



STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION

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December 31, 1990

Dear X-----,

X----- has forwarded your letter of October 25, 1990, to me for a response. You have requested a ruling on the taxable status for various items that X----- (hereinafter X-----) sells. Various of X----- California customers have requested it to process sales tax credits for items that their auditors claim should be exempt. You attached a list of the items in question which also included a description and general use statement. In a subsequent telephone conversation with one of your personnel, the Mahurkar Tray and gloves was added to the list. It has the same use as the Mahurkar Kit (already listed) but contains more items.

First, we note that the Board of Equalization's staff may not issue tax rulings; only the Board itself may do so. However, we can give you our opinion regarding the correct application of tax to X-----'s sales of the items which you listed.

OPINIONA. Sales and Use Tax Generally.

In California, except where specifically exempted by statute, Revenue and Taxation Code Section 6051 imposes a sales 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. State Bd. of Equalization (1974) 99 Cal.App.3d 765, 769 [114 Cal.Rptr. 571].)

B. Exemption for Prescription Medicines

Section 6369(a) interpreted and implemented by Title 18, California Code of Regulations, Regulation 1591 (regulations are Board rulings that have the force and effect of

law), provides that sales of medicines, when prescribed and sold or furnished under certain conditions, are exempt from sales or use tax. The statute goes on to specifically exclude from the definition of "medicines" items in the nature of instruments, apparatus, appliances, contrivances, devices, or other equipment or article and the replacement parts thereof (§6369(b)(2).) As a general rule, then, items used to apply medicine or treatment to the patient are not considered to be medicines. Over the years, however, the Legislature has provided exceptions to that general rule.

1. Hemodialysis Products.

a. Hemodialysis Machines and Related Supplies.

Effective October 1, 1977, Revenue and Taxation Code Section 6369 was amended to provide the following exemption:

"Any appliances and related supplies necessary as the result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste shall be deemed to be dispensed on prescription within the meaning of this section."

(Section 6369(f). In 1978 a new subsection (f) was added and this section was redesignated as 6369(g).)

We have previously concluded that artificial kidney machines and related supplies qualify as "medicines" under this section. As such, tax will not apply to the sale of such items. We have also determined that items qualifying as "related supplies" under this section must be necessary and integral to the proper functioning of the dialysis machines or substances or preparations intended for external or internal application to the human body of the patient undergoing dialysis. Accordingly, items which are used by technicians while operating the dialysis process or which are not utilized by the dialysis patient are not exempt from tax under this section.

b. Hemodialysis Products.

Section 6369.1 of the Sales and Use Tax Law provides as follows:

"There are exempted from the taxes imposed by this part the gross receipts from the sale, and the storage, use or other consumption in this state of hemodialysis products supplied to a patient on order of a licensed physician and surgeon pursuant to Section 4050.7 or 4227 of the Business and Professions Code and which constitute medicines as defined in Section 6369."

See also, Regulation 1591(a)(b).

It is critical to recognize that Section 6369.1 does not enlarge the class of items which may be exempt from the tax. To qualify for exemption under Section 6369.1 a particular item must be a "medicine" in accordance with the definition of that term as it is used in Section 6369.

The change which Section 6369.1 made in the law was to enable hemodialysis patients to acquire such medicines directly from manufacturers and distributors.

2. Catheters.

Prior to October 1, 1977 only those catheters which were permanently (i.e., for at least six months) "implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remained permanently or dissolved in the body" were considered exempt medicines. (§6369(c)(2); Regulation 1591(b)(2).

Effective October 1, 1977, Revenue and Taxation Code section 6369 was amended to add:

"Mammary prostheses, and any appliances and related supplies necessary as a result of any surgical procedure by which an artificial opening is created in the human body for the elimination of natural waste." (Section 6369(g) .)

"Prosthetic devices, and replacement parts for such devices, designed to be worn on or in the person of the user to replace or assist the functioning of a natural part of the human body." (Section 6369(c)(4).)

As a result of the 1977 amendments, certain drainage catheters were considered exempt medicines under section 6369(g) because they were utilized as a result of a surgical procedure by which "an artificial opening is created in the human body for the elimination of natural waste." Certain other drainage catheters were still considered taxable because they were utilized through a "natural opening." Since 1977 several types of drainage catheters have been classified as exempt medicines even though they were utilized through a natural opening. The main requirement was that the catheters had to be worn on the person of the user or be permanently implanted. The interpretation to allow drainage catheters used as a result of a natural opening was an extension of the exemption provided to catheters in section 6369(g). As a consequence, the requirement for post-surgical use was maintained. Certain other catheters which are used for diagnostic purposes, irrigation, feeding and administration were not considered exempt under any part of section 6369 and tax applies to their sale.

