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STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION

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October 2, 1989

REDACTED TEXT

Dear Mr. REDACTED TEXT:

This is in response to the questions you raised in your letters of January 27, 1989 and August 29, 1989 and at our meetings of March 29, 1989 and August 22, 1989.

Before we answer your specific questions, we have general comments with respect to the issue of taxation of catheters. A catheter is a slender tube inserted into a body passage,, vessel or cavity for passing fluids or making examinations. Implicit is the concept or external access to an internal location. Catheters may be distinguished from shunts, stents and sumps. A shunt or stent is a device used to re-route air, fluids or solids. A sump is used for drainage. A multi-lumen device has multiple tubes encased in a single tube extending the full length of the device. Dual lumen suction or drainage devices pass air through one lumen and allow drainage through a second lumen. These lumen devices are used to irrigate and then suction. Balloons are inflated with either air or sterile water. Catheters requiring stiff insertion are placed with the assistance of a stylet. In the past, this office has tended to use the term catheter generally to refer to all tubular devices inserted in or into the body for medical purposes. However, we are really referring to the following types of tube-type devices: catheters, shunts, stents, tubes, drains and sumps. Hereinafter the term "catheter(s)" is used in the broad sense.

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.

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-surgical¹ 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, all catheters are taxable, with three 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).

The specific questions you raised at our meetings of March 29, 1989 and August 22, 1989 follow:

1. Products which contain or are derived from animals bred for human consumption.

Q: Porcine grafts are made from the skins of animals bred for human consumption. On December 5, 1974, we wrote to you our opinion that Bovine grafts and porcine skins used as skin grafts for burn patients were taxable. The porcine grafts are used only as temporary biological dressings and do not qualify as exempt prosthetic devices under section 6369(c)(4) because they do not replace or assist the functioning of a natural part of the human body. According to the information you have obtained, porcine grafts do facilitate skin growth and the skin is an organ of the body. You wish to know whether this changes the 1974 ruling.

¹ We have frequently used the term “post-operative” as well as post-surgical. However, the more precise term is post-surgical.

A: We are of the opinion that although porcine grafts may, to some extent, facilitate skin growth, their primary purpose is as a temporary biological dressing. As such, they do not qualify as exempt prosthetic devices and tax would apply to their sale.

Q: Sheep, Goat, Bovine sera. Are blood products of animals bred for human consumption which are used in laboratories as a test medium taxable?

A: the blood components of various animals bred for human consumption are TAXABLE. The exemption provided by Revenue and Taxation Code Section 6358 for "any form of animal life of a kind the products of which ordinarily constitute food for human consumption" applies only to the sale of live animals. It does not extend to the sale of the products themselves when the products are not otherwise exempt as, for example, food products for human consumption.

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2. Prosthetic Devices and Drainage Devices.

Prosthetic Devices

Products which are prosthetic devices, worn on or in the person of the user, to replace or assist the functioning of a natural part of the human body. In order to qualify as an exempt prosthetic device under section 6369(c)(4) the item must either be implanted or fully worn on the body.

Specific Questions/Answers

Q: How does the Board of Equalization define the term "person" as it is used in section 6369?

A: the term "person" as used in Revenue and Taxation Code Section 6369 would be considered to be the "patient" - - an individual awaiting or under medical care and treatment - - the recipient of the services given. The term "person" does not include organs which have been temporarily removed from the body proper.

Q: Is there a minimum time period that something is worn (minutes, hours, days, etc.)?

A: The term "worn" means to be on the person. The minimum time period would not be seen in terms of minutes, hours, days, but should be viewed in terms of location of the procedure and the procedure itself. We limit terms by location of use but not by duration of use.

Q: Is there a location of use presumption (not in the operating room, only when physically carried by person, etc.)?

A: Yes, for certain items location of use is an important distinction. For certain implantable items, prosthetic devices, and ostomy devices the devices are exempt if utilized post-surgically. The same item used only as part of a surgical procedure would be taxable. In your letter of August 29, 1989, you raise the problem that certain of the items discussed are considered exempt if used post-surgically and taxable when used during a procedure. While we recognize that this is a burdensome distinction, it is one imposed by statute and must therefore be maintained. There is no statutory basis for allowing a blanket exemption covering all types of uses of these items. A distinction is also made concerning whether or not the item is fully worn on the person of the user. "Worn on" the person requires some physical attachment and must be fully worn on the person. This attachment need only consist of being taped on the body and may be of a temporary nature. As long as part of the item is attached and the entire device is fully worn on the person, it will be considered worn on or in the person. If part of the device is not on the person of the user, it will not qualify as an exempt device.

