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.

REPLY BRIEF

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Pursuant to Rule 208(a)(3), SCACR, the Appellant South Carolina Department of Revenue (Department) files its Reply to the Initial Brief of Respondent.

ARGUMENTS

I. THE LEGAL ANALYSIS AND FACTUAL CONCLUSIONS OF HOME MEDICAL SYSTEMS, INC. V. SOUTH CAROLINA DEPARTMENT OF REVENUE, 382 S.C. 556, 677 S.E.2D 582 (2009) ARE CONTROLLING IN THIS CASE.

The Respondent, CareAlliance Health Services, d/b/a Roper St. Francis Medical Healthcare, Inc. (Respondent or hospital), argues that the factual conclusions with regard to Certificates of Medical Necessity (CMN) drawn in Home Medical Systems, Inc. v. South Carolina Department of Revenue, 382 S.C. 556, 677 S.E.2d 582 (2009) are not applicable to the instant controversy. Initial Brief of Resp't 23. Specifically, Respondent argues that although the Court in Home Medical stated a CMN[1] was not equivalent to a prescription, the Court did not limit what qualifies as a legal prescription for purposes of Title 12. Id. This argument is without merit, as the Home Medical decision very clearly drew a line of demarcation that stands for the proposition that every order issued by a doctor does not qualify as a prescription. The Court in Home Medical refused to recognize that a CMN – a document that is far more detailed than the doctor's order in question here, in writing, and issued for a particular patient – qualified as a prescription.

[1]In its brief, the Respondent defines a CMN as a "standard form used by Medicare and Medicaid for reimbursement of over-the-counter medicines." Initial Brief of Resp't 23. However, nothing in the record indicates that a CMN is limited to over-the-counter medicines. The Court defined a CMN as "a standard form used by Medicare and Medicaid; it is signed by a physician and details the customer's diagnosis and medical necessity for the item." Home Medical, 382 at 559, 677 S.E.2d at 584. Additionally, the example of the CMN attached as Exhibit A to the Department's Motion for Summary Judgment and Memorandum in Support dated August 26, 2014 demonstrates that a CMN does not apply solely to over-the-counter medicines. (R. pp. 370, 395; Department's Mot. Summ. J. 6 n. 4.)

Thus, Home Medical created a threshold for what constitutes a prescription and is clearly controlling in this case. It necessarily follows that any physician's order that is less than a CMN cannot then qualify as a prescription.

Nevertheless, the Administrative Law Court (ALC) failed to apply this binding precedent in any fashion to the scenario outlined by the Respondent. At best here there is an oral order of a doctor which is later condensed into a mere requisition sheet.[2] The ALC erred in finding that the Respondent's conduct satisfies the prescription requirement of S.C. Code Ann. § 12-36-2120(28) (2014). The Respondent's choice to purchase some surgical implants on a per-patient basis by simply calling out the type of device needed to a vendor or nurse, and then later memorializing that oral order on a requisition sheet sent to the manufacturer does not and cannot qualify as a prescription under the South Carolina Pharmacy Act.[3] Significantly, this practice does not meet the threshold for what constitutes a prescription for the purposes of the prosthetic device sales tax exemption as set out by the Supreme Court in Home Medical. Initial Brief of Appellant 17 – 20. To allow this piecemeal conduct of the Respondent to qualify as a prescription for the purposes of section 12-36-2120(28)(a) would essentially require this Court to disregard the Supreme Court's 2008 decision in Home Medical.

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[2]According to Melanie Hutcherson, a national sales manager for one of the device manufacturers, a requisition sheet contains a patient sticker with the surgery date, the surgeon's name, the patient's name, and the medical record number and the bar code stickers from each of the devices that were used during the surgery. (R. p. 197, lines 4 – 25; Hutcherson Dep. 11:4 – 25.)

[3]The hospital conducts its business this way for economic purposes as Scott Ferguson, the hospital procurement director for medical and surgical supplies, testified in his deposition. (R. p. 160, line 14 – p. 161, line 7; Ferguson Dep. 10:14 – 11:7.)

