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SC SUPREME COURT

THE STATE OF SOUTH CAROLINA
In The Supreme Court

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 Respondent,
Healthcare,.....

v.

South Carolina Department of Revenue, ... Appellant.

PETITION FOR REHEARING

Pursuant to Rule 221(a) of the South Carolina Appellate Court Rules, Respondent, CareAlliance Health Services d/b/a Roper St. Francis Healthcare, ("Roper" or the "Hospital") hereby files this petition for rehearing of the above-referenced matter, which resulted in Opinion number 27627 filed April 20, 2016 (the "Opinion"). This Petition for Rehearing is based on the grounds that the Court overlooked and/or misapprehended several matters of fact and law and that the opinion conflicts with federal law.

BACKGROUND

As this Court is aware, the central issue in this matter is whether the Hospital's purchases of certain prescription prosthetic devices (primarily orthopedic reconstructive implants such as artificial hips, knees and shoulders) are exempt from sales and use tax under S.C. Code Ann. §12-6-2120(28) because they are "sold by prescription."

The parties stipulated that all of the prosthetic devices at issue are Federal Food and Drug Administration ("FDA") regulated Class II and Class III prescription prosthetic devices. (Joint Stipulations of Fact at ¶6, R. at 779). These devices come in boxes that bear a label stating "RX only," which means they may only be sold by prescription. (Deposition of John McCrosson, M.D. dated 6/13/13 ("McCrosson Dep. II") at 40:6-41:19, R. at 252:6-253:19 and Affidavit of John McCrosson, M.D. ("McCrosson Aff.") at ¶3, R. at 760). The evidence in the record established that the sales transactions between the various manufacturers and the Hospital for these devices take place in Roper hospital operating rooms. (McCrosson Dep. II at 13:2-17 and 44:1- 45:10, R. at 237:2-17; and 256:1- 257:10; Deposition of Brett M. Baker, M.D. dated 7/2/13 ("Baker Dep.") at 15:20- 17:12, R. at 140:20- 142:12). As Dr. McCrosson testified, he issues an oral order for the Hospital's purchases of the orthopedic prosthetic devices he 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 247:7-24). Dr. McCrosson further testified that his order for an orthopedic prosthetic device is a prescription as required by law. (Id. at 28:22- 29:11, R. at 809:22-810:11). The testimony established that

Roper purchased all of the orthopedic prosthetic devices at issue upon the prescription or order of physicians like Dr. McCrosson, who were board certified and authorized to prescribe such devices in their practices. (Affidavit of Charles Trescott Ferguson ("Ferguson Aff.") at ¶3(b), R. at 759; McCrosson Aff. at ¶4, R. at 760).

The parties also agreed that the sales transactions at issue are between the manufacturer and the hospital. (Ferguson Aff. at ¶2 and 3(b), R. at 759; SCDOR Final Brief at p.10 (stating that "[t]he transactions at issue in this matter involve the sale of a prosthetic device by a manufacturer to a hospital")). When the manufacturer's representative brings a device to the operating room, it is owned by the manufacturer (Deposition of Charles Trescott Ferguson ("Ferguson Dep.") at 11:15- 12:5, R. at 161:15- 162:5; Baker Dep. at 15:20- 17:12, R. at 140:20- 142:12). 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.¹ (McCrosson Dep. II at 13:2-17 and 44:1- 45:10, R. at 237:2-17 and 256:1- 257:10; and Baker Dep. at 15:20- 17:12, R. at 140:20- 142:12.) The physicians do not purchase these devices. The parties agreed and the record is clear that the Hospital purchased these devices.

¹ This prescription is then memorialized in writing in a number of ways, including, in the hospital's computer system, by a sticker on the box of the implant 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 247:25- 248:20; see also McCrosson Aff. at ¶5, R. at 760; Baker Aff. at ¶6, R. at 757.)