Q: How does one distinguish "administer" from "assist" and is this a valid or necessary distinction?

A: Although, as you point out something can assist the body but also administer at the same time, we have distinguished between items which assist a specific part of the human body (exempt) and items which administer (taxable).

Catheters, Leg Drainage Bags, Drains, Tubes, Trocar, etc.

CATHETERS - - are sections of specially shaped latex (or other soft material) tubing which:

- 1) place something in the body (food, medicine, irrigation fluid, dyes and diagnostic media) during or following a procedure (feeding tube, subclavian catheter, irrigation catheter, cholangiograph catheter, enema tube, etc.);
- 2) remove something from the body (urine, fecal materials, digestive by-products, air, liquid and solid waste resultant from surgical procedures, irrigation products, blood) for a period of time (balloon catheter or similar in-dwelling device);
- 3) move fluids within the body (cranial fluid to stomach, bile through ducts, blood to heart, blood around damaged artery or vein) on a temporary, semi- or permanent basis (ventriculoperitoneal catheter, nephrostomy stent, graft, aneurysm shunt);
- 4) provide a method of accessing the body's internal organs for diagnostic purposes or system monitoring (heart catheterization);
- 5) open, clear, manipulate, probe or dilate a tract, artery, vessel or other body part (dilation catheter);

- 6) assist a body organ or system which is not functioning or has been removed (a-V shunt for dialysis);
- 7) support and hold open a channel between two points (ureteral stent);
- 8) assist and organ which is non-functioning or has been removed;

Some of these devices are placed or worn in or on the body through natural openings. Others are inserted through an opening made as a result of a surgical procedure. A device may place or remove the material in question through gravity, capillary action, forced suction, or pressure. Waste that is removed may be collected in a container via additional tubing for disposal or processed and re-infused.

- a) LEG DRAINAGE BAGS, FECAL COLLECTORS, BILLIARY DRAINAGE BAGS AND URINARY INCONTINENCE POUCHES - - are worn on the individual where mobility is permitted (distinguishable from drainage bags which are not worn on the person of the user or suction receptacles and containers which are in-line set-ups used in conjunction with mechanical suction systems.)

If worn on the person of the user (taped-on bag is fully worn) - - EXEMPT. When a bag is not worn because of a mobility problem - - TAXABLE unless exempt under section 6369(g) related supplies for ostomy devices.

- b) DRAINS. Drains are sections of specially shaped latex (or other soft material) tubing used to remove waste from the body. [Drains operated by mechanical means are often classed as sumps (Salem and NG).] One end of the drain tube is inserted in the patient with the other end going to a receptacle or cannister. The vacuum pressure is created by a mechanical pump. Drains operated by manual pumping are used frequently in post-op wound drainage situations (penrose, flat, round, angled) in conjunction with a closed wound drainage system (pleur-evac, hemovac, hystovac). (See below.)

Mechanical suction systems, suction receptacles or containers - - TAXABLE when used during a procedure. EXEMPT as a related supply when used in conjunction with a drain placed in an artificial opening post-surgically.

1. Sumps – drains operated by mechanical means – The drain is EXEMPT but the mechanical pump is TAXABLE when used during a procedure. EXEMPT as a related supply when used in conjunction with a drain placed in an artificial opening post-surgically.

2. Drains with manual pumps - - When used post-surgically in conjunction with closed wound drainage system, the drain is EXEMPT and the pump is EXEMPT.

d) TUBES. Tubes are also sections of specially shaped latex (or other soft material) tubing used to suction waste, irrigate or feed (NG, stomach, irrigation, or feeding).

1. Suction waste - - during surgery - - TAXABLE
- - post-surgical - - EXEMPT
2. Irrigate - - TAXABLE unless also used as drainage tube.
3. Feed - - TAXABLE (unless also suction).

e) PERFUSION SYSTEMS - - used to redirect blood around a damaged body part during an operation to repair or replace that body part (includes shunts, a-v cannulas, perfusion catheters, heart/lung/cardioplegia systems and cardiotomy reservoirs). TAXABLE if used in operating room. EXEMPT when used post-surgically.

f) CELL SAVER SYSTEMS - - used to provide for recovery of blood for auto-transfusion removing waste and returning blood to body (includes either manual or mechanical capture systes, tubing, receptacles and centrifuge). Some systems used during surgery only. Others are used post-surgically. (Pleur-evac auto transfusion systems; Thora-Klex.)

