DEPARTMENT OF STATE REVENUE

Revenue Ruling #2019-02ST
June 5, 2019

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ISSUES

Sales and Use Tax - Applicability of Medical Exemptions to Continuous Glucose Monitoring System

Authority: IC 6-2.5-1-18; IC 6-2.5-1-23; IC 6-2.5-1-25; IC 6-2.5-2-1; IC 6-2.5-3-2; IC 6-2.5-5-8; IC 6-2.5-5-18; IC 6-2.5-5-19.5; 45 IAC 2.2-5-27; 45 IAC 2.2-5-36; *Indiana Dep't of State Revenue, Sales Tax Division v. RCA Corp.,* 310 N.E.2d 96 (Ind. Ct. App. 1974); *Indiana Dept. of State Revenue v. Kimball Int'l Inc.*, 520 N.E.2d 454 (Ind. Ct. App. 1988).

A taxpayer ("Company") is seeking a determination regarding the following issues:

1. Whether Company's continuous glucose monitoring system, sold as one unit with a receiver, transmitter, and sensor (or the transmitter and sensor when sold separately), is durable medical equipment that is exempt from sales and use tax.
2. Whether Company's continuous glucose monitoring system, sold as one unit with a receiver, transmitter, and sensor (or the transmitter and sensor when sold separately), is a prosthetic device used to correct a malfunctioning pancreas and is exempt from sales and use tax.
3. Whether Company's continuous glucose monitoring system's sensor and transmitter fall within the exemption for blood glucose level measuring strips and are exempt from sales and use tax.

STATEMENT OF FACTS

Company is based outside of Indiana. Company manufactures and distributes continuous glucose monitoring system. Company provides the following information regarding its continuous glucose monitoring system:

> Over 30 million Americans have diabetes. It is estimated that diabetes is the 7th leading cause of death in the United States. Many states, including Indiana, have responded to this health crisis by specifically exempting diabetes treatment supplies such as blood glucose test strips from sales and use tax. At the time this exemption was enacted, blood glucose test strips were the only reliable way, approved by the FDA, to measure blood glucose for the purpose of making diabetes treatment decisions.
>
> Today, diabetes patients have more options available. [Company] sells [a continuous glucose monitoring system, or "CGM"] approved by the FDA to replace blood glucose monitoring strips for diabetes management and treatment. A CGM can be used independently or as part of an Artificial Pancreas Device System.
>
> [Company's] CGM system consists of three separate parts: the sensor, the transmitter, and the display device. An auto-applicator helps insert the sensor just beneath the skin. This sensor can remain in the skin for seven to ten days. The sensor continuously measures glucose levels just beneath the skin and sends data wirelessly to a display device through the transmitter. The transmitter can be used for up to three weeks.
>
> The display device is a small touch screen receiver that displays real-time glucose data.
>
> The sensor, transmitter, and receiver are sold by prescription only. The system may be sold with each element bundled together. It may also be sold with or without the receiver. Replacement sensors and transmitters may also be sold separately.
>
> [Company's] CGM system was . . . approved by the United States Food and Drug Administration (FDA) to replace blood glucose monitoring strips. The FDA specifically approved the [Company] CGM for use in "diabetes treatment decisions." This makes [Company's] CGM a therapeutic device, not just a diagnostic monitor. In response to FDA approval, the Centers for Medicare and Medicaid Services (CMS) have approved payment for [Company's] CGM, including replacement sensor and transmitters, as durable medical

equipment. The CMS ruling notes that the CGM receiver qualifies as durable medical equipment, with the sensors and transmitters qualifying as essential accessories. The receiver is useless without the sensors and transmitters.

The FDA has also recognized the role of CGM systems as a prosthetic device. CGM systems are an essential component of an Artificial Pancreas Device System (APDS).

APDS systems are designed to closely mimic the functions of a healthy pancreas. A healthy pancreas will do both of the following: (1) monitor blood glucose levels; and (2) regulate blood glucose levels. An APDS replaces these functions by artificial means. An APDS typically consists of three devices: a [CGM], a blood glucose meter (used to calibrate the [CGM]), and an insulin infusion pump. The [CGM] replaces the pancreas' monitoring function. The blood glucose meter calibrates the [CGM]. The insulin infusion pump replaces the pancreas' regulating function. These devices can be sold as a closed loop or as individual devices. [Company] sells a stand-alone CGM that would be used with manual insulin injections as opposed to an automatic insulin pump.

DISCUSSION

Taxpayer requests that the Department find that the CGM system is exempt from Indiana gross retail tax as either durable medical equipment or a prosthetic device pursuant to IC 6-2.5-5-18(c) or as blood glucose monitoring supplies pursuant to IC 6-2.5-5-19.5.

