COLORADO
Department of Revenue
Taxation Division

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PLR-14-007

October 20, 2014

XXXXXXXXXXXXXXX
Attn: XXXXXXXXXXX
XXXXXXXXXXXXXXX
XXXXXXXXXXXXXXX
XXXXXXXXXXXXXXX

Re: Cancer Treatment Therapy

Dear XXXXXXXXXX,

You submitted on behalf of XXXXXXXXXXX ("Company") a request for a private letter ruling to the Colorado Department of Revenue ("Department") pursuant to Department Rule 24-35-103.5. This letter is the Department's private letter ruling.

Issue

Is the rental of Company's cancer treatment therapy subject to Colorado sales or use tax?

Conclusion

The rental of Company's cancer treatment therapy is exempt from Colorado sales and use tax as medical equipment and related accessories for electrotherapy dispensed pursuant to a prescription.

Background

Company created XXXXXXXXXXX ("Product") to treat solid tumors of the head. The treatment works by producing alternating electrical fields within the human body that are believed to disrupt the rapid cell division exhibited by cancer cells. The alternating electrical fields are applied to the brain through electrodes placed on the scalp. The therapy delivers non-invasive alternating electric fields through insulated array's that are attached to the mechanism and placed directly on the skin in the region surrounding the tumor. The arrays are removed and replaced two or three times per week. The arrays are replaced to ensure sufficient contact with the patient's skin.

The device is powered by a rechargeable battery in a bag that is carried by patients so they may maintain mobility, or the device may be plugged in while the patient is stationary. Patients pay a monthly fee for the therapy which is broken down into a

charge for the durable components and a monthly fee to purchase transducer arrays. Around-the-clock technical support is included in the fees.

There are three primary components to Product therapy:

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

To obtain the therapy, physicians certified by Company write a prescription for the patient and submit the prescription to Company's shipping facility. 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 technical staff and the certified physician are trained to administer Product to the patient in advance of training the patient to use Product. The day the patient begins treatment, the local technical support staff delivers the components to the patient, they train and educate the patient on the proper way to administer the treatment and the technical aspects of the Product. The patient is provided with a user's manual and the technical support phone number. The patient receives an agreement to review and sign once they are trained on how to apply the therapy themselves.

It is the patient's responsibility to request additional arrays. Company replaces batteries once capacity falls below a certain threshold. After initial treatment begins, Company typically ships arrays and other components directly to patients.

Company bills the patient's third-party insurance provider, managed care company, or in some cases, the patient directly. Company's monthly invoice includes all equipment and transducer arrays in one lump-sum charge. If a patient decides to discontinue the therapy, they return the equipment and any remaining supplies to Company at Company expense. Because the arrays cannot be reused, Company is responsible for the collection and proper disposal of the arrays.

Company received FDA approval to market Product as a stand-alone treatment for adults with confirmed gliobastoma ("GBM") that recurs. GBM is the most common and most aggressive malignant brain tumor. In addition, Product is an FDA-approved Class III medical device. Medical devices are classified into Class I,II, and III. Regulatory control increases from Class I to Class III. Durable medical equipment is generally Class I or II medical devices.

Discussion

Colorado levies sales and use tax on the sale or use of tangible personal property. However, sales and use of certain medical products are exempt. Company argues that there are several exemptions under which the sale of Product may apply: (1) prescription drug; (2) medical, feeding, and disposable supplies; and (3) durable medical equipment. In addition, the sale of Product may also apply to the sale of equipment and related accessories for electrotherapy.

1. Prescription Drug

Company argues that Product is exempt as a prescription drug because the common definition of "drug" is any substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or other animals. Colorado statutes define drug to mean:

1. "Drug" means:
    a. Substances recognized as drugs in the official compendia;
    b. Substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in individuals or animals;
    c. Substances, other than food, intended to affect the structure or any function of the body of individuals or animals; and
    d. Substances intended for use as a component of any substance specified in (i), (ii), and (iii) of this paragraph (a).
2. "Drug" does not include devices or their components, parts, or accessories.