During surgery - - TAXABLE
Post-surgically - - EXEMPT

g) ENDOTRACHEAL (tracheal tubes - - used to assist the patients in breathing before, during or after an operation (inserted in windpipe and attached to a ventillator), also used in ICU-stays with patient several days.

Tube - - During surgery - - TAXABLE
- - Post-surgically - - EXEMPT
Ventillator - - During surgery - - TAXABLE
- - Post-surgically - - EXEMPT

h) TEMPORARY PACEMAKER/DIAPHRAGM LEADS AND PACEMAKERS - - used for temporary heart or diaphragm pacing. All leads are worn on person of user with many pacemakers also being worn on person of user.

Temporary leads - - EXEMPT
Pacemakers - - Strapped to patient - - EXEMPT
On bed - - TAXABLE

i) ARTIFICIAL HEARTS OR OTHER EXTERNALLY CONNECTED DEVICES - - used in lieu of a transplant heart or other body part until one is made available (includes blood tubing, mobile pump and other mechanical contrivances). TAXABLE

- 1) INTRAORTIC BALLOON CATHETERS AND PUMPS - - inserted into the body to assist the heart and circulatory system in re-establishing blood pressure in (predominantly) traumatic or aneurysm patients. EXEMPT

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3. Appliances and related supplies necessary for use in conjunction with an artificial opening which has been surgically created in the human body for the elimination of natural waste.
- Already includes ostomy, colostomy, urostomy, and tracheostomy appliances and supplies.
 - Already includes hemodialysis machines, appliances and supplies.
 - Has been ruled to include wound drainage systems and suprapubic catheters.

Specific Questions/Answers

Q: From where does the 24-hour time requirement originate?

A: There is no 24-hour requirement. The only requirement is that the items remain with the patient post-surgically.

Q: From where does the condition of post-surgical use only originate?

A: Revenue and Taxation Code Section 6369(g) provides that:

“Mammary prostheses, and 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.”

Because the statute provides that the appliances and relate supplies be necessary as a result of a surgical procedure, we have determined that the appliances and related supplies must be used post-operatively.

Q: Is there a primary purpose test? For example, gastrostomy, nephrostomy and jejunostomy tubes are used primarily to drain waste through an artificial opening but may also be used to irrigate or administer medicine.

A: Yes. The items in question would qualify for exemption because they are used to drain waste through an artificial opening.

Q: Are tracheostomy and colostomy care kits which contain the supplies required by the patient to administer self-care exempt?

A: Yes, they would fall under the "necessary related supplies" language found in section 6369(g) and be considered exempt.

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4. Orthotic Devices

Specific Questions/Answers

Q: Is there a primary purpose test for tubular and bias stockinettes?

A: Yes. The tubular and bias stockinettes are only considered exempt medicines when they are used as orthotic devices - - designed to be worn on the person of the user as a brace, support or correction for the body structure. Tubular or bias stockinettes which are used as a drape or as a headress in the operating room would not qualify as exempt orthotic devices.

Q: Is the rule concerning taxability of post-operative shoes used in lieu of casts incorrect based on the intent of the statute?

A: No. The statute specifically excludes supportive devices for the foot, except a biomechanical foot orthoses or those which are integral parts of a leg brace or artificial leg.

Q: Is there a definitive rule concerning traction materials, i.e., is there a distinction between property worn on the person of the user vs. that which is only in contact with the body (as in a sling arrangement)?

A: Traction materials must be fully worn on the person of the user. Some sling arrangements, (e.g., an arm sling worn around the neck or shoulder) would be considered to be fully worn on the person of the user. Others would not.

5. Administration Sets and Administration Kits

You question whether medicine sold with an administration set valued at less than 10% of the value of the sale is exempt from tax. (See letters of 9/29/80 from Armstrong and 11/30/88 letter from Stipe.)