LEGAL ARGUMENT

I. Background on the South Carolina Sales and Use Tax Exemption for Prosthetic Devices "Sold by Prescription"

As previously briefed to this Court, 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 parties agree that a hospital can qualify for this exemption if it meets the requirements of the exemption statute. See SCDOR Final Brief at p. 8 (stating that "if the hospital's purchases of prosthetic devices are retail sales, such are subject to tax *unless specifically exempted*" but arguing that Roper does not meet the requirements of the exemption statute in this case)(emphasis added).

Although the South Carolina sales tax exemption statute does not elaborate on the term "sold by prescription," case law referencing SCDOR revenue rulings states 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. This Court found that Roper failed to satisfy the first prong of this test, i.e. that the sales at issue must require a prescription, and then concluded that it "need not reach the second prong." Order at p. 7.

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 24.) 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 261:22- 264:4 for discussion of several dictionaries defining prescription as the lawful order of a physician or something similar.)

The next question is whether the sale of the Class II and III prosthetic devices at issue to Roper requires a prescription. As will be discussed below, federal law governs this inquiry. See infra § II and 21 U.S.C. § 360j (e)(1).

II. This Court Erred in Failing to Find that Federal Law Requires that the Sale of a Class II or Class III Device to a Hospital Must be on the Order or Prescription of a Physician.

This Court erred in failing to find that federal law requires that the sale of a Class II or III device to a hospital must be on the order or prescription of a physician. 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). See also Affidavit of Mary K. Pendergast ("Pendergast Aff.") at ¶6(a), R. at 763 (stating 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).

The Secretary has exercised this authority 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 763.²

² 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* ...

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).³

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 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

as medicines sold by prescription since federal law requires that ... TPN solutions be sold by prescription when sold to the patient."

³ 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 763.

appropriate, warn his or her patient.⁴ As the ALC noted, the "overarching purpose of the regulation is to require a gate-keeper to protect consumers from purchasing potentially dangerous products." See Reconsideration Order at 2, R. at 24.

Based on the above law, the ALC properly concluded that federal law requires a prescription for the sales of the Class II and III prosthetic devices at issue to a hospital. In its Order, however, this Court held otherwise:

By its terms, [§ 801.109(a)] allows Class II or Class III prescription prosthetic devices to be sold directly to a practitioner, on the order of a practitioner, or on the prescription of a practitioner. *Id.* Thus, it envisions a sale can occur *to a practitioner*, with no prescription or order requirement. We therefore reject the Hospital's assertion and the ALC's finding [that] the devices at issue can *only* be sold by prescription. Instead, the regulation allows for a sale directly between a vendor and *practitioner, as an agent of the Hospital.*

The ALC's broad interpretation of the federal regulation is fundamentally at odds with the plain reading of the regulation and the strict construction afforded a tax exemption. Accordingly, we hold the ALC erred in finding section 801.109(a) satisfies the first prong of *Home Medical*. The statute expressly allows a *practitioner* to be in possession of a prosthetic device without a prescription or order. We therefore reverse the ALC because these devices do not require a prescription for the purpose of qualifying for a tax exemption.

Order at p. 6-7 (emphasis as to "only" in original; all other emphasis added).

As will be discussed below, the Court appears to misunderstand that the sales at issue are not to practitioners, but rather are to the Hospital. See infra § III. This factual error, in turn, may have led the Court to mistakenly conclude that prescriptions

⁴ The law is also consistent with the testimony of Mary Pendergast, former Deputy Commissioner and Senior Advisor to the Commissioner of the FDA. See Roper's Final Brief, Statement of Facts, at pp. 5-6 (summarizing her testimony).

are not required for the sales at issue, which are to a *hospital*. The federal law set forth above clearly requires a prescription for such sales. It provides that the Class II and III devices must be labeled unless they are (a) "to be sold only to . . . [a] practitioner . . ." (the situation this Court appears to have addressed), or (b) "to be sold only . . . on the prescription or other order of such practitioner. . . ." (which applies to all cases, like the one here, where the sale is not to a practitioner). Therefore, the Court should have concluded that federal law requires that sales to a hospital of the prescription prosthetic devices at issue here may only be sold on the prescription or order of a physician.