Furthermore, the Supreme Court's incorporation of S.C. Revenue Ruling #03-02's the three-prong test for the prosthetic device sold by prescription exemption into its decision in Home Medical is also controlling in this matter. Respondent attempts to sidestep Home Medical by arguing that the decision can be factually distinguished, but has failed to show how or why. Initial Brief of Resp't 23. The only factual distinction is that the products at issue in that case were different. The logic and application of the laws in this state related to prescriptions and sales taxes, however, are indisputably applicable. Thus, the Supreme Court's analysis in Home Medical controls this case.

II. ASSOCIATED MEDICAL V. SOUTH CAROLINA TAX COMMISSION, UNPUB. OP. NO. 97-UP-447 (CT. APP. AUG. 26, 1998) IS RELEVANT TO THIS MATTER.

As stated in the Department's Initial Brief, the rationale employed by this Court in the unpublished Associated Medical v. South Carolina Tax Commission, Unpub. Op. No. 97-UP-447 (Ct. App. Aug. 26, 1998) case was later incorporated into a policy document, S.C. Revenue Ruling #03-02. Initial Brief of Appellant 12. The Supreme Court in Home Medical subsequently agreed with the Department and incorporated that same rationale when it adopted the Department's three-prong test for evaluation of the medicines and prosthetic device sales tax exemption. Thus, contrary to the Respondent's assertion, the Court of Appeals' analysis in Associated Medical remains persuasive here.

The Respondent argues that the test applied by this Court in Associated Medical for medicine is not applicable here. Initial Brief of Resp't 25. While it is true that this case involves prosthetic devices and not medicine, the exemption statute is the same – "medicine and prosthetic devices sold by prescription" are exempt from sales tax – and thus, the analysis to determine the proper application of the exemption does not change.

S.C. Code Ann. § 12-36-2120(28)(a). The prongs of the Home Medical test at issue in this case are identical to two of the prongs used to determine whether sales of medicine are exempt under section 12-36-2120(28)(a). The Respondent attempts to distinguish medicine by stating "a pharmacist is allowed to lawfully purchase both prescription and over-the-counter ('OTC') drugs for inventory without a doctor's order." Initial Brief of Resp't 25 (citing the Pharmacy Code, S.C. Code Ann. § 40-43-10 et. seq.). However, the Pharmacy Code applies to devices as well. See S.C. Code Ann. § 40-43-10 et. seq. Nothing in the Pharmacy Code states that it applies to all devices except prosthetic devices. Id. Accordingly, a pharmacist could lawfully purchase prosthetic devices for inventory without a doctor's order. No appreciable legal difference exists between sales of prosthetic devices and sales of medicine for purposes of the sales tax exemption. Thus, the analysis applied to medicine in Associated Medical, which focuses on the sales transaction, is relevant to the analysis of whether the prosthetic devices in this case are sold by prescription and should be considered by this Court.

III. THE FIRST PRONG OF THE HOME MEDICAL TEST STATING THAT THE SALE MUST REQUIRE A PRESCRIPTION LOGICALLY IMPLIES THAT A PRESCRIPTION MUST BE PRODUCED BEFORE THE SALES TRANSACTION CAN OCCUR.

The Respondent complains that the Department tries to add to the statutory requirements of section 12-36-2120(28)(a) when it uses the language "must produce a prescription" to explain the prosthetic device exemption. Initial Brief of Resp't 24. In doing so, the Respondent misapprehends the first prong of the Home Medical test, which provides that the sale of prosthetic devices must require a prescription. The first prong focuses on the sales transaction itself and not so much on the nature of the item being

