TAXPAYER INFORMATION RULING LR 18-005

July 2, 2018

Thank you for your letter dated February 12, 2018, requesting a taxpayer information ruling ("TIR") on behalf of your unnamed client ("Taxpayer"), and the additional information you provided in your letters dated April 20, 2018 and May 7, 2018. Specifically, you requested a determination of whether Taxpayer's continuous glucose monitoring ("CGM") systems are classified as prosthetic appliances or durable medical equipment ("DME") and exempt pursuant to the Arizona transaction privilege tax ("TPT") statutes.

Pursuant to Arizona Revised Statutes (A.R.S.) § 42-2101, the Arizona Department of Revenue ("Department") may issue taxpayer information rulings to taxpayers and potential taxpayers on request.

ISSUE:

- Whether Taxpayer's gross proceeds derived from the sale of CGM systems are deductible from Taxpayer's tax base pursuant to the deductions provided under Arizona Revised Statutes ("A.R.S.") § 42-5061(A)(13) for DME or A.R.S. § 42-5061(A)(9) for prosthetic appliances.

- Whether Taxpayer's gross proceeds derived from the sale of replacement sensors used in CGM systems are deductible from Taxpayer's retail tax base pursuant to the Arizona Administrative Code ("A.A.C.") R15-5-156(C).

RULING:

The versions of Taxpayer's CGM systems that have been approved by the FDA as *therapeutic* devices and therefore approved by Medicare satisfy the definition of DME under A.R.S. § 42-5061(A)(13). They are primarily and customarily used to serve a medical purpose; they are not useful in the absence of illness and are appropriate for use in the home. In addition, the component parts that make up the CGM system can withstand repeated use since all three components comprising the CGM system work as

part of an integral system. Finally, the CGM systems are normally used in accordance with a prescription.

Because the Department determined that the version(s) of Taxpayer's CGM system approved by Medicare qualifies as DME, and the income derived from the sale of the system, including the sale of component and replacement parts, is not subject to the retail TPT, the Department need not determine whether Taxpayer's CGM system also qualifies as a prosthetic appliance.

SUMMARY OF FACTS:

The following facts are a summary based on your ruling request dated February 12, 2018, as well as the additional information provided in your letters dated April 20, 2018 and May 7, 2018:

Taxpayer's primary offices are located in ***. However, its *** and one of its *** *** are located in ***. Taxpayer has developed *** CGM systems which it has sold for several years.

The CGM system is used in the treatment of people with diabetes. In a person without diabetes, the pancreas measures the amount of glucose in the blood and releases insulin to regulate the blood-sugar levels. In a diabetic person, the pancreas may be unable to produce enough insulin or may be unable to produce any insulin at all. Taxpayer's CGM system enables patients to accurately measure their blood-sugar levels so they can take steps to maintain a normal blood-sugar level (e.g. by administering the appropriate dosage of injectable insulin).

Taxpayer's CGM system differs from traditional glucose monitors in that it is capable of delivering glucose readings every *** minutes without any action on the part of the patient. The CGM system comprises:

- A disposable sensor that is inserted under the skin. It senses the blood-sugar levels;
- A transmitter that connects to the sensor and wirelessly transmits glucose readings; and
- A handheld receiver (or ***) that displays glucose readings.

The disposable sensors are approved to be used for seven (7) continuous days. The transmitter is reusable and has either a three-month life or a six-month life depending on the generation of the product. The handheld receiver has a life of two or more years.

Taxpayer has several CGM systems. In the latest version of the CGM system, the transmitter *** transmits glucose readings *** to the patient's *** rather than to a ***. *** *** are provided free of charge for use with the CGM system.

The CGM system may be used without a traditional glucose monitor. However, it is recommended that patients continue using a traditional glucose meter to confirm its calibration. The traditional glucose monitor is not required to calibrate the CGM system. To calibrate the CGM system, the patient inserts a test strip – similar to a test strip used by traditional glucose monitors – into the CGM during the CGM's warmup period. This start-up procedure establishes a daily base-line which is used by the CGM system for continuous monitoring during the day. The traditional glucose monitor is not needed or used during the ongoing continuous monitoring. Taxpayer's newest CGM model does not need a test strip for calibration.

The CGM system is sold initially as a complete package and then as individually priced components to patients; bundles are sold to doctors and hospitals. The CGM system is also designated as reimbursable by Medicare. Medicare reimbursement began in early 2017. Pursuant to the Food and Drug Administration ("FDA") Regulations, sales to individual patients require a prescription and/or statement of medical necessity.