Indiana imposes an excise tax called "the state gross retail tax" (or "sales tax") on retail transactions made in 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. IC 6-2.5-5-18(c) provides an exemption for certain medical devices and equipment 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 IC 16-42-19-3) from a licensed practitioner:
(1) Durable medical equipment.
. . .
(3) Prosthetic devices, including artificial limbs, orthopedic devices, dental prosthetic devices, eyeglasses, and contact lenses.
(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.

IC 6-2.5-5-19.5 provides an exemption for blood glucose monitoring supplies. It provides in relevant part the following:

(b) For purposes of this section, "blood glucose monitoring supply" means blood glucose measuring strips, lancets, and other similar diabetic supplies furnished without charge.
. . .
(d) Transactions involving the following are exempt from the state gross retail tax:
(1) . . . a blood glucose monitoring supply, and the packaging and literature for a blood glucose monitoring supply.
(2) Tangible personal property that will be used as a drug sample or a blood glucose monitoring supply or that will be processed, manufactured, or incorporated into:
(A) a drug sample or a blood glucose monitoring supply; or
(B) the packaging or literature for a drug sample or a blood glucose monitoring supply.

The first question is whether the CGM would meet the definition of "durable medical equipment," which is defined in IC 6-2.5-1-18 in pertinent part as follows:

(a) "Durable medical equipment" means equipment, including repair and replacement parts for the equipment, that:
(1) can withstand repeated use;
(2) is primarily and customarily used to serve a medical purpose;
(3) generally is not useful to a person in the absence of illness or injury; and
(4) is not worn in or on the body.
The term does not include mobility enhancing equipment.

To reiterate, the CGM consists of the receiver, the sensor, and the transmitter, which are sometimes sold together as one unit, or are all sold separately. While the receiver, the sensor, and the transmitter meet the second and third criteria of this definition, the first and fourth criteria appear not to be. Regarding the fourth criterion, parts of the CGM are worn in or on the body, as the sensor is applied just beneath the skin and the transmitter is placed on top of the skin. However, Company compares the CGM to durable medical equipment at issue in a prior Revenue Ruling issued by the department. In Revenue Ruling 2014-04ST (20150527-IR-045150142NRA), a device which treated solid tumors included electrodes and arrays that were attached to the head that operated in conjunction with an electric field generator. The device was effectively a combination of durable equipment that was not worn in or on the body (the generator) and components that were worn on the body (the arrays and electrodes). The department ruled that this device as a whole was durable medical equipment, and that such equipment can include components like electrodes and arrays which are attached to the body, as opposed to being worn in or on the body.

Company also cites to a Streamlined Sales and Use Tax Agreement (SSUTA) Interpretive Opinion, which determined that the receiver component of the CGM would meet the definition of durable medical equipment, but the sensor and transmitter were determined to be undefined under the SSUTA, which suggests they are not themselves durable medical equipment.[1] However, Company again points to the prior Revenue Ruling for the proposition that Indiana has ruled that similar attachments, such as arrays and electrodes, worn in or on the body, can be considered a necessary part of exempt durable medical equipment.

The difference between the treatment at issue in the prior Revenue Ruling and the CGM is that the treatment's electrodes and arrays were physically connected to the main unit, and it was only functional when connected to one another, whereas the sensor and transmitter of the CGM are not physically connected to the receiver. In fact, while the receiver is useless without the sensor and transmitter, the inverse is apparently not true, as the sensor and transmitter can be used with a smart phone, smart watch, or other compatible electronic device. Essentially, the treatment at issue in the prior Revenue Ruling could be viewed as one unit, and the CGM consists of separate units that are not all essential for complete functionality. Viewed in isolation, the Department would concur with the SSUTA ruling that the sensor and transmitter are not durable medical equipment, while the receiver would be.

Regarding the second issue, whether the CGM would meet the definition of a "prosthetic device," IC 6-2.5-1-25 defines "prosthetic device" as follows:

"Prosthetic device" means 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.

Company avers that the CGM system may be used as necessary parts of APDS, which replace functions of the pancreas. While the APDS may be a prosthetic device, the CGM as a whole does not appear to meet the definition of a "prosthetic device." The sensor and transmitter are worn in and on the body, respectively, but the receiver is not. More importantly, none of the components of the CGM 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. The CGM is instead a diagnostic device that alerts the user that they need to self-administer insulin. Therefore, none of the components meet the definition of a prosthetic device.

It would appear that only the receiver qualifies for one of these terms as durable medical equipment. However, the exemption at IC 6-2.5-5-18 also requires that durable medical equipment or prosthetic devices must be prescribed to the end user purchaser by a licensed practitioner in order for the transaction to qualify for the exemption. A "prescription" is defined by IC 6-2.5-1-23 as "an order, a formula, or a recipe issued in any form of oral, written, electronic, or other means of transmission by a licensed practitioner authorized by Indiana law." The Department's regulations at 45 IAC 2.2-5-27 further 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.