sold. Assoc. Med., Op. No. 97-UP-447. The sale of a prosthetic device in this instance is only exempt if the sales transaction requires a prescription. In its brief, the Respondent proffers the following statement from the ALC's Order Granting in Part and Denying in Part Motions for Reconsideration in its continued effort to conflate the separate prongs of the test: "the second prong [of the Home Medical test – the device must actually be sold by prescription] 'implies that there are situations in which a prescription is required for sale, but the sale is not actually accomplished by a prescription.'" Initial Brief of Resp't 17. While it is absolutely necessary that a prescription actually be used to effect a sale, the first prong of Home Medical is designed to ensure that the benefit of the sales tax exemption is not afforded in situations where prescriptions are used but the sales transaction itself does not require a prescription. The Department's phrasing the first prong as "whether a hospital must produce a prescription" in order to purchase a prosthetic device does nothing more than place the appropriate emphasis on the requirements of the sales transaction. This phraseology is simply another way of asking the seminal question whether the sales transaction between a hospital and a device manufacturer/vendor requires a prescription. This inquiry must be answered in the negative and no credible evidence produced by the Respondent alters this conclusion.[4] Doctors and hospitals are able to purchase medicines and prosthetic devices without the use of a prescription. Inasmuch as the sales transactions at issue here involving doctors,

[4]When Dr. John McCrosson, one of the hospital's witnesses, was asked if he thought a prescription would have to be produced in order for the manufacturer to sell a prosthetic device to the hospital, he stated "[i]f they don't have one, then it's not required . . . ." (R. p. 259, line 18 – p. 260, line 5; McCrosson Video Dep. 76:18 – 77:5.)

hospitals and device manufacturers do not require prescriptions, the first prong of Home Medical is not met, and therefore, the exemption must be denied.

If a sale actually requires a prescription, it logically follows that a seller will not make the sale if the buyer fails to produce a prescription. The evidence here indicates that no prescriptions supporting the sales of these devices are ever produced and given to the seller. The respective testimonies of Melanie Hutcherson, a national sales manager for Zimmer, Inc. (one of the device manufacturers often used by the hospital), and Scott Ferguson, the hospital's procurement director for medical and surgical supplies, establish that prescriptions were not required to be produced in order for the manufacturer to sell prosthetic devices to the hospital and further, that the hospital did not use prescriptions to purchase the prosthetic devices. Ms. Hutcherson's testimony demonstrates that manufacturers do not ask for prescriptions prior to selling prosthetic devices to a hospital. (R. p. 196; Hutcherson Dep. 10:1 – 25.) Additionally, 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.) Similarly, Mr. Ferguson testified that the only documentation he sends to the manufacturer is a purchase order. (R. p. 163, line 13 – p. 164, line 10; Ferguson Dep. 13:13 – 14:10.) Neither a requisition sheet nor a purchase order qualifies as a prescription. The evidence in this case proves that a prescription was never produced for the transactions at issue. Because a prescription was never produced, the Court can infer that the sales transactions at issue in this case did not require prescriptions.[5]

[5]Perhaps the best evidence of this proposition is the fact that the ALC found in this case that the hospital's bulk purchases of some "prescription type" prosthetic devices

IV. THE FEDERAL REGULATION RELIED ON BY THE RESPONDENT, 21 C.F.R. SECTION 801.109(A), DOES NOT ESTABLISH THAT THE SALE OF PROSTHETIC DEVICES TO A HOSPITAL REQUIRES A PRESCRIPTION.

The Respondent continues to rely solely upon section 801.109(a) to suggest that the sales transactions at issue require prescriptions. The Department maintains that this regulation is wholly inapplicable to the matter at hand as it is merely an exemption to the federal labeling requirement. See Initial Brief of Appellant 23 – 24. However, assuming *arguendo* the regulation does have some application, the regulation does not state that the sale of prosthetic devices to a hospital requires a prescription. To the contrary, the regulation provides that a prescription is an option, not a mandate. The language in the regulation stating a device can be sold "on the prescription **or *other* order** of such practitioner" clearly recognizes that a distinction exists between a prescription and some "other order" of a practitioner. 21 C.F.R. section 801.109(a)(2) (emphasis added). The inclusion of the term "other order" clearly contemplates the use of some medical order other than a prescription for the purposes outlined in the regulation. Accordingly, a prosthetic device can be sold to a hospital on some "other order" of a practitioner without having adequate directions for use on its label, and the FDA will not consider that device misbranded. Therefore, the FDA regulation does not mandate that the sales of prosthetic devices from a manufacturer to a hospital require a prescription and the ALC erred in

