

Cite as Det. No. 95-122, 15 WTD 86 (1995).

BEFORE THE INTERPRETATIONS AND APPEALS DIVISION
DEPARTMENT OF REVENUE
STATE OF WASHINGTON

In the Matter of the Petition)	<u>D</u> <u>E</u> <u>T</u> <u>E</u> <u>R</u> <u>M</u> <u>I</u> <u>N</u> <u>A</u> <u>T</u> <u>I</u> <u>O</u> <u>N</u>
for Request of Ruling on Tax)	
Liability of)	No. 95-122
)	
. . .)	Registration No. . . .
)	

RULE 18801; RCW 82.08.0281, RCW 82.12.0275: SALES AND USE TAXES -- EXEMPTION -- CONTRAST MEDIA -- DELIVERY SYSTEMS. Inflation devices from which contrast media are released into balloon catheters to inflate the balloons when used under a physician's order on specific patients are exempt from retail sales and use taxes as part of the contrast media's delivery system. The contrast media do not need to be released into the patient's body.

Headnotes are provided as a convenience for the reader and are not in any way a part of the decision or in any way to be used in construing or interpreting this Determination.

NATURE OF ACTION:

Pursuant to WAC 458-20-100 (Rule 100), subsection (9), an out-of-state medical products manufacturer requests a written opinion whether sales tax applies to the items it sells, primarily, to hospitals.¹

FACTS:

De Luca, A.L.J. -- In a July 11, 1994 letter, the taxpayer requested an opinion from the Department of Revenue (Department) concerning whether the several medical products it manufactures outside Washington and sells to Washington customers are subject

¹Identifying details regarding the taxpayer and the assessment have been redacted pursuant to RCW 82.32.410.

to or exempt from retail sales tax. The taxpayer's products are used in the treatment of coronary artery disease through a procedure known as percutaneous transluminal coronary angioplasty (PTCA). The Department's Taxpayer Information and Education Section (TI&E) responded by letter on July 27, 1994. TI&E informed the taxpayer, without explanation, that its coronary balloon dilatation catheters, coronary guide wires, coronary guiding catheters, and accessories, including the taxpayer's inflation device, angioject (syringe), hemostatic valve, guide wire introducer, torque device, a PTCA accessory kit, and the guide wire accessory kit, were exempt from sales tax.

On September 1, 1994, TI&E revised its earlier letter by informing the taxpayer, without explanation, that the following specific products are subject to sales tax: the non-perfusion coronary balloon dilatation catheters², the coronary guide wire, the taxpayer's inflation device, the guide wire introducer, the torque device, and the PTCA kit.

Apparently, both TI&E letters concede the coronary guiding catheter, the angioject (syringe), the hemostatic valve, and the guide wire accessory kit (whose primary component is the hemostatic valve) are exempt from sales tax because TI&E's first letter declared them exempt and its second letter did not identify them as taxable items. Because these products are not at issue, we need not discuss them further. TI&E's second letter also informed the taxpayer it had the right to appeal the opinion to the Department's Interpretation and Appeals Division (I&A) pursuant to Rule 100.

The taxpayer appealed by letter and asks whether the non-perfusion catheters and the other products declared taxable are taxable or exempt. During a telephone conference, the taxpayer's representatives requested an opinion on related matters which we will describe below.

The taxpayer states its appeal to I&A concerning the catheters is based on additional facts not contained in its letter to TI&E. The taxpayer explains that PTCA is a technique used to widen narrowings in the coronary artery without surgery. The coronary balloon dilatation catheter is the key component of the PTCA procedure. Because arterial narrowings vary greatly in their types, shapes, and composition, cardiologists require great flexibility when performing the PTCA procedure.

²A non-perfusion catheter does not allow blood to flow when the balloon is inflated.

The taxpayer manufactures one category of single-use, non-perfusion catheters called over-the-wire (OTW) catheters. The taxpayer explains OTW catheters extend over a separate guide wire. The OTW catheters are available in various combinations of balloon diameters, balloon lengths, and may accept a variety of guide wire diameters. The taxpayer's OTW catheters are multi-lumen. A lumen is a cavity or channel within a tube. Generally, one lumen allows the balloon to inflate and the second lumen allows for the insertion of the contrast guide wire and/or contrast media or anti-spasmodic drugs. Widening arteries and injecting prescription drugs and contrast media can be done during the same operation. Depending on the patient, the cardiologist decides whether to insert contrast media or anti-spasmodics directly into a lumen. The cardiologist may also insert a guide wire directly into the lumen along with the contrast media.

