PRIVATE TAXPAYER RULING LR05-002

June 13, 2005

This private taxpayer ruling is in response to your letter dated December 28, 2004, as supplemented by your letters dated January 11, January 27, May 3, and May 6, 2005, in which you requested a private taxpayer ruling on behalf of your client, ... Specifically, you requested, on behalf of . . . , that the Department rule that the stent system sold by . . . to Arizona hospitals is exempt from Arizona transaction privilege tax. Pursuant to Arizona Revised Statutes ("A.R.S.") § 42-2101, the Department may issue private taxpayer rulings to taxpayers and potential taxpayers on request.

Below is a restatement of the facts as provided in both the "Facts" section of, and copies of brochures included with, your request for a private taxpayer ruling made on behalf of . . . and supplemental letters.

Statement of Facts:

Coronary Artery Disease ("CAD") occurs when the inner walls of the coronary arteries, which surround the heart, thicken due to plaque (a buildup of cholesterol, fatty deposits, calcium, and other elements). Angioplasty, one of the treatments for CAD, is a procedure used to open blocked arteries. A catheter (a thin tube) is inserted through the groin or wrist and then threaded through a major blood vessel to the site of the blockage. A small balloon on the tip of the catheter is then expanded to reduce the blockage. This procedure may also involve the placement of a coronary stent. Coronary artery stents help reduce the risk of restenosis. Restenosis is a renarrowing of the artery following angioplasty. Stents are small expandable tubular structures that are implanted into a vessel and expanded to fit the size, shape, and bend of the vessel wall. The stents prop open the vessel and help prevent further blockages. The stent remains in the artery and the artery wall heals around it as the stent continues to support the vessel.

. . . is a manufacturer and distributor of medical devices, including different types of stent systems. . . .'s products are primarily sold to physicians, hospitals, and other medical facilities. The majority of the stent systems sold by . . . to numerous Arizona hospitals are drug-eluting coronary stent systems. Drug-eluting stents are designed to deliver a drug locally to minimize restenosis and reduce the need for additional treatment in the stented area. The stent comes premounted on a balloon catheter based delivery system, which is used to open blocked arteries and allow for expansion of the stent.

The stent has been coated with the drug paclitaxel and a polymer. The paclitaxel/polymer coating has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls, minimizing release into the bloodstream. . . . does not require a written prescription on purchases of the stents. Warning labels are included on . . .'s product indicating "Caution: Federal law restricts this product to sale by or on the order of a

physician." The drug paclitaxel meets the requirement under 21 U.S.C. § 353(b)(4)(A). The coronary stent system is sold and invoiced at one price.

Issues:

. . .'s issues as presented in your letter dated December 28, 2004:

1. Is a stent system an exempt prosthetic device?

2. If . . .'s customer is a for profit hospital, which uses the stent system to provide non-taxable services (coronary stenting) and the hospital charges the patient for the stent system within the service charge, is the sale of the stent system from . . . to the hospital a sale for resale? If so, can . . . receive a resale certificate from its customer (the hospital)?

3. If the transaction between . . . and its customer is a sale for resale and the customer provides a resale certificate to . . . today, can . . . file a refund claim for the sales tax paid on the stent systems previously sold to its customer?

4. If the stent is drug coated, is the delivery device (balloon catheter) exempt similar to a delivery hose for prescribed oxygen pursuant to A.R.S. § 42-5061(A)(8)?

Your Position:

. . .'s position as stated in your letter dated December 28, 2004:

> It is . . .'s opinion that the stent system sold by . . . to Arizona heart hospitals is 100% exempt. The stent systems [sic] is a non-taxable prosthetic device (stent), which is exempt pursuant to A.R.S. § 42-1310.01(A)(9) [sic, A.R.S. § 42-5061(A)(9)] and A.R.S. § 42-5061(A)(8).