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were not sold by prescription. The fact that the hospital can purchase some prosthetic devices without prescriptions inevitably leads to the conclusion that none of the sales transactions here require prescriptions. To the extent the taxpayer maintains otherwise, it has failed to supply evidence to support its proposition.

ruling that it does.[6]

In addition, the Respondent appears to argue that the "learned intermediary rule" supports its argument that section 801.109 states a hospital is required to have a prescription in order to purchase prosthetic devices. Initial Brief of Resp't 19 – 20. To the contrary, the Department submits that the "learned intermediary rule" supports the Department's position on this issue. As the Respondent stated in its brief, the learned intermediary rule "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." Id. at 19 (internal citations omitted). Therefore, when a manufacturer sells a prosthetic device to a physician (or in this case a hospital), the manufacturer discharges its duty of care to the patient because the physician (who, in this case, the hospital authorizes to perform surgery in its facilities) provides the warnings directly to the patient. A patient only needs to be warned if the patient will be using the device. Here, the physician uses the device (even though the hospital purchases it) and discusses the risks and benefits of using said device with the patient prior to the surgery. Thus, even though the manufacturer is selling the device to the hospital, it discharges its duty to warn the patient because the physician working in the hospital has a duty to warn the patient prior to performing surgery on the patient. The shifting of the duty to warn does not mean that the sale to a hospital requires a prescription; it simply means the

[6]Whatever "other order" is satisfactory for purposes of the FDA regulation is not sufficient for purposes of the sales tax exemption for "prosthetic devices sold by prescription" under § 12-36-2120(28)(a) Any contention by the Respondent that a prescription and "other order" are the same for purposes of the sales tax exemption is simply disingenuous.

manufacturer's duty to warn is discharged when a physician will be using the device. The Respondent's statement that "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" is, therefore, incorrect. Initial Brief of Resp't 20. While the law may place the burden on the physician to adequately advise the patient in this context, it does not mean that the sale of a prosthetic device to a hospital requires a prescription. In sum, neither section 801.109 itself nor section 801.109 in connection with the learned intermediary rule mandates that the sale of a prosthetic device to a hospital requires a prescription.

V. THE RADIOACTIVE ISOTOPES DISCUSSED IN S.C. REVENUE RULING #96-4 ARE DISTINGUISHABLE FROM THE ORTHOPEDIC PROSTHETIC DEVICES AT ISSUE IN THIS CASE.

The Respondent points to S.C. Revenue Ruling #96-4, which concludes "[s]ales of radioactive isotopes by nuclear pharmacies to hospitals are exempt from the sales and use taxes per S.C. Code Section 12-36-2120(28)(a)," to support its argument that federal law does not require that a particular patient be identified when the order is made. Initial Brief of Resp't 29. This is the proverbial "red herring." The circumstances set forth in S.C. Revenue Ruling #96-4 are the exception, not the rule. In that revenue ruling, the Department based its conclusion on the fact that the State Board of Pharmacy took the administrative position that radioactive isotopes could only be sold to hospitals and doctors by prescription. S.C. Rev. Rul. #96-4 at 3. The Department then observed that "unlike medicines and supply items purchased for general inventory, radioactive isotopes can only be purchased for a specific patient pursuant to a prescription and cannot be administered to any other patient." Id. Nothing in S.C. Revenue Ruling #96-4 states that

radiopharmaceuticals can be sold without a specific patient in mind. Furthermore, unlike the taxpayer in S.C. Revenue Ruling #96-4, the hospital here has never provided the Department with any credible evidence that orthopedic prosthetic devices can only be sold to a hospital by prescription.[7] To the contrary, orthopedic prosthetic devices can be sold to a hospital without a prescription and without a specific patient in mind. Therefore, radioactive isotopes are distinguishable from the orthopedic prosthetic devices in this case.

