

Memorandum

425.0481

To : Mr. Mike Kitchen
Audit Review and Refunds

Date: January 11, 1993

From : John L. Waid
Tax Counsel

Subject: **SR – XX-XXXXXX**
S--- J---'s H---
Class Claim for Refund

As you know, an attorney in Washington State has filed Claims for Refund of sales and use taxes from sales of intravenous ("IV") sets and chemical reagents on behalf of twelve hospitals and three medical supply vendors. He is promoting this claim as a class claim under Regulation 5057.5. This memorandum sets forth the position of the Legal Division regarding the application of tax to sales of such items.

I. FACTUAL BACKGROUND

The Claim for Refund, filed June 7, 1991, describes the items which are the subject of the Claim as follows:

A. Intravenous ("IV") Sets.

"An IV set is the material required to transfer liquid or gaseous medication from the bag or container into the patient. It consists of two parts: tubing and access device. The tubing is the sterile plastic apparatus consisting of plastic tubes and a controlling device (either gravity feed or machine monitored). The tubing has injection ports or sites. The access device is either a needle (peripheral access device) or a catheter (central access device) which is inserted into a blood vessel or other part of the body or a mask or other face piece.

"Included in the term IV sets are similar items: blood sets, hyperalimentation sets, nasogastric sets, gastronomy parts, anaesthesia sets, radiology sets, face covers and tubes for medical gases...."

(Claim for Refund, 2:28-3:24.)

B. Diagnostic Substances or Preparations ("Reagents").

"When a person is ill, a sample of cells, tissues or organ is removed from the body and tests are performed on the body sample. Diagnostic substances are applied externally to the body sample to assist the treating physician in diagnosing to disease. ... [¶] ... While the 'medicines' need not be applied to the patient to gain exemption, they must be applied to the human body. Purdue Frederick Co. v. State Board of Equalization, 267 Cal. Rptr. 482 (Cal. App. 2 Dist. 1990). Diagnostic substances are applied externally to parts of the human body i.e., cells, tissues, organs...."

(Claim for Refund, 5:28-6:13.)

II. OPINION

A. Sales and Use Tax Generally.

In California, except where specifically exempted by statute, Revenue and Taxation Code Section 6051 imposes an excise tax, computed as a percentage of gross receipts, upon all retailers for the privilege of selling tangible personal property at retail in this state. (Unless otherwise stated, all statutory references are to the Revenue and Taxation Code.) "[I]t shall be presumed that all gross receipts are subject to tax until the contrary is established. The burden of proving that a sale of tangible personal property is not a sale at retail is upon the person who makes the sale ..." (§ 6091.) "Exemptions from taxation must be found in the statute." Market St. Ry. Co. v. Cal. St. Bd. of Equal. (1953) 137 Cal.App.2d 87, 96 [290 P.2d 201.] The taxpayer has the burden of showing that he clearly comes within the exemption." Standard Oil Co. v. St. Bd. of Equalization (1974) 39 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

B. Prescription Medicines.

Section 6369, interpreted and implemented by Title 28, California Code of Regulations, Regulation 1591, provides that sales of medicine, when prescribed and sold or furnished under certain conditions for the treatment of a human being, are exempt from sales or use tax. (Reg. 1591(a).) Subdivision(b)(1) defines "medicine" to "mean and include any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and which is commonly recognized as a substance or preparation intended for such use." However, Regulation 1591(c)(2) adds that "medicines" do not include "articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices, or other mechanical, electronic, optical or physical

equipment or article or the component parts and accessories thereof." (Sales and Use Tax Regulations are Board promulgations which have the force and effect of law.) As a rule, then, items used to diagnose a condition or to apply medicine or treatment to the patient are not considered to be medicines.

