



STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION

450 N STREET, SACRAMENTO, CALIFORNIA
PO BOX 942879, SACRAMENTO, CALIFORNIA 94279-0043
TELEPHONE (916) 445-1441
FAX (916) 445-2388
www.boe.ca.gov

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First District, Hayward

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JAMES E. SPEED
Executive Director

August 30, 2002

Dear Interested Party :

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for the September 11, 2002 Business Taxes Committee meeting. This meeting will address the proposed amendments to Regulation 1591, Medicines and Medical Devices.

Action 1 on the Agenda consists of items on which we believe industry and staff are in full agreement. Actions 2, 3, 4, and 5 concern proposed revisions regarding "worn on the body," supportive devices for the foot, breast and tissue expanders, and wound dressings.

If you wish to have any consent items (Action 1) discussed fully at the Committee meeting, you must contact a Board Member prior to September 6, 2002 to request removal of the item from the Consent Agenda. In addition, please notify Ms. Charlotte Paliani, Program Planning Manager, after you contact a Board Member's Office. Ms. Paliani may be reached at (916) 324-1825.

Thank you for your input on these issues and I look forward to seeing you at the Business Taxes Committee meeting at **9:30 a.m.** on **September 11, 2002** in Room 121 at the address shown above.

Sincerely,

/s/Ramon J. Hirsig

Ramon J. Hirsig
Deputy Director
Sales and Use Tax Department

RJH: tdm

Enclosures

cc: (all with enclosures)

Honorable John Chiang, Member, Fourth District
Honorable Johan Klehs, Member, First District
Honorable Dean Andal, Member, Second District
Honorable Claude Parrish, Member, Third District
Honorable Kathleen Connell, State Controller
Mr. John Thiella, Board Member's Office, Fourth District (MIC 72)
Mr. Steven Kamp, Board Member's Office, Fourth District (MIC 72)
Ms. Jean Alexander, Board Member's Office, First District
Mr. Arnulfo Hernandez, Board Member's Office, First District (MIC 71)
Ms. Rita Perry, Board Member's Office, First District (MIC 71)
Mr. Paul Steinberg, Board Member's Office, Second District (via e-mail)
Mr. Neil Shah, Board Member's Office, Third District
Mr. Romeo Vinzon, Board Member's Office, Third District
Ms. Kimberly Jones, Board Member's Office, Third District
Mr. Matthew Zylowski, Board Member's Office, Third District
Ms. Marcy Jo Mandel, State Controller's Office
Mr. James E. Speed (MIC 73)
Mr. Timothy Boyer (MIC 83)
Ms. Janice Thurston (MIC 82)
Mr. David Levine (MIC 85)
Mr. Warren Astleford (MIC 82)
Mr. John Waid (MIC 82)
Ms. Jean Ogrod (via e-mail)
Mr. Jeff Vest (via e-mail)
Mr. Randy Ferris (via e-mail)
Mr. Steve Ryan (via e-mail)
Mr. Rey Obligacion (via e-mail)
Mr. John Abbott (via e-mail)
Chief, Agency Planning and Research Division (MIC 75)
Ms. Jennifer Willis (MIC 70)
Mr. Dave Hayes (MIC 67)
Ms. Charlotte Paliani (MIC 92)
Mr. Joseph Young (via e-mail)
Mr. Jerry Cornelius (via e-mail)
Mr. Jeffrey L. McGuire (via e-mail)
Mr. Vic Anderson (MIC 40 and via e-mail)
Mr. Larry Bergkamp (via e-mail)
Mr. Geoffrey E. Lyle (MIC 50)
Ms. Lauren Simpson (MIC 50)
Mr. Todd MacMurray (MIC 50)
Ms. Leila Khabbaz (MIC 50)
Mr. Dan Tokutomi (via e-mail)

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

<p>Action 1 — Consent Items Agenda, pages 3-4, 10.</p>	<p>Adopt proposed amendments to Regulation 1591 as agreed upon by staff and interested parties.</p>
<p>Action 2 — “Fully Worn” on the Body Subdivisions (b)(4) and (b)(5). Agenda, pages 7, 8, 10, 12. Issue Paper Alternative 1.</p>	<p>Adopt either: Staff’s recommendation to keep the “fully worn” on the body requirement. <p align="center">OR</p> E&Y’s proposal to replace the “fully worn” on the body requirement with a sustained physical contact test.</p>
<p>Action 3 — Supportive Devices for the Foot Subdivisions (b)(4) and (c)(2) Agenda, pages 8, 12. Issue Paper Alternative 1.</p>	<p>Adopt either: Staff’s recommendation not to change the regulation in regards to supportive devices for the foot. <p align="center">OR</p> E&Y’s proposal to name “shoe inserts” as items that do not qualify as medicines and to remove “foot orthoses” from the list of items that do not qualify as medicines.</p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

<p>Action 4 — Sales of Breast/Tissue Expanders</p> <p>Subdivisions (b)(2), (b)(4), and (b)(5) Agenda, page 5, 6, 7, 11. Issue Paper Alternative 1.</p>	<p>Adopt either:</p> <p>Staff’s recommendation not to change the regulation in regards to breast and tissue expanders.</p> <p align="center">OR</p> <p>Nielsen’s proposal to exempt sales of breast and tissue expanders as permanently implanted articles, orthotic devices, prosthetic devices, and mammary prosthesis.</p>
<p>Action 5 — Wound Dressings</p> <p>Subdivisions (b)(4) and (c)(2) Agenda, page 7, 11. Issue Paper Alternative 2.</p>	<p>Adopt either:</p> <p>Staff’s recommendation not to change the application of tax to wound dressings.</p> <p align="center">OR</p> <p>Smith’s proposal to exempt sales of wound dressings.</p>
<p>Action 6 – Authorization to Publish</p>	<p>Recommend the publication of amendments to Regulation 1591 as adopted in the above actions.</p> <p>Operative Date: None. Implementation: 30 days following OAL approval</p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Staff and Industry’s Proposed Regulatory Language
<p>Action 1 — Consent Items</p>	<p>1591 MEDICINES AND MEDICAL DEVICES</p> <p>(a) DEFINITIONS.</p> <p>(4) HEALTH FACILITY. “Health Facility” as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, which provides that:</p> <p><u>A. Section 1200 of the Health and Safety Code whereby a “clinic” means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility.</u></p> <p><u>B. Section 1200.1 (a) As used in this chapter, “clinic” also means an organized outpatient health facility which, pursuant to Section 1204.1, provides direct psychological advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with Section 2900) of Division 2 of the Business and Professions Code to patients in the home as a incident to care provided at the clinic facility. (b) Psychological clinics, as defined in Section 1204.1, shall not be considered primary care clinics for the purposes of any state grants, state loans, or other state aid. (c) Any reference in any statute to Section 1200 shall be deemed and construed to also be a reference to this section.</u></p> <p><u>C. Section 1250 of the Health and Safety Code, which provides that a “health facility” means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.</u></p> <p>“As used in this chapter ‘health facility’ means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24 hour stay or longer....”</p> <p>(9) MEDICINES. “Medicines” means 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 that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Staff and Industry's Proposed Regulatory Language
	<p>(d) APPLICATION OF TAX – IN GENERAL.</p> <p>Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:</p> <p>(1) Prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or</p> <p>(2) Furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or</p> <p>(3) Furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or</p> <p>(4) Sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or</p> <p>(5) Sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or</p> <p>(6) Effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.</p> <p><u>(8) CPM MACHINES. A continuous passive motion machine (CPM) is an orthotic device whose sale or use is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</u></p> <p><u>(9) ENTERAL FEEDING, TPN, IDPN DEVICES. Tax does not apply to the sale or use of the following prosthetic devices when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. Tax does not apply to sales of needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.</u></p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith
<p>Action 4 — Sales of Breast/Tissue Expanders</p>	<p>(b) “MEDICINES”.</p> <p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants.</p>	<p>(b) “MEDICINES”.</p> <p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; <u>breast tissue expanders and tissue expander</u>; and ear implants.</p>	<p>(b) “MEDICINES”.</p> <p>Smith does not have a proposal for (b)(2).</p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith
<p>Action 4 — Sales of Breast/Tissue Expanders</p>	<p>Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription</p>	<p>Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; <u>and</u> defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription</p>	<p>Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; <u>and</u> defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription</p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith
	<p>(B) Any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or</p> <p>(C) Any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.</p> <p>(5) PROSTHETIC DEVICES. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>(B) Any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or</p> <p>(C) Any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.</p> <p>(5) PROSTHETIC DEVICES. Prosthetic devices and their replacement parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>(B) Any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or</p> <p>(C) Any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.</p> <p>Smith does not have a proposal for (b)(5).</p>