VI. THE "WORK AUTHORIZATION" USED BY THE TAXPAYER IN BOYKIN V. S.C. TAX COMM'N, CASE NO. 1989-CP-02-590 (AIKEN CO. CT. OF COMMON PLEAS NOV. 22, 1989) IS DISTINGUISHABLE FROM THE DOCTORS' ORAL ORDERS IN THIS CASE.

In order to satisfy the second prong of the Home Medical test, the hospital must prove that prescriptions were actually used to purchase the prosthetic devices at issue. According to the Respondent, the doctor's oral order for the device in the operating room constituted the prescription.[8] In support of its argument, the Respondent compared the oral orders of a doctor in an operating room to the work authorizations issued by dentists for the construction of dental prosthetics. The Department submits that a work

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[7]As discussed at length in the Appellant's Initial Brief and briefly in section IV above, 21 C.F.R. section 801.109(a)(2) does not require that a sale of a prosthetic device to a hospital be by prescription.

[8]As has been explained, the Department disputes this assertion. See Initial Brief of Appellant 29 – 32. Nevertheless, should the Court find, as a matter of law, that a doctor's oral order for a device issued in an operating room constitutes a prescription, the hospital has still failed to meet its burden of proof in this matter. Specifically, the hospital failed to present any evidence that prescriptions were actually used in each of the transactions for which it seeks an exemption. In order to establish that a prescription was actually used in each transaction at issue, the hospital would have to provide documentation to prove a prescription was actually used in said transaction. See S.C. Code Ann. § 12-36-2540 (2014); 2 Am. Jur. 2d Administrative Law § 354 (2004).

authorization is easily distinguishable from an oral order of a doctor in an operating room.

The Respondent appears to argue that the doctor's oral order in this case constitutes a prescription because a South Carolina court has previously held a dentist's work authorization constitutes a prescription as a matter of law. Initial Brief of Resp't 34, n. 13 (citing Boykin v. S.C. Tax Comm'n, Case No. 1989-CP-02-0590 (Aiken Co. Ct. of Common Pleas Nov. 22, 1989)).[9] However, the Department addressed the applicability of the Boykin decision to the purchase of a prescription-type medicine by a doctor in S.C. Private Letter Ruling #93-5 and explained that a work authorization is "required to contain, among other things, 'a description of the work to be done, with diagrams, if necessary' and a 'specification of the type and quality of materials to be used.' The dentist essentially instructs the dental lab how to construct a prosthetic device." S.C. Private Letter Rul. #93-5 at 4.[10] In this case, all the doctor does in the operating room when he "orders" the device is tell the vendor what device to hand to the circulating nurse. (R. p. 238, line 11 – p. 240, line 4; McCrosson Video Dep. 16:11 – 18:4; See also R. p. 227, line 20 – p. 228, line 4; McCrosson Dep. 68:20 – 69:4 (Dr. McCrosson

[9]The decision in Boykin is a Circuit Court decision and, therefore, lacks any precedential value. Furthermore, in July of 1989, the Legislature amended S.C. Code Ann. § 12-35-550 (the sales tax exemption statute at the time) to exempt the gross proceeds of the sale of dental prosthetic devices, resolving the question of whether sales of dental prosthetic devices to dentists are exempt from sales tax. Act. No. 189 (1989 – 1990 session).

[10]See also S.C. Code Ann. § 40-15-280 (2011), which applies solely to dentists, dental hygienists, and dental technicians. Section 40-15-280 is entitled "'Prescription' defined" and states "'[p]rescription' means a written order for dental technological work which has been issued by a licensed dentist." The statute also outlines what the prescription must contain.

explains that when the vendor is not at the hospital, he tells the circulating nurse directly which device he needs)). An oral request for a specific device is not the same as a written instruction to a dental lab on how to construct a prosthetic device; it is also not sufficient to constitute a prescription for purposes of the sales tax exemption.

