THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM THE ADMINISTRATIVE LAW COURT

HONORABLE SHIRLEY C. ROBINSON, ADMINISTATIVE LAW JUDGE

CASE NO. 12-ALJ-17-0405-CC
Appellant Case No. 2014-001457

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

v.

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

RETURN TO PETITION FOR REHEARING

Pursuant to Rule 240(e) of the South Carolina Appellate Court Rules (SCACR), Appellant, South Carolina Department of Revenue (Department) hereby files this return to the Respondent's, CareAlliance Health Services, d/b/a Roper St. Francis Healthcare (Respondent or Hospital), Petition for Rehearing, which it filed on May 20, 2016. As the moving party, the Respondent must "state with particularity the points supposed to have been overlooked or misapprehended **by the court**." Rule 221(a), SCACR (emphasis added). The Respondent cannot use a Petition for Rehearing to rehash arguments that it overlooked or misapprehended. See Kennedy v. S.C. Retirement System, 349 S.C. 531, 352, 564 S.E.2d 322, 322 (2001) (stating "[t]he purpose of a petition for rehearing is not

to present points which lawyers for the losing parties have overlooked or misapprehended, nor is it the purpose of the petition for rehearing to have the case tried in the appellate court a second time.") In its Petition, the Respondent alleges the Court overlooked or misapprehended several points of law, facts, and arguments. Contrary to the Respondent's assertion, the Court did not overlook or misapprehend any law, facts, or arguments. In reality, the Respondent is seeking another opportunity to reargue this case before this Court.

Specifically, the Respondent argues that the Court "erred in failing to find that federal law requires that the sale of [the orthopedic prosthetic devices at issue] to a hospital must be on the order or prescription of a physician." (Resp't Pet. Reh'g 5.) It appears that that the Respondent's basis for that argument is twofold: (1) the Court misapprehended federal law in finding that 21 C.F.R. § 801.109(a) (2011) is merely a labeling regulation, (Resp't Pet. Reh'g 9), and (2) the Court misapprehended the transaction at issue. (Resp't Pet. Reh'g 10 - 12.) Next, the Respondent argues the Court "erred in equating the sale of [the orthopedic prosthetic devices at issue] with non-prescription supplies. (Resp't Pet. Reh'g 12.) Thirdly, the Respondent alleges that the Court erred in relying on the Department's reference to a "Brace and Boot Shop" as an example of a retailer whose sales are exempt under S.C. Code Ann. § 12-36-2120(28)(a) (2014). (Resp't Pet. Reh'g 13 – 15.) Similarly, the Respondent states "to the extent the Court found that an order is not a prescription, such a finding would be erroneous." (Resp't Pet. Reh'g 15.) Finally, the Respondent argues the Court "erred in finding that the other bone, muscle, and tissue implants did not replace a missing part of the body."

(Resp't Pet. Reh'g 17.) As will be discussed more fully herein, the Respondent failed to identify any points the Court overlooked or misapprehended in regards to its arguments.

Therefore, the Department respectfully submits that this Court should deny the Respondent's Petition for Rehearing because the Court did not overlook or misapprehend any law, facts, or arguments that impact the Court's decision. Specifically, the Court correctly outlined the facts surrounding the transaction at issue in this case – a sale of an orthopedic prosthetic device from a manufacturer/vendor to the Hospital. (Order 2.) Moreover, the Court correctly held that section 801.109(a) merely dictates labeling requirements and does not establish that the transaction at issue required a prescription. (Order 6 – 7.)

I. The Court Properly Held that 21 C.F.R. § 801.109(a) does not Satisfy the First Prong of Home Medical Systems, Inc. v. South Carolina Department of Revenue, 382 S.C. 556, 677 S.E.2d 582 (2009).

The Respondent complains that the Court erred in failing to find that federal law requires that the orthopedic prosthetic devices at issue be sold by prescription. (Resp't Pet. Reh'g 5.) However, contrary to the Respondent's assertion, this Court properly applied federal law and found that the Respondent's do not satisfy the first prong of Home Medical Systems, Inc. v. South Carolina Department of Revenue, 382 S.C. 556, 677 S.E.2d 582 (2009). The Respondent bases its argument on its misunderstanding of section 801.109(a). While the Respondent wants section 801.109(a) to say that a sale of a regulated device requires a prescription in order to be sold to a hospital, the regulation does not state such. What this regulation actually says is that a device is exempt from certain **labeling requirements** as long as the device is in the hands of a manufacturer or

practitioner and is being sold only to that practitioner or on the prescription or other order of that practitioner. The Court properly found this is a labeling requirement and that such does not make the sale of orthopedic prosthetic devices require a prescription.

As further evidence of the Respondent's misunderstanding, the Respondent makes the following assertion in its Petition:

> 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 directions for use to a hospital requires a prescription or order of a physician.