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith
<p>Action 4 — Sales of Breast/Tissue Expanders</p>	<p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES.” (2) 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</p>	<p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, <u>breast tissue expanders and tissue expanders</u>, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES.” (2) 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</p>	<p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES.” (2) 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</p>
<p>Action 5-“Wound Dressings”</p>			

AGENDA — September 11, 2002 Business Taxes Committee Meeting
Regulation 1591, Medicines and Medical Devices

Action Item	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith
<p>Action 3- Supportive Devices for the Foot</p> <p>Action 2-“Fully Worn” on the Body</p> <p>Action 3-Supportive Devices for the Foot</p>	<p>parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.</p>	<p>parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices <u>such as shoe inserts</u> (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), <u>or thermophore pads,</u> or foot orthoses.</p>	<p>parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.</p>

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Regulation Agenda.doc

Issue Paper Number 02-012



- Board Meeting
- Business Taxes Committee
- Customer Services and Administrative Efficiency Committee
- Legislative Committee
- Property Tax Committee
- Other

Worn on the Body
Regulation 1591, Medicines and Medical Devices

I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be amended to change the application of tax to orthotic and prosthetic devices?

II. Staff Recommendation

Staff recommends the following amendments to Regulation 1591, with no operative date:

- Add a reference to Health and Safety Code section 1200 and 1200.1 in subdivision 1591(a)(4) in order to include surgical clinics in the definition of “health facilities” without the operative date contained in the statute. See Issue Paper (IP) page 3 and agenda item 1.
- Add new subdivision (e)(8) to exempt sales of continuous passive motion (CPM) machines. See IP page 3 and agenda item 1.
- Move the exemption for enteral feeding tubes, etc. from subdivision (b)(5) to new subdivision (e)(9), Enteral Feeding, TPN, IDPN Devices. See IP page 3 and agenda item 1.
- Incorporate non-substantive amendments in subdivisions (b)(4) and (d). See Exhibit 3, pages 3-6 and agenda item 1.

III. Other Alternative(s) Considered

Alternative 1

In addition to the amendments recommended by staff, Mr. Glenn Bystrom of Ernst & Young (E&Y) and Mr. Eric Miethke of Nielsen, Merksamer, Parrinello, Mueller & Naylor, LLP (Nielsen) propose to:

- Amend subdivisions (b)(4) and (b)(5) of Regulation 1591, *Medicines and Medical Devices*, to replace the fully worn on the body requirement with a sustained physical contact test. See IP pages 7-8 and agenda item 2.
- Add language in subdivisions (b)(4) and (c)(2) to name “shoe inserts” as items that do not qualify as medicines and to remove “foot orthoses” from the list of items that do not qualify as medicines. See IP pages 8 and agenda item 3.
- Exempt sales of “tissue and breast expanders” in subdivisions (b)(2), (b)(4), and (b)(5). See IP pages 8-9 and agenda item 4.

Alternative 2

In addition to the amendments recommended by staff, Ms. Janet Smith of Smith Bio-Medical (Smith) proposes to exempt sales of wound dressings in subdivisions (b)(4) and (c)(2). See IP page 10 and agenda item 5.

Issue Paper Number: **02-012**

IV. Background

Surgical Clinics – Subdivision (a)(4)

Assembly Bill 646 (Horton), Chapter 706 (2001), amended Revenue and Taxation Code (RTC) section 6369 to incorporate a cross-reference to section 1200 of the Health and Safety Code. This law change, operative April 1, 2002, expands the definition of “health facilities” to include surgical clinics and similar outpatient health facilities for the treatment of human beings, and results in sales of medicines to surgical clinics receiving the same exemption as was previously available to hospitals.

In addition, on December 20, 2001, the Board published its Memorandum Opinion in the Matter of Bergen Brunswick Drug Company and concluded that sales of prescription medicines to surgery centers qualify as exempt sales of medicines, even though the surgery centers were not health facilities as defined under Health and Safety Code section 1250. The Memorandum Opinion is retroactive past the operative date of the amendment to RTC section 6369.

“Worn on the Body,” Wound Dressings

History

Sales of medicines were subject to tax until January 1, 1962, when a specific exemption was enacted for sales of prescription medicines. Over the years, a number of bills have been enacted to extend this exemption to other related commodities or articles. In 1977, the Legislature extended the exemption to include sales of various prosthetic and orthotic devices. Regulation 1591, which was initially adopted in 1962, was amended accordingly to exempt sales of orthotic and prosthetic devices that meet defined conditions, including the requirement that these devices be designed to be worn on the body of the user. The regulation was further amended in 1978 and 1999 to add specific examples of orthotic and prosthetic devices that are included or excluded from the term “medicines.” Effective March 2000, the Board incorporated its long-standing interpretation and further clarified precisely what is meant by the language “worn on the body,” stating that “if any part of the orthotic device is not worn on the person, the device is not a medicine for purposes of this regulation.” The regulation was also amended in December 2000 to clarify that specified devices used to administer liquid nutrition are included in the term “prosthetic devices.” Articles that are in the nature of compresses and dressings have been specifically excluded from the definition of medicines in the statute and in the regulation since 1963.

Current Application of Tax

Under current law, sales of devices or appliances, and articles that 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 are subject to tax since the statute specifically excludes these items from the definition of “medicines.” (RTC section 6369(b)(2).) Accordingly, sales of wound dressings are generally subject to tax. However, the Legislature has included within the definition of “medicines” certain named devices, instruments, apparatus, appliances, and physical equipment. Among other things, RTC section 6369(c) provides that the following devices are included in the definition of “medicines” under defined conditions. As noted in the following subdivisions, one of these conditions is that they be worn on the body of the user (emphasis added):

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(c)(3)(A) - Orthotic **devices**, other than orthodontic devices, **designed to be worn on the person of the user as a brace, support, or correction for the body structure**, and replacement parts for these devices...

(c)(4) - Prosthetic **devices**, and replacement parts for those 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**...

In addition to the foregoing limitation on their exempt sales, orthotic and prosthetic devices must be generally sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6) of Regulation 1591. (See Exhibit 3).

Action Medical Products, Inc. Memorandum Opinion – Exhibit 4.

The Board's April 18, 2002 Memorandum Opinion in the Matter of Action Medical Products, Inc. found that the petitioner's continuous passive motion (CPM) machines that are not fully worn on the body serve the identical medical rehabilitation purposes as those that are fully worn on the body. The Board concluded that the CPM machines at issue in this case qualify as orthotic devices pursuant to section 6369, subdivision (c)(3)(A), even though they were not fully worn on the body.

In a letter dated June 10, 2002, the California State Association of Counties (CSAC) commented on proposed amendments made by interested parties to expand the definition of "worn on the body" that is currently provided in the regulation, and to include all wound dressings in the term "medicines." CSAC expressed concerns over the fiscal impact that these amendments may have on counties and local agencies that provide medical services to those least able to pay for health care.

V. Staff Recommendation

A. Description of the Staff Recommendation

Staff recommends amending Regulation 1591 as follows, with no operative date:

- Add a reference to Health and Safety Code sections 1200 and 1200.1 in Regulation 1591(a)(4) in order to include surgical clinics in the definition of "health facilities" without the operative date contained in the statute. This will conform the regulation to AB 646, Chapter 706 (2001) and to the Board's Memorandum Opinion in the Matter of Bergen Brunswig Drug Company.
- Include CPM machines in the list of Specific Applications in Regulation 1591(e), making sales of these devices exempt from tax. This will conform the regulation to the Board's Memorandum Opinion in the Matter of Action Medical Products Inc. Sales of devices that are not specifically listed as exempt in the regulation remain subject to tax.
- Move the exemption for sales of enteral feeding, TPN, and IDPN tubes, etc. from 1591(b)(5) to new subdivision (e)(8). In a decision designed to ensure that liquid nutrition and the items used to administer the liquid nutrition to the patient (bags, tubes, etc.) are exempt in any medical setting, the Board adopted language considering the liquid nutrition as a "preparation or similar substance" and the delivery items as "prosthetic devices." Staff's recommendation is that this unique interpretation of prosthetic devices be identified within a separate subdivision of Regulation 1591.

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- Incorporate non-substantive amendments in subdivisions (b)(4) and (d).

