North Carolina Department of Revenue

Pat McCrory
Governor

Lyons Gray
Secretary

August 19, 2014

FEIN: [redacted]

[redacted]

Attention: [redacted]

Re: [redacted]
Private Letter Ruling Request

Dear Mr. [redacted]

We have the Form NC-PLR, Request for Private Letter Ruling, remittance of $5,000.00, your letter dated February 27, 2014, and the remaining information you submitted by electronic mail on July 29, 2014. You have inquired as to your above-referenced client's North Carolina sales and use tax liability on its transactions in this State.

You advise that your client, [redacted] ("[redacted]"), "is a [redacted] company dedicated to the development and commercialization of [redacted] ["[redacted] therapy"] for the treatment of cancer patients with solid tumors. [redacted]

. . . . [redacted]

."

"There are three primary components to the [redacted] therapy:

- An electrical field generator, connection cables, a portable battery, power supply, rack and a power cord.
- INE transducer arrays.
- Ancillary items and accessories consisting of boxes, [redacted] bags, operations manuals and self-exchange kits.

The therapy is designed for continuous use throughout the day – the patient is able to maintain a normal daily routine while treating the disease.

- The therapy delivers non-invasive alternating electric fields through insulated arrays that are attached to the mechanism and placed directly on the skin in the region surrounding the tumor. Typically the arrays are removed and replaced two to three times per week. The arrays are replaced to ensure sufficient contact with the patient's skin.

- The components of the therapy are small, weighing six pounds and are powered by a rechargeable battery in a bag that is carried by the patient so they maintain mobility.
- The system can be plugged in while the patient is stationary.
- Patient pays a monthly fee for the therapy which is one consolidated charge that includes all equipment and transducer arrays.
- Around the clock technical support is included in the fees."

A certified physician must write a prescription for a patient and submit it to [redacted] shipping facility in [redacted] "The prescription is filled and the components of the therapy are shipped to the closest local technical support staff specialist or to the certified physician's office. The patient will receive an agreement to review and sign once they are trained how to apply the therapy themselves. The technical staff and the certified physician are trained on how to administer the [redacted] therapy to the patient in advance."

The local technical staff deliver the components to the patient the day he starts treatment, and "they train and educate the patient on the proper way to administer the treatment and the technical aspects of [redacted] therapy. The patient is provided with a user manual and technical support phone number. The patient then receives additional training and guidance and treatment initiation from their physician. The ongoing care of the patient and the medical assessments are conducted by the treating physician. . . ."

You have provided a copy of the [redacted] System Service Agreement, which provides that a patient pays a "rental fee" for the components of the therapy (the "System"). The System includes the electric field generator and the INE transducer arrays. "The rental fee for the System, including use of the [electric field generator], related power supplies/accessories and Arrays for 30 days is [redacted]." You have advised that [redacted] monthly fee includes any additional transducer arrays a patient may need.

N.C. Gen. Stat. § 105-164.3 provides that the term "[s]ale or selling" means "[t]he transfer for consideration of title, license to use or consume, possession of tangible personal property or digital property or the performance for consideration of a service. The transfer or performance may be conditional or in any manner or by any means. The term includes . . . [a] lease or rental. . . ." N.C. Gen. Stat. § 105-164.3(17) provides the term "[l]ease or rental" means "[a] transfer of possession or control of tangible personal property for a fixed or indeterminate term for consideration. . . ."

N.C. Gen. Stat. § 105-164.13(12)a provides an exemption from sales and use tax for the sale at retail and the use, storage, or consumption in this State of prosthetic devices for human use. A "[p]rosthetic device" is defined in N.C. Gen. Stat. § 105-164.3(30b) as "[a] replacement, corrective or supporting device worn on or in the body that meets one of the conditions of this subdivision. The term includes repair and replacement parts for the device.

a. Artificially replaces a missing portion of the body.
b. Prevents or corrects a physical deformity or malfunction.
c. Supports a weak or deformed portion of the body."

N.C. Gen. Stat. § 105-164.13(12)c provides an exemption from sales and use tax for the sale at retail and the use, storage, or consumption in this State of durable medical equipment sold on prescription. N.C. Gen. Stat. § 105-164.3(8b) defines the term "[d]urable medical equipment" as "[e]quipment that meets all of the conditions of this subdivision. The term includes repair and replacement parts for the equipment. The term does not include mobility enhancing equipment.

a. Can withstand repeated use.
b. Primarity and customarily used to serve a medical purpose.
c. Generally not useful to a person in the absence of an illness or injury.
d. Not worn in or on the body."

N.C. Gen. Stat. § 105-164.13(12)d. provides an exemption from sales and use tax for the sale at retail and the use, storage, or consumption in this State of durable medical supplies sold on prescription. N.C. Gen. Stat. § 105-164.3(8c) defines the term "[d]urable medical supplies" as "[s]upplies related to use with durable medical equipment that are eligible to be covered under the Medicare or Medicaid program."

With respect to your client's income tax treatment of the items included in the [redacted] therapy it rents to patients, you have advised that all components of the [redacted] System are considered fixed assets, except for the INE transducer arrays, which are "treated as inventory and expensed through cost of goods sold." Based on the information you have provided, it is our opinion that [redacted] rental of the [redacted] Therapy and transducer arrays to a patient are a rental of durable medical equipment and durable medical supplies. Such rentals on prescription to patients are exempt from sales and use tax under the provisions of N.C. Gen. Stat. §§ 105-164.13(12)c and (12)d. N.C. Gen. Stat. § 105-164.3(29) defines "[p]rescription" as [a]n order, formula, or recipe issued orally, in writing, electronically, or by another means of transmission by a physician, dentist, veterinarian, or another person licensed to prescribe drugs." [redacted] must keep sales records and the prescription in order to substantiate any such exempt sales.

This ruling is based solely on the facts submitted to the Department of Revenue for consideration of the transactions described. If the facts and circumstances given are not accurate, or if they change, then the taxpayer requesting this ruling may not rely on it. If a taxpayer relies on this ruling and the Department discovers, upon examination, that the fact situation of the taxpayer is different in any material aspect from the facts and circumstances given in this ruling, then the ruling will not afford the taxpayer any protection. It should be noted that this document is not to be cited as precedent and that a change in statute, a regulation, or case law could void this ruling.

If you have any questions, you may reach me at the number listed at the bottom of the first page of this letter.

Very truly yours,

[redacted]
Administration Officer
Sales and Use Tax Division

[redacted]

cc: [redacted], Director of Sales and Use Tax Division