In its Order, this Court also states that §801.109 addresses the labeling requirements of regulated devices. Order at p. 6. To the extent the Court intends to indicate that labeling requirements have no relevance to this matter involving South Carolina sales and use tax statutes, this would be a mistake. The "sold by prescription" exemption statute has been interpreted to require that the sale of the prosthetic devices at issue must require a prescription. See Home Medical, 382 S.C. at 563-564, 677 S.E.2d at 586-587. Whether a device requires a prescription is governed by federal law as set forth above. 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). 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 763). Thus, the federal law is indeed relevant to this sales tax exemption matter. It requires that a physician like Dr. McCrosson issue a prescription for the prosthetic devices at issue in order for the sale to the Hospital to take place.

Finally, the evidence and testimony in this case established that the devices at issue are sold in packages that bear the label "RX only," which means that they may only be sold by prescription. See McCrosson Dep. II at 40:6-41:19, R. at 252:6-253:19 and McCrosson Aff. at ¶3, R. at 760). This Court now holds that such devices do not require a prescription in spite of the federal mandate and in spite of the label that is required to be placed on the boxes containing these devices for shipment in interstate commerce.

Roper would respectfully request that this Court reconsider the above facts and federal law as applied to the sale of Class II and III devices *to a hospital* and rule that such sales do require a prescription.

III. This Court Appears to Have Misunderstood that the Sales at Issue Were Not to Physicians but Rather Were to the Hospital.

In its Order, this Court appears to misunderstand that the sales at issue were not to physicians but rather were to the Hospital. See e.g. Order at p. 7 (stating that the regulation allows sales to a "*practitioner* as an agent of the Hospital" and stating that "[t]he statute expressly allows a *practitioner* to be in possession of a prosthetic device without a prescription or order.") (emphasis added). However, the facts in the record establish that all sales at issue were to the Hospital. Ferguson Aff. at ¶2 and 3(b). Dr. McCrosson did not act as agent for the Hospital in purchasing the subject devices. Instead, he only issued the necessary prescriptions for the sales to take place. Even if a physician had acted as an agent for the Hospital in making these purchases, the Hospital (i.e. the principal) made all purchases of the devices at issue and paid for all of the devices. Id. Even SCDOR agreed that the Hospital made the

purchases at issue. See SCDOR Final Brief at p.10 (stating that "[t]he transactions at issue in this matter involve the sale of a prosthetic device by a manufacturer to a hospital").⁵

IV. Whether a Sale to a Practitioner Requires a Prescription is Irrelevant as that Issue was Not Before the Court.

After mistakenly finding that the devices in question were sold to practitioners, the Court then concluded that purchases by a physician for his or her own use do not require a prescription under the relevant federal regulations. Order at p. 7. It is true that § 801.109(a) does not explicitly require a prescription for a sale to a practitioner (versus a hospital); however, a prescription is implicit and necessarily used due to the fact that the practitioner is ordering it for himself for his own use. As Mary Pendergast, former Deputy Commissioner and Senior Advisor to the Commissioner of the FDA, explained, if a physician is purchasing the device him or herself for his or her own use, then a prescription is not explicitly 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*

⁵ In a Revenue Legal Counsel Opinion for the Arkansas Department of Revenue (a copy of which is attached hereto as Ex. A and which can be found on the Department's website), the discussion in Question Three is on all points with this issue. That opinion discusses several situations involving sales of prosthetic device to hospitals where the physician procures the device via a prescription for a specific patient and whether they are exempt under an exemption statute that requires that the device be sold to a specific patient pursuant to prescription written prior to sale. It states as follows: "Many prosthetic devices cannot be purchased directly by a patient. A prosthetic device that would be exempt if it could be purchased directly by the patient is exempt if the physician procures the device from a medical supplier on behalf of a specific patient." The opinion then concludes: "Both Scenario 1 and 2 involve prosthetic devices to be purchased on behalf of specific patients pursuant to a prescription/work order written before sale and therefore are exempt...." Arkansas Revenue Legal Counsel Opinion no. 20151106 at p. 2-3 (January 21, 2016).

physician. (Pendergast Dep. at 55:15- 56:1, R. at 281:15- 282:1). She further elaborated as follows: "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." Id.