Alternative 1

See pages 7-9 for a full description of Alternative 1. E&Y proposes to amend subdivisions (b)(4) and (b)(5) of Regulation 1591 to replace the fully worn on the body requirement with a sustained physical contact test. In addition, E&Y proposes to add “shoe inserts” to the list of items not considered to be medicines in Regulation 1591(b)(4) and (c)(2) and to remove “foot orthoses” from the same list in subdivision (c)(2).

Nielsen proposes to remove the specific exclusion of breast/tissue expanders from the definition of “prescription medicines” in Regulation 1591(b)(2). In addition, Nielsen contends that breast/tissue expanders should qualify as exempt medicines under any of the following provisions: “permanently implanted articles” in Regulation 1591(b)(2), “prosthetic devices” in Regulation 1591(b)(5), “mammary prosthesis” in Regulation 1591.1(b)(2), and “orthotic devices” in Regulation 1591(b)(4).

For the following reasons, staff is opposed to Alternative 1:

RTC section 6369 has two components: (1) the items must be “devices” and (2) the devices must be “worn on the person” of the patient. Both of these elements must be given effect. In administering the statutory phrase “devices ... worn on the person of the user,” a line must be drawn between devices that are worn on the person of the user and those that are not. Staff believes the logical place to draw that line is that the entire device must be worn on the person of the user, which has been the Board’s long-standing interpretation of the statute. In order to perform their function, all prosthetic and orthotic devices must be attached to the body in some way. Therefore, it is logical to assume that the phrase “worn on the body” is intended to limit the exemption. While the term “device” is not defined in the Revenue and Taxation Code, it is defined in the Health and Safety Code. Health and Safety Code Section 109920(b) defines “device” as meaning “any instrument, apparatus, implement, machine, contrivance, ... or other similar or related article, including any component, part or accessory that is ... [i]ntended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment or prevention of disease in humans or any other animal.” This definition has been in the Code since 1939 and is the definition on which RTC section 6369(b)(2) is based. “Worn” is defined as “to be fitted with or have on the person habitually.” (Wm. Morris, ed., The American Heritage Dictionary. New York: American Heritage Publishing Co. 1975.) Based on the language of both statutes, the Board’s interpretation since 1977 has been that mere attachment to the body is not enough to qualify for the statutory exemption.

In staff’s opinion, the word “sustained” is not capable of precise definition. Is “sustained” measured by the time the device is continuously attached to the patient at each therapy session or do we add sessions together? “Sustained” denotes “prolonged” or “extended”—that is, a long period of time. The CPM devices exempted by the Board in Action Medical would likely not qualify under this standard as they are attached to the patient for only short periods of time during therapy sessions. On the other hand, many of the devices, such as “bedside” pacemakers, that both interested parties and staff agree are not covered, are attached to the patient for very long periods of time. “Sustained” replaces the bright-line test of “fully worn” with a standard that would be difficult for staff and taxpayers to interpret.

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E&Y suggests that to clarify the regulation, “foot orthoses” should be deleted from the list of items specifically excluded from the definition of medicines in subdivision (c)(2). Staff believes that this change would result in an unclear and misleading regulation subdivision. A “foot orthosis” is defined by the medical industry as an orthotic, or supportive, device for the foot. RTC 6369 provides that orthopedic shoes and supportive devices for the foot are subject to tax unless they are custom-made biomechanical foot orthoses or are an integral part of a leg brace or artificial leg. Therefore, the current inclusion of “foot orthoses” with the listed items that are subject to tax already clarifies the statute. Staff believes that deleting the term would incorrectly imply that all foot orthoses should be regarded as “medicines.” E&Y’s suggestion to add the phrase “such as shoe inserts” to subdivisions (b)(4) and (c)(2) (see below) would provide an example of one type of orthopedic supportive device. However, the addition of “such as shoe inserts” into the following sentences in subdivisions (c)(2) and (b)(4) raises concerns regarding the false implication that supportive devices for the foot are shoe inserts and nothing else.

(b)(4) ORTHOTIC DEVICES. (excerpt)

Orthopedic shoes and supportive devices for the foot, such as shoe inserts, do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses, and

(c)(2) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES”. (excerpt)

“Medicines” does not include arch supports, cervical pillows, exercise weights, hospital beds, orthopedic shoes and supportive devices such as shoe inserts (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes, sacro-ease seats, shoe modifications, spenco inserts, traction units, or thermophore pads, ~~or foot orthoses~~.

The term supportive devices for the foot means more than just shoe inserts. For example, toe separators, bunion shields, or toe aligning splints are all supportive devices for the foot that are not considered shoe inserts. Supportive devices for the foot refers to all foot orthoses and not just shoe inserts. In addition, wording in subdivision (b)(4)(A) already excludes shoe inserts from the definition of “custom-made biomechanical foot orthosis.”

Regulation 1591 specifically excludes tissue and breast expanders from the term “medicines.” Regulation 1591(b)(2) discusses articles permanently implanted in the human body. For an article to qualify as a medicine under this subdivision it must meet the following requirements: (1) it must assist the functioning of any natural organ, artery, vein, or limb, and (2) it must remain or dissolve in the body. A tissue expander (breast expander) does not replace or assist the function of a natural part of the human body nor does it remain or dissolve in the body. Subdivision (b)(2) explains that an article is considered “permanently implanted” if it is not reasonably anticipated that it will be removed. The breast and tissue expanders in question are always removed as soon as they have served their purpose. Therefore, they cannot be considered permanently implanted. As such, their sales are subject to tax. Staff notes that Sales and Use Tax Annotation 425.0163 (10/6/93) which states that an item is considered to be permanently implanted if the intent was that it remain in place for at least six months, is inconsistent with the provisions of Regulation 1591. Specifically, since this annotation was superseded by amendments to Regulation 1591(b)(2) in November 1999, annotation 425.0163 has been removed.

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A tissue expander does not qualify as a prosthetic device under Regulation 1591(b)(5) in that it does not replace or assist the function of a natural part of the human body. As noted above, the tissue expander forces the skin to grow tissue that it would not normally produce. In the case of a mastectomy, the skin would normally grow over the wound. The tissue expander forces skin to grow in enough quantity to use it to construct a breast. Often, it is used to produce extra skin to replace injured skin elsewhere in the body. This appears to be little different than the production of artificial skin outside the body for the same purpose. The property used to produce such skin would not be a prosthetic device. A device used to force the body to produce the skin would similarly not qualify.

The tissue expander does not qualify as an orthotic device under Regulation 1591(b)(4) in that it does not operate as a brace or support for the body structure. The term orthotics is generally understood in the medical industry as the science and art of making and fitting devices concerned with the preservation, restoration, and development of form and function of the skeletal structure. (Stedman's Medical Dictionary, 25th ed. 1990, p. 1102.) As a result, the tissue expander, concerned as it is with the skin rather than the skeleton, cannot be said to operate as a brace or support for the skeletal structure. Thus a tissue/breast expander does not qualify as “medicine” under Regulation 1591(b)(4).

Finally, tissue expanders also do not qualify as mammary prostheses under Regulation 1591.1(b)(2). (Because a mammary prostheses falls under Regulation 1591.1 it is therefore outside the scope of this regulation.) A “prosthesis” is defined as a “[f]abricated substitute for a diseased or missing part of the body.” (Stedman's Medical Dictionary, 25th ed. 1990, p. 1271.) The tissue expander may fabricate a substitute for a missing breast, but is not itself the substitute. Therefore it cannot be considered a mammary prosthesis. Moreover, if the Board were to determine that tissue expanders sold for the purpose of breast reconstruction were medicines but tissue expanders sold for the purpose of manufacturing extra skin for grafts in other places were not, retailers and auditors both would incur much time and expense determining the purpose of the expanders. There is no category specified in the statute which would include tissue expanders within the term “medicines.”

Alternative 2

See pages 10-11 for a complete description of Alternative 2. Smith proposes to amend the regulation to exempt all prescription sales of wound dressings. For the following reasons, staff is opposed to Alternative 2:

Wound dressings are specifically excluded from the term “medicines” in both the statute and the regulation. Dressings are not “devices.” Specifically, they are not considered to be orthotic devices that are worn on the body as a brace or support to correct the body structure, or prosthetic devices that assist or replace the functioning of a natural part of the human body. As such, their sales are generally subject to tax.

The text of staff's proposed amendments to Regulation 1591 is attached as Exhibit 3 and a comparison of staff's and interested parties' proposed language is attached as Exhibit 2.

