DEPARTMENT OF STATE REVENUE

Revenue Ruling #2015-19ST January 15, 2016

NOTICE: Under <u>IC 4-22-7-7</u>, this document is required to be published in the Indiana Register and is effective on its date of publication. It shall remain in effect until the date it is superseded or deleted by the publication of a new document in the Indiana Register. The publication of this document will provide the general public with information about the department's official position concerning a specific issue.

ISSUES

Sales and Use Tax - Exemptions Applicable to Sales of Medical Supplies and Devices

Authority: <u>IC 6-2.5-1-25</u>; <u>IC 6-2.5-2-1</u>; <u>IC 6-2.5-3-2</u>; <u>IC 6-2.5-5-8</u>; <u>IC 6-2.5-5-18</u>; <u>45 IAC 2.2-5-27</u>; Sales Tax Information Bulletin #48 (September 2015).

A company ("Taxpayer") is seeking a determination regarding whether its product is a prosthetic device and is exempt from Indiana gross retail and use tax.

STATEMENT OF FACTS

Taxpayer is in the business of developing devices to address urological issues. Taxpayer developed a new device (the "Product") that "is designed to correct a physical deformity in the male urinary tract know as Benign Prostatic Hyperplasia ("BPH")." Taxpayer describes the Product further as follows:

BPH involves hyperplasia (an increase in the number of cells) of certain cells in the prostate gland that surrounds the urethra. This increase in cells results in the formation of large nodules in the transition zone of the prostate. When sufficiently large, the nodules deform the urethra and increase resistance to flow of urine from the bladder.

The [Product] corrects this deformation with permanent adjustable transprostatic implants placed by a health care provider during a cystourethroscopy. Each permanent adjustable transprostatic implant is sold to hospital or medical facilities in its own sterile, individual housing, which is designed to couple to a urethroscope. The housing is single use; it is not reloadable or reusable.

The housing includes a handle for positioning the implant and coupling to the urethroscope, a retractable needle for puncturing the capsule of the prostate gland, and a tensioning spring within the handle for allowing adjustment of the implant during placement. The [Product] is a permanent implant made up of standard surgical implantable materials: a nitinol capsular tab, a stainless steel urethral tab, and polyester suture that connects the two tabs.

Together, the permanent adjustable transprostatic implant and its housing form the [Product] for which this request is made. As discussed above, the [Product] is sold to hospitals or medical facilities to correct a physical deformity and must be prescribed by a physician.

The implant and its housing are sold together as an indivisible unit. The urethroscope is sold separately and is not included in the [Product]. The Food & Drug Administration cleared the implant and housing to be used together as an indivisible unit. The Centers for Medicare & Medicaid Services ("CMS") reimburse the placement of the implant and housing as an indivisible unit under a single procedure code . . . which describes the procedure using the [product] as "cystourethroscopy, with insertion of permanent adjustable transprostatic implant." Finally health care providers have been reimbursed by CMS for the use of the [Product] . . . which has the description "Prosthetic implant, not otherwise specified." These reimbursements under the prosthesis description were applied to the implant and housing as an indivisible unit.

DISCUSSION

Taxpayer requests that the Department rule whether: (1) the Product is a prosthetic device, and (2) that it is exempt from Indiana gross retail and use tax.

Indiana imposes an excise tax called "the state gross retail tax" (or "sales tax") on retail transactions made in

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Indiana. IC 6-2.5-2-1(a). A person who acquires property in a retail transaction (a "retail purchaser") is liable for the sales tax on the transaction. IC 6-2.5-2-1(b). Indiana also imposes a complementary excise tax called "the use tax" on "the storage, use, or consumption of tangible personal property in Indiana if the property was acquired in a retail transaction, regardless of the location of that transaction or of the retail merchant making that transaction." IC 6-2.5-3-2(a).

In general, all purchases of tangible personal property are subject to sales and/or use tax unless an enumerated exemption from sales and/or use tax is available. <u>IC 6-2.5-5-18</u>(c) provides in pertinent part:

Transactions involving the following are exempt from the state gross retail tax if the end user acquires the property upon a prescription or drug order (as defined in $\underline{IC 16-42-19-3}$) that is required by law for the transaction from a licensed practitioner:

. . .

(3) Prosthetic devices, including artificial limbs, orthopedic devices, dental prosthetic devices, eyeglasses, and contact lenses (and including a repair or a replacement part).

(4) Other medical supplies or devices that are used exclusively for medical treatment of a medically diagnosed condition, including a medically diagnosed condition due to:

- (A) injury;
- (B) bodily dysfunction; or
- (C) surgery.