Yes. There is a distinction between an administration set and a kit. In our letter of September 29, 1980, we were referring to the former. Mr. Stipe's letter of November 30, 1988 stated the rule for medical kits or trays which contain taxable and exempt items. The rules for the two items are as follows:

Administration Set (medicine with applicator) – Value of the taxable portion is less than 10% - - entire lump sum price is exempt from tax.

Medical Kits and Trays – Tax applies to the entire sales price of medical kits and trays unless the sales price is allocated between taxable and non-taxable items.

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We have attached the lists of items submitted in your August 29, 1989 letter as Exhibits A and B.

Very truly yours,

Mary C. Armstrong
Senior Tax Counsel

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Attachments

bc: Audit Evaluation and Planning

EXHIBIT A

Leg drainage bags, fecal collectors and urinary incontinent pouches are worn on the person of the user attached to an in-dwelling drainage catheter or rectal tube whereas plain drainage bags (which do not indicate “leg”) and urine meters, while being attached to an in-dwelling drainage catheter, are not worn.

Leg drainage bags, fecal collectors, and urinary incontinence pouches are exempt. Other urinary drainage bags are taxable.

Billiary (drainage) bag is attached to the T-tube for drainage of bile from the bile duct. It is worn on the person of the user.

Billiary (drainage) bags are exempt.

Endotrach tubes are tubes used in conjunction with ventilators, inserted into the mouth and down the windpipe, may be placed either during surgery prep and remain with the patient until the completion of the surgical procedure or for hours or days until the patient is able to breathe unaided. Endotrach tubes are also placed in the emergency room or at the floor level to assist patients in breathing under a variety of conditions.

Endotrach tubes are exempt.

Gastrostomy tubes, used to both remove waste and feed, are inserted through the stomach wall into the stomach and remain in place for days at a time. The use of these tubes for removal of waste (all types) is seeing increased acceptance as the alternative is a rectal tube which, when left in place for the customary term, cause extreme irritation to the rectal lining. Gastrostomy tubes are used frequently for patients with cancer caused obstructions.

Gastrostomy tubes are exempt.

Nasal tube or airway is use strictly during a procedure an does not remain with the patient.

Nasal tubes or airways are taxable.

Levin, Dennis, Minnesota, Miller-Abbott and Cantor tubes are naso-gastro-intestinal (NG) tubes inserted through the nose into the stomach. They tend to be placed for an extended term and are used to de-compress the stomach or provide suction capability where obstructions are present.

Levin, Dennis, Minnesota, Miller-Abbott and Cantor tubes are exempt.

Ewald tube is inserted through the bowel into the large intestine and is used primarily for diagnostic purposes.

Ewald tubes are taxable.

Rectal tube is inserted through the bowel into the large intestine and is used primarily for waste removal. Hospitals are using these tubes for prolonged access and waste removal.

Rectal tubes are exempt.

Entriplex, Keofeed, and Enteral tubes are all feeding tubes and are rarely used for any other purpose.

Entriplex, Keofeed, and Enteral tubes are taxable.

Sengstaken-Blakemore tube is used to stop bleeding in the upper gastro-intestinal area and is only used for a procedure.

Sengstaken-Blakemore tubes are taxable.

Hickman, Broviac, and Groshong catheters are all subclavian catheters used to place dye, medication or other special products directly into the body.

Hickman, Broviac, and Groshong catheters are taxable.

Yankauer suction tube is used for oral suctioning and is hand-held rather than worn.

Yankauer suction tubes are taxable.

Salem sump tube and Replogle suction catheter (for infants and children) are dual lumen NG tubes which are typically left in place for suctioning purposes. Irrigation may be done in conjunction with suction activity.

Salem sump tube and Replogle suction catheter (for infants and children) are exempt.

(Red Rubber) Robinson (a.k.a., Rob-Nel) catheter is an all-purpose catheter and is not worn on or in the patient.

“(Red Rubber) Robinson (a.k.a., Rob-Nel) catheters are taxable.

Saratoga sump drain is a general purpose drain used following surgery, and stays with the patient, for site evacuation through the surgical opening.

Saratoga sump drains are exempt.

Foley-style catheter is placed through the urethra into the bladder for continuous in-dwelling drainage. Foley-style catheters are manufactured with a wide variety of tips, each named for a doctor and having a different shape, e.g., Carson, Coude, Councill, Tiemann, Emmett, Ainsworth, Suggs, Wheeler, Alcock, Hotter, Naegeli, and Creevy).