DISCUSSION:

General

Arizona imposes the TPT on the privilege of conducting business in Arizona. The authority to levy TPT is found in A.R.S. § 42-5008. The tax is levied on the seller, rather than the customer. However, the seller may legally pass the economic burden of the tax onto its customers. The Arizona TPT is imposed under sixteen separate business classifications. A.R.S. § 42-5023 states that it is "presumed that all gross proceeds of sales and gross income derived by a person from business activity classified under a taxable business classification comprise the tax base for the business until the contrary can be established."

A.R.S. § 42-5061 imposes TPT under the retail classification. The retail classification is comprised of the business of selling tangible personal property at retail. The tax base for the retail classification is the gross proceeds of sales or gross income derived from the business. All sales of tangible personal property are subject to the TPT under the retail classification unless specific a statutory deduction or exclusion exists.

In relation to medical equipment such as Taxpayer's CGM system, two retail deductions may be applicable. A.R.S. § 42-5061(A)(13) provides a deduction from the tax base for DME and A.R.S. § 42-5061(A)(9) provides a deduction from the tax base for prosthetic appliances as defined in A.R.S. § 23-501 and as prescribed or recommended by certain licensed health professionals.[1]

Durable Medical Equipment

Under A.R.S. § 42-5061(A)(13), sales of DME are deductible from the retail tax base. This deduction only applies to DME that meets all of the following criteria:

- It has a centers for Medicare and Medicaid services common procedure code;
- It is designated reimbursable by Medicare;
- It is prescribed by a person who is licensed under certain chapters of Title 32 of the Arizona Revised Statutes;[2]
- It can withstand repeated use;
- It is primarily and customarily used to serve a medical purpose;
- It is generally not useful to a person in the absence of illness or injury; and
- It is appropriate for use in the home.

If the DME does not meet all of the above criteria, it is not deductible from the retail tax base unless another statutory deduction or exclusion applies.

The Department's *Procedure For Implementation Of The Exemption For Durable Medical Equipment - TPP 93-1* discusses this deduction. TPP 93-1 notes:

> "… [T]he health care procedure code (HCPC) is for payment determinations and, therefore, not required by Medicare for reimbursement purposes. However, a code is eventually assigned to the equipment if Medicare intends to reimburse for it."

Thus, if Medicare reimburses for a DME, a HCPC code is usually assigned.

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[1] A.R.S. § 42-5061(A)(9) specifically refers to professionals who are licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17 or 29. These chapters refer to podiatrists, chiropractors, dentists, physicians etc.

[2] A.R.S. § 42-5061(A)(13) specifically refers to professionals who are licensed pursuant to title 32, chapter 7, 8, 13, 14, 15, 17 or 29. This list is similar to the list provided in A.R.S. § 42-5061(A)(9) with a few exceptions.

The Department of Health and Human Services Centers for Medicare and Medicaid Services issued a ruling, CMS-1682-R, on January 12, 2017 ("CMS Ruling") that addresses whether "therapeutic" CGMs, which provide information that can be used to make diabetes treatment decisions meet the definition of DME.[3] The CMS Ruling describes all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions as "non-therapeutic" CGMs. It noted:

> "In the case of a non-therapeutic CGM, the device is approved to complement, not replace, blood glucose monitors, and therefore, no component of this device is considered to perform the medically necessary function of a glucose monitor. In the case of a *therapeutic* CGM, the device is approved to *replace* blood glucose monitors for making diabetes treatment decisions, and therefore, the system as a whole can replace the blood glucose monitor for certain patients."[4]

Of importance is the fact that the CMS Ruling made the distinction between therapeutic CGMs which are covered by Medicare and non-therapeutic CGMs which are not covered. It noted:

> "Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors. In our view, such devices are not used for making diabetes treatment decisions, such as changing one's diet or insulin dosage based solely on the readings of the CGM, and therefore, has not been covered under Medicare because they are not considered to serve the medical purpose of making diabetes treatment decisions."[5]

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[3] Under federal rules (See §1861(n) of the Social Security Act, 42 CFR 414.202 and § 110.1 of chapter 15 of the Medicare Benefit Policy Manual), DME qualification is similar to Arizona. It must be equipment that:

- Can withstand repeated use;
- Has an expected life of at least 3 years
- Is primarily and customarily used to serve a medical purpose (Arizona statutes do have this requirement);
- Generally is not useful to a person in the absence of an illness or injury; and
- Is appropriate for use in the home.

See §1861(n) of the Social Security Act, 42 CFR 414.202 and § 110.1 of chapter 15 of the Medicare Benefit Policy Manual.

[4] CMS Ruling, page 9.

[5] CMS Ruling, page 6-7.

Thus, not all CGM systems have been approved by the FDA as *therapeutic* devices and therefore not all CGM systems are approved by Medicare. Accordingly, only those versions or generations of Taxpayer's CGM systems that are approved by the FDA as a therapeutic device and are therefore approved by Medicare satisfy the Medicare reimbursement criteria for Arizona TPT purposes.[6] Those therapeutic CGM systems also likely satisfy the requirement for having the HCPC.