Taxpayer asserts that its Product is a prosthetic device. The Department's Sales Tax Information Bulletin #48 further clarifies the exemption for prosthetic devices, as it applies to purchases made by patients pursuant to a prescription by a licensed practitioner:

The following sales and/or rental of durable medical equipment, devices, drugs, and other supplies are exempt from Indiana sales and use tax provided the end user patient acquires the property upon a prescription or drug order (as defined in <u>IC 16-42-19-3</u>) that is required by law (if such property requires a prescription or drug order by law, subject to the conditions set out below) for the transaction from a licensed practitioner: . . .

• Sales of prosthetic devices that are a replacement, corrective, or supportive device worn on or in the body to: artificially replace a missing part of the body; prevent or correct physical deformity or malfunction; or support a weak or deformed part of the body. Such devices include:

(1) Artificial limbs

(2) Orthopedic devices designed to correct deformities and/or injuries to the human skeletal system including the spine, joints, bones, cartilages, ligaments, and muscles

(3) Dental prosthetic devices used for the replacement of missing teeth such as bridges and artificial dentures

(4) Corrective eyeglasses and contact lenses

The term "prosthetic device" is defined in <u>IC 6-2.5-1-25</u> as:

[A] replacement, corrective, or supportive device, including repair and replacement parts for the device, worn on or in the body to:

- (1) artificially replace a missing part of the body;
- (2) prevent or correct physical deformity or malfunction; or
- (3) support a weak or deformed part of the body.

Analyzing the Product in the context of the plain meaning in <u>IC 6-2.5-1-25</u>, the Product would be considered a prosthetic device because it is a "corrective device" which "corrects a physical malfunction," and is "worn in the body."

While the Product is a prosthetic device, in order for the Product to be exempt as a prosthetic device under <u>IC 6-2.5-5-18</u>(c), the Product must be sold or rented to an end user purchaser pursuant to a valid prescription or drug order. Implicit in that requirement is the necessity that the item be transferred for consideration to a purchaser who possesses a prescription for the item. <u>45 IAC 2.2-5-27</u> clarifies the definition of "prescribed" as follows:

(a) The term "person licensed to issue a prescription" shall include only those persons licensed or registered to fit and/or dispense such devices.

(b) Definition: The term "prescribed" shall mean the issuance by a person described in [subsection (a)] of a certification in writing that the use of the medical equipment[,] supplies[,] and devices is necessary to the

purchaser in order to correct or to alleviate a condition brought about by injury to, malfunction of, or removal of a portion of the purchaser's body.

When sold to a physician or hospital, the device is not sold to an end user purchaser who possesses a prescription for the item and, therefore, such a transaction is not exempt from Indiana sales and use tax pursuant to $\underline{IC \ 6-2.5-5-18}$. Here, Taxpayer states that the Product is sold directly to doctors and hospitals; however, Taxpayer has not established that the Product is sold to patients, or that patients pay for it themselves or through their insurance. Therefore, the Product is not exempt under $\underline{IC \ 6-2.5-5-18}$ if it is not sold directly to the end user patient by Taxpayer or a licensed practitioner. However, the product may be exempt under $\underline{IC \ 6-2.5-5-8}$ (b), which provides:

Transactions involving tangible personal property other than a new motor vehicle are exempt from the state gross retail tax if the person acquiring the property acquires it for resale, rental, or leasing in the ordinary course of the person's business without changing the form of the property.

If Taxpayer sells the Product to a doctor or a hospital, and the doctor or hospital subsequently sells the Product to an end user patient, then the Product would be exempt from tax when sold to the doctor or hospital under $\frac{|C 6-2.5-5-8}{|C 6-2.5-8}$ (b).

RULING

The Product is a prosthetic device; however, because the Product is not sold or rented to a patient end user by a licensed practitioner pursuant to a prescription, the Product is not exempt from Indiana sales and use tax pursuant to IC 6-2.5-5-18. However, it may be exempt under IC 6-2.5-5-8(b) as a sale for resale.

CAVEAT

This ruling is issued to the taxpayer requesting it on the assumption that the taxpayer's facts and circumstances as stated herein are correct. If the facts and circumstances given are not correct, or if they change, then the taxpayer requesting this ruling may not rely on it. However, other taxpayers with substantially identical factual situations may rely on this ruling for informational purposes in preparing returns and making tax decisions. 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 respect from the facts and circumstances given in this ruling, then the ruling will not afford the taxpayer any protection. It should be noted that subsequent to the publication of this ruling a change in statute, regulation, or case law could void the ruling. If this occurs, the ruling will not afford the taxpayer any protection.

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