(Resp't Pet. Reh'g 7.) The Respondent's first statement is correct – if a manufacturer sells a device on the prescription or order of a practitioner then the device is exempt from federal labeling requirements. The Respondent's second statement, however, is inaccurate. The correct and actual converse of the first statement would be that a regulated device in the hands of a manufacturer that is not sold pursuant to a prescription or order of a practitioner is not exempt from federal labeling requirements. Nowhere in section 801.109 can one find a requirement that the sale of an orthopedic prosthetic device from a manufacturer to a hospital require a prescription. The Respondent has made this unsupported leap throughout this matter and its inclusion in its Petition demonstrates that the Respondent petitioned the Court in an attempt to rehash arguments it has already made. Section 801.109 only dictates when a device need not be labeled. Despite the Respondent's repeated efforts, this federal labeling regulation does not create a requirement that orthopedic prosthetic devices only be sold by prescription. Thus, in

ruling that section 801.109(a) does not satisfy the first prong of Home Medical, the Court did not overlook or misapprehend any law, facts, or arguments.

II. The Court Correctly Found that the Sales Transaction at Issue was Between a Manufacturer/Vendor and the Hospital.

The Respondent argues that the Court misapprehended the facts in this case, and incorrectly concluded that the sales at issue were to a physician and not the Hospital. To the contrary, the Court clearly recognized that the transaction at issue was between the manufacturer/vendor and the Hospital. In fact, several statements within the Court's Order accurately and correctly state the facts surrounding the transaction thereby showing the Court understood the transaction. For example, on page 4 of the Court's Order, the Court stated "DOR contends the ALC erred in finding a prescription is required for the sale of an orthopedic device **between the Hospital and vendor** because of federal regulations. We agree" (emphasis added). While the Court does state that "the regulation allows for a sale directly between a vendor and a practitioner, as an agent of the Hospital," it is clear based on the context of the Order that the Court focused on whether the Hospital could purchase the orthopedic prosthetic devices without a prescription. (Order 7.) While the Court may have referenced the physician being an agent of the Hospital, it did not rest its conclusion on that contention. The Court recognized and the facts support the conclusion that the physician in the operating room is the person who may take the device from the vendor. That does not mean the physician purchased the device. To the contrary, the Court recognized that the transaction at issue is the sale of orthopedic prosthetic devices from the manufacturer/vendor to the Hospital. Thus, while the practitioner accepted the device on

behalf of the Hospital and used the device, it is the Hospital who was purchasing the device from the manufacturer/vendor. This analysis is consistent with the facts in the record. Thus, the Court did not misapprehend or overlook any facts relating to the transaction at issue.

Moreover, even if the Court considered the transaction to be that of manufacturer/vendor to physician, such does not change the outcome of this case. Regardless of whether the sales transaction was between the manufacturer/vendor and the Hospital or the manufacturer/vendor and the physician, the Respondent still failed to satisfy the first prong of Home Medical because it failed to identify a single statute, regulation, case, or agency ruling that says a hospital must have a prescription in order to purchase an orthopedic prosthetic device. Therefore, even if the Respondent's assertion that the Court misapprehended the transaction was correct, the Respondent's Petition for Rehearing should be denied because those facts do not affect the Court's decision.

III. The Court did not Err in Equating the Sale of the Orthopedic Prosthetic Devices at Issue with Other Hospital Medical Supplies.

The Respondent claims the Court misapprehended the Department's argument relating to 10 S.C. Code Ann. Regs. 117.308.3 and 117.308.8 (2011). (Resp't Pet. Reh'g 12 – 13.) Specifically, the Respondent alleges that "the Court's Order states that SCDOR relied on S.C. Code Reg. §117-308.3 [sic] to make this argument . . . ." (Resp't Pet. Reh'g 12.) However, the Court's Order does not state such, and a close reading of the Court's Order does not support the Respondent's argument. (Order 5.) Instead, the Court recited two arguments made by the Department: (1) that Regulations 117.308.3 and 117.308.8 provide that doctors and hospitals are the end users of the supplies they use in

the provision of their medical services; thus, the sales of those supplies to a hospital or doctor are taxable retail sales, and (2) that hospitals do not need prescriptions to purchase the supplies that it needs to serve its patients.

The Department's overarching position in this case is that a hospital does not need a prescription to purchase any of its supplies, whether they are prosthetic devices, MRI machines, medicines, surgical instruments, or bandages. The Department has asserted throughout this matter that a corporate entity cannot purchase items by prescription because that entity can never receive a prescription. (See e.g., R. p. 380; Dept's Brief 21 – 23.) The Department's position is supported by the affidavit of Steven Silverman, the Director, Office of Compliance, Center for Devices and Radiological Health, United States Food and Drug Administration, wherein, Mr. Silverman attested that prohibiting the sale of prescription devices to properly-licensed healthcare facilities in the absence of a prescription would be adverse to the public health because healthcare facilities need immediate access to such devices to properly care for its patients. (R. p. 773.) This logic applies to any supplies a healthcare facility, like the Hospital, would need to properly care for its patients. Thus, the Court did not err in equating the orthopedic prosthetic devices at issue with other hospital medical supplies like bandages.