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B. Pros of the Staff Recommendation

- Conforms the regulation to the Board’s December 12, 2001 and April 18, 2002 Memorandum Opinions.
- Makes the exemptions for CPM and enteral feeding supplies easy to find in the regulation.
- Maintains current and historical Board and staff interpretation of the phrase “worn on the body.”
- Maintains clarification of the exemption of orthotic/prosthetic devices by keeping the “fully worn” requirement which is clearer than a “sustained physical contact” test.

C. Cons of the Staff Recommendation

- Requires regulatory change.

D. Statutory or Regulatory Change

No statutory change is required. However, staff’s recommendation requires an amendment to Regulation 1591.

E. Administrative Impact

Staff will be required to notify taxpayers of the amendments to the regulation through an article in the Tax Information Bulletin, and to update and distribute the amended regulation.

F. Fiscal Impact

1. Cost Impact

There will be no additional cost. As stated above, it is anticipated that taxpayers would be notified of the amendments to the regulation through an article in one of the scheduled Tax Information Bulletins (TIBs). The costs associated with the distribution of TIBs, which are routinely prepared and distributed to taxpayers, are accommodated within the Board’s existing budget.

2. Revenue Impact

The revenue loss is estimated at \$662,000 annually. See Revenue Estimate (Exhibit 1).

G. Taxpayer/Customer Impact

Staff expects that this amendment will maintain ease of compliance, as the “fully worn” test has been the Board’s longstanding interpretation.

H. Critical Time Frames

The proposed amendments have no operative date.

VI. Alternative 1

A. Description of the Alternative

Alternative proposals were submitted by E&Y and Nielsen. Since these two interested parties agree with each other’s proposal, E&Y’s and Nielsen’s combined proposals will be presented as Alternative 1. In addition to the amendments recommended by staff, E&Y and Nielsen propose to:

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- Amend subdivisions (b)(4) and (b)(5) of Regulation 1591, *Medicines and Medical Devices*, to replace the fully worn on the body requirement with a sustained physical contact test.
- Add language in subdivisions (b)(4) and (c)(2) to name “shoe inserts” as items that do not qualify as medicines and to remove “foot orthoses” from the list of items that do not qualify as medicines.
- Exempt sales of “tissue and breast expanders” in subdivisions (b)(2), (b)(4), and (b)(5).

E&Y argues that language in Regulation 1591 and in numerous annotations improperly limits the exemption for orthotics beyond the authority found in RTC section 6369(c) by requiring the orthotic device to be “fully worn.” The exemption provided by RTC section 6369(c) for orthotic and prosthetic devices is restricted to those devices that are “designed to be worn on (or in) the person of the user.” E&Y notes that something can be designed to be *worn* and not be *fully* worn. Therefore, the following two sentences, added to the end of the second paragraph of Regulation 1591(b)(4) in 1999 and 2000, respectively, narrow the exemption beyond the plain language of the statute by excluding from the term medicine an orthotic device if any part of it is not worn on the person:

All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

E&Y points out that of the 395 annotations in the Business Taxes Law Guide that pertain to medicines, 41 contain the words “fully worn.” One in particular attempts to define what is meant by “worn on the body.” Annotation 425.0168.300, added in 1984 and revised in 1996, defines that to mean “the item is either completely below the surface of the body or is attached to the body.” It goes on to state “Worn on the person requires some physical attachment and must be fully worn on the person.” There are many annotations that interpret “designed to be worn on (or in) the person of the user” to mean only those orthotics and prosthetics that are “fully” worn. However, authority for the restrictive language “fully worn” is not found in RTC section 6369(c).

Furthermore, considering that the statutory wording for exempt orthotics and prosthetics is nearly identical with respect to the requirement that these devices be worn on or in the person of the user, E&Y proposes applying the same interpretation of what is meant by this to both subdivisions (b)(4)—orthotics—and (b)(5)—prosthetics—of Regulation 1591. E&Y proposes that the interpretation be based on two requirements—that the devices and their replacement parts (1) have sustained physical contact with the body and (2) the purpose is the treatment of the body structure. However, E&Y’s language specifically excludes I.V. sets from the exemption.

In 1977 when the exemption for orthotic devices was enacted, “orthopedic shoes and supportive devices for the foot” were excluded. According to E&Y, the material in the bill file for SB 588 makes it clear that, with the exception of orthopedic shoes, the legislature intended the same tax treatment for orthotic devices for the foot as for all other orthotic devices. E&Y contends that the only discussion on “supportive devices for the foot” was in the context of over-the-counter shoe inserts and support stocking. Furthermore, E&Y argues that with the passage of AB 99 in 1987, which provided an exemption for “custom made biomechanical foot orthoses” which are custom made shoe inserts, further legislative guidance was provided as to the meaning of “supportive devices for the foot.” In order to provide regulatory guidance, E&Y suggests that the phrase “such

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as shoe inserts” be added to the regulation and “foot orthoses” be removed from the list of items that do not qualify as medicines.

Nielsen proposes to remove the specific exclusion of breast/tissue expanders from the definition of “prescription medicines” in Regulation 1591(b)(2). In addition, Nielsen contends that breast/tissue expanders should qualify as exempt medicines under any of the following provisions: “permanently implanted articles” in Regulation 1591(b)(2), “prosthetic devices” in Regulation 1591(b)(5), “mammary prosthesis” in Regulation 1591.1(b)(2), and “orthotic devices” in Regulation 1591(b)(4).

Tissue expanders are a Silastic® (a soft, flexible, inert silicone rubber) bag with a self-sealing injection port. They are used as an integral part of a surgical procedure to reconstruct breasts after cancer surgery. They are used to develop surgical flaps and additional tissue coverage. In this application, the expander is used to expand the skin remaining after the mastectomy to accommodate the saline implant that will remain permanently. They are also used in the repair of catastrophic burns or wounds, by stretching adjacent skin to create a flap to cover the burn or wound.

In general, the tissue expander is surgically implanted under the skin adjacent to the area that requires reconstruction. The expander is left inside the patient for an indefinite period of time, but sufficient time necessary to stretch the skin sufficiently to accommodate the permanent implant or cover the burn or wound. It is then removed and discarded.

Nielsen contends that breast/tissue expanders are medical devices which qualify as a “medicine” (Regulation 1591(a)(9)) that are “sold to a licensed physician...or health facility for the treatment of a human being” (Regulation 1591(d)(4)).

Nielsen contends that breast/tissue expanders are “medicines” under Regulation 1591(b)(2) “permanently implanted articles.” For the purposes of Regulation 1591, Nielsen argues, the term “permanently implanted” has never been interpreted literally, but rather has been interpreted as being met if the “intent was that it remain in place for at least six months even if for some reason it had to be removed sooner.” (Annotation 425.0163) In its June 17, 2002 letter, Nielsen provided a copy of a brochure (McGhan Medical Corp.) that states that tissue expanders are “temporary” devices that should be left in place until “adequate tissue has developed.” The brochure notes that this “typically” requires four to six months. However, a declaration from Dr. Debra Johnson, M.D., F.A.C.S. indicates six months is about average for implantation. (See Exhibit 5)

Nielsen also argues, in its June 17, 2002 letter, that breast/tissue expanders also meet the definition of a “prosthetic device.” (Regulation 1591(b)(2)) The breast/tissue expander, Nielsen contends, replaces the functioning of a natural part of the human body and is designed to be worn on or in the person of the user.

Nielsen, in its June 17 letter, goes on to say that expanders also are an orthotic device designed to be worn on the person of the user as a correction for the body structure. Regulation 1591(b)(4) lists a “stump shrinker” as an “orthotic device.” A stump shrinker, Nielsen contends, is the opposite of a tissue expander, but both concern resizing tissue.

Nielsen goes on to say that the expanders also fit the definition of “mammary prosthesis” and should be exempt pursuant to Regulation 1591.1(b)(2).

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The text of E&Y and Nielsen’s proposed amendments to Regulation 1591 can be found in the comparison table in Exhibit 2.

B. Pros of the Alternative

- Provides consistency between the regulation and the Board’s Memorandum Opinion in the Matter of Action Medical by removing the “fully” worn on the body requirement.
- Clarifies the meaning of “supportive devices for the foot” by referencing shoe inserts as an example.
- May make breast expanders and tissue expanders less expensive for cancer patients and burn victims.

C. Cons of the Alternative

- Requires regulatory change.
- Changes current and historical staff interpretation regarding “worn on the body.”
- Includes a multiple-based exemption for a permanently implanted article, a prosthetic device and an orthotic device in the regulation, which is difficult for both retailers and audit staff to administer.

D. Statutory or Regulatory Change

No statutory change is required. However, this alternative requires an amendment to Regulation 1591.