More importantly, the factual scenario of a sale to a practitioner was not before this Court and is irrelevant to this matter. SCDOR has never argued that the sales at issue were to practitioners, and the parties are in agreement that the Hospital made the purchases. See supra, §III. The only issue here is whether sales of Class II and III prosthetic devices *to a hospital* require a prescription. As was discussed in §II above, federal law requires a prescription for all such sales.

V. The Court Erred in Equating the Sale of Class II and Class III Prescription Prosthetic Devices with Non-Prescription Supplies.

This Court appears to mistakenly equate the sale of Class II and III prosthetic devices to that of non-prescription supplies like bandages. See Order at p. 4. No one argues that supplies are dangerous or require a prescription, and neither the Legislature nor SCDOR drew this parallel. Although the Court's Order states that SCDOR relied on S.C. Code Reg. §117-308.3 to make this argument, said argument does not appear to be in SCDOR's Briefs. Rather SCDOR cited that regulation for the general proposition that sales to hospitals are generally considered to be retail sales (and thus subject to tax unless specifically exempt) (see SCDOR's Final Brief at pp. 9 and 13). Additionally, this analysis is flawed because the two items are demonstrably different in that supplies like bandages are unregulated items with no restrictions on their sale, unlike the federally regulated prescription prosthetic devices at issue here.

Moreover, the Legislature granted an exemption from sales and use tax for sales of prosthetic devices sold by prescription (which must also replace a missing part of the body) and not for non-prescription supplies like bandages. Clearly, devices that can cause harm to the public as determined by the FDA are in a completely different category than the supplies that do not require a prescription.

To the extent the Court was citing to S.C. Code Reg. §117-308.3 and 308.8 as support for the proposition that the Hospital need not have a prescription to purchase the devices at issue, this would also be erroneous. These regulations simply provide that doctors and hospitals are consumers of supplies and equipment used in providing services to patients and such sales are considered retail sales subject to tax unless specifically exempted. These regulations do not address the requirements for the sale of Class II and III devices, and they cannot and do not alter federal law, which requires that a prescription be used to purchase such devices. See supra §II.

VI. The Court Erred in Relying Upon SCDOR's Unsubstantiated Statement at Oral Argument that the Exemption at Issue was Intended for Patients who Purchase a Prosthetic Device from a Brace and Boot Shop.

In its Order, this Court stated “Moreover, the DOR suggested the exemption was intended for individual patients who purchase a prosthetic device with a prescription from a brace and boot shop, not for a hospital or doctor rendering services by implanting prosthetic devices.” Order at p. 5. During oral argument, this Court seemed rightfully concerned 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. However, the Court then appears to have relied on SCDOR's bald

assertion that patients purchasing prosthetic devices from a brace and boot shop would qualify as support for the proposition that the exemption does apply in some situations.

First, SCDOR pointed to no regulation, revenue ruling or case law that establishes how a brace and boot shop could qualify under the terms of the statute. As previously mentioned, in order for a prosthetic device to qualify for the exemption, Home Medical requires that (a) the sale must require a prescription, (b) the device must actually be sold by a prescription, and (c) the device must replace a missing part of the body (versus replacing a missing function). Home Medical, 382 S.C. at 563-64, 677 S.E.2d at 586-87. There is not a shred of evidence in the record to support these requirements as to sales that take place at a brace and boot shop. 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;⁶ and (c) devices sold at a brace and boot shop replace a missing part of the body rather than a non-qualifying missing function. Furthermore, upon information and belief, none of those statements, if made, would be true.

It is difficult to comprehend how one could determine that a sale to a hospital of a prescription device that complies with the requirements of C.F.R. §

⁶ Indeed, upon information and belief, no one is employed at a brace and boot shop that is qualified to be in possession of Class II and III prescription prosthetic devices, and upon further information and belief, brace and boot shops are not registered with the South Carolina Pharmacy Board or the Secretary of Health and Human Services as retailers that may possess and distribute such devices. Certainly there is no evidence in the record that establishes that they are so registered. And if not properly registered, a brace and boot shop would be in violation of federal and state law if it possessed these devices. See S.C. Code Ann. §40-43-140(A)(2) and §40-43-83(A); 21 U.S.C. §360.