In summary, catheters are generally taxable, with three major exceptions: (1) catheters which are permanently implanted are exempted under section 6369(c) (2); (2) catheters which are used for drainage purposes through artificial openings are non-taxable under section 6369(g) 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 section 6369(c)(4). Catheters may also be exempted if an integral and necessary part of another exempt item.

C. Tax Consequences to X-----

Turning now to the specific items on your list, we conclude as follows:

1. Mahurkar Kit
Part Number: 13793-001, 13871-001

Description: Dual lumen polyurethane central venous catheter with kit containing items needed for catheter placement via Seldinger Technique.

Intended Use: Short-term use for hemodialysis or abperesis.

We have previously considered that tubing and catheters are necessary and integral supplies used in conjunction with artificial kidney dialysis machines. Sales of such catheters are not subject to tax under section 6369(g).

I need to make a general comment here. You list the use of a number of items, such as the Mahurkar Kit, as being for "abperesis". I have searched three medical dictionaries, including Stedman's Medical Dictionary, 5th ed. (Washington, DC, 1982) and am unable to locate any reference to such a procedure. Could this word be a typo? The closest I can come to it is "pheresis" which Stedman's defines as a "procedure in which blood is removed from a donor, separated, and a portion retained, with the remainder returned to the donor." (Ibid. at p.1072). This is a procedure used by blood banks and centers which supply blood products to them. We have previously concluded that except for the sales of items such as blood bags and tubing containing the blood or blood products, which are sold to the blood banks along with their contents, the sale of items used in the pheresis process are subject to tax. If "pheresis" is not what you had in mind, please let me know the correct word and describe the process. In the meantime, you should treat the sales of items sold for "abperesis" as taxable.

a. Mahurkar Gloves and Tray.

According to the information I received over the phone, this kit contains more items than the Mahurkar Kit and has the same uses. As noted above, we have previously concluded that not all supplies used in dialysis are exempt as "related supplies". You do not list the items contained in the Gloves and Tray Set, but as a general guideline, items such as placement items (shunts, etc.) disposable filters, tubing, solutions, cleansing swabs and agents, bandages, blood pumps and dressings are all necessary and integral supplies when used in conjunction with artificial kidney dialysis machines. We have consistently concluded that gloves are peripheral to the dialysis process and so not "related supplies". Sales of gloves are thus taxable.

Kits present a special taxing problem. It has been the Board's long-established position that tax applies to the entire sales price of medical kits, dispensed by prescription only, used in connection with artificial kidney machines if the kit is sold for a lump-sum price. If X----- separates the price of the kit between taxable and non-taxable items, tax is applicable only on the price charged for the taxable items. (See, II Bus. Tax. Law Guide, Annot. 425.0510. Annotations are excerpts from previous board staff opinions, serve as a guide to staff positions.)

2. Peritoneal Catheters

Part Number: 10890-014, 10888-012, 10890-003

Description: Silicone rubber straight peritoneal catheter with either one or two dacron felt cuffs.

Intended Use: Short or long-term access to the peritoneal cavity for either peritoneal dialysis or intraperitoneal chemotherapy.

3. Peritoneal Catheters

Part Number: 11313-014, 11313-013

Description: Silicone rubber peritoneal catheter with coiled distal end with either one or two dacron felt cuffs.

Intended Use: Short or long-term access to the peritoneal cavity for either peritoneal dialysis or intraperitoneal chemotherapy.

4. Lifecath

Part Number: 15476-001

Description: Silicone rubber peritoneal catheter with coiled distal end with either one or two dacron felt cuffs.

Intended Use: Access to the peritoneal cavity for either peritoneal dialysis or intraperitoneal chemotherapy.

5. Peritoneal Dialysis Kits

Part Number: 17278-009, 17278-008

Description: Kit contains a peritoneal catheter and necessary items for placing the catheter by Modified Seldinger Technique.

Intended Use: Placement of peritoneal catheter for either short or long-term use.

6. Permcath

Part Number: 15543 -001, 15132-001

Description: Silicone rubber dual lumen central venous catheter dacron felt cuff.

Intended Use: Short or long-term use for hemodialysis or abperesis .