. . .'s position as stated in your supplemental letter dated January 27, 2005:

> . . . sells stent systems to a for profit hospital. The hospital in turn uses the stent system within non-taxable services (coronary stenting). The hospital charges its patients for the non-taxable services, which include the cost of the stent systems. Therefore, pursuant to Sec. 42-5061(S), A.R.S. [sic, A.R.S. § 42-5061(V)(3)], the sale of stent systems to the hospital is a sale for resale, since the hospital resells the stent to the patient within the charges for the non-taxable services (coronary stenting).
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> . . .

A.R.S. § 42-5061(A)(8) states 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. The tax imposed on the retail classification does not apply to the gross proceeds of sales or gross income from drugs and medical oxygen, including delivery hose, mask or tent, regulator and tank, on the prescription of a member of the medical, dental or veterinarian profession who is licensed by law to administer such substances.

. . .

As we provided in our letter dated December 28, 2004, drug-eluting stents are designed to deliver a drug locally to minimize restenosis and reduce the need for additional treatment in the stented area. The stent system consists primarily of an expandable metal mesh tube (stent) that helps restore blood flow by serving as permanent vessel support for a newly widened artery formerly blocked by plaque deposits. The stent comes pre-mounted on a balloon catheter based delivery system, which is used to open blocked arteries and allow for expansion of the stent. The stent has been coated with the drug paclitaxel and polymer. The paclitaxel/polymer coating has been designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls, to minimize release into the blood stream.

A delivery hose for oxygen is exempt pursuant to A.R.S. § 42-5061(A)(8) because it is used to delivery [sic] medical oxygen on the prescription of a member of the medical, dental or veterinarian profession who is licensed by law to administer such substances. Similarly, the balloon catheter based delivery system is used within a prescribed surgery (coronary stenting) by a for-profit hospital to deliver a stent coated with a drug for a controlled release from the stent surface. Therefore the delivery device used within the coronary stenting is used in a similar manner as a delivery hose for medical oxygen. The only difference is, instead of the delivery hose, there is a balloon catheter based delivery system and instead of the medical oxygen, there is the stent coated with the drug paclitaxel and polymer designed to allow for a consistent and controlled release of the drug from the stent surface into the artery walls, to minimize release into the blood stream. Although . . . does not require a written prescription on purchases, warning labels are included on . . .'s products indicating Federal law restricts this product (stent system) to sale by or on the order of a physician. Since sales of stent systems are restricted by Federal law only by or on the order of a physician and the stent systems are used within a prescribed surgery (coronary stenting), we believe this meets the A.R.S. § 42-5061(A)(8) requirement of "on the prescription of a member of the medical, dental or veterinarian profession who is licensed by law to administer such substances". Therefore, the balloon catheter based delivery system is exempt pursuant to A.R.S. § 42-5061(A)(8).

Applicable Law:

A.R.S. § 42-5061(A) states that "[t]he 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."

A.R.S. § 42-5061(A)(9) exempts from the retail classification "[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a health professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17, or 29." These chapters refer to podiatrists, doctors of chiropractic, dentists, physicians and surgeons, naturopathic physicians, nurses, osteopathic physicians and surgeons, and homeopathic physicians.

A.R.S. § 23-501 defines "prosthetic appliance" as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ."

A.R.S. § 42-1329 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."

Arizona Administrative Code ("A.A.C.") defines "prosthetic appliance" as "an artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ." In addition, A.A.C. R15-5-156(C) states that the sale of component and repair parts for an exempt prosthetic appliance is exempt.

A.R.S. § 42-5061(A)(8) exempts from the retail classification "[d]rugs and medical oxygen, including delivery hose, mask or tent, regulator and tank, on the prescription of a member of the medical, dental or veterinarian profession who is licensed by law to administer such substances."