E. Administrative Impact

Staff will be required to notify taxpayers of the amendments to the regulation through an article in the Tax Information Bulletin, and to update and distribute the amended regulation.

F. Fiscal Impact

1. Cost Impact

There will be no additional cost. As stated above, it is anticipated that taxpayers would be notified of the amendments to the regulation through an article in one of the scheduled Tax Information Bulletins (TIBs). The costs associated with the distribution of TIBs, which are routinely prepared and distributed to taxpayers, are accommodated within the Board’s existing budget.

2. Revenue Impact

The revenue loss is estimated at \$17,500,000 annually. See Revenue Estimate (Exhibit 1)

G. Taxpayer/Customer Impact

Taxpayers may be confused by the uncertainty over the meaning of “sustained” physical contact.

H. Critical Time Frames

The proposed amendment has no operative date.

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VII. Alternative 2

A. Description of the Alternative

Smith proposes to include prescription sales of wound dressings in the category of exempt orthotic devices. Smith contends that there is no clearer example of a group of products that are “worn on the body,” with no part intentionally touching any other surface, than wound dressings. In addition, Smith argues that in order to meet Federal, State and HMO requirements for reimbursement, all dressings must be prescribed, just like medicines.

The text of Smith’s proposed amendments to Regulation 1591 can be found in the comparison table in Exhibit 2.

B. Pros of the Alternative

- May make wound dressings less expensive for patients.
- May provide less confusion for taxpayers as all prescription sales of wound dressings would be exempt. Currently, sales of dressings that are impregnated with medicine are exempt while all other sales of dressings are taxable.

C. Cons of the Alternative

- Inconsistent with the statute
- Requires regulatory change.
- Changes current and historical staff interpretation.

D. Statutory or Regulatory Change

No statutory change is required. However, this alternative requires an amendment to Regulation 1591.

E. Administrative Impact

Staff will be required to notify taxpayers of the amendments to the regulation through an article in the Tax Information Bulletin, and to update and distribute the amended regulation

F. Fiscal Impact

1. Cost Impact

There will be no additional cost. As stated above, it is anticipated that taxpayers would be notified of the amendments to the regulation through an article in one of the scheduled Tax Information Bulletins (TIBs). The costs associated with the distribution of TIBs, which are routinely prepared and distributed to taxpayers, are accommodated within the Board’s existing budget.

2. Revenue Impact

The revenue loss is estimated at \$10,900,000 annually. See Revenue Estimate (Exhibit 1).

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G. Taxpayer/Customer Impact

Staff expects that this amendment will maintain ease of compliance, as all sales of dressings would be treated the same. Currently, sales of dressings that are impregnated with medicine are exempt while all other sales of dressings are taxable.

H. Critical Time Frames

The proposed amendment has no operative date.

Prepared by: Program Planning Division, Sales and Use Tax Department

Current as of: 8-1-02

BOARD OF EQUALIZATION
REVENUE ESTIMATE
FORMAL ISSUE PAPER #02-012

Worn on the Body
Regulation 1591, Medicines and Medical Devices

Staff Recommendation

Staff recommends the following amendments to Regulation 1591, with no operative date:

- Add a reference to Health and Safety Code section 1200 and 1200.1 in subdivision 1591(a)(4) in order to include surgical clinics in the definition of “health facilities” without the operative date contained in the statute.
- Add new subdivision (e)(8) to exempt sales of continuous passive motion (CPM) machines.
- Move the exemption for enteral feeding tubes, etc. from subdivision (b)(5) to new subdivision (e)(9), Enteral Feeding, TPN, IDPN Devices.
- Incorporate non-substantive amendments in subdivisions (b)(4) and (d).

Alternative 1

In addition to the amendments recommended by staff, Mr. Glenn Bystrom of Ernst & Young (E&Y) and Mr. Eric Miethke of Nielsen, Merksamer, Parrinello, Mueller & Naylor, LLP (Nielsen) propose to:

- Amend subdivisions (b)(4) and (b)(5) of Regulation 1591, *Medicines and Medical Devices*, to replace the fully worn on the body requirement with a sustained physical contact test.
- Add language in subdivisions (b)(4) and (c)(2) to name “shoe inserts” as items that do not qualify as medicines and to remove “foot orthoses” from the list of items that do not qualify as medicines.
- Exempt sales of “tissue and breast expanders” in subdivisions (b)(2), (b)(4), and (b)(5).

Alternative 2

In addition to the amendments recommended by staff, Ms. Janet Smith of Smith Bio-Medical (Smith) proposes to exempt sales of wound dressings in subdivisions (b)(4) and (c)(2).

Background, Methodology, and Assumptions

Two general assumptions were used in computing estimates. We assume that population proportion is equivalent to consumption or incident proportions in the United States (U.S.). Thus, the proportion of California's population to U.S. population, 12.0 percent, was applied to values of U.S. data to obtain values for California. We also assume that growth in dollar and incident values is steady. Where possible, average growth rates were calculated and used to project data from the last year of available values to 2002.

Staff Recommendation

The only portion of the staff recommendation that has any revenue impact is that portion dealing with Continuous Passive Motion (CPM) machines.

Background

The regulation would specify that CPM machines are exempt from the sales and use tax. CPM machines are typically comprised of three sections: the limb carriage, the motor drive and the control unit. Many lower-limb devices house all components in one low, rectangular case that rests on a mattress. Some have separate control modules while others suspend the leg carriage from an overhead traction frame. Upper limb devices include stand-mounted units that can be wheeled to the bedside, tabletop units, and portable, battery-powered units. Some CPM machines can be used both in the hospital and at home. Home use can entail rental charges of up to \$75 per day. However, most rent for \$55 per day. The number of days patients use a CPM unit varies widely.

No government data exist for CPM machines alone. They are lumped into broader classes of medical therapy devices. Additionally, we found no industry publications that had data on these devices.

Assumptions

- Rentals represent the taxable transactions that apply to CPM devices. Most CPM devices are sold to companies that rent them out. We assume that the leases would be subject to tax and these devices are not purchased tax-paid.

Methodology

A search of the Food and Drug Administration (FDA) on-line databases was conducted. CPM units are classified as powered exercisers (product code BXB) which also include powered tread mills and exercise bikes. There are 59 registered establishments coded BXB. A search of the registration database was conducted for each establishment that gave some variation of CPM as the common or generic name of its registered device(s). Some registered establishments had more than one company. In all, 12 establishments representing 15 companies were identified.

An informal survey was conducted, using the official correspondents as the initial point of contact. One contact was excluded from the survey because he was located in Germany. Three phone numbers were disconnected or no longer in service. One could not be reached. Another indicated that his company sold surgical and orthopedic soft goods only. Of the six remaining contacts, two had U.S. market data. One contact had combined rental values for CPM units and other electrotherapy devices, cryo therapy devices, and orthopedic bracing

products. A former product manager of the second company had done a market study in 2001 using 1998 data on CPM machines. U.S. rentals were valued at \$97 million. The market study used an annual growth rate of 2.5 percent. Both contacts were asked about what portion of CPM rentals were for devices that were partially worn. Due to some confusion over the meaning of "partially worn," both were asked to assume that "partially worn" means the controller module is not worn on the body. One contact indicated that about 75 percent were partially worn. The other estimated 65 to 70 percent were partially worn due to a growing market for fully worn shoulder and hand devices. For this estimate, we used 70 percent.

We applied the 2.5 percent growth rate to the market study's 2001 estimate of \$97 million, yielding \$99.4 million in U.S. rentals for 2002. Seventy percent, or \$69.6 million, is the value of U.S. rentals of partially worn CPM units. At 12 percent, the California rental market is valued at \$8.4 million. Applying a statewide average sales tax of 7.92 percent produces an estimated \$662,000 in revenue losses for 2002. This assumes the leases are subject to tax and the equipment is not purchased tax-paid.

Alternative 1

Clarifying the meaning of supportive devices for the foot will have no revenue impact. Two estimates were calculated for this alternative: one for devices potentially impacted by a test of "sustained physical contact," and one for breast and tissue expanders. Each is addressed separately here.

Sustained Physical Contact

Background

The classification of medical devices differs somewhat among government service and regulatory bodies. For example, the Board considers Transcutaneous Nerve Stimulators (TENS) exempt prosthetic devices. The FDA classifies them as neurological therapeutic devices. Medi-Cal includes TENS devices in a miscellaneous category for durable medical equipment. Due to the lack of a single classification system, no device or class of devices could be excluded due solely to the fact that the devices were not classified as orthotics or prosthetics.