The taxpayer reiterates it does not advise cardiologists on the use of individual lumens during PTCA procedures. Instead, it designs and manufactures the OTW catheters to allow cardiologists maximum flexibility when performing PTCA procedures. Accordingly, its literature provides only technical information about the product, including, for example, identifying the component parts and dimensions. However, the cardiologists are the ones who must decide how to use the catheters and lumens in their patients.

The taxpayer further asks whether it can accept resale certificates from hospitals for its sales of such items to them. It also requests an opinion whether all of its disposable, single-use products are exempt from sales tax.

ISSUES:

1. Are disposable, single-use medical products per se exempt from sales tax. 2. Are these non-perfusion catheters and disputed accessories subject to sales tax? 3. May the taxpayer accept resale certificates from hospitals purchasing its products to be used for PTCA procedures?

DISCUSSION:

The first issue we address is whether sales of all of the taxpayer's single-use products are exempt per se from sales tax. They are not.

RCW 82.08.0281 and RCW 82.12.0275 exempt the sale or use of prescription drugs from retail sales tax and use tax, respectively. RCW 82.08.0283 and RCW 82.12.0277 exempt the sale or use of insulin, prosthetic and orthotic devices, ostomic items

and medically prescribed oxygen from retail sales tax and use tax, respectively. WAC 458-20-18801 (Rule 18801) derives from these statutes. We will discuss below the fact that some of the taxpayer's products are not themselves prosthetic or orthotic devices or ostomic items and are not specifically identified by Rule 18801 as exempt. Furthermore, some of these products do not deliver or apply exempt items such as sutures, prescribed drugs, contrast media, or medical gases. Therefore, some of the products when sold alone are subject to sales tax whether they are disposable or reusable. We will also discuss below that some of these otherwise taxable items may be exempt when sold as part of a kit whose primary contents are exempt. Det. No. 92-164, 12 WTD 205 (1994).

We next address which of the taxpayer's single-use products are exempt. The taxpayer states it manufactures the non-perfusion catheters with multiple lumens capable of delivering anti-spasmodic prescription drugs and/or contrast media. Under Rule 18801 prescription drugs and contrast media used under a physician's order as part of a medical treatment for a specific patient are exempt from sales tax. Catheters and other components of delivery systems for prescribed drugs, medical gases, and contrast media are also exempt under Rule 18801.

The taxpayer's non-perfusion catheters are used to deliver prescribed drugs and/or contrast media or, at least, are capable of delivering such substances. Consequently, the taxpayer's non-perfusion catheters are exempt from sales tax. See also, Det. No. 91-261S, 12 WTD 23 (1992) and the Department of Revenue's February 24, 1995 Special Notice to medical supply vendors stating that, among other items, delivery catheters and delivery systems for prescribed drugs and contrast media are exempt from sales tax.

We next address whether the accessory products are taxable or exempt. The taxpayer explains:

A coronary guide wire is loaded into the balloon dilatation catheter through the use of a guide wire introducer. The coronary guide wire and coronary balloon dilatation catheter are advanced through the coronary guiding catheter. A torque device is placed on the end of the coronary guide wire and is used to steer the coronary guide wire to the artery until its tip is beyond the narrowing. Coronary guide wires are used to support the coronary balloon dilatation catheter as it is advanced across the artery narrowing. Their steerability is necessary to maneuver the coronary balloon dilatation catheter to the correct branches of the coronary arteries.

We have already noted TI&E has ruled that the coronary guiding catheter is exempt. However, we find the guide wire introducer, the coronary guide wire, and the torque device are not exempt from sales tax because they are not designed for and do not deliver either prescribed drugs or contrast media. Instead, they are tool-like instruments used to maneuver the tax exempt coronary balloon dilatation catheter into place. 12 WTD 205, at 208, supra.