As noted above, catheters used with artificial kidney dialysis machines are considered "related supplies" the sales of which are not taxable pursuant to Section 6369(g).

We have previously determined that intravenous infusion systems are "appliances", etc., which are excluded from the definition of "medicines" by section 6369(b)(2) and Regulation 1591(c)(2). Thus sales of catheters used in intraperitoneal chemotherapy are generally taxable. However, if the catheters herein are permanently implanted (§6369(c)(2)) or are used for drainage during the chemotherapy process, either through a surgical incision (§6369(g)) or through a natural opening (§6369(c)(4)), then their sales are exempt from tax.

7. PermCath Tray

Part Number: 17680-001

Description: Tray contains PermCath and items for patient preparation as well as items needed to place the PermCath via Modified Seldinger Technique.

Intended Use: Short or long-term use for hemodialysis or abperesis.

See the discussion on kits under Section 1.a., "Mahurkar Gloves and Tray," above.

8. PermCath Repair Kit

Part Number: 15169-001

Description: Kit which contains external catheter replacement section and accessory items to repair a damaged PermCath.

Intended Use: Repair of damaged external portion of PermCath.

9. Peri-Patch Peritoneal Catheter Extension Set

Part Number: 12559-001

Description: A silicone rubber replacement section for repair of peritoneal catheters.

Includes a double barbed connector and Beta Cap Closure System (cap, adapter, clamp)

Intended Use: One of three parts used to repair the damaged external portion of a peritoneal catheter.

10. Silicone Adhesive, Type A, Medical Grade

Part Number: 10807-001

Description: Silicone adhesive, sterile, provided in 8 gm. tubes.

Intended Use: Used in the repair of various X----- catheters (along with other components).

Neither section 6369(g) nor section 6369.1 specifically refer to repair parts for hemodialysis machines or products. Unless the statute providing the exemption from tax specifically mentions repair or replacement parts, as well as the purchase of the original equipment, sales of repair or replacement parts are generally subject to tax. (See, e.g., National Aircraft Leasing, Ltd. v. State Board of Equalization (1979) 90 Cal.App.3d 549 [153 Cal.Rptr. 400].) However, although exemption statutes are strictly construed, they are not construed so as to bring about an unnatural or absurd result. The courts have indicated that grants of exemption from taxation may be allowed where the intention to do so is either expressed in direct terms or fairly inferable from the language of the statute. (Pasadena University v. Los Angeles Court (1923) 190 Cal. 786, 790-791 [214 P. 8687.]

In this case, section 6369(g) includes "related supplies" within the exemption, and section 6369.1 discusses "hemodialysis products." We have previously concluded that the language of these statutes is broad enough to include repair or replacement parts since these parts are "products" and are necessary and integral to the proper functioning of the dialysis machines and other related items, so as to themselves be "related supplies". Thus, we conclude that the sales of items used to repair kidney dialysis machines and related supplies and hemodialysis products, as defined above, are 'exempt from tax.

Please remember that this exemption only applies to parts used to repair or refurbish items the sales of which are not subject to tax. Tax applies to sales of repair or replacement parts for items the sales of which are taxable pursuant to Regulation 1546.

11. Beta-Cap Adapter

Part Number: 14661-001

Description: Ultem adapter

Intended Use: Placed in the proximal end of X----- peritoneal catheters to allow the catheters' connection to other mating parts (Beta-Cap Cap, injection sealing cap, transfer set).

12. Beta-Cap Cap

Part Number: 10806-003

Description: Part of Beta-Cap Closure System (adapter, cap, clamp) which provides an infection barrier for peritoneal catheters when used with povidone-iodine solution. Cap is a closure cap to be used with part number 14661-001 only.

Intended Use: Placed in the proximal end of X----- peritoneal catheters to allow the catheters' connection to other mating parts (Beta-Cap Cap, injection sealing cap, transfer set).

As with repair parts, the taxability of the sales of parts used to adapt an item to use depends in part on the taxability of the sales of the item being used. As noted above, the language of sections 6369(g) and 6369.1, and also 6369(c)(2) ("other articles") is broad enough to indicate a legislative intent to include items such as adapting parts within the exemption. Thus, we conclude that sales of parts sold for the purpose of adapting catheters to use are exempt from tax if the catheter is put to an exempt use.

13. Peri-Patch Glue Mold

Part Number: 12524-001

Description: A hinged polypropylene mold (1-1/2" long) with locking ring.

Intended Use: One of three parts used to repair the damaged external portion of a peritoneal catheter.

