Letter Ruling 09-7: Sales Tax on Medical Devices and Delivery Components

September 16, 2009

I. Issue

You request a letter ruling on the application of the Massachusetts sales tax, G.L. c. 64H, to sales of various medical devices by ********** (“Taxpayer”). Specifically, you ask whether these devices are exempt from sales tax under G.L. c. 64H, § 6(l). In support of your request you supply the following facts.

II. Facts

The Taxpayer sells medical products used during minimally invasive surgical procedures. Most of the Taxpayer’s products are disposable. Some of the Taxpayer’s products are used in therapeutic procedures and subsequently discarded; others are implanted in or attached to the human body to assist in the functions of blood circulation, digestion, excretion, and urination; other products are implanted in the human body to repair damage caused by injury or disease. The Taxpayer’s products are primarily sold to physicians, hospitals, and other health care facilities, but sales are not restricted to licensed health care practitioners. Food & Drug Administration warning labels are included on all the Taxpayer’s products.

Product #1 – Drug Eluting Stent Systems

Drug-eluting stents are designed to perform the function of a coronary stent and also to deliver a drug locally to minimize the reoccurrence of stenosis[1] and/or to reduce the need for additional treatment in the affected area. The stent consists primarily of an expandable metal mesh tube that helps restore blood flow, serving as a permanent vessel support for a newly widened artery formerly blocked by plaque deposits. The stent is coated with the drug ********** (hereinafter “Drug P”) and a polymer. The coating of Drug P and the polymer is designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls. The stent comes pre-mounted on a delivery system composed primarily of a balloon catheter and plastic wire, which are used to deliver the stent to the affected area and deploy it. The delivery components are only used during the stent procedure and are then discarded.

Product #2 – Stent Systems

The Taxpayer sells coronary, esophageal, biliary, ureteral, and airway stents,[2] most of which are made of metal mesh, silicone, or other flexible materials. Most of the Taxpayer's stents come pre-mounted on delivery systems composed primarily of wire and catheters. Delivery components are used to place a stent into position during the stenting procedure and are then discarded. Some stents are sold separately from the necessary delivery components.

After being inserted or placed inside the body, the Taxpayer's stents remain in the body for an indefinite period of time to maintain the flow of bodily fluids. Stents are typically required because surgery or disease has occluded or removed a portion of the normal anatomical links within or to and from organs that permit the regular flow of bodily fluids or air. If not for the stents, the patients' bodily functions would shut down. Below is a quick description of the different types of stents:

- Coronary stents maintain blood flow in vessels that would otherwise become occluded and are similar in function and appearance to drug-eluting stents (see Product #1), except that the standard coronary stents do not release a drug.[3]
- Biliary stents provide for the movement of bile from the liver to other organs, after disease or surgery has interrupted regular flow from one organ to another.
- Esophageal stents are implanted in patients' throats to enable them to swallow.
- Ureteral stents are inserted into patients' urinary tracts to maintain the flow and output of urine.
- Airway stents dilate and maintain open patients' airways.

Product #3 - Drainage Catheter Systems, Including Stents

Drainage catheters are used for ongoing drainage of body fluids, such as intra-abdominal fluids, bile, urine, etc. Internal drainage catheters drain fluids from one organ or system into another organ or system. External drainage catheters drain fluids from one organ or system to a natural or artificially created orifice. Drainage catheters are regularly placed in patients for long periods. Patients who require drainage catheters are unable to absorb or eliminate waste body fluids through typical body functions.

Drainage catheter systems include the stents, plastic or metal guidewires, introducers, connecting tubes, and tubing known as cannulae. The components other than the stents and the catheters are used to place those two components into position and are then discarded.

Some drainage catheter systems that the Taxpayer sells are generally indicated for use for the course of patients' inability to absorb or eliminate waste, whether due to illness, injury, or sedation, but physicians may choose to use those systems as part of surgical procedures. Other drainage catheter systems that the Taxpayer sells are sold for multiple purposes, both for replacement of patients' bodily functions or for use during surgical procedures.

Product #4 – Detachable Coils

Detachable coils are small coils made of platinum, used to fill in or occlude intracranial aneurysms. A coil's platinum construction allows it to conform to the irregular shape of a patient's aneurysm and to make it visible on X-ray. A coil comes pre-mounted on plastic delivery wire and is fed through a micro-catheter to the site of the aneurysm. The delivery wire allows the physician to reposition or withdraw the coil during the procedure. Once properly positioned within the aneurysm, the coil is detached from the delivery wire via electrolytic detachment. Delivery wires and micro-catheters are only used once and are then discarded.