We address the remaining two items declared taxable by TI&E: the taxpayer's inflation device and the PTCA kit. After the physician has placed a deflated coronary balloon dilatation catheter in position in the artery narrowing, the physician forces the contrast media into the balloon, thereby inflating the balloon. The contrast media originates in the taxpayer's inflation device which is connected to the balloon catheter outside the patient's body. In addition to inflating the balloon, the contrast media is necessary to detect the exact location of the balloon when expanded. The taxpayer asserts the contrast media is critical to the treatment and diagnosis of the patient's heart disease, because the inflated balloon opens up the narrowing of the coronary artery by splitting and compressing the plaque against the wall of the artery. The balloon may be inflated and deflated several times during PTCA. Finally, the taxpayer's inflation device measures and monitors the amount of pressure of the contrast media flow required to inflate the balloon.

[1] As noted, Rule 18801(5)(g) provides that sales tax does not apply to the purchase of contrast media ". . . when . . . used under a physician's order as part of a medical treatment for a specific patient." As shown, physicians use the contrast media in treating their specific patients. The contrast media flows from the taxpayer's inflation device through the catheter to the balloon. The contrast media can be and often is withdrawn from the balloon and the patient during and at the end of the PTCA procedure. Without the inflation device and the balloon catheter, the contrast media is ineffective because it is unable to reach the treatment area. In order to be exempt, the rule does not require the contrast media be injected into a patient's bloodstream or otherwise remain in the patient's body after the physician has used it in the patient. By then, the contrast media has served its purpose of inflating the balloon, detecting the problem area, and compressing the plaque. Thus, contrast media serves a different purpose than prescription drugs which are injected or otherwise delivered into and remain in a patient's body to be effective.

In 12 WTD 23, supra, at 26, the Department held that if all an angioplasty procedure does is inflate a balloon catheter to

expand a narrowed artery, it is not exempt because it does not deliver drugs or replace body parts or functions. The determination continues by noting that such single-function catheters are seldom used and multiple-function (multiple lumens) catheters delivering contrast media and prescription drugs are more common and are exempt. We wish to clarify the ruling in 12 WTD 23 by holding if a single-function balloon catheter is inflated with contrast media then the catheter is exempt as part of the contrast media's delivery system. We find the present taxpayer's inflation device is part of the delivery system because it is not conceptually distinct from the contrast media. Deaconess Medical Center v. Department of Rev., Docket No. 87-2-2055-7 (Thurston County Superior Court, 1989). Therefore, the taxpayer's inflation device is exempt from sales tax.

The PTCA kit is also exempt. It is composed of the taxpayer's inflation device, a hemostatic valve, a guide wire introducer, and a torque device. As discussed above, the inflation device and the hemostatic valve are exempt. The other two items are not exempt by themselves. However, the exempt items are by far and away the most valuable items. The taxpayer's inflation device costs \$80, and the hemostatic valve about \$25, while the guide wire introducer is \$3 and the torque device is \$5. Because the primary items in the pack are part of the delivery system and not conceptually distinct from the exempt contrast media, the pack as a unit is exempt. 12 WTD 23, at 27, 12 WTD 205 at 208, supra, and Rule 18801.

The last issue is whether the taxpayer may accept resale certificates from hospitals purchasing its products. WAC 458-20-102 (Rule 102) governs resale certificates. It provides in part:

Except as hereinafter noted, all sales are deemed to be retail sales unless the seller takes from the buyer a resale certificate signed by and bearing the registration number and address of the buyer, to the effect that the property purchased is:

(1) For resale in the regular course of business without intervening use,

It would be improper for the taxpayer to accept resale certificates when hospitals and their physicians use the taxpayer's products in PTCA procedures on patients because such use by the hospitals is intervening use. The contractual relationship between a hospital and a patient is not one of sale, but of service. Det. No. 90-35A, 9 WTD 289 (1990). The hospitals are using the products as part of the medical services they provide to their patients. The hospitals are not reselling the products to the patients.

Rather than accepting resale certificates, the taxpayer may accept from purchasers of the above-described exempt items the exemption certificate described in Rule 18801(6).

DECISION AND DISPOSITION:

Taxpayers are entitled to request a ruling pursuant to Rule 100(9). Normally, a taxpayer would be permitted to rely upon the ruling for reporting purposes and as support of the reporting method in the event of an audit. This ruling is based upon only the facts that were disclosed by the taxpayer and will not necessarily be binding on the Department should the position of the Department change. It also shall not be binding if there are relevant facts which are in existence but not disclosed at the time this opinion was issued; if, subsequently, the disclosed facts are ultimately determined to be false; or if the facts as disclosed subsequently change and no new opinion has been issued which takes into consideration those changes.

DATED this 22nd day of June, 1995.