See comments under sections 8. 9. & 10 above.

14. Infusion T

Part Number: 11300-003

Description: A closed vascular access made of three components: a double beveled connector with protective caps, an injection site, and 6" length of polyvinylchloride tubing.

Intended Use: The infusion T connects to A-V cannula to provide access to blood system or the administration of meds, fluids, or blood sampling.

As noted above, items used to administer medication or other preparations or for running tests on the patient are generally considered appliances, etc., excluded from the definition of "medicines" by section 6369(b)(2). However, items that are intended for internal application to the human body as part and parcel of the dialysis process are "related supplies" within the meaning of section 6369(g). As a result, if the medicines, fluids, or blood sampling is administered as an integral part of the dialysis process, the infusion T used to administer them would be considered a "related supply" the sales of which are exempt from tax. If used in day-to-day patient care, however, its sales would be taxable.

15. Beta-Cap Clamp

Part Number: 10805-001

Description: A peritoneal catheter clamp

Intended Use: To "clamp-off" the external portion of a peritoneal catheter.

See discussion under items 11 and 12 above.

X----- may sell its products free of sales tax to its California customers who use them for dialysis by accepting in good faith from the purchaser a certificate containing the

information required by Regulation 1667 stating that the products are to be used for hemodialysis. X----- may also accept exemption certificates from its customers who know at the time of purchase that they will use the products for both dialysis and non-exempt purposes. The responsibility for allocating tax on taxable and non-taxable uses will be on the purchaser.

For your convenience, I have enclosed copies of Regulations 1591 and 1667. I hope the above discussion has answered your questions. If you need anything further, please do not hesitate to write again.

Sincerely,

John L. Waid
Tax Counsel

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STATE BOARD OF EQUALIZATION

916-324-3828

May 14, 1991

Gentlemen:

I am writing to respond to X-----'s letter to me of March 15, 1991, and X-----'s Letter to me of March 15, 1991, both regarding the above taxpayer, X----- (hereinafter X-----) You wrote to request reconsideration and clarification of some of the conclusions contained in my letter to X----- dated December 31, 1991. In that letter I discussed the applicability of sales and use tax to X----- sales of dialysis products and medical kits, and also discussed the records necessary to support X-----'s claim of exemption. In your letters you supplied additional information regarding X-----'s products and also made several suggestion on the necessary records.

I set forth at length the legal basis for our opinion in my letter. For the sake of brevity I will not repeat it here. The issues you raised fall into three groups:

(A) Dialysis v. Pheresis

X-----'s letter confirmed that the process which was termed in X-----'s letter as "abperesis" is actually pheresis. X----- further confirmed that the products which X----- listed in his letter were used primarily for hemodialysis through the use of an artificial kidney machine, for peritoneal dialysis, and for pheresis. You apparently do not dispute my conclusion that items used for pheresis are not machines pursuant to Section 6369(b)(2). (all statutory reference are to the Revenue and Taxation code unless otherwise stated.)

Both of you supplied information regarding peritoneal dialysis which X----- had not given. X----- described the process as follows:

"... Peritoneal Dialysis is a procedure for removing impurities (natural waste per Section 6369(g)) from the blood stream through the use of the peritoneal cavity as a receptacle for a dialysis solution (FDA prescription medicine). In this process, the dialysate fluid in a sterile plastic container is attached to a permanently implanted catheter in the abdominal wall and the fluid is allowed to flow by gravity into the peritoneal cavity where it is allowed to remain for periods of about 4 hours.

"During this time the plastic container remains attached to the catheter and is rolled up and taped to the abdomen. Waste is removed from the blood stream through osmotic action through the membranes of the cavity. At the conclusion of this period, the plastic container is unrolled and the fluid in the peritoneal cavity is allowed to flow back into the container through gravity force. The plastic container with the waste products and used

dialysate is then discarded and a fresh container with fluid is attached to the catheter and the process is repeated.”

We are of the opinion that because the peritoneal dialysis bags are attached to the body of the patient by means of a catheter which creates an artificial opening in the human body in order that the bags and dialysate solution (itself a prescription medicine: Annot. 425.0480) can function in the place of the inoperative kidneys for the “elimination of natural waste” that peritoneal dialysis bags and catheters are covered under Section 6369(g). As such, these items are “deemed to be dispensed on prescription” within the meaning of Section 6369, and tax will not apply to their sales.