We, thus, look to the definition of device to determine whether Product is a device. Colorado statutes define device to mean: an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required under federal law to bear the label..."

We are led to the federal definition of device to determine what devices are required to bear a medical device label. The Food and Drug Administration (FDA) statute define device to mean:

> (h) The term "device" (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
>
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

Product is a "device" and not a "drug" because it is a machine intended to affect the structure or function of the body and does not achieve that through chemical action within or on the body and is not dependent upon being metabolized, which are common means by which drugs achieve these same results. Moreover, Company represents that its Product is classified by the FDA as a Class III medical device. Given that the definition of "drug" specifically excludes devices, we conclude that Product is not a prescription drug.

2. Medical, Feeding, and Disposable Supplies
Colorado exempts from sales and use tax:

> All sales of medical, feeding and disposable supplies, including any related accessories, for incontinence, infusion, enteral nutrition, ostomy, urology, diabetic care, and wound care dispensed pursuant to a prescription.

Company provides no argument as to why Product should be exempt as a medical, feeding, and disposable supply. However, Product cannot qualify for this exemption because Product is not used for incontinence, infusion, enteral nutrition, ostomy, urology, diabetic care, or wound care.

3. Durable Medical Equipment
Colorado exempts from sales and use tax all sales of durable medical equipment. Durable medical equipment means:

> equipment, including repair and replacement parts for such equipment, dispensed pursuant to a prescription, that:
> a. can withstand repeated use;
> b. is primarily and customarily used to serve a medical purpose
> c. is general not useful to person in the absence of illness or injury; and
> d. is not worn in or on the body.

Product can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is not useful to a person in the absence of an illness. The only qualification that seems to be in question is whether Product is not worn in or on the body.

Product is comprised of a battery pack and electrodes that deliver an electrical charge from the battery to the scalp in the region surrounding the tumor. The battery pack is carried by the patient so they may maintain mobility or the device may be plugged in while the patient is stationary.

This is a close question as to whether this device is worn on the body. The device can be "worn on the body" when a person carries the device in a pack to maintain mobility. However, the device is also not worn on the body when the patient is at rest. Conversely, the arrays are attached to the scalp and, thus, appear to be "worn on the body". The Department does not believe the arrays can be classified as an accessory to Product. Accessories means, "an object or device not essential in itself but adding to the beauty, convenience, or effectiveness of something else." The arrays are essential to the device delivering the alternating electric fields because without the arrays, there is no safe means by which the device can deliver the alternating electric field. In any event, we need not reach a determination regarding this durable medical equipment exemption because we conclude that the Product qualifies for another exemption, discussed below.

4. Electrotherapy

Colorado exempts from sales and use tax "all sales of equipment and related accessories for....electrotherapy dispended pursuant to a prescription." Although not raised in the request for ruling, the Department believes that this exemption applies and, therefore, should be addressed in this ruling..

Electrotherapy is not defined by statute. However, the department believes that the electrotherapy is generally defined as the use of electrical energy for medical treatment. Product represents that its Product uses electrical energy by attaching electrodes directly on the skin in the region surrounding the tumor, and these electrodes supply electrical energy to create electric fields that travel across the upper part of the brain in different directions to help slow or stop recurrent GBM cancer cells from dividing. Thus, sales and use of Product and its related accessories qualify as electrotherapy and are exempt from state and state-administered sales and use taxes.

Miscellaneous

This letter represents the good faith opinion of Department personnel who are knowledgeable on state taxes issues. However, the Department does not make a specific determination here on any of the issues raised and the Department is not bound by this general information letter.

The Department administers state and state-administered local sales and use taxes. This letter does not address sales and use taxes administered by home-rule cities and home-rule counties. You may wish to consult with local governments which administer their own sales or use taxes about the applicability of those taxes. Visit our web site at www.colorado.gov/revenue/tax for more information about state and local sales taxes.

Enclosed is a redacted version of this letter. Pursuant to statute and regulation, this redacted letter will be made public within 60 days of the date of this letter. Please let me know in writing within that 60 day period whether you have any suggestions or concerns about this redacted letter.

Sincerely,

Neil L. Tillquist
Colorado Department of Revenue