The CMS Ruling indicates the therapeutic CGM system completely replaces the traditional glucose monitor used at home by patients. Thus, in relation to the other DME criteria for Arizona TPT purposes, the system is appropriate for use in the home in a similar manner as the traditional glucose monitor. For the same reason, it not useful to persons in the absence of illness and it is primarily and customarily used to serve a medical purpose.

The CGM system must also be shown to be able to withstand repeated use to qualify as DME. Generally speaking, medical supplies which are disposable, single-use items by nature are not considered durable within the meaning of the definition of DME because they cannot withstand repeated use. However, if an item is considered part of an exempt integrated system, then all items required as part of the system as a whole is considered exempt as well. *Department of Revenue v. Cyprus Sierrita Corp*., 177 Ariz. 301, 867 P.2d 871(1994) (chemicals meet the definition of "machine" because they were an "integral part of a complicated process"). See also *RenalWest L.C. v. Arizona Department of Revenue*, 189 Ariz 409, 943 P. 2d 769 (1997) (retail exemption for prosthetic appliance applied to solutions, testing equipment, and supplies used in the dialysis process in addition to the equipment used because dialysis is an integrated process, and all the items are necessary to safely perform the procedure.).

In this case, the sensors are changed weekly. However, they are inserted under the skin only once and remain in place for that duration. They cannot be re-inserted, so they are single-use, disposable items. That notwithstanding, they are an integral part of the CMS system which does not work without them. The transmitter and receiver are used from three to six months and two years respectively to transmit and display blood-sugar levels. All these items function together as part of an integrated system so that continuous monitoring of the patient's blood-sugar levels is possible. Because all the items, as a whole must be used together, and two of the three items may be used repeatedly, the system as a whole is able to withstand repeated use.

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[6] Taxpayer appears to have several versions of CGM systems.

Finally, the statutory exemption requires that the DME must be prescribed or recommended by certain licensed professionals, such as physicians. This does not mean that the doctors and hospitals that purchase the CGM systems must themselves have prescriptions. It is sufficient that the doctors and hospitals provide the CGM systems to patients for use as a result of a licensed professional's prescription. The device itself does not have to be purchased pursuant to a prescription. *RenalWest L.C. v. Arizona Dept. of Revenue,* 189 Ariz. 409, 943 P.2d 769 (1997) (For-profit business that provided prosthetic devices to patients whose doctors had prescribed dialysis was entitled to exemption from use tax, on theory that prosthetic devices which it purchased were "prescribed by a physician," even though business did not itself have doctor's prescription or recommendation to purchase dialysis equipment.) Thus, the sale of the CMS system to patients as well as to doctors and hospitals qualify for the deduction.[7]

Even though Taxpayer also sells individual component parts of the CGM system to customers, the component parts making up the system are exempt for purposes of A.R.S. § 42-5061(A)(13) by virtue of Arizona Administrative Code ("A.A.C.") R15-5-156(C) which provides that the gross receipts derived from the sale of component and repair parts for tangible personal property that is exempt under subsection B (referring to DME, among other exclusions) are not subject to tax. Thus, even if the component parts of the Medicare approved CMS systems are sold separately, each separate sale is not subject to tax. This also applies to repair or replacement parts, including the CGM sensors that must be replaced weekly.

Because the Department determined that the version(s) of Taxpayer's CGM system approved by Medicare qualifies as DME, and the income derived from the sale of the system, including the sale of component and replacement parts, is not subject to the retail TPT, the Department need not determine whether Taxpayer's CGM system also qualifies as a prosthetic appliance.

This response is a taxpayer information ruling (TIR) and the determination herein is based solely on the facts provided in your request. The determinations are subject to change should the facts prove to be different on audit. If it is determined that undisclosed facts were substantial or material to the Department's making of an accurate determination, this taxpayer information ruling shall be null and void. Further, the determination is subject to future change depending on changes in

[7] Also note that (1) the sale for resale deduction or (2) sales to qualifying hospitals or health care organizations as provided under A.R.S. § 42-5061(A)(25) could also apply.

statutes, administrative rules, case law, or notification of a different Department position.

If the Department is provided with required taxpayer identifying information and taxpayer representative authorization before the proposed publication date (for a published TIR) or date specified by the Department (for an unpublished TIR), the TIR will be binding on the Department with respect to the taxpayer that requested the ruling. In addition, the ruling will apply only to transactions that occur or tax liabilities that accrue from and after the date the taxpayer receives the ruling. The ruling may not be relied upon, cited, or introduced into evidence in any proceeding by a taxpayer other than the taxpayer who has received the taxpayer information ruling. If the required information is not provided by the specified date, the taxpayer information ruling is non-binding for the purpose of abating interest, penalty or tax.