801.109 (i.e. that a sale to a hospital must be made on the prescription or order of a physician), where a prescription was, in fact, used and where the device replaced a missing part of the body does not qualify as an exempt “prosthetic device sold by prescription,” but a sale of unknown items at a brace and boot shop that have not been established to require a prescription, where no prescription has been shown to be used and where there is no evidence that such items replace a missing part of the body would be eligible for the exemption. There are simply no facts in the record that would support such an interpretation.

VII. To the Extent the Court Found that an Order is Not a Prescription, Such a Finding Would be Erroneous.

To the extent that the Court's Order could be interpreted to find that because the language in the federal regulation says “prescription or other order,” a prescription is not required because an order could always be used, this would be erroneous. 21 C.F.R. § 801.109(a)(emphasis added). First, 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 prescription means anything other than the plain and ordinary meaning that it is the lawful order of a physician. See McCrosson Aff. at ¶4, R. at 760 (stating that his oral order is a prescription). The regulation is simply using these two synonymous terms interchangeably. Additionally, such an argument, which SCDOR made and which the ALC rejected below, flies in the face of common sense and would result in no device ever being tax exempt under this statute. 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 2-3, R. at 24-25. Even the hypothetical brace and boot shop example, which was provided by SCDOR during oral argument as an example of the type of transaction for which the Legislature intended the exemption to apply, would be easily disqualified by SCDOR. Assuming that prescription prosthetic devices that replace a missing part of the body were sold there pursuant to prescriptions (which, as previously discussed in §VI, is not supported by any evidence in the record and, upon information and belief, is not accurate), SCDOR could argue, as it has in this case, that an "order" of a physician could always be used to purchase such devices instead of a "prescription," and, thus, a prescription is not required.

SCDOR also argued that interpreting prescription and order synonymously would mean that federal regulations always require a prescription for the sale of regulated prosthetic devices, which would render the first element of the test meaningless as it would always be satisfied. SCDOR Brief at 24. This critique has no merit. If the FDA does not designate a prosthetic device as a *prescription* device, i.e. one that requires a prescription to be sold, then the first prong of the test would not be met. Thus, for example, 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 279:10-12) such that no prescription is required for its sale, then that prosthetic device would not qualify for this exemption.

The FDA regulation is promulgated to protect the public from prosthetic devices that are dangerous in the hands of the general public. It is SCDOR that adopted the test holding that a sale of a prosthetic device must "require" a prescription in order to qualify for the exemption. SCDOR cannot now complain that FDA regulations that limit sales of dangerous devices (i.e. Class II and III devices) to prescription would always qualify for the exemption from sales tax.

VIII. The Court Erred in Finding that the other Bone, Muscle and Tissue Implants Did Not Replace a Missing Part of the Body.

This Court found 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 contention 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

As set forth above, 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 thus, a rehearing and/or entry of a new Opinion is warranted.

Respectfully submitted,

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: Bryson M. Geer, by Blake T. Williams,
John C. von Lehe, Jr. *with permission*
SC Bar No. 5719
Bryson M. Geer
SC Bar No. 13606
Nelson Mullins Riley & Scarborough LLP
151 Meeting Street / Sixth Floor
Post Office Box 1806 (29402-1806)
Charleston, SC 29401-2239
(843) 853-5200

Raymond P. Carpenter, Esq.
(admitted pro hac vice)
E-Mail: rcarpenter@rclaw.us.com
Raymond P. Carpenter and Associates, LLC
625 Colonial Park Drive, Suite 201
Roswell, GA 30075
(770) 998-2722

Attorneys for Respondent

Charleston, South Carolina
May 20, 2016



STATE OF ARKANSAS
**Department of Finance
and Administration**

REVENUE LEGAL COUNSEL

Post Office Box 1272, Room 2380
Little Rock, Arkansas 72203-1272
Phone: (501) 682-7030
Fax: (501) 682-7599
<http://www.arkansas.gov/dfa>

