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SC SUPREME COURT

THE STATE OF SOUTH CAROLINA  
In The Supreme Court

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APPEAL FROM THE ADMINISTRATIVE LAW COURT

Shirley C. Robinson, Administrative Law Judge

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

Appellate Case No. 2014-001457

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CareAlliance Health Services d/b/a Roper St. Francis                      Respondent,  
Healthcare, .....  
v.  
South Carolina Department of Revenue, .....                      Appellant.

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**RESPONDENT'S REPLY IN SUPPORT OF PETITION FOR REHEARING**

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Respondent CareAlliance Health Services d/b/a Roper St. Francis Healthcare ("Roper") respectfully submits the following Reply in Support of its Petition for Rehearing (the "Petition") and in response to Appellant South Carolina Department of Revenue's ("SCDOR") Return to Roper's Petition ("SCDOR's Return"). For the reasons presented in the Petition and hereinbelow, the Court should grant the Petition.

**I. The Relevant Federal Regulations and the South Carolina Pharmacy Code Clearly Impose a Requirement that the Sale of Certain Prescription Prosthetic Devices be To or On the Order of a Practitioner.**

In its Return, SCDOR states that Roper "failed to identify a single statute, regulation, case or agency ruling that says a hospital must have a prescription in

order to purchase a prosthetic device." Id. at p. 6. It also argues that the federal regulations cited by Roper are only "labeling" regulations and do not create a requirement that any devices be sold by prescription. Id. at p. 4.

As set forth in more detail in Roper's Petition, federal law requires a prescription for the sales of the Class II and III prosthetic devices at issue when sold to a hospital. Petition at pp. 5-10. Roper summarized the relevant federal regulations as well as the policy considerations behind this requirement in its Petition and will not repeat this law fully herein. Id. (citing 21 U.S.C. § 360j (e)(1) and 21 C.F.R. § 801.109(a)). Suffice it to say that federal law most certainly restricts the sale of devices that would be dangerous in the hands of the general public and requires that these devices be sold either directly to a practitioner or upon the order of a practitioner. See 21 C.F.R. § 801.109(a) and Petition at pp. 5-10. As a hospital is not a practitioner, it may only purchase Class II and III prosthetic devices upon the order of a practitioner.

That these restrictions are contained in labeling provisions does not diminish their relevance or the weight of their authority. Labeling requirements address the very important and necessary restrictions on the transfer of dangerous items sold in interstate commerce, and there is no question these regulations would cover the sales of the devices in question, which are shipped by the manufacturers to the Hospital in interstate commerce.

Moreover, South Carolina appears to follow this federal law, as it is required to do,<sup>1</sup> and has adopted it in the following sections of the South Carolina

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<sup>1</sup> 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. (Pendergast Aff. at ¶6(b), R. at 763). Although FDA regulations do provide an appeal process for

Pharmacy Code: (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*" (emphasis added) 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.*" (emphasis added).<sup>2</sup> Petition at pp. 6-7, n. 2. Indeed, the South Carolina Pharmacy Code adopts the very language from the federal regulation (21 C.F.R. § 801.109) that this Court now holds does not require a prescription. If the Court fails to review its ruling, the unintended consequence could well reach beyond the sales and use tax code and adversely affect compliance with the requirements of the Pharmacy Code. That these "labeling" regulations impose a requirement that certain devices be sold only to a physician or by a physician's order could not be stated more clearly than the South Carolina Pharmacy Code has done.<sup>3</sup>

Thus, Roper would respectfully request that the Court reconsider the relevance and importance of these federal regulations and the South Carolina Pharmacy

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states to request exemptions from such restrictions, South Carolina has not requested such an exemption. (*Id.* at ¶6(d), R. at 763).

<sup>2</sup> Roper also cited S.C. Private Rev. Op. # 01-4, which 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 the sales and use tax ... as medicines sold by prescription *since federal law requires that ... [TPN] solutions be sold by prescription when sold to the patient.*" (emphasis added).

<sup>3</sup> Roper's Petition also noted that the record in this case reflects the undisputed fact that the boxes in which the devices are shipped confirm this requirement (bearing the label "Rx Only", which Dr. McCrosson verified means that they may only be sold by prescription). Petition at p. 10.

Code and conclude that both federal law and the Pharmacy Code dictate that the sales of the prescription prosthetic devices at issue to a hospital do require a prescription.

