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LR 14-3: Portable Medical
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Letter Ruling 14-3: Application of Massachusetts sales tax to portable medical device under G.L. c. 64H, s. 6(I)

April 11, 2014

I. Introduction

You request a letter ruling on behalf of your client, ***** ("Taxpayer") regarding the application of the Massachusetts sales tax, G.L. c. 64H, to sales of ***** ("the Device") a portable medical device used to treat solid tumors of the head. Specifically, you ask whether sales of the Device qualify for exemption under G.L. c. 64H, § 6(I), which provides an exemption for, in relevant part, equipment worn as a correction or substitute for any functioning portion of the body. You state the facts as follows.

II. Facts

Taxpayer is a commercial-stage oncology company dedicated to the development and commercialization of tumor treating fields therapy ("TTFields therapy"). The Device provides TTFields therapy (an alternative to chemotherapy) for the treatment of cancer patients who have solid tumors of the head. TTFields therapy is a low-toxicity treatment that uses low-intensity, alternating electric fields to exert physical forces on the electrically charged components of dividing cancer cells. The therapy is intended to disrupt cell division and cause cancer cell death. It 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 use of the Device allows patients to maintain their normal daily activities while receiving continuous anti-cancer treatment.

The Device is a Class III medical device that received pre-market approval by the FDA.

Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

There are 3 primary components to the Device:

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

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

- The Device 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 Device 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 Device can be plugged in while the patient is stationary.
- Patients pay a monthly fee for the use of the Device 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.

To obtain a Device, certified physicians write a prescription for the patient and submit the prescription to Taxpayer's shipping facility location in New Hampshire. The prescription is filled and the components of the Device 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 he or she is trained how to use the Device.

Taxpayer bills the patient's third party insurance provider, managed care company or in some cases, the patient directly. Taxpayer provides a monthly invoice that includes all equipment and transducer arrays in one consolidated charge. If a patient decides to discontinue TTFields therapy, the patient returns the equipment and any remaining supplies to Taxpayer at Taxpayer's expense. As the arrays cannot be reused, Taxpayer is responsible for collection and proper disposition of the arrays.

III. Issue

Is the retail sale of the Device described above exempt from Massachusetts sales tax pursuant to G.L. c. 64H, §6(l)?

IV. Ruling

For reasons discussed below, and based on the facts as you state them, we rule that the retail sale of the Device is exempt from Massachusetts sales tax under the clause in G.L. c. 64H, § 6(l) that exempts sales of "other equipment worn as a correction ... for any functioning portion of the body."

V. Discussion

Massachusetts imposes a 6.25 percent sales tax on sales and rentals of tangible personal property in Massachusetts of any vendor, unless otherwise exempt. See G.L. c. 64H, § 2. The exemptions from the sales tax are found in section 6 of chapter 64H. Section 6(l) exempts:

(l) Sales of medicine, insulin needles and insulin syringes on prescription of registered physicians and sales of insulin; sales of oxygen, blood or blood plasma; sales of artificial devices individually designed, constructed or altered solely for the use of a particular crippled person so as to become a brace, support, supplement, correction or substitute for the bodily structure including the extremities of the individual; sales of artificial limbs, artificial eyes, hearing aids and *other equipment worn as a correction or substitute for any functioning portion of the body*; (emphasis added) sales of artificial teeth by a dentist and the materials used by a dentist in dental treatment; sales of eyeglasses, when especially designed or prescribed by an ophthalmologist, oculist or optometrist for the personal use of the owner or purchaser; sales of crutches and wheel chair for the use of invalids and crippled person; and sales of baby oil; and the rental, sale and repairs of kidney dialysis machines, enteral and parenteral feedings, and feeding devices, suction machines, oxygen masks, oxygens cannulas, ultrasonic nebulizers, life sustaining resuscitators, incubators, heart pacemakers, canes, all types of hospital beds for home use, tripod quad canes, breast prosthesis, alternating pressure pad units and patient lifts, when prescribed by a physician.

The Device sold by the Taxpayer is not among the items specifically exempted under G.L. c. 64H, § 6(l). On numerous occasions, the Commissioner has ruled that certain items not specifically designated as exempt under this provision may nonetheless be exempt if their purpose and function is consistent with the purpose of items that are specifically enumerated in the statute. See, e.g., Letter Rulings 09-7; 09-6; 05-1; 02-6; 98-18; 98-5.