Foley-style catheters are exempt.

Suction catheters, as a general class, (not otherwise indicated) are often hand-held, are attached to a wall-mounted suction system and may have a regulating thumb n-hole for adjusting suction pressure and continuity. These are not worn on the person.

Non-specific suction catheters are taxable.

Urethral and ureteral catheters are used both for procedures and continuous in-dwelling post-surgical drainage. They are worn in the person, placed through the urethra and ureters. Some of these catheters may also be used for drainage prior to a surgical procedure or for administering dye in a diagnostic procedure.

Urethral and ureteral catheters are exempt if used post-surgically.

Jejunostomy tube is placed through the abdominal wall into the small intestine for the primary purpose of feeding in event of small intestine obstruction. The tube is fully worn on the person, however, there is no waste removal customary through the tube. (Note: here is an example of opposite views of use. Other practitioners say that this is not a feeding tube, only a tube for waste removal and irrigation. It is understandable that a single tube would not be used for both functions.)

Jejunostomy tubes or catheters are taxable.

Nephrostomy tube or catheter is place percutaneously into the kidney for irrigation and drainage. The tube is worn on the person of the user.

Nephrostomy tubes or catheters are exempt.

Stents, as a general class, are implanted for various lengths of time to provide flow of (typically) fluid from on internal organ to another by maintaining open passages. They are fully worn and remain implanted for from days to years.

Stents (e.g., billiary, laryngeal, ureteral, nephrostomy, nephrourethral, etc.) are exempt.

Male external catheter is worn externally on the person of the user to provide drainage into a leg bag.

Male external catheters are exempt.

EXHIBIT B

<u>Product Name or Type</u>	<u>Tax Status</u>	
Catheters, tubes or drains		
Thoracic	Exempt	
Trocar	Exempt	
Mallecot	Exempt	
Pezzar	Exempt	
Mediastinal	Exempt	
Penrose	Exempt	
Salem	Exempt	
Replogle	Exempt	
Saratoga	Exempt	
Red Rubber Robinson (Rob-nel)	Taxable	
Tracheostomy	Exempt	
Endotracheal	Exempt	
Cystocath	Exempt	
Suprapubic	Exempt	
Bonnanno	Exempt	
T-Tube	Exempt	
Duodenal	Exempt	
Gastrostomy	Exempt	
Jejunostomy	Taxable	
Nephrostomy	Exempt	
Rectal	Exempt	
Urethral	Exempt	
Ureteral	Exempt	
Foley-style*	Exempt	*common tip styles:
Levin	Exempt	Carson, Coude,
Miller-Abbott	Exempt	Councill, Tiemann,
Minnesota	Exempt	Emmett, Ainsworth,
Dennis	Exempt	Suggs, Wheeler,
Cantor	Exempt	Alcock, Hotter,
Sengstaken-Blakemore	Taxable	Neageli, and Creevy
Yankauer	Taxable	
Entriflex	Taxable	
Keofeed	Taxable	
Enteral	Taxable	
Ewald	Taxable	
Nasal (airway)	Taxable	
Hickman	Taxable	
Broviac	Taxable	
Groshong	Taxable	
(external) Mail	Exempt	
Suction (hand-held)	Taxable	
Intraortic Balloon	Exempt	

<u>Product Name or Type</u>	<u>Tax Status</u>	
Miscellaneous tubes		
Stents**	Exempt	**Common names: biliary, laryngeal, ureteral, nephrostomy, nephrourethral, etc.
Shunts	Exempt	Common types: Ventriculo- peritoneal, a-v, Leveen, Gott aneurysm, endolymphatic
Closed Wound Drainage Systems	Exempt	Common names: Double Seal, Heimlich, Hystovac, Hemovac, J-vac, Pleur-evac, Pneumo, and Mediastinal
Auto-transfusion Systems	Exempt	Exempt when part of a closed wound drainage system.
Waste Collection Bags		
Urinary <u>Leg</u>	Exempt	
Fecal collection	Exempt	
Urinary Incontinence	Exempt	
Biliary (drainage)	Exempt	
Bile	Exempt	
Penis Pouch	Exempt	
Ventricular drainage	Exempt	
Pediatric Urine	Exempt	

Orthopedics

Tubular stockinette

Exempt

Exempt when used
as an orthotic device

Bias stockinette

Exempt

Exempt when used
as an orthotic device