January 21, 2016



Re: Gross Receipts Tax – Prosthetic Device
Opinion Number 20151106

Dear [REDACTED]

Your letter dated November 5, 2015, has been referred to me for response. You requested a written legal opinion letter confirming that the sale of your company's [REDACTED] meets the definition of a sales and use tax exempt prosthetic device pursuant to Ark. Code Ann. § 26-52-433(a)(2), Ark. Code Ann. § 26-52-433(b)(6)(A), and Arkansas Regulation GR-38.2.H.4. You described the [REDACTED] as a "permanent adjustable transprostatic implant placed by a healthcare provider during a cystourethroscopy." The implant is described as a "permanent implant made up of standard surgical implantable materials; a nitinol capsular tab, a stainless steel urethral tab, and polyester suture that connect the two tabs." The implant and the housing are sold together as an indivisible unit and must be prescribed by a physician. The housing is "single use; it is not reloadable or reusable." Although the housing is designed to couple to a urethroscope, your letter notes that your inquiry addresses only the [REDACTED] and not the urethroscope.

I will address the question of whether the device meets the definition for the exemption by each section of code or rule.

Question 1: Does the [REDACTED] meet the definition of a sales and use tax exempt prosthetic device pursuant to Ark. Code Ann. § 26-52-433(a)(2)?

Arkansas Gross Receipts tax (sales tax) is applicable to the sale of all tangible personal property unless the sale is specifically exempted from the tax. *See* Ark. Code Ann. § 26-52-301. The Arkansas Supreme Court, when reviewing tax exemption cases, has stated that taxation is the rule and exemption is the exception. *Cheney v. Georgia-Pacific Paper*, 237 Ark. 161, 371 S.W.2d 843 (1963). Ark. Code Ann. § 26-52-433(a)(1) reads as follows:

(a)(1) Gross receipts or gross proceeds derived from the rental, sale or repair of durable medical equipment prescribed by a physician, mobility enhancing equipment prescribed by a physician, a prosthetic device prescribed by a physician, and disposable medical supplies prescribed by a physician shall be exempt from all state and local sales and use taxes.

EXHIBIT A

According to Ark. Code Ann. § 26-52-433(a)(2), the exemption applies only "to a...prosthetic device sold to a specific patient pursuant to a prescription written before the sale." Ark. Code Ann. § 26-52-433(b)(5) provides that a prescription is "an order, formula, or recipe issued in any form and transmitted by an oral, written, electronic, or other means of transmission by a duly licensed physician or practitioner authorized to issue prescriptions under Arkansas law."

Because the [REDACTED] is a prosthetic device intended to be purchased on behalf of patients pursuant to a prescription/chart order written before sale it meets the statutory definition of a sales and use tax exempt prosthetic device pursuant to Ark. Code Ann. § 26-52-433(a)(2).

Question 2: Does the [REDACTED] meet the definition of a sales and use tax exempt prosthetic device pursuant to Ark. Code Ann. § 26-52-433(b)(6)(A)?

Ark. Code Ann. § 26-52-433(b)(6)(A) defines "prosthetic device" as a replacement, corrective, or supportive device worn on or in the body to: (1) artificially replace a missing portion of the body; (2) prevent or correct physical deformity or malfunction; or (3) support a weak or deformed portion of the body. According to your letter, the [REDACTED] is designed to correct a physical deformity in the male urinary tract known as Benign Prostatic Hyperplasia ("BPH"). BPH involves an increase in certain cells in the prostate gland that surrounds the urethra. The increase in cells results in the formation of large nodules that can deform the urethra and increase resistance to flow of urine from the bladder.

Because the [REDACTED] is designed to correct this deformity or malformation, it does meet the definition of a sales and use tax exempt prosthetic device pursuant to Ark. Code Ann. § 26-52-433(b)(6)(a).

Question 3: Does the [REDACTED] fall under Arkansas Gross Receipts Tax Rule GR-38.2.H.4 as exempt from tax?

