not at issue here; however, even if they were, nothing in this ruling could be construed to exempt sales to hospital pharmacies of prescription medicines. Thus, the ALC's interpretation does not result in the two more recent statutes (S.C. Code Ann. §§12-36-2120(63) and (80)) or amendments to S.C. Code Ann. §12-6-2320(28) being superfluous.

SCDOR also resorts to scare tactics in its Brief when it argues that the economic impact on SCDOR's revenue of the ALC's determination could be "staggering." (SCDOR Brief at 28.) First, this argument is a two-edged sword; the amount is no more staggering than the amount that South Carolina taxpayers are overpaying in sales and use taxes for devices the statute clearly exempts. Additionally, the legislature was, in fact, well-aware that the exemption could be interpreted exactly as the ALC has done. As discussed in Boykin v. South Carolina Tax Commission,[11] a member of the Tax Commission wrote to a South Carolina senator back in 1974 to inform the Senate that while the exemption statute was originally intended to exempt only prescriptions ordered by individual patients from the drug sales tax, the wording actually used in the

[11] Boykin v. S.C. Tax Comm'n, Case No. 1989-CP-O200590 (Aiken Co. Ct. of Common Pleas Nov. 22, 1989).

statute was much broader than that and would include sales to hospitals among others. (Letter from H. Wayne Unger of the S.C. Tax Commission to Senator Rembert C. Dennis, dated June 19, 1974, R. at ___). The letter also informs Senator Dennis that the revenue estimate for the fiscal impact of the exemption should be increased in order to take into consideration that hospitals, doctors, nursing homes, and others may take advantage of the exemption statute as it is broad enough to include sales to these entities. Id. The legislature "is presumed to have fully understood the meaning of the words used in a statute," and thus to understand, as did Mr. Unger, what this language provided. The Original Blue Ribbon Taxi Corporation v. SCDMV, 380 S.C. 600, 604, 670 S.E.2d 674, 676 (2008)). Furthermore, the legislature chose not to amend the statute as to this issue following Mr. Unger's 1974 letter explaining the scope of the statute as written.

II. THE ALC PROPERLY FOUND THAT PHYSICIANS' ORAL ORDERS FOR SPECIFIC PATIENTS, WHICH ARE LATER MEMORIALIZED IN WRITING, CONSTITUTED PRESCRIPTIONS.

SCDOR asserts that the ALC erred in finding that the oral orders of the Roper physicians, which were ultimately memorialized in writing, were prescriptions. To the contrary, the ALC's findings were correct as prescriptions may be written or oral under federal law. 21 U.S.C. § 360j (e)(1)(providing that devices may be restricted to sale, distribution or use "only upon the written or oral authorization of a practitioner licensed by law to administer or use such device"); see also Pendergast Dep. at 49:7-14, R. at ___ (stating that a physician's order may be oral, electronic or written, but oral orders must be memorialized in writing); (McCrosson Aff. at ¶4, R. at ___ (stating that oral orders constitute prescriptions); Baker Aff. at ¶4, R. at ___ (same); McCrosson Dep. II

at 44:1- 45:10, R. at ____ (same).) Common knowledge and general usage also support the fact that physicians often "call in" or otherwise electronically notify pharmacies to prescribe medications.[12] There is simply no requirement in the law that a prescription must be in writing so long as the prescription is memorialized in writing. State law also uses the term "order" interchangeably with the term "prescription." See e.g. S.C. Code Ann. §40-43-30 (defining a "medical order" as "a lawful order of a practitioner which may or may not include a prescription drug order" and defining "prescription drug order" as "a lawful order from a practitioner for a drug or device").

SCDOR claims that Home Medical held that a Certificate of Medical Necessity ("CMN") did not constitute a prescription and that such a form would contain more information than the memorialized prescriptions in this case, and thus it asserts that the ALC erred in finding that the orders of physicians were prescriptions. SCDOR Brief at 31-32. The Court in Home Medical does not explain why a CMN is not equivalent to a prescription, but the focus of its holding is that a CMN cannot convert a non-prescription item into a prescription item, and thus, the non-prescription formulas did not qualify as medicines sold by prescription. Stated differently, by definition, medicine that can be purchased over the counter, does not require a prescription; thus, OTC medicines cannot meet the prong of the test (which is applicable only to prescription medicines and not to devices) that it "must be of the **type** that requires a prescription."

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[12] As Dr. McCrosson explained, patients cannot go purchase the devices at issue directly, and thus it would make no sense for physicians to write a prescription to a pharmacy for the devices at issue. (McCrosson Dep. I at 51:8- 52:4, R. at ___.) In fact, even the South Carolina Pharmacy Code allows oral prescriptions. S.C. Code Ann. §40-43-86(F)(6) (allowing prescribing practitioner to ". . . authorize his agent to transmit a prescription drug order orally or electronically to the pharmacy . . . ").

Home Medical, 382 S.C. at 565-66, 677 S.E.2d at 587-88. Unlike Home Medical, the prescription prosthetic devices at issue here are stipulated FDA regulated Class II and Class III prescription prosthetic devices (Joint Stipulations of Fact at ¶ 6, R. at ___), which require prescriptions.[13]

SCDOR then argues that under the South Carolina Pharmacy Code, the orders of the physicians in this case were chart orders and not prescriptions. First, Roper would respectfully suggest that the ALC erred in adopting the definition of "prescription drug order" in the South Carolina Pharmacy Act for the term "prescription" in the Tax Code. As the ALC correctly noted in her first order, the Pharmacy Code definitions do not apply to the tax code. Home Medical, 382 S.C. at 566, 677 S.E.2d at 588 at n. 7; S.C. Code Ann. §40-43-30 ("definitions contained herein are "[f]or purposes of this chapter").[14] The ALC later reversed her position saying that the admonishment in Home Medical only applied where the tax code had already defined a term. (Reconsideration Order at 3, R. at ___.)

Roper submits that there are other reasons that the admonishment should apply, namely the provisions of the Pharmacy Code itself, which state that the definitions therein are for purposes of the Pharmacy Code (and not the Tax Code). As the name suggests, the Pharmacy Code is primarily concerned with regulating pharmacies in the

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[13] Furthermore, a court in South Carolina has previously determined that a "work authorization" of a dentist qualified as a prescription as a matter of law. Boykin v. S.C. Tax Comm'n, Case No. 1989-CP-O200590 (Aiken Co. Ct. of Common Pleas Nov. 22, 1989). at 2, R. at ____(responding to the SC Tax Commission's argument that in order for a prosthetic device to be exempt, the item must be sold directly to the patient and finding "no credible construction of the statute which restricts, in any manner, the persons who are intended to benefit from this exemption").

[14] See also MSJ Order at 6-7, R. at ___; Roper's Response to SCDOR's MSJ at 8, R. at ___.

State of South Carolina and does not and could not regulate the sale of prescription drugs and devices in a way that is contrary to FDA regulations. As previously stated, the FDA is clear that prescriptions can be both oral and written under federal law. See 21 U.S.C. § 360j (e)(1).

Even if the Pharmacy Code definitions did apply to the Tax Code, there are numerous other reasons why SCDOR's arguments are not persuasive. First, federal law preempts state law as to whether a prescription is required for a hospital to purchase a prescription prosthetic device. See supra I(A). As South Carolina has not obtained an exemption from these requirements, it cannot now argue that the prescription devices at issue can be ordered in a manner not in keeping with those requirements. (Id.; McCormack Dep. at 93-94, R. at ___ (wherein SCDOR's Senior Administrator for Policy within the Office of General Counsel, Tax and Regulatory Services, agreed that SCDOR does not set the requirements for devices to be sold by prescription and that that is done by other agencies).)

Additionally, although SCDOR is asking the ALC to adopt the definitions of the Pharmacy Code, the Pharmacy Code does not even define "sold by prescription" or "prescription." Instead, the closest term defined by the Pharmacy Code, which governs permitting and regulations related to *pharmacies*, is a "prescription drug order", which is defined as simply "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 course of legitimate practice. . . ." See S.C. Code Ann. §40-43-30(7); Roper's Opposition to SCDOR's MSJ at 9-10, R. at ___.

"Prescription" is clearly a more general term than "prescription drug order." No prescription could be written for a prosthetic device that would meet the requirements of S.C. Code Ann. §40-43-86(E), which is clearly directed towards prescription drugs, as many of the requirements are simply inapplicable to devices (for example, number of re-fills, strength, dosage, etc.). To impose these rules on prosthetic devices would mean that they could never be exempt, which cannot be in accordance with legislative intent. (Roper's Opposition to SCDOR's MSJ at 10-11, R. at ___.) Even SCDOR admits that "[t]he 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." (SCDOR Brief at 30, n. 22.) This is absolutely true in this case and is unnecessary when there is a definition from a more appropriate source (the FDA regulations) that does not pose the same threat of inconsistencies.

Finally, SCDOR contrasts the term "prescription drug order" with the term "chart order" and argues that the two terms are mutually exclusive thus suggesting that the order of a physician in a hospital setting can never be a prescription. (SCDOR Brief at 30-31.) As previously stated, "prescription drug order" is defined 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 course of legitimate practice. . . ." S.C. Code Ann. §40-43-30(7). Chart order is defined as:

> 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).

Assuming that the Pharmacy Code is even applicable here, which Roper submits it is not, the ALC explained the fallacy in SCDOR's argument:

> The important difference between the definition of 'prescription drug order' and 'chart order' is the word 'specific' in the definition of 'prescription drug order' and 'hospital or extended care facility' in the definition of 'chart order.' I find that while the format of the sale is better represented by the definition of 'chart order,' a chart order can constitute a prescription as in this case.

(Reconsideration Order at 4, R. at __.) The ALC further found that in this case, while the sale might look more like a chart order because the physician signed off on a requisition sheet, at all times the device was procured for a specific patient. (Id.)

III. THE ALC PROPERLY FOUND THAT THE HOSPITAL PURCHASED PATIENT SPECIFIC PROSTHETIC DEVICES BY PRESCRIPTION AS THAT TERM IS USED IN THE SOUTH CAROLINA SALES TAX STATUTE.

The evidence in the record is uncontroverted that prescriptions were actually used in the sale of "patient specific" prescription prosthetic devices from the manufacturer to the hospital thus satisfying the second prong of the 3-prong test for prosthetic devices. More specifically, each sales transaction at issue takes place in a Roper hospital operating room. (McCrosson Dep. II at 13:2-17 and 44:1- 45:10, R. at ___; Baker Dep. at 15:20-17:12, R. at ___.) When the manufacturer's representative brings a device to the operating room, it is owned by and in the possession of the manufacturer's representative (Ferguson Dep. at 11:18- 12:5, R. at ___; Baker Dep. at 15:20- 17:12, R. at ___), who is "regularly and lawfully engaged in the manufacture of such devices." The manufacturer's representative then hands the device over for sale to

the hospital upon the oral order or prescription of a physician. (McCrosson Dep. II at 13:2-17 and 44:1- 45:10, R. at ___; Baker Dep. at 15:20- 17:12, R. at ___.) The physicians have further testified that these oral orders constitute their prescriptions. (McCrosson Aff. at ¶4, R. at ___; Baker Aff. at ¶4, R. at ___.) The physicians then implant the devices into the patient (McCrosson Dep. II at 40:19- 41:12, R. at ___) and later memorialize the orders in writing. (McCrosson Aff. at ¶5, R. at ___; Baker Aff. at ¶6, R. at ___; McCrosson Dep. II at 25:25- 26:20.) As the ALC found, these patient specific orders of physicians, which are later memorialized in writing, constitute prescriptions. (MSJ Order at 11, R. at ___.)

Most of SCDOR's arguments to the contrary focus on its mistaken impression of what a prescription is; for example, it asserts that it must be in writing initially, that it must be "submitted" or "sent," that the prescription must be for the hospital, that it must contain all of the items required by the Pharmacy Code for a "prescription drug order" (even those that clearly could not apply to a devices such as dosage and strength of the drug prescribed), etc. (SCDOR Brief at 32-33.) Roper has addressed these arguments in §§ I and II above and will not repeat them herein. If the proper definition of "prescription," i.e. an oral or written order of a physician, is applied, then it is clear that the record contains undisputed evidence that patient specific prescriptions were actually used to purchase the prescription prosthetic devices in this case.

IV. THE ALC PROPERLY FOUND THAT THE "OTHER BONE, TISSUE AND MUSCLE IMPLANTS" REPLACED MISSING PARTS OF THE BODY.

SCDOR asserts that the ALC erred in finding that the other bone, muscle and tissue implants replace a missing part of the body because Roper did not present evidence to

establish that these implants replace a missing part of the body. This argument is without merit as the ALC may make such a basic and logical conclusion under the facts of this case. There is no conceivable argument that a physician would implant a reconstructive musculoskeletal device into a patient's bone, muscle or tissue if that patient were not missing some bone, muscle or tissue. Thus, the ALC properly concluded that these implants replace a missing part of the body.

CONCLUSION

For the foregoing reasons, Roper respectfully requests that the decision of the ALC be affirmed.

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Charleston, South Carolina
December 23, 2014

THE STATE OF SOUTH CAROLINA
In The Court of Appeals

APPEAL FROM THE ADMINISTRATIVE LAW COURT

Shirley C. Robinson, Administrative Law Judge

Case No. 12-ALJ-17-0405-AP

Appellate Case No. 2014-001457

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

v.

South Carolina Department of Revenue, ... Appellant.

PROOF OF SERVICE

I the undersigned Administrative Assistant of the law firm of Nelson Mullins Riley & Scarborough, LLP, attorneys for CareAlliance Health Services d/b/a Roper St. Francis Healthcare, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified by mailing a copy of the same by United States Mail, postage prepaid, to the following address(es):

Pleadings: Initial Brief of Respondent

Respondent's Designation of Matter to be Included in the Record on Appeal

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December 23, 2014

The Honorable Jenny Abbott Kitchings
Clerk of Court
SC Court of Appeals
PO Box 11629
Columbia, SC 29211

RE: CareAlliance Health Services d/b/a Roper St. Francis Healthcare v. South Carolina Department of Revenue
Docket No.: 12-ALJ-17-0405-CC
Appellate Case No. 2014-001457
Our file No.: 38103/09000

Dear Ms. Kitchings:

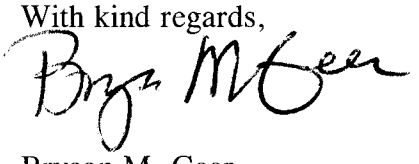
Enclosed are the originals and one copy of the following documents in the above matter:

1. Initial Brief of Respondent;
2. Respondent's Designation of Matter to be Included in the Record on Appeal; and
3. Proof of Service.

Please file the original pleadings and return the clocked-in copies to us via our courier. By copy of this letter, we are serving these pleadings on counsel for the Respondent.

Thank you for your assistance with this matter.

With kind regards,



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