In Letter Ruling 09-7, the Commissioner ruled that sales, among other things, of drug-eluting stents, esophageal stents, drainage catheters, detachable coils, transvaginal

anchors, injectable implants, ligators, anti-bleeding clips, vena cava filters, implantable catheter ports, regenerative human tissue matrices, and synthetic vascular grafts are all worn within and without, attached to, or inserted within the body as corrections or substitutes for functioning portions of the body. Accordingly, we ruled that sales of such items were exempt from Massachusetts sales tax under the clause exempting "equipment worn as a correction or substitute for any functioning portion of the body."

In order to be exempt under this clause, the Commissioner has indicated that an item must qualify as "equipment" that is "worn" as a correction or substitute for any functioning portion of the body, or, in the alternative, an item must have a purpose and function consistent with items worn in this way. The Commissioner has issued a number of rulings interpreting this clause, as well as a similar clause in the § 6(l) exemption. See, e.g., Letter Rulings 09-6; 05-1[1]; and 98-5[2].

The Commissioner has ruled previously on the Massachusetts sales tax treatment of various types of stimulator devices. See, e.g., Letter Rulings 09-6 (Bone Growth Stimulators); 82-24 (Stimulation Systems); LR 81-78 (Nerve and Muscle Stimulators); and LR 81-61 ((Transcutaneous Electrical Nerve Stimulation Kits). In analyzing the taxability of such items, the Commissioner focused on the function they performed in determining whether they fell within the scope of the § 6(l) exemption.

In the most recent ruling on the subject, Letter Ruling 09-6, the Commissioner considered whether electrical bone growth stimulators, which were described as "portable, non-invasive devices which use a low level of electrical current to activate the body's natural healing process and stimulate bone growth in treating fractures and to stimulate bone fusions" were exempt under the clause of G.L. c. 64H, § 6(l) that exempted equipment worn as a correction or substitute of any functioning portion of the body. We concluded that the stimulators corrected a deficiency in the body's natural healing process by generating electrical current that is normally produced by the bones. We further concluded that although the bone growth stimulator at issue was not worn in the precise manner that a hearing aid or prosthetic device is worn, its purpose was consistent with items worn as a correction or substitute for a functioning part of the body (*i.e.*, bones). We also distinguished other types of electrical stimulators that did not activate the body's natural healing process by promoting bone growth, or any permanent healing, but were instead used primarily to control pain. *Id.*, citing Letter Rulings 81-78; and 82-24. See also Letter Ruling 81-61.

We find the reasoning of Letter Ruling 09-6 to be applicable to the Device at issue here. The Device, which is worn on the body, acts as a correction for a portion of the body, *i.e.*, the human brain, which is suffering from cancerous tumors.

VII. Conclusion

While the Device is not expressly exempt under the statute, we conclude that it falls under the scope of the exemption for "other equipment worn as a correction ... for any functioning portion of the body" in G.L. c. 64H, § 6(l). With respect to its various components sold together for a single price, we conclude that such items are exempt under the rationale of Letter Rulings 02-6 and 09-6.[3]

Very truly yours,

/s/Amy Pitter

Amy Pitter
Commissioner of Revenue

[1] In Letter Ruling 05-1, the Commissioner concluded that a wound closure device worn on the skin was exempt. Acknowledging that the device was not worn in the precise way that a hearing aid or prosthetic device is worn, we concluded that it was used to protect the body from contamination and act as a substitute for the skin during the wound healing process. As such, the Commissioner ruled that the device's purpose and use was consistent with items worn as a correction or substitute for a functioning part of the body, *i.e.*, the skin. Therefore, the device and related supplies fell within the scope of the § 6(l) exemption.

[2] In Letter Ruling 98-5, we concluded that a medical device that assisted the female bladder by preventing accidental leakage of urine was within the scope of the clause exempting sales of artificial limbs, artificial eyes, hearing aids, and other equipment worn as a correction or substitute for any functioning portion of the body.

[3] In Letter Ruling 02-6, the Department ruled on the taxability of sales and rentals of kidney dialysis machines and various medical supplies and equipment to patients who were receiving dialysis. While the kidney dialysis machine itself was specifically exempt when prescribed by a physician, other items used in the dialysis process were not expressly exempt. In analyzing the taxability of those items, we examined whether they were directly integrated with the purpose and function of the machine. We concluded that if an item was so inextricably connected to the use of the kidney dialysis machine that dialysis could not be performed without it, then the item was exempt (*e.g.*, the water system used in connection with the dialysis unit), because it fell within the scope and purpose of the exemption for the kidney dialysis machine. We concluded that the purpose of artificial kidney dialyzers (whether or not disposable), blood tubing sets, fistula needles/catheter needles, syringes, dialysate solution was consistent with the purpose of exempt kidney dialysis machines and that the items were therefore exempt if sold on a physician's prescription.