**II. Whether the Devices at Issue were Sold to Physicians or the Hospital is Critical because Federal Law and the South Carolina Pharmacy Code Dictate that Sales to Hospitals Require Prescriptions Whereas Sales to Physicians Do Not.**

In its Petition, Roper stated that it appeared that the Court may not have understood that the devices at issue were sold to the Hospital and not to physicians (or "practitioners," the more general term used in the federal regulations and this Court's Order). Petition at pp. 10-11 (citing examples in the Order wherein the Court appeared to state that the sales at issue were to practitioners or discussed the law regarding sales to practitioners). In its Return, SCDOR states that "the Court clearly recognized that the transaction at issue was between the manufacturer/vendor and the Hospital" but asserts that "even if the Court considered the transaction to be that of manufacturer/vendor to physician, such does not change the outcome of the case . . . . SCDOR's Return at pp. 5-6.

SCDOR's assertion that it does not matter whether the Court understood that the sales at issue were to the Hospital is simply wrong. Focusing on the proper party, i.e. the Hospital, is absolutely critical to reaching the correct result in this case as federal law (which the South Carolina Pharmacy Code has adopted as discussed above) require a prescription for sales to a hospital whereas a sale to a practitioner does not require a prescription because the prescription is implied by the fact that the practitioner is placing the order. See supra § I and Petition at pp. 5-10 and 11-12 (citing, *inter alia*, 21 C.F.R. § 801.109(a) and Pendergast Dep. at 55:15- 56:1, R. at

281:15- 282:1). Thus, Roper would respectfully request that the Court reconsider the application of the federal regulations and the implications for compliance with the South Carolina Pharmacy Code discussed in § I above to this case in light of the fact that the sales at issue were to the Hospital and not to physicians.

**III. There is No Evidence in the Record to Support SCDOR's Brace and Boot Shop Example and therefore No Evidence in the Record that any Taxpayer Could ever Qualify under the Exemption Statute, which the Legislature Cannot have Intended.**

In its Petition, Roper asserted that the Court should not have relied on SCDOR's unsupported assertion that patients purchasing prosthetic devices from a brace and boot shop would qualify as support for the proposition that the exemption does cover some situations. SCDOR provided this example during oral argument in response to comments by the Court that appeared to indicate concern that under SCDOR's interpretation of the statute, no taxpayer could ever qualify for this exemption, which could not have been the Legislature's intent. Roper pointed out in its Petition that SCDOR had not referenced any regulation, revenue ruling or case law that would establish how a brace and boot shop could qualify under the terms of the statute and had not introduced any evidence in the record to support these requirements as to sales that take place at a brace and boot shop. Petition at pp. 13-15. More specifically, no evidence was presented that (a) devices sold by a brace and boot shop are FDA regulated devices that require a prescription for sale; (b) prescriptions are actually used in purchases made at a brace and boot shop; and (c) devices sold at a brace and boot shop replace a missing part of the body rather than a non-qualifying missing function.

Id. at 14.

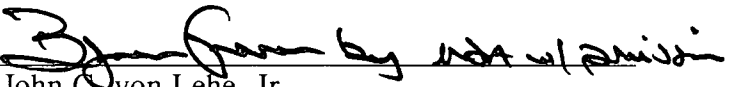
In its Return, SCDOR states that "Respondent has not put forth any statute, regulation, or court case disagreeing with the Department's assertion. Instead the Respondent rests upon the bare assertion of "information and belief" that the Department's example is incorrect. Even if the Department's example is 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." SCDOR Return at p. 9. SCDOR's position that parties can simply put evidence in the record via unsupported statements of purported facts in their appellate briefing or during oral argument on appeal and then claim that unless the other side puts forth evidence or law to the contrary, then such statements can properly be relied upon would turn the rules of evidence on their head. The time to place facts in the record is during the trial of a matter. SCDOR failed to do so and does not cite to any evidence in the record or any law that would support its brace and boot shop example. Therefore, Roper would respectfully request that the Court reconsider its ruling in light of the fact that there is no evidence in the record to support the brace and boot shop example and thus no evidence that the exemption statute would apply to any prosthetic device under SCDOR's interpretation of the statute, which cannot have been the Legislature's intent.

#### CONCLUSION

As set forth above and in its Petition previously filed, Roper respectfully requests that this Court grant its Petition for Rehearing as the Court's Opinion in this matter overlooked or misapprehended several factual and legal matters and also conflicts with federal law and the South Carolina Pharmacy Code, and thus, a rehearing and/or entry of a new Opinion is warranted.

Respectfully submitted,

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June 23, 2016

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**CERTIFICATE OF SERVICE**

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I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for CareAlliance Health Care 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 delivering a copy of the same, via U.S. Mail to the following address(es):

Pleadings:

**RESPONDENT'S REPLY IN SUPPORT OF PETITION  
FOR REHEARING**

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