The test of "sustained physical contact" is nebulous. We were unable to obtain a satisfactory accounting of the types of devices that would be impacted. For purposes of this estimate, we used the criteria below to identify those devices that could be impacted by Alternative 1.

Criteria for inclusion

- The device is currently taxable.
- The device has an orthotic or prosthetic function. It braces, supports, or corrects the body structure, or it replaces or assists the functioning of a natural part of the human body.
- The purpose of the device is therapeutic.
- The device contacts some part of the patient's body while in use. Neither the proportion of the device's surface area contacting the body nor the duration of contact matters. Direct contact with the skin is unneeded. A barrier such as clothing or a cast may exist.
- The device is not a foot orthosis, or an auditory, ocular, ophthalmic, or dental device.

We were unable to obtain data on specific devices. However, the U.S. Census Bureau collects fairly detailed data on types of products. We selected those product types that were likely to include devices that met our criteria for inclusion.

The U.S. Census Bureau conducts the Economic Census every five years ending in years two and seven. Each report provides statistics from the current and prior census. It publishes Current Industrial Reports (CIR) every non-census year for a much smaller number of product classes. Each report provides statistics for the current and prior reporting periods. Product data reported in a CIR are aggregated as summary data in the Economic Census reports.

The medical products selected for this estimate fall in one of three classes, each reported separately by the Census Bureau. The most detailed data appear at the level of 10-digit product codes of the North American Industrial Code System (NAICS). NAICS replaced the Standard Industrial Codes (SIC) in 1997. To get the most detailed data, we used the following reports:

- Product data on powered (electrical) medical therapy devices are reported in the CIR, *Electromedical and Irradiation Equipment*. The pertinent data appear in Table 2 of reports for 1998, 1999, and 2000.
- Product data on mechanical medical therapy devices are reported in the Economic Census of *Surgical and Medical Instrument Manufacturing*. The pertinent data appear in Table 6a of the report for 1997.
- Product data on orthotic and prosthetic devices are reported in the Economic Census of *Surgical Appliance and Supplies Manufacturing*. The pertinent data appear in Table 6a of the report for 1997.

We used product shipment data, not manufacturer shipment data. This is an important distinction because one set of statistics reports total shipments for each type of product while the other set reports total shipments of manufacturers making the same type of product as their primary product plus whatever else they make.

Assumptions

- The value of shipment data collected by the Census Bureau represents the entire output of U.S. manufacturers by product type.
- The value of shipments represents the wholesale value.
- The proposal affects 25 percent of shipment values.
- Providers pay the sales and use tax on the wholesale value of medical products.
- A ratio of net exports to total shipments for a class of products applies to all product types included in the classification. Net exports were used to eliminate sales to other countries in order to arrive at the value of U.S. sales.
- For each of the three product classes, the calculated ratios of net exports would be essentially the same, whether calculated from SIC reported data or NAICS reported data.

Methodology

We estimated the value of shipments in 2001 and 2002 for products in the CIR by calculating average annual percent changes from 1997 to 2000. We multiplied each product's 2000 shipment value by its average annual percent change to obtain its 2001 shipment value. The same method was used to obtain each product's 2002 shipment value. An average annual percent change was obtained by dividing the result of a product's 2000 shipment value minus its 1997 shipment value by three. The 2000 CIR withheld data on pacemakers to avoid disclosing data of individual companies. However, values for 1997 to 1999 appeared in previous reports.

The 2000 shipment value of pacemakers was estimated by calculating the average annual percent change in shipment values (21.1%) from 1997 to 1999 and multiplying the 1999 shipment value of pacemakers by the percent change.

We estimated the value of shipments in the years 1998 to 2002 for products in the Economic Census in the same way. An average annual percent change was obtained for each product by dividing the result of its 1997 shipment value minus its 1992 shipment value by five. The 1998 shipment value of each product was then multiplied by its average annual percent change to obtain the estimated 1999 value. The same calculation was performed for each year to 2002. To avoid disclosing the data of individual companies, the 1997 Census withheld the 1992 shipment value of surgical, orthopedic, prosthetic, and therapeutic appliances and supplies. We used an average annual percent change of 2.4 percent derived from the total shipments of four other types of products in the same class that were also selected for inclusion in this estimate.

In general, exports have exceeded imports of medical products in value. To establish ratios of net exports to shipments, we used import, export, and total shipment data in the *U.S. Industry and Trade Outlook 2000*, Tables 44-3, 44-5, and 44-9. The *Outlook* used data as reported under the SIC system. We estimated 2001 and 2002 shipment, export, and import values by calculating the average of yearly percent changes from 1996 to 2000 and multiplying the values for the previous year by the percent change. The ratio is calculated by subtracting import value from export value and dividing the result by total shipment value. Estimated 2002 ratios are 10.8 for electromedical equipment (Table 44-9), 36.8 for surgical and medical instruments (Table 44-3), and 34.4 for surgical appliances and supplies (Table 44-5). We used ratios of net exports to shipments to estimate 2001 and 2002 value of net exports for each product. A net export value was obtained by dividing estimated shipment value by the ratio. To derive U.S. sales, we subtracted each product's estimated net export value from its estimated shipment value.

Products Impacted by an Exemption Test of Sustained Physical Contact 2002 Projections (thousands \$)

Product	U.S.	U.S.	U.S.	CA Sales	CA
	Shipment	Net			CA Sales
	Value	Exports	Sales	(12.0%)	(7.92%)
<i>Electromedical and Irradiation Equipment</i>					
Pacemakers	32,308	2,991	29,317	3,518	279
Ultrasound therapy	2,131,509	197,362	1,934,147	232,098	18,382
All other (powered) medical therapy equipment	1,700,207	157,427	1,542,780	185,134	14,663
<i>Surgical and Medical Instruments</i>					
Surgical and medical mechanical therapy appliances	96,248	2,615	93,633	11,236	890
<i>Surgical Appliance and Supplies Manufacturing</i>					
O & P intraocular lenses, O & P appliances	457,548	13,301	444,247	53,310	4,222
Other O & P appliances	1,198,167	34,830	1,163,337	139,600	11,056
Other surgical and orthopedic products	1,793,953	52,150	1,741,803	209,016	16,554
Parts for surgical, O, P, and therapeutic appliances	185,921	5,405	180,516	21,662	1,716
Surgical, O, P, and therapeutic appliances	42,153	1,225	40,928	4,911	389
TOTAL	7,638,014	467,306	7,170,708	860,485	68,151

O = Orthopedic P = Prosthetic

We estimate U.S. sales will be \$7.2 billion in 2002 for all product types that could be impacted by a sales tax exemption test of sustained physical contact. At 12 percent, the estimated value for California is \$860.5 million. At 7.92 percent, state and local taxes are estimated to be

\$68.2 million. We realize that Alternative 1 would impact only a portion of the devices included in the product types we identified. Some devices are already exempt. Some will remain taxable. The definition of sustained physical contact has not been made clear to us. We have no way of knowing exactly what portion of the above sales would be impacted by Alternative 1. However, as an indication of the order of magnitude of the revenue impact, if we assume that 25 percent of estimated sales of devices in these product types are impacted, \$215.1 million in sales would be exempt. The sales and use tax revenue associated with these sales amounts to \$17.0 million.

Breast and Tissue Expanders

Background

According to the American Society of Plastic Surgeons (ASPS), skin expansion is the most common technique used in post mastectomy reconstruction. A tissue expander is a balloon with a valve mechanism. The expander is inserted beneath the skin and chest muscle. The surgeon periodically injects a salt-water solution through the valve into the balloon over a period of several weeks or months. After the skin has stretched enough, it may be removed and replaced with a more permanent implant. Expanders are also used to repair damaged skin. Once the wound has healed, the expander is inserted under healthy skin next to the damaged area. Depending on the area to be reconstructed, tissue expansion can take as long as three to four months. Most common is 6 to 10 weeks. When the skin has stretched enough to cover the affected area, the expander is removed and the skin repositioned.

The ASPS has been the sole source of cosmetic and reconstructive plastic surgery statistics since 1992. In 2000, ASPS expanded its annual survey. It included procedures performed by ASPS members as well as other physicians most likely to perform plastic surgery procedures. Responses were extrapolated to the entire population of more than 23,000 physicians. Results of the survey were based on a 95 percent confidence level with a maximum error range of 4.5 percent.

Assumptions

- Tissue expanders are most likely to be used for reconstructive surgeries following mastectomies and burn injuries.
- One tissue expander is used per procedure.
- Skin expanders are used in 50 percent of reconstructive surgeries on burns.