Product #5 – Transvaginal Anchor Systems

A transvaginal anchor system is used in a surgical procedure to ameliorate female urinary

incontinence. System components include a selection of needles, a sling made of synthetic mesh netting, and a delivery device with a squeeze handle. The mesh sling is secured by anchors implanted into the pubic bone to support the bladder, bladder neck, urethra, and sphincter. The delivery device and needles are only used once and are then discarded.

Product #6 – Trade Name A Injectable Implants

The ********** (hereinafter "Trade Name A") Injectable Implant is used to augment soft tissue growth to treat stress urinary incontinence in adult females; the procedure in which the Injectable Implant is used is referred to as "urethral bulking." The objective of the procedure is to cause tissues of the bladder neck and/or urethra to adhere. The implant is packaged with an injection needle used with the procedure and is then discarded.

Product #7 – Ligators

The ********** (hereinafter "Ligator") is used to treat variceal bleeding, allowing multiple ligations to be performed with a single insertion of an endoscope. The Ligator is packaged and sold with multiple bands, a handle unit, trip wire, and irrigation catheter. All the related components are used once and discarded.

Product #8 – Anti-Bleeding Clips

********** (hereinafter "anti-bleeding clips") are used to stop bleeding or hemorrhage of blood through a vessel or organ of the body. An anti-bleeding clip is packaged with a handle and detachable catheter, to be used during the procedure and then discarded.

Product #9 – Vena Cava Filter Systems

This is a permanently implanted filtering device designed to prevent pulmonary embolism. The filter is a tiny net, inserted with a specially designed carrier catheter, inserted into the superior or inferior vena cava. (The two vena cava are large veins that return blood to the body; the superior vena cava returns blood from the lower portions of the body.) Upon discharge from the carrier, the filter secures itself to the vessel wall and becomes a permanent implant. The vena cava filter is packaged with an introducer catheter system used during the procedure and then discarded.

Product #10 – Implantable Catheter Port Systems

This product is implanted in patients who required intravenous fluids, antibiotics, chemotherapy agents, nutritional support, and/or blood products. The physician implants a peripherally inserted central catheter, usually referred to as a PICC line, port, or central venous catheter to get access to the patient's vein. Intravenous fluids are then administered through the venous access site into the patient. The delivery component is only used during the implantation procedures and is then discarded.

Product #11 – Human Tissue Regeneration Matrices

Human tissue regeneration matrices are used to repair or replace damaged or inadequate tissue during graft, implant, and reconstructive surgical procedures. The matrix is recognized by the patient's body as a human tissue, and the matrix grows and ages normally along with the original host tissue. With time, the matrix becomes indistinguishable from the surrounding host tissue.

It should be noted that stents, catheters, coils, anchors, implants, ligators, anti-bleeding clips, vena cava filters, and catheter ports described above cannot be placed within patients without delivery components, whether the components come premounted or are sold separately. The patents on many of the Taxpayer's products and the U.S. Food and Drugs Administration's approval specify that the related delivery components be sold as part of integrated systems, which include a component placed or implanted within the body and components that place or implant the first

component.

Product #12 – Synthetic Vascular Grafts

Surgeons use vascular grafts to repair or replace injured or diseased segments of arteries. Synthetic vascular grafts, as opposed to vascular grafts from the patient's or a donor's tissue, are made from such substances as Dacron, collagen, and polytetrfluroethylene ("PTFE"), also known as double velour. A synthetic vascular graft is placed in a patient's vascular system with the expectation that it will function for the duration of the patient's anticipated lifetime.

Product #13 – Trade Name B Introducer Sheaths

The ********** (hereinafter "Trade Name B") Introducer Sheath is used to facilitate passage of catheters, guidewires, etc., into and through the body. The primary intent of the Trade Name B Introducer sheath is the introduction of devices, although the sidearm of the sheath may be used to introduce drugs into the vasculature. The product is packaged and sold with a guidewire and dilator used during the procedure and then discarded.

Product #14 – Guidewires

Guidewires are inserted into a vessel and directed to the area of the body requiring treatment. After placement, the guidewire is used to insert a catheter during an angiography, angioplasty, or drainage procedure. The guidewire is used during the procedure and is then discarded.