Even if the Court's reference to bandages was misplaced, the Court's logic still applies. Surgical instruments, for example, are regulated devices and must be labeled with adequate directions for use unless exempt. See 21 C.F.R. § 801.109(b) (referencing "surgical instruments"). Moreover, surgical instruments are not purchased with a specific patient in mind, but rather are sterilized and reused on numerous patients. Under the

Respondent's interpretation of section 801.109(a), a hospital could not purchase a surgical instrument without a prescription. However, because surgical instruments are not purchased for a specific patient, a prescription for a surgical instrument could never exist. Thus, if the Respondent's theory was correct, a hospital could never purchase a surgical instrument. Hospitals do purchase surgical instruments and other medical supplies, however, demonstrating that the Respondent's theory is incorrect. Furthermore, the Court clearly understood the Department's overarching argument that a hospital does not need a prescription to purchase any supplies it needs, whether those supplies are prosthetic devices, surgical instruments, or bandages.

IV. The Court did not Err in Relying on the Department's Reference to a "Brace and Boot Shop" as an Example of a Retailer Whose Sales are Exempt Under § 12-36-2120(28)(a).

The Respondent asserts that the Court erred in relying on the Department's reference to a "brace and boot shop" as an example of a retailer whose sales are exempt under § 12-36-2120(28)(a). (Resp't Pet. Reh'g 13 – 15.) Other than stating the Court should not have relied on the Department's statement, the Respondent does not explain what point the Court overlooked or misapprehended. A reading of the Court's Order demonstrates that the Court clearly understood the Department's example and did not overlook or misapprehend any law, facts, or arguments. During oral argument in this matter, the Court asked the Department to give an example of a transaction that would be exempt as "a prosthetic device sold by prescription." The Department explained that a sale of a prosthetic limb from an orthotics and prosthetics shop, also known as a brace and boot shop, to an individual patient is an example of a transaction that is exempt under

§ 12-36-2120(28)(a).[1] The Department also referenced this example in its Brief on page 26. Notably, the Respondent did not take issue with this example in its Brief or during oral argument, but now would like to say that the Court improperly relied on this example. The Respondent has not put forth any statute, regulation, or court case disagreeing with the Department's assertion. Instead, the Respondent rests upon the bare assertion of "information and belief" that the Department's example is incorrect. Even if the Department's example was incorrect, though there is no evidence of such, it does not appear that the Court relied on the Department's example in reaching its conclusion. Instead, the Court reviewed section 801.109(a) and correctly determined that the regulation does not satisfy the first prong of Home Medical. Thus, no error exists as the Court did not rely on the brace and boot shop example in reaching its conclusion.

V. The Court Properly Held that the Record Lacked Substantial Evidence Supporting the Administrative Law Court's (ALC) Finding that Other Bone, Muscle, and Tissue Implants Replaced a Missing Part of the Body.

The Court properly held that the "record is devoid of any evidence to support the ALC's finding that other bone, muscle, and tissue implants replaced missing parts of the body." (Order 7.) The Respondent disputes this holding but offers no citation to evidence in the record contradiction the Court's holding. The Respondent cannot point to facts disputing this contention because no such facts exist in the record. Instead, the Respondent asserts the ALC can "make such a basic and logical conclusion under the

[1]The Respondent believes that the Department's example is incorrect. However, the Department has audited brace and boot shops and, based on the information provided during those audits, determined that the sales transactions satisfied the three prong test set forth in Home Medical.

facts of this case." (Resp't Pet. Reh'g 17.) Contrary to the Respondent's assertions, this "basic and logical conclusion" is not supported by substantial evidence. The Respondent fails to cite to any facts that support the ALC's finding or any legal authority for the proposition that the ALC can make "basic and logical" conclusions without any facts to support such conclusions. As the Court correctly explained, it may reverse a lower court's decision that is "clearly erroneous in view of the substantial evidence on the record as a whole." (Order 3.) (internal citations omitted). In this case, the record contained no evidence to support the ALC's conclusion. To that extent, the Court did not misapprehend or overlook any facts, law, or arguments relating to the other bone, muscle, and tissue implants.