Arkansas Gross Receipts Tax Rule GR-38.2.H.4 states the following:

Many prosthetic devices cannot be purchased directly by a patient. A prosthetic device that would be exempt if it could be purchased directly by the patient is exempt if the physician procures the device from the medical supplier on behalf of a specific patient. A prosthetic device that is purchased for use or consumption in the performance of nontaxable medical services or otherwise not purchased on behalf of a specific patient does not meet the requirements of Ark. Code Ann. § 26-52-433.

Your letter posits four scenarios in which the [REDACTED] is sold to hospitals. The first scenario, direct delivery, involves a direct sale by a [REDACTED] salesperson that hand delivers the item to the doctor or medical provider on a procedure date for a specific patient. All sales under this scenario would be individually billed to a doctor's practice, hospital or medical center in an amount corresponding to a written prescription or hospital work order. The second scenario, direct shipment, is a direct sale of [REDACTED] ordered by the doctor and shipped by [REDACTED] directly from one of its facilities to the doctor, hospital or medical

center in advance of a procedure date for a specific patient. All sales under this scenario would be individually billed as described in Scenario 1. Both Scenario 1 and 2 involve prosthetic devices to be purchased on behalf of specific patients pursuant to a prescription/work order written before sale and therefore are exempt from tax under Rule GR-38.2.H.4 and the previously discussed applicable statutes.

The third scenario discussed in your letter is consignment. Your letter describes the consignment process as having the [REDACTED] products "stored at the customer site and title is retained by [REDACTED] until a purchase order is issued by a specific doctor with a written prescription/hospital work order included with that purchase order. On the prescription/hospital work order is the name of the specific patient receiving the implant[s]. At that point, the products are removed from [REDACTED] consignment inventory and transferred to the hospital/medical provider. [REDACTED] would retain in its files a copy of the prescription or hospital work order to support such invoice."

In order to demonstrate [REDACTED] entitlement to the exemption, this office requests that [REDACTED] keep a spreadsheet that contains the following information:

- a. Invoice date;
- b. Hospital/medical provider name;
- c. Invoice number;
- d. Description of the item – which will match the item description on the invoice;
- e. Item price, state and local taxes paid;
- f. Service date;
- g. Patient name;
- h. Doctor name; and
- i. Patient ID.

In order to support a finding that these devices are exempt under the consignment scenario no consideration can be charged or paid between the provider and supplier until after a prescription is issued and an item withdrawn from consignment inventory.

The fourth scenario in the letter involves all other sales of the [REDACTED] to a doctor's practice, hospital or medical center, including bulk sales to be held in inventory by the medical provider. These are taxable transactions and, according to your letter, not within the scope of this letter ruling request.

In accordance with Arkansas Gross Tax Rule GR-75, this opinion is based upon my understanding of the facts as set out in your inquiry and as current Arkansas laws and rules govern those facts. Any change in the facts or law could result in a different opinion. This opinion will not be binding upon the Department for any topic not specifically addressed herein. The taxpayer may seek a supplemental opinion should it desire guidance in any topic not addressed within this opinion. Please be advised that this opinion may only be binding upon the Department for three (3) years from the date of issuance. See Arkansas Gross Receipts Tax Rule GR-75,
http://www.dfa.arkansas.gov/offices/policyAndLegal/Documents/et2008_3.pdf.

Sincerely,

Mary Kathryn Williams
Revenue Legal Counsel

CERTIFICATE OF SERVICE

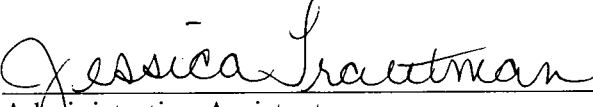
I, the undersigned Administrative Assistant of the law offices of Nelson Mullins Riley & Scarborough LLP, attorneys for CareAlliance Health Care Services d/b/a Roper St. Francis Healthcare, do hereby certify that I have served all counsel in this action with a copy of the pleading(s) hereinbelow specified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

Pleadings:

RESPONDENT'S PETITION FOR REHEARING

Counsel Served:

Lauren Acquaviva
Milton G. Kimpson
Counsel for Litigation
Office of General Counsel for Litigation
South Carolina Department of Revenue
PO Box 12265
Columbia, SC 29211


Administrative Assistant

May 20, 2016

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