(B) Kits, Trays, and Related Supplies

You take issue with my conclusion that if a Medical tray or kit contains both taxable and non-taxable items, then, unless segregation is made, the gross receipts from the sale of the entire tray are subject to tax. You make the following assertion regarding my conclusion (using X-----’s words): “You have failed to consider prior counsel opinions which held that, if the value of the taxable items were less than 10% of the value of the tray or kit, the entire charge would be regarded as exempt.”

I have reviewed the two prior legal opinions to X----- which discuss the taxation of administration kits and medical kits: a letter of X----- dated September 29, 1980, and one of X-----dated November 30, 1988. I have also reviewed other opinion letters to other people on the same subject. As X----- pointed out, the 10% rule you cite is not a rule of general application but is instead limited to the sales of combination food and non-food packages and is found in Regulation 1602(b). No such rule exists in Regulation 1591. We thus conclude that X-----’s reference to the 10% rule in her letter is limited to the context before her at the time. There, the patient was being fed through an intravenous set of a liquid nutrition product which, though a food product, was determined to have been sold as a “medicine” under Regulation 1602(a)(5) due to the fact that it was administered by doctor's order. Therefore, Regulation 1602(b) applied in that context. Accordingly, the Board staff's long-standing interpretation when dealing with medical kits or trays containing taxable and non-taxable items has been and remains that tax is measured by the lump sum price of the kit or tray unless the sales price is allocated between taxable items and exempt items. (Annot. 425.0510.)

(C) Certificates

The discussions of this topic in your letters leaves me in some confusion as to the nature of your question. X-----’s letter appears to dispute my statement that X----- in order to sell its dialysis products free of tax, may accept an exemption certificate containing the information required by Regulation 1667, while X----- indicates that he feels that my statement indicating that the certificate must state that the products are to be used for hemodialysis is too narrow. In order to give a more complete opinion, I will try to answer both questions.

As you are aware from your experience in the field of sales and use taxes, sales of items considered to be prescription medicines under Regulation 1591 are not exempt merely because

the items are “medicines” as defined by that regulation. They must also be sold or furnished under the conditions prescribed by Regulation 1591(a). “Medicines” which are purchased over the counter without a prescription are not exempt from tax when sold to purchasers without a doctor's order. The same items, however, are exempt from tax when sold to a health facility, physician, or pharmacy, and later furnished to patients by doctor's order. They are also, of course, excluded from tax when purchased for resale. Therefore, the use to be made of the product by the purchaser determines whether or not the sale is subject to tax. To that end, Regulation 1591(p)(3) provides as follows: “Persons making purchases of item exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667”. Thus, advice regarding the need for an exemption certificate is consistent with the Regulation.

Upon further review, however, I have determined that my previous advice was too narrow in scope. We have, as you noted, previously approved as complying with Regulation 1667 certificates whereby the purchaser certifies that its purchases meet the requirements of either Section 6369 or Regulation 1591. We recommended the reference to Regulation 1591 as that regulation encompasses medical exemptions found in statutes additional to Section 6369 - e.g., Section 6369.]. Additionally, we recognize that, in the case of items such as dialysate, X----- may be selling dialysis supplies to persons who will consume, resell, or make both uses of the products. For example, in the case of items such as dialysate, we assume that health facilities will generally keep an inventory supply of the item and withdraw a certain amount for use within the facilities and sell a certain amount to patients for home use. In situations where there will be both a consumption and a resale, the item must be purchased under a “resale” - certificate substantially complying with Regulation 1668 since there is no way to determine at the time the buyer purchases the entire store of items what amount it will self-consume and what amount it will re-sell to patients.

In summary, we agreed that peritoneal dialysis bags and catheters are deemed sold on prescription under Section 6369(g) as well as kidney dialysis machines and related supplies so that tax does not apply to the sales of the peritoneal dialysis bags and catheters which X----- described in his letter. We do not, however, render an opinion as to what are “related supplies” with reference to peritoneal dialysis equipment. We re-iterate our conclusion that the entire gross receipts from the sales of medical trays are included in the measure of tax when the trays contain both exempt and taxable items and no segregation is made. We further agree that X----- in order to substantiate its sales as exempt, may accept from its purchasers either resale certificates or exemption certificates substantially in compliance with Regulation 1667, and that to be in compliance the certificate need not specifically mention dialysis but aver compliance with either Section 6369 or Regulation 1591.

I hope the above discussion has answered your question. If you need anything further, please do not hesitate to write again.

Sincerely,

John L. Waid
Tax Counsel

JLW:es