VI. The Court Properly did not Reach the Issue Regarding Whether an Order Constitutes a Prescription.

In order to qualify for the exemption under § 12-36-2120(28)(a) as a "prosthetic device sold by prescription," the transaction must satisfy all three prongs set forth in Home Medical: "[1]the sale must require a prescription **and** [2] the device must actually be sold by prescription **and** [3] the device must replace a missing part of the body." 382 S.C. at 564, 677 S.E.2d at 587 (emphasis added). Thus, if any one prong is not satisfied, the transaction is not exempt. Here, the Court held that the Respondent failed to satisfy the first prong of Home Medical. Therefore, whether the Respondent satisfied the remaining two prongs is irrelevant. More significantly, the Court explicitly stated that it "[b]ecause we find the Hospital is unable to satisfy the first prong, we need not reach the second prong." (Order 7.) Since the Court did not need to determine whether the other two prongs were satisfied, it did not need to discuss whether an order constitutes a

prescription. Therefore, whether the Court misapprehended or overlooked any facts or law regarding the second prong is irrelevant since the Court did not need to reach that issue in order to reverse the ALC's decision.

VII. The Respondent's Citation to the State of Arkansas Department of Finance and Administration's Letter is Improper and Irrelevant.

In its Petition, the Respondent cites to a Revenue Legal Counsel Opinion from the Arkansas Department of Finance and Administration (Opinion).[2] (Resp't Pet. Reh'g 11, n. 5.) This Opinion is not in the record, nor was it discussed in the Respondent's Brief or at oral argument. The Department asserts that the Court should not consider this document, as such document is not properly before this Court, and the Respondent cannot now bring in information on a petition for rehearing that it failed to present to the lower court or during the appeal. See Kennedy, 349 S.C. at 352, 564 S.E.2d at 322 (the Court refused to consider the appellants previously unpresented evidence). Instead, if the Respondent chooses to assert that the Court misapprehended or overlooked facts regarding the transaction at issue, the Respondent must point to facts in the record to support its assertion.

Even if the Opinion was properly before the Court, which it is not, it is not clear why this Court should consider the Opinion. The Opinion is not relevant, it is not binding on this Court, it is hearsay, and it is not even persuasive as it does not address South Carolina law. The Opinion explains why a hospital's purchases of prosthetic devices are exempt under **Arkansas law**. Specifically, and contrary to South Carolina

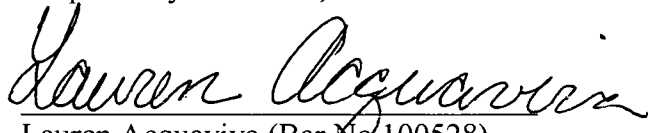
[2]It is not clear exactly why the Respondent cites to this opinion. It appears to be an attempt to explain why the sales at issue were to the Hospital, not the physician.

law, Arkansas has a tax rule that provides that "[a] prosthetic device that would be exempt if it could be purchased directly by a patient is exempt if the physician procures the device from the medical supplier on behalf of a specific patient." AK Revenue Legal Counsel Op. No. 20151106 (January 21, 2016) (citing AK Gross Receipts Tax Rule GR-38.2.H.4). South Carolina has no such rule. Moreover, Arkansas does not have a three-prong test like South Carolina. Specifically, Arkansas' exemption statute does not have an element wherein the sales transaction must require a prescription in order to be exempt. Thus, the analysis in the Opinion is irrelevant as Arkansas' law differs from South Carolina's law.

CONCLUSION

As explained above, this Court properly held that the ALC erred in finding section 801.109(a) satisfied the first prong of Home Medical. In so holding, the Court did not overlook or misapprehend any law, facts, or arguments. Therefore, the Court should deny the Respondent's Petition for Rehearing in this matter.

Respectfully submitted,



Lauren Acquaviva (Bar No. 100528)
Counsel for Litigation
Milton G. Kimpson (Bar No. 7917)
General Counsel for Litigation
P.O. Box 12265
Columbia, SC 29211-9979
Attorneys for Appellant
South Carolina Department of Revenue
(803) 898-5110
Lauren.Acquaviva@dor.sc.gov

Columbia, South Carolina
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HONORABLE SHIRLEY C. ROBINSON, ADMINISTATIVE LAW JUDGE

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Appellant 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, Tonie M. Miranda, do hereby certify that I have caused to be mailed postage pre-paid, a copy of the Department's Return to Petition for Rehearing in re: CareAlliance Health Services, d/b/a Roper St. Francis Healthcare, Respondent v. South Carolina Department of Revenue, Appellant, Trial Court Case No. 12-ALJ-17-0405-CC, Appellate Case No. 2014-001457 to John C. von Lehe, Jr., Esquire and Bryson M. Geer, Esquire, Nelson Mullins Riley & Scarborough, LLP, P.O. Box 1806, Charleston, SC 29402-1806, and Raymond P. Carpenter, Esquire, Raymond P. Carpenter and Associates, LLC, 625 Colonial Park Drive, Suite 201, Roswell, GA 30075 on this 9th day of June, 2016.

Tonie M. Miranda