Methodology

Data from the ASPS 2000 survey were used to estimate the number of breast reconstruction and burn repair procedures performed in the U.S. in 2002. More detailed data on breast surgery statistics were limited to ASPS members only. The percent change in U.S. population (about 1 percent) was used to estimate the increase in these procedures. We estimate that breast reconstruction surgeries increased from 80,908 to 82,534 in 2002. Reconstructive surgeries to repair burns increased from 31,058 procedures in 2000 to 31,683 in 2002. The 2000 breast surgery statistics indicate that the tissue expander technique was used in 32 percent of breast reconstruction surgeries. Another 7 percent used a procedure that may involve tissue expanders, the Latissimus dorsi muscle flap procedure. A contact at the corporate headquarters of one manufacturer of tissue expanders estimated that expanders might be used for about half of these procedures. We used 35.5 percent to estimate that tissue expanders were used in 29,300 breast reconstruction surgeries. No data were available on the

number of expanders used for burn repair. Assuming that expanders are used in 50 percent of burn repairs, an additional 15,842 tissue expanders were used.

Prices on tissue expanders were provided by a contact in a company that manufactures breast and tissue expanders. The average price of tissue expanders used for breast reconstruction was \$1,600. The company's prices for other expanders as well as prices posted on the website of another manufacturer were used to obtain the average price of multi-purpose tissue expanders. The average price was \$434. We multiplied the average prices by U.S. procedures to obtain values of \$46.9 million for breast reconstruction and \$6.9 million for burn repair. At 12 percent, we estimate Californians will expend \$5.6 million on expanders for breast reconstruction and \$825,000 on expanders for burn repair. We estimate state and local sales taxes on expanders used for these two procedures (7.92 percent) in 2002 will be \$511,000.

Alternative 2

Background

The *Surgical Appliance and Supplies Manufacturing* 1997 Economic Census contains data on surgical dressings. There are six types at the 10-digit NAICS product code level. We used data from the 8-digit code level which is the aggregate of the six types. Due to the switch from SIC to NAICS codes, the 1992 data were not available or comparable.

Assumptions

- Surgical dressings represent the entire universe of wound dressings that would be impacted by exempting the sale of wound dressings from state and local sales taxes.
- The growth rate of surgical dressings is the same as the average annual growth rate of 2.4 percent used to calculate the change in shipment values of surgical, orthopedic, prosthetic, and therapeutic appliances and supplies in Alternative 1.
- The value of shipments of surgical dressings represents the entire U.S. output of surgical dressings.
- The value of shipments represents the wholesale value of surgical dressings.
- Providers pay the sales and use tax on the wholesale value of surgical dressings.
- A ratio of net exports to total shipments of 34.4 for surgical appliances and supplies applies to surgical dressings.

Methodology

The value of shipments of surgical dressings in 1997 was \$1.0 billion. At a 2.4 percent annual rate of growth, the value of U.S. shipments in 2002 is estimated at \$1.2 billion. Applying a ratio of net exports to total shipments of 34.4 yields estimated net exports of \$34.2 million. The value of surgical dressings sold in the U.S. in 2002 is estimated to be \$1.1 billion. At 12.0 percent of national sales, California sales of surgical dressings are estimated to be \$137.2 million. In 2002, we estimate state and local sales taxes to be \$10.9 million.

Revenue Summary

Staff Recommendation

The estimated loss in 2002 revenue as a result of exempting from the sales and use tax \$8.4 million in rentals of CPM machines would be as follows:

	<u>Revenue Effect</u>
State loss (5%)	\$418,000
Local loss (2.25%)	\$188,000
Special District loss (0.67%)	56,000
Total	<u>\$662,000</u>

Alternative 1

The estimated loss in 2002 revenue as a result of exempting from the sales and use tax \$215.1 million in sales of medical devices that meet the test of sustained physical contact (SPC) and in exempting \$6.5 million in sales of breast and tissue expanders (BTE) would be as follows:

	<u>SPC Revenue Effect</u>	<u>BTE Revenue Effect</u>	<u>Total Revenue Effect</u>
State loss (5%)	\$10.8 million	\$0.32 million	\$11.1 million
Local loss (2.25%)	4.8 million	0.14 million	4.9 million
Special District loss (0.67%)	1.4 million	0.05 million	1.5 million
Total	<u>\$17.0 million</u>	<u>\$0.51 million</u>	<u>17.5 million</u>

Alternative 2

The estimated loss in 2002 revenues as a result of exempting from the sales and use tax \$137.2 million in sales of wound dressings would be as follows:

	<u>Revenue Effect</u>
State loss (5%)	\$6.9 million
Local loss (2.25%)	3.1 million
Special District loss (0.67%)	0.9 million
Total	<u>\$10.9 million</u>

Preparation

This revenue estimate was prepared by Ms. Beth Lindley, Research and Statistics Section. This revenue estimate was reviewed by Mr. David E. Hayes, Manager, Research and Statistics Section, and Ms. Charlotte Paliani, Program Planning Manager, Sales and Use Tax Department. For additional information, please contact Ms. Lindley at (916) 445-0840.

Current as of August 6, 2002.

Proposed Regulatory Changes Regarding Application of Tax to Medicines and Medical Devices
Comparison of Current and Proposed Language for Regulation
 Current as of August 6, 2002

Action Item	Current Regulatory Language	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith	Summary Comments
	<p>Regulation 1591, Medicines and Medical Devices</p> <p>(b) "MEDICINES".</p> <p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in</p>	<p>Regulation 1591, Medicines and Medical Devices</p> <p>(b) "MEDICINES".</p> <p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in</p>	<p>Regulation 1591, Medicines and Medical Devices</p> <p>(b) "MEDICINES".</p> <p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in</p>	<p>Regulation 1591, Medicines and Medical Devices</p> <p>(b) "MEDICINES".</p> <p>[No submission received]</p>	

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<p>Action 4 –Breast Tissue Expanders and Tissue Expanders</p>	<p>subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p>	<p>subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p>	<p>subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; <u>breast tissue expanders and tissue expanders</u>; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p>		<p>Staff believes that sales of breast/tissue expanders should be subject to tax as they are not permanently implanted. The breast/tissue expanders in question are always removed as soon as they have served their purpose.</p> <p>Interested parties believe that sales of breast/tissue expanders should be exempt as they are implanted for between three to nine months with six months being the average.</p>

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Action Item	Current Regulatory Language	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith	Summary Comments
<p>Action 4 –Breast Tissue Expanders and Tissue Expanders</p>	<p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(b)(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section</p>	<p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(b)(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section</p>	<p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; <u>and</u> defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.</p> <p>(b)(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section</p>	<p>(b)(4) ORTHOTIC DEVICES. Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section</p>	

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Action Item	Current Regulatory Language	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith	Summary Comments
	<p>6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>Staff believes the “fully worn” on the body requirement should not be changed. This has been the Board’s long standing interpretation of the statute.</p>

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Action Item	Current Regulatory Language	Regulatory Language Proposed by Staff	Regulatory Language Proposed by E&Y and Nielsen	Regulatory Language Proposed by Smith	Summary Comments
<p>Action 2-“Fully Worn” on the Body Requirement</p>	<p>rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces</p> <p>All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.</p>	<p>rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces</p> <p>All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. <u>Except as provided in subsection (e)(8),</u> if any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.</p>	<p>and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces</p> <p>All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.</p>	<p>and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces</p> <p>All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.</p>	<p>tax.</p> <p>Smith believes that “wound dressings” are orthotic devices that are “fully worn” on the body with no part touching any other surface and as such their sales should be exempt from tax.</p> <p>Staff believes the “fully worn” on the body requirement should not be changed. To keep the regulation internally consistent, the phrase “except as provided in subdivision (e)(8) must be added.</p> <p>Interested parties believe the “fully worn” on the body requirement narrows the exemption beyond</p>

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<p>Action 3- Supportive Devices for the Foot</p>	<p>Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.</p> <p>(b)(5) PROSTHETIC DEVICES. Prosthetic devices and their</p>	<p>Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.</p> <p>(b)(5) PROSTHETIC DEVICES. Prosthetic devices and their</p>	<p>Orthopedic shoes and supportive devices for the foot, <u>such as shoe inserts</u>, do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.</p> <p>(b)(5) PROSTHETIC DEVICES. Prosthetic devices and their</p>	<p>Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.</p> <p>[No submission received]</p>	<p>the plain language of the statute and that it should be removed.</p> <p>Staff believes there is no reason to add "shoe inserts" to the list of taxable items and that this in no way clarifies the regulation.</p> <p>Interested parties believe audit staff is mis-interpreting this area of the regulation and that by adding "shoe insert" as an example of a taxable item, proper clarification will be provided</p>

