

New York State Department of Taxation and Finance
Office of Counsel
Advisory Opinion Unit

TSB-A-15(7)S
Sales Tax
March 17, 2015

STATE OF NEW YORK
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION

PETITION NO. S140228A

The Department of Taxation and Finance received a Petition for Advisory Opinion from [REDACTED] (“Petitioner”). Petitioner asks whether its sale of their tumor treating fields device (“Device”) is exempt from sales and use tax in New York as medical equipment pursuant to New York Tax Law §1115(a)(3). We conclude that the Device and any required replacement parts qualify as medical equipment and are exempt from sales and use tax.

Facts

Petitioner is a commercial-stage oncology company dedicated to the development and commercialization of the Device, which is used for the treatment of adult patients with 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. Petitioner asserts that there are no non-medical uses for the Device.

There are three primary components to the Device: 1) An electric field generator, connection cables, a portable battery, power supply, rack and a power cord, 2) INE transducer arrays (insulated electrodes that adhere to the body and deliver the electric fields), and 3) ancillary items and accessories consisting of a carry bag, TTF Bags, operation manuals and self-exchange kits. The self-exchange kit, or “health and hygiene” kit, contains medical items such as tape, gauze, Surgilast (a tubular elastic stretch net designed to serve as a secondary dressing, applying gentle pressure to keep bandages or other medical devices securely in place without adhesive tape) and surgical scissors. The “TTF” bags are anti-static bags made of plastic that

surround the product for protection during shipment. All of the ancillary items are integral to the long-term safe use of the Device and none of the accessory equipment, except the self-exchange kit, can be used except in conjunction with the Device.

To obtain the Device, a certified physician writes a prescription for the patient and submits the prescription to Petitioner's shipping facility located outside of New York State. The prescription is filled and the components of the device are shipped to the closest local technical support staff (who are employed by Petitioner) or to the certified physician's office. The patient will receive an agreement to review and sign once he or she is trained to use the device. The technical support staff and the certified physician are trained to use the device in advance.

The day the patient starts treatment, the local technical support staff delivers the components of the Device to the patient. The local support staff will then train and educate the patient on the proper way to administer the treatment and the technical aspects of the device. 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 his or her physician. The treating physician is responsible for the ongoing care of the patient. All medical questions are referred to the treating physician.

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

Petitioner provides a monthly invoice containing one line item that combines the charge for the durable components and a monthly fee to purchase transducer arrays. Also included in this charge is around-the-clock technical support. Petitioner bills the patient's third-party insurance provider, managed care company or, in some cases, the patient directly, but does not bill the treating physician's office.

If a patient decides to discontinue the therapy, he or she returns the equipment and

any remaining supplies to Petitioner at Petitioner's expense. As the arrays cannot be reused, Petitioner is responsible for collection and proper disposition of the arrays.

Analysis

Retail sales of tangible personal property and certain enumerated services are subject to sales tax. *See* Tax Law § 1105(a),(c). As relevant here, Tax Law § 1115(a)(3) exempts medical equipment and supplies from the tax imposed by Tax Law § 1105(a) to the extent they are primarily and customarily used for medical purposes and not generally useful in the absence of illness, injury or physical incapacity. *See* 20 NYCRR § 528.4(e)(2).

Section 528.4(e) of the Sales Tax Regulations defines medical equipment:

(1) Medical equipment means machinery, apparatus and other devices (other than prosthetic aids, hearing aids, eyeglasses and artificial devices which qualify for exemption under section 1115(a)(4) of the Tax Law), which are intended for use in the cure, mitigation, treatment or prevention of illnesses of diseases or the correction or alleviation of physical incapacity in human beings.

The exemption contained in Tax Law § 1115(a)(3) and 20 NYCCR § 528.4 does not apply to the sale of medical equipment and supplies for use in performing medical and similar services for compensation.

Petitioner's Device is used for the treatment of cancer patients with solid tumors of the head. Petitioner asserts that the equipment and supplies are not useful for purposes other than the medical use described above. Accordingly, the Device and the associated supplies would be considered medical equipment.

If Petitioner sells or leases its products for use in providing medical care for compensation, Petitioner must collect sales or use tax due from the purchaser. However, when the purchaser is the patient/end-user of the Device, the exemption applies and no sales tax is due.

Similarly, the items in the “health and hygiene” kit are medical supplies exempt under 20 NYCRR § 528.4(g), other than when sold for use in providing medical care for compensation.

Any charges for the training provided by either the treating physician or the technical support staff to the patient are not taxable, because education services are not among the enumerated taxable services.

Finally, replacement parts for medical equipment are exempt from tax provided such replacement parts are identifiable as medical equipment replacement parts. Therefore, so long as Petitioner clearly identifies any and all replacement parts for the Device as such, they would be exempt from sales tax. *See* 20 NYCRR § 528.4 (e)(3).

DATED: March 17, 2015

/S/

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