Product #15 – Safety Percutaneous Endoscopic Gastrostomy Kits

Safety percutaneous endoscopic gastrostomy kits ("safety PEG kits") consist of components used to create an initial gastrostomy (an artificial opening into the stomach) to be used for enteral feedings. The components in a safety PEG kit typically include: a syringe prefilled with a topical anesthetic or an empty syringe ampule of topical anesthetic; scalpel; scissors; shielded injection needles in more than one size; a retrieval snare; a PEG tube; guidewires; catheter; port; clamps; internal and external bolsters;[4] surgical drape; gauze pads; drainage sponges; and assorted applicators containing a skin prep substance, lubricating jelly; antibiotic ointment; and iodine.

Product #16 – Suture Capturing Devices

The suture capturing device is a surgical instrument used to throw, catch, and retrieve sutures, especially in body cavities that are difficult to reach. The suture capturing device is predominantly used in procedures intended to correct female urinary stress incontinence. The Taxpayer sells separately sutures in a variety of fibers especially designed for the suture capturing device.

III. 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 exemption to 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; 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 a 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.

None of the devices sold by the Taxpayer is expressly exempt under G.L. c. 64H, § 6(l). The Commissioner has ruled that certain items not specifically 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 05-1; 02-6; 98-18; 98-5.

You assert that Taxpayer's products qualify for exemption under two specific provisions: first, as "medicine" [5] when prescribed by a physician, and second, as "equipment worn as a correction or substitute for any functioning portion of the body." With respect to the latter, you have provided a list of the principal components of Taxpayer's products that you assert correct or substitute for functioning portions of the body and the specific functions that each product is intended to substitute for or correct.

- A drug-eluting stent maintains the necessary opening in an artery by mechanical and pharmaticeutical means, enabling the functioning of the blood circulatory system.
- An esophageal stent enables a patient to swallow, a necessary function in the digestive and respiratory systems. Other stents enable a variety of bodily systems to maintain their functionality, despite disease and/or surgical removal.
- A drainage catheter enables the elimination of otherwise-toxic waste body fluids.
- An implantable catheter port allows the introduction of intravenous fluids, blood products, and a number of therapeutic agents into patients who are unable to ingest or absord those substances through other means, especially patients whose medical conditions do not permit conventional access through the veins or mouth.
- A PEG tube is a means for nourishment for patients who cannot consume food by mouth.
- A synthetic vascular graft enables the continued functioning of a patient's blood circulation system.
- A suture capturing device is used by surgeons to suture and correct patients' pelvic structure.
- A detachable coil corrects a potentially fatal intracranial aneurysm.
- A transvaginal anchor system provides support for the patient's pelvic floor and aids in the correct functioning of several body functions.
- The Trade Name A Injectable implant adds to existing tissue in the bladder and/or urethra and encourages the growth of new tissue same locations, aiding in the correct functioning of the body's urinary functions.
- A ligator prevents blood loss by typing tissues during surgical procedures.

We agree that many of the products described above act as a correction or substitute for a functioning portion of the body. In order to be exempt under this clause, they must also qualify as "equipment" that is "worn" as such a correction or substitute, or, in the alternative, items whose purpose is consistent with items worn in this way. The Commissioner has issued a number of rulings interpreting this clause, as well as a similar clause[6] in § 6(l) exemption. *See, e.g.,* Letter Rulings 05-1; 02-6; 98-18; 98-5.

In Letter Ruling 05-1, the Commissioner concluded that a wound closure device worn on the skin was exempt. Although the device was not worn in the precise way that a hearing aid or prosthetic device is worn, we concluded that it was used in such a manner as to protect the body from contamination and to act as a substitute for the skin during the wound healing process. As such, the Commissioner ruled that its 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.

In Letter Ruling 02-6, the Department ruled on the taxability of sales and rentals of water filtration system equipment and various supplies necessary for the process of kidney dialysis. While kidney

dialysis machines are specifically exempt if prescribed by a physician, the related equipment and supplies are not expressly exempted under the statute. In analyzing the taxability of those items, we examined whether they were directly integrated with the purpose and function of the machines. We concluded that a related water filtration system, so inextricably connected to the use and function of the exempt machine that the exempt machine cannot function without it, is also exempt.[7]

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.