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	<p>replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers,</p>	<p>replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers,</p>	<p>replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers,</p>		

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	<p>intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p> <p>For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also</p>	<p>intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>	<p>intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).</p>		

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<p>Action 2-“Fully Worn” on the Body Requirement</p>	<p>include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.</p> <p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p>	<p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p>	<p><u>Prosthetic devices and their replacement parts that replace or assist the functioning of a natural part of the human body are designed to be worn on or in the patient if they (1) have sustained physical contact with the body and (2) the purpose is the treatment of the body structure. This paragraph shall not apply to I.V. sets.</u></p> <p>Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited</p>		<p>See comments on pages 4 and 5.</p>

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<p>Action 4 –Breast Tissue Expanders and Tissue Expanders</p>	<p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials</p>	<p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials</p>	<p>to, acetabular cups, atrial valves, <u>breast tissue expanders and tissue expanders</u>, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials</p>		<p>See comments on page 2.</p>

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<p>Action 5-Sales of Wound Dressings</p> <p>Action 3-Supportive Devices for the Foot</p>	<p>and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES"</p> <p>(2) 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. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease</p>	<p>and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES"</p> <p>(2) 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. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease</p>	<p>and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES"</p> <p>(2) 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. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices <u>such as shoe inserts</u> (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease</p>	<p>(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES"</p> <p>(2) 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. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease</p>	<p>See comments on pages 5 and 6.</p> <p>See comments on page 7.</p>

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<p>Action 2-:Fully Worn” on the Body</p> <p>Action 3- Supportive Devices for the Foot</p>	seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.	seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.	seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), <u>or</u> thermophore pads, or foot orthoses.	seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.	<p>See comments on pages 4 and 5.</p> <p>See comments on page 7.</p>

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Proposed Regulation 1591. MEDICINES AND MEDICAL DEVICES.

References: Sections 6006 and 6369 Revenue and Taxation Code.

(a) DEFINITIONS.

(1) ADMINISTER. "Administer" means the direct application of a drug or device to the body of a patient or research subject by injection, inhalation, ingestion, or other means.

(2) DISPENSE. "Dispense" means the furnishing of drugs or devices upon a prescription from a physician, dentist, optometrist, or podiatrist. Dispense also means and refers to the furnishing of drugs or devices directly to a patient by a physician, dentist, optometrist, or podiatrist acting within the scope of his or her practice.

(3) FURNISH. "Furnish" means to supply by any means, by sale or otherwise.

(4) HEALTH FACILITY. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, which provides that:

(A) Section 1200 of the Health and Safety Code whereby a "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility.

(B) Section 1200.1 (a) As used in this chapter, "clinic" also means an organized outpatient health facility which, pursuant to Section 1204.1, provides direct psychological advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with Section 2900) of Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility. (b) Psychological clinics, as defined in Section 1204.1, shall not be considered primary care clinics for the purposes of any state grants, state loans, or other state aid. (c) Any reference in any statute to Section 1200 shall be deemed and construed to also be a reference to this section.

(C) Section 1250 of the Health and Safety Code, which provides that a "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer.

~~"As used in this chapter "health facility" means any facility, place or building that is organized, maintained, and operated for the diagnosis, care, prevention, and treatment of human illness, physical or mental, including convalescence and rehabilitation and including care during and after pregnancy, or for any one or more of these purposes, for one or more persons, to which the persons are admitted for a 24-hour stay or longer...."~~

(5) PHARMACIST. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of section 4200 of the Business and Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law."

(6) PHARMACY. "Pharmacy" means an area, place, or premises licensed by the California State Board of Pharmacy in which the profession of pharmacy is practiced and where prescriptions are compounded. Pharmacy includes, but is not limited to, any area, place, or premises described in a license issued by the California State Board of Pharmacy wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. Pharmacy shall not include any area specifically excluded by paragraph (b) of section 4037 of the Business and Professions Code.

(7) PRESCRIPTION. "Prescription" means an oral, written, or electronic transmission order that is issued by a physician, dentist, optometrist, or podiatrist licensed in this state *and* given individually for the person or persons for whom ordered. The order must include all of the following:

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- (A) The name or names and address of the patient or patients.
- (B) The name and quantity of the drug or device prescribed and the directions for use.
- (C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.

- (F) If in writing, signed by the prescriber issuing the order.

(8) **PHYSICIANS, DENTISTS, OPTOMETRISTS, AND PODIATRISTS.** "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the Osteopathic Medical Board of California and includes an unlicensed person lawfully practicing medicine pursuant to section 2065 of the Business and Professions Code, when acting within the scope of that section.

(9) **MEDICINES.** "Medicines" means 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 that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) "MEDICINES." The term "medicines" means and includes the following items:

(1) **PREPARATIONS AND SIMILAR SUBSTANCES.** Preparations and similar substances intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which are commonly recognized as a substance or preparation intended for such use qualify as medicines. Tax does not apply to the sale or use of such medicines sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

"Preparations and similar substances" include, but are not limited to, drugs such as penicillin, and other antibiotics, "dangerous drugs" (drugs that require dispensing only on prescription); alcohol (70% solution) and isopropyl; aspirin; baby lotion, oil, and powder; enema preparations; hydrogen peroxide; lubricating jelly; medicated skin creams; oral contraceptives; measles and other types of vaccines; topical creams and ointments; and sterile nonpyrogenic distilled water. Preparations and similar substances applied to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease qualify as medicines. "Preparations and similar substances" also include Total Parenteral Nutrition (also called TPN), Intradialytic Parenteral Nutrition (also called IDPN), and food provided by way of enteral feeding, except when the TPN, IDPN, or food provided by enteral feeding qualifies as a meal under Regulation 1503. For purposes of this regulation, TPN, IDPN, and enteral feeding are means of providing complete nutrition to the patient; TPN and IDPN are provided in the form of a collection of glucose, amino acids, vitamins, minerals, and lipids, TPN being administered intravenously to a patient who is unable to digest food through the gastrointestinal tract and IDPN being administered to hemodialysis patients as an integral part of the hemodialysis treatment; enteral feeding is the feeding of the patient directly into the gastrointestinal tract.

(2) **PERMANENTLY IMPLANTED ARTICLES.** Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components;

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implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

Implantable articles that do not qualify as "permanently" implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; defibrillator programmer and high voltage stimulator used with an implanted defibrillator; and tissue and breast expanders. The sale or use of these items is subject to tax.

(3) **ARTIFICIAL LIMBS AND EYES.** Artificial limbs and eyes, or their replacement parts, including stump socks and stockings worn with artificial legs and intraocular lenses for human beings, qualify as medicines as provided by Revenue and Taxation Code section 6369 (c)(5). Tax does not apply to the sale or use of these items when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(4) **ORTHOTIC DEVICES.** Orthotic devices and their replacement parts, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace bandages, ankle braces, anti-embolism stockings, athletic supporters (only for patients recovering from rectal or genital surgery), casts and cast components, cervical supports, neck collars, cervical traction devices, clavicular splints, post-surgical corsets, elbow supports, head halters, pelvic traction devices, post-operative knee immobilizers and braces, legging orthoses, rib belts and immobilizers, rupture holders, sacral belts, sacro-lumbar back braces, shoulder immobilizers, slings, stump shrinkers, sternum supports, support hose (and garter belts used to hold them in place), thumb and finger splints, trusses, and wrist and arm braces. All of the above must be worn on the body of the person and act as a brace, support or correction for body structure to qualify as a medicine. Except as provided in subdivision (e)(8), if any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation.

Orthopedic shoes and supportive devices for the foot do not qualify as medicines unless they are an integral part of a leg brace or artificial leg or are custom-made biomechanical foot orthoses. "Custom-made biomechanical foot orthosis" means a device that is made on a positive model of the individual patient's foot. The model may be individually constructed from suitable model material such as plaster of paris, stone, or wax, and may be manually constructed or fabricated using electronic technology.

"Custom-made biomechanical foot orthosis" do not include:

(A) Any pre-made or pre-molded foot orthosis or shoe insert even if it has been modified or customized for an individual patient by the practitioner regardless of the method of modification;

(B) Any foot orthosis fabricated directly on the patient's foot regardless of the method and materials used and regardless of its individual character; or

(C) Any foot orthosis fabricated inside of the patient's shoe regardless of the