C. Tax Consequences.

1. IV Sets.

Durable medical equipment in general has always been excluded from the definition of "medicine" in Section 6369. When the section was enacted in 1961, certain medical devices were excluded. (Stats. 1961, Ch. 866, § 1.) The exclusion was re-cited in 1963 as Section 6369(b) and expanded to read pretty much as it does today. (Stats. 1963, Ch. 716, § 1.)

Subsequent legislation has limited the scope of this exclusion. Orthotic and Prosthetic devices designed to be fully worn on the person of the user were included in the definition of "medicines" as Section 6369(c)(3) & (4) in 1977. (Stats. 1977, Ch. 1245.) Programmable drug infusion devices to be worn on or implanted in the person of the user were included as "medicines" beginning in 1983. (Stats. 1982, Ch. 1589.)

As described in the Claim for Refund, IV sets are used for the purpose of introducing drugs, nutrients, and diagnostic substances into patients. They are made of metal or other durable components and so are not "substances or preparations". They are not worn on the person of the patient. They also do not depend on being metabolized within the body to achieve their intended purposes. (See, Health & Saf. Code § 26009.) We have long held that such items are devices or appliances within the meaning of Section 6369(b)(2). (See, Reg. 1591(c)(2).) Sales of such devices are thus subject to tax.

As noted above, programmable drug infusion devices designed to be fully worn on the person of the user were specifically exempted by the legislature in 1982. Thus, infusion devices which do not meet that definition are excluded from this exemption. "It may be presumed that these amendments were made with full knowledge of the construction which had been placed upon the statute by the Board of Equalization, yet there was no modification of the legislation which would require a contrary interpretation. This is a factor that may be considered in determining the meaning of the terms intended by the legislature." (Coca-Cola Co. v. S.B.E. (1945) 25 Cal.2d 918, 922 [156 P.2d 1].) "It has been held that where an administrative officer or board has adopted a regulation defining certain transactions as coming within the scope of a sales tax statute, and the Legislature subsequently reenacts the statute without amendment in this regard, the reenactment amounts to a legislative confirmation of the prior existing rules of interpretation." (Universal Engineering Co. v. S.B.E. (1953) 118 Cal.App.2d 36, 41 [256 P.2d 1059].) Since the legislature did not amend the statute to alter our position that sales of non-programmable drug infusion devices not designed to be fully worn on the person of the user are taxable, our interpretation is

presumptively correct.

The Claim for Refund refers to catheters being one of the access devices for the IV sets. The rule is, however, that sales of catheters are generally taxable, with three major exceptions: (1) catheters which are permanently implanted are exempted under Regulation 1591(b)(2)); (2) catheters which are used for drainage purposes through artificial openings are non-taxable under section Regulation 1591(j) dealing with ostomy materials (this exemption includes supplies); and (3) catheters or other types of drainage devices used for drainage through natural openings are non-taxable as prosthetic devices under Regulation 1591(b)(5). They may also be exempted if they are an integral and necessary part of another exempt item. The catheters described in the Claim are temporarily (presumably) inserted in order to infuse medication or nutrients into the patient. They are not permanently implanted, nor do they act as drains nor are they related to another exempt item. They do not come within any exception to the general rule.

2. Reagents.

As described in the Claim for Refund, reagents are applied to samples of tissues, cells, and organs taken from the patient's body. They are thus used completely externally and never applied to the body of the patient. We have long held that such reagents are not applied internally or externally to the body of the patient and so do not come within the definition of medicines contained in Regulation 1591(b)(1). (See, former Annot. 425.0540, now deleted because the product at issue therein is no longer made.)

We do not agree that the holding in Purdue Frederick alters this result. There was no question in that case that the item at issue therein - surgical scrub - was considered a medicine. (Ibid. at 1027.) The issue there was to whose body- the patient's or the doctor's - did the item have to be applied in order to qualify for the exemption. There is nothing in the opinion to indicate that a substance which never touches the patient's person but is applied only to tissues removed from it for testing purposes would qualify as a medicine under the above authority.

JLW:es

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