IV. Rulings

Based on the reasoning of the above letter rulings, we conclude as follows:

1. sales of the drug-eluting stents, esophageal stents, drainage catheters, detachable coils, transvaginal anchors, Trade Name A 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 rule that sales of Products numbered 1 through 14 are exempt from Massachusetts sales tax as “equipment worn as a correction or substitute for any functioning portion of the body.”

2. While the related delivery components of the above items are not expressly exempted under the statute, they nevertheless are critical and essential to the placement and deployment of these items. We thus conclude under the rationale of Letter Ruling 02-6, that they are also exempt as being inextricably connected with the exempt Products # 1-14, as equipment worn as a correction or substitute for a functioning portion of the body. under G.L. c. 64H, § 6(l).

3. With respect to Product #15, the safety PEG kits contain both taxable and nontaxable items. Some items contained in the kits may be viewed as having a purpose or function that is consistent with specifically exempted enteral and parental feedings and feeding devices. Under the reasoning of Letter Ruling 02-6, those items that are inextricably connected with the use and function of these devices would be exempt if sold separately. Other items, (i.e. scalpel, scissors, injection needles, surgical drape, gauze pads, drainage sponges, and assorted applicators containing a skin prep substance and lubricating jelly) are subject to tax. When such kits are sold together for a single price, the rules of DOR Directive 94-3 apply. That is, when an item sold at retail contains a combination of both taxable tangible personal property and tax exempt tangible personal property (“combination unit”), the vendor should separately state the portion of the sales price of the taxable tangible personal property and collect sales tax on that portion of the sales price. The separately stated prices of the taxable property and the tax exempt property must reasonably reflect the value of each type of portion of the sales price of the taxable property. If the vendor does not separately state the portion of the sales price, the tax will be calculated on the sales price of the entire “combination unit”.

4. Sales of Product #16 are taxable because, unlike the other products at issue in this ruling, suture capturing devices are not equipment inextricably connected to the use and function of any of the exempt products at issue. Unless they fall within some other exemption provision, they are subject to sales tax.

Very truly yours,

/s/Navjeet K. Bal

Navjeet K. Bal
Commissioner of Revenue

NKB:MTF:wrd

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[1] Stenosis is the narrowing of a blood vessel, which will restrict blood flow if not corrected. Restenosis is the reoccurrence of stenosis, which may occur in a patient previously treated to clear blockage.

[2] Other medical device companies manufacture and sell stents that may be placed within other parts of the body.

[3] You have not included in this request coronary stent systems that are only used for or during a specific procedure and are then removed.

[4] Bolsters are used to attach the PEG tube to the interior and exterior abdominal walls.

[5] You assert that most of the products at issue qualify as "medicine" as defined in previous letter rulings. The Commissioner has referred to the following definition of "medicine" from Webster's New Collegiate Dictionary (1979): "a substance or preparation used in treating disease; . . . something that affects well-being." *See, e.g.,* Letter Rulings 08-12; 08-3; 98-6; 88-4. However, the Commissioner has not concluded that all items qualify as "medicine" for purposes of G.L. c. 64H, § 6(l). In Letter Ruling 08-3, the Commissioner determined that sales of injectable solutions used to minimize facial wrinkles were taxable, because substances used only for cosmetic purposes do not qualify as "medicine", even though the solutions met the U.S. Food & Drug Administration's definition of a "medical device." *Compare* Letter Ruling 08-12; exempting as "medicine" a product called "BOTOX cosmetic" because, notwithstanding its label, its prescribed use was to treat and remedy a medical condition (glabellar lines) by blocking neuromuscular transmission and entering the nerve terminals and inhibiting the release of acetylchlorine, which is the chemical that causes the muscles to contract. Because we reach our conclusion on other grounds, we do not address whether any of Taxpayers' products might qualify as "medicine".

[6] In Letter Ruling 98-18, we applied this analysis to another clause of G.L. 64H, § 6(l) and concluded that certain surgically implanted orthopedic devices such as above plates, nails, and external fixators were exempt from tax. Based on the facts of that ruling, we concluded that the purpose of the implant products was consistent with an artificial device expressly exempted under that clause.

[7] In LR 02-6, the Department also ruled that supplies used to evaluate and maintain the quality of the water filtration system were taxable, as they are not consistent with the function of the kidney dialysis machine, as they do not treat kidney disease.