More importantly, Home Medical has further evolved this logic by limiting the types of doctors' orders that qualify as prescriptions. To the extent that the Boykin decision inserted written work authorizations for dental devices into the category of prescriptions, it has since been distinguished by the Home Medical case. The Supreme Court's holding in Home Medical that a CMN does not constitute a prescription clearly does not extend "prescription status" to oral orders given in an operating room or requisition sheets, and thus, the Respondent's argument that Boykin is applicable here is lacking. Therefore, the non-binding Circuit Court's determination in Boykin that a work authorization is a prescription is simply not relevant to this case.

VII. THE ALC'S DECISION TO EXEMPT PRESCRIPTION PROSTHETIC DEVICES PURCHASED BY THE HOSPITAL ON A PER-PATIENT BASIS DOES NOT COMPORT WITH LEGISLATIVE INTENT.

In its Initial Brief, the Department argued that the ALC's decision did not comport with legislative intent. Initial Brief of Appellant 26 – 29. In an attempt to counter that argument, the Respondent uses a letter from a member of the Tax Commission sent to a South Carolina senator back in 1974 that was attached as Exhibit C to the Order in Boykin. (R. pp. 805 – 806.) This letter informs the senator that the wording used in the exemption statute could have a much broader interpretation than intended. Assuming the Legislature even knew about the potential for a broad interpretation of the exemption statute, events occurring since 1974 demonstrate that the

Legislature ultimately did not intend for the exemption statute to be interpreted as broadly as the ALC interpreted the exemption statute in this case.

As far back as 1988, the Department has interpreted "sold by prescription" to mean the items must be sold pursuant to a prescription and the sale must require a prescription. See S.C. Rev. Rul. #96-4 at n. 1 (citing S.C. Technical Advice Memorandum #88-23). Furthermore, in S.C. Revenue Ruling #03-2, the Department stated the following based on Associated Medical:

> [S]ales to doctors, nursing homes, **hospitals** and similar institutions are not sales "by prescription" and do not qualify for the exemption found in Code Section 12-36-2120(28), unless such prescription medicines are used by the doctor to prevent respiratory syncytial virus or in "the treatment of cancer, lymphoma, leukemia, or related diseases, [or] ...used to relieve the effects of any such treatment."

S.C. Rev. Rul. #03-2 at 5 – 6 (emphasis added). The Department went on to state that "sales of prosthetic devices, other than dental prosthetic devices, to a **hospital**, nursing home, or a similar institution or doctor are not exempt since such sales do not require a prescription and are not sold by prescription." Id. at 6 (emphasis added). Therefore, the Department's long-standing interpretation of the exemption statute is that a hospital is not required to have a prescription to purchase prosthetic devices. If a hospital is not required to have a prescription to purchase prosthetic devices, its purchases of those devices cannot be exempted. Presumably, the Legislature has been aware of the Department's interpretation and application of this exemption statute. Knowing the Department's interpretation, the Legislature has chosen not to amend or clarify the statute in this regard. Therefore, the history of the interpretation of this exemption statute demonstrates that the Legislature did

not intend for the statute to be interpreted so broadly so as to exempt sales of prosthetic devices to hospitals and like institutions.

VIII. THIS COURT SHOULD CONSIDER THE AFFIDAVIT OF STEVEN SLIVERMAN, DIRECTOR OF THE OFFICE OF COMPLIANCE FOR THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH OF THE U.S. FOOD AND DRUG ADMINISTRATION (FDA), WHICH THE DEPARTMENT FILED IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO THE AFFIDAVITS OF MARY PENDERGAST AND CHARLES FERGUSON.