Conclusions and Ruling:

For the reasons stated below, the Department rules as follows:

1. A.R.S. § 42-5061(A)(9) excludes "[p]rosthetic appliances as defined in § 23-501 prescribed or recommended by a professional licensed pursuant to title 32, chapter 7, 8, 11, 13, 14, 15, 16, 17 or 29." A.R.S. § 23-501(7), in turn, defines a "prosthetic appliance" as "an artificial device necessary to support or take the place of a part of the body, or to increase the acuity of a sense organ." In addition, A.A.C. R15-5-156 defines a "prosthetic appliance" as an "artificial device which fully or partially replaces a part or function of the human body or increases the acuity of a sense organ."

   Given the exclusion for prosthetic appliances, and the definitions of a "prosthetic appliance" cited above, the Department concludes that the drug-eluting stent at issue is exempt from transaction privilege tax under the retail classification. The stent, although

coated with drugs to minimize restenosis, is used to support or take the place of a part of the artery. Therefore, the coronary stent qualifies as an exempt prosthetic appliance.

Nevertheless, the stent at issue comes premounted on a balloon catheter based delivery system that does not meet the definition of a "prosthetic appliance," as it merely opens the blocked artery and allows for expansion of the stent. Therefore, the balloon catheter based delivery system is not exempt as a prosthetic appliance.

. . . sells and invoices the coronary stent system at one price. If . . . invoices the stent separate from its delivery system, the stent will qualify as an exempt prosthetic appliance.

2. Moreover, the sale of the balloon catheter based delivery system is not exempt as a sale for resale. A.A.C. R15-5-156 states that "[g]ross receipts from the sale of nonprescription drugs and other medical supplies to doctors . . . are not taxable if the tangible personal property qualifies as a sale for resale and the doctor. . . is a retailer in the business of reselling such property." In this case, however, the doctor provides the delivery system as part of the nontaxable "service charge" for the stenting procedure. As stated in A.A.C. R15-5-104, "[g]ross receipts from the sales of tangible personal property to a person engaged in a professional or personal service occupation or business are taxable if the tangible personal property is used or consumed in the performance of the service or is sold only as an inconsequential element of the nontaxable service provided" (emphasis added). The delivery system at issue is sold to a person engaged in a professional service occupation, namely a doctor, and used in the performance of the stenting procedure. Therefore, the sale of the delivery system is not a sale for resale, but a taxable sale to a professional for use in his or her nontaxable services.

3. The Department does not reach a conclusion regarding a refund claim as the sale of the coronary stent system is not a sale for resale.

4. In addition, although the paclitaxel/polymer coating on the drug eluting stent system meets the definition of a prescription drug, the balloon catheter based delivery system falls outside the scope of A.R.S. § 42-5061(A)(8). The statute is narrowly drawn to exempt only delivery devices used for medical oxygen. The paclitaxel/polymer coating, however, meets the definition of a "prescription drug." A "prescription drug" is defined in A.A.C. R15-5-156(A)(5) as a drug on prescription. A "drug on prescription," in turn, is defined in A.A.C. R15-5-156(A)(1) as a substance that can only be dispensed on the direction of a member of the medical, dental, or veterinary profession who is licensed by law to administer such drug, and which cannot be purchased without such authorization. A "legend drug" is considered a drug on prescription. A "legend drug" is defined in A.A.C. R15-5-156(A)(3) as a drug that bears the statement "CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT A PRESCRIPTION." Therefore, the paclitaxel/polymer coating is exempt from transaction privilege tax and may be invoiced either separately or together with the exempt coronary stent.

The conclusions of this private taxpayer ruling do not extend beyond the facts as presented in your letters dated December 28, 2004, January 11, January 27, May 3, and May 6, 2005.

This response is a private taxpayer ruling and the determinations herein are 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 ruling shall be null and void. Further, the determination is subject to future change depending on changes in statutes, administrative rules, case law or notification of a different Department position.

The determinations in this private taxpayer ruling are applicable only to the taxpayer requesting the ruling and may not be relied upon, cited nor introduced into evidence in any proceeding by a taxpayer other than the taxpayer who has received the private taxpayer ruling.

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