Company claims that IC 6-2.5-5-18 does not require that the CGM be sold under a prescription, and that it can be sold to a hospital or doctor exempt from tax under IC 6-2.5-5-18. However, this is clearly not the case. IC 6-2.5-5-18 requires that any equipment subject to the exemption must be sold to an end user "upon a prescription or drug order . . . from a licensed practitioner." In other words, durable medical equipment or prosthetic devices are exempt only when the end user acquires the product with a prescription from a licensed practitioner. The department has consistently held that doctors, hospitals, and other medical offices and professionals are not eligible to purchase these types of equipment exempt pursuant IC 6-2.5-5-18.[2] In the Revenue Ruling cited above, one of the reasons the device was exempt was because the device was only ever purchased by the end user:

> Further, in addition to the Treatment being prescribed to patients, Taxpayer has established that the Treatment is sold to patients, that patients pay for it themselves or through their insurance, and that the Treatment is delivered to the patients. The patients also use the Treatment themselves, at their home or at work, and without the aid of the prescribing physician (except that their prescribing physician is trained on how to use the Treatment and may presumably administer it at times). In other words, it is not a type of medical supply purchased by a licensed practitioner and consumed in their professional use. 45 IAC 2.2-5-36.

IC 6-2.5-5-18 requires a prescription from a licensed practitioner issued directly to a specific end user purchaser. Therefore, the purchase of the CGM could not be exempt under IC 6-2.5-5-18 if it is not sold directly to the end user patient by Company or a licensed practitioner.[3] However, the product may be exempt under 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 Company sells the CGM to a hospital, doctor's office, or medical professional, and the CGM is subsequently sold to an end user patient, then the Product would be exempt from tax when sold to the hospital or medical professional under IC 6-2.5-5-8(b). The Taxpayer shall require the hospital, doctor's office, or medical professional purchasing the CGM to provide a valid exemption certificate (Form ST-105) at the time of purchase in order to qualify for this "sale for resale" exemption.

Alternatively, Company maintains that the CGM applicator, sensor, and transmitter are also exempt blood glucose level measuring strips for purposes of the exemption under IC 6-2.5-5-19.5, which provides an exemption for transactions involving blood glucose monitoring supplies. Subsection (b) of this statute provides that a blood glucose monitoring supply "means blood glucose measuring strips, lancets, and other similar diabetic supplies furnished without charge." Unlike the exemption at IC 6-2.5-5-18, this exemption does not contain the same limitation that the end user purchaser must purchase the equipment pursuant to a prescription.

Company claims that the CGM system is different from most blood glucose meters, and that it is more like a traditional blood glucose monitoring supply, calling the applicator and sensor the "operational equivalent" of blood glucose measuring strips.

In applying any tax exemption, the general rule in Indiana is that "tax exemptions are strictly construed in favor of taxation and against the exemption." *Indiana Dept. of State Revenue v. Kimball Int'l Inc.*, 520 N.E.2d 454, 456 (Ind. Ct. App. 1988). A statute which provides a tax exemption is strictly construed against the taxpayer. *Indiana Dep't of State Revenue, Sales Tax Division v. RCA Corp.,* 310 N.E.2d 96, 97 (Ind. Ct. App. 1974). "[W]here such an exemption is claimed, the party claiming the same must show a case, by sufficient evidence, which is clearly within the exact letter of the law." *Id.* at 100-101.

Company's CGM applicator and sensor are not blood glucose monitoring strips. They are intended to replace blood glucose monitoring strips. Furthermore, because Company charges for the CGM components, they would

not qualify for the exemption under IC 6-2.5-5-19.5 because the term "blood glucose monitoring equipment" only refers to those diabetic supplies that are furnished without charge. Therefore, IC 6-2.5-5-19 cannot apply to the purchase of the CGM applicator, sensor.

RULING

Company's CGM (the receiver, the sensor, and the transmitter) would not be eligible for the exemption under IC 6-2.5-5-18 because the CGM is not sold to the end user patient, regardless of whether it qualifies as durable medical equipment or a prosthetic device. Company's CGM applicator, sensor, and transmitter are similarly not exempt under IC 6-2.5-5-19.5 because they are not diabetic supplies furnished without charge and are instead intended to replace blood glucose monitoring equipment.

However, the CGM would be exempt if sold to a hospital, doctor's office, or medical professional as a sale for resale under IC 6-2.5-5-8(b) if the CGM is subsequently resold by the hospital, doctor's office, or medical professional to an end user patient.

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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[1] Streamlined Sales and Use Tax Agreement Compliance Review and Interpretations Committee, Interpretive Opinion 2015-1

[2] *See* Revenue Ruling #2016-01ST (20160831-IR-045160366NRA); Revenue Ruling #2015-16ST (20160330-IR-045160125NRA)

[3] For this reason, the general category of "other medical supplies or devices" under IC 6-2.5-5-18(c)(4) would not be applicable, even if the three components met the description within this subsection.

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