In the Respondent's Statement of Facts, it asserts that this Court should not consider the affidavit of Steven Silverman, which the ALC properly kept in the record after the Respondent moved to exclude it. Initial Brief of Resp't 12 – 13. In support of its position, the Respondent notes the Department's statement at the summary judgment motion hearing that Mr. Silverman's affidavit could be removed from the record and that it was immaterial. Initial Brief of Resp't 13 (internal citation omitted). This statement is taken out of context and such a claim is disingenuous at best. What the Counsel for the Department actually said was that Mr. Silverman's affidavit could be removed from the record and the law would still support the Department's position. (R. p. 127, lines 12 – 15; Hr'g Tr. 84:12 – 15.) In other words, all Mr. Silverman's affidavit did was clarify section 801.109, unlike the Respondent's expert witness Mary Pendergast.[11] Counsel for the Department's statement merely offered that if the ALC interpreted the regulation correctly, it would not need to rely on Mr. Silverman's affidavit. The Department's statement that the ALC could remove Mr. Silverman's affidavit from the record and still

[11]To the extent Mary Pendergast's testimony and affidavits contained statements interpreting the regulation to mean "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," those statements would be equally objectionable. Initial Brief of Resp't 12. The fact that Mr. Silverman does not agree with Ms. Pendergast does not make his statements irrelevant.

find for the Department is taken out of context by the Respondent, and the Court should consider the affidavit of Mr. Silverman with the deference that an affirmed statement given under oath by the acting Director of the Office of Compliance for the Center for Devices and Radiological Health with the FDA should be afforded.

In further support of this argument, the Department reiterates that Steven Silverman, a current FDA official and not a hired expert witness, is in the best position to help the Court understand 21 C.F.R. section 801.109. The Respondent argues "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." Initial Brief of Resp't 12. To the contrary, Mr. Silverman stated in his affidavit that "[t]here is nothing in the [Federal Food, Drug, and Cosmetic (FDA)] Act or its regulations that prohibits device manufacturers from selling prescription devices to properly-licensed healthcare facilities that do not have patient-specific physician orders for such devices at the time of purchase by the healthcare facility . . . ." (R. p. 773; Silverman Affidavit ¶ 7.) That statement is very clear, specific, and relates to the issue of whether a hospital is required by the FDA to have a prescription to purchase a prosthetic device. To that extent, this Court should consider the affidavit.

Finally, the Respondent alleges that the Department introduced a new witness on the eve of the hearing and that "[w]ithout 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." Initial Brief of Resp't 12. However, the record indicates that the opposite is true. First, the Respondent had been on notice that the Department was attempting to secure testimony from an FDA employee

since at least June of 2013. (See R. pp. 284 – 285; Department's First Mot. for a Continuance.) Therefore, the Respondent's allegation that the Department introduced a new witness on the eve of the hearing is misleading. The Department turned over Mr. Silverman's affidavit as soon as it became available. (See R. pp. 677 – 683; Department's Response to Roper's Mot. to Exclude Steven Silverman's Aff.) Second, Mr. Silverman's affidavit clearly addresses the question posed to him – "whether or not a doctor or hospital can legally purchase and possess Class II and Class III regulated devices prior to their use or administration on a patient without writing a prescription." (R. p. 678; Id. at 2.) Since the facts in dispute revolve around that question and Mr. Silverman's affidavit answers that question, the affidavit does relate to factual issues in dispute in this matter. Thus, this Court should consider Mr. Silverman's affidavit as it is relevant to this matter. Furthermore, this Court should consider Mr. Silverman's affidavit as it will aid the Court in understanding the federal regulation the Respondent argues satisfies the first prong of the Home Medical test.

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,

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CERTIFICATE OF COUNSEL

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

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PROOF OF SERVICE

I, Jean M. O'Connor, hereby certify that I have caused to be mailed a copy of the South Carolina Department of Revenue's Brief of Appellant and Reply Brief in the above-referenced case, by depositing the same in the United States Mail, postage prepaid, on March 16, 2015, addressed to the attorneys of record, John. C. von Lehe, Jr., Esquire and Bryson M. Geer, Esquire, Nelson Mullins, PO Box 1806, Charleston, SC 29402, and Raymond P. Carpenter, Esquire, 625 Colonial Park Drive, Ste. 201, Roswell, GA 30075, and by hand delivery to the Court of Appeals, 1205 Pendleton St., Columbia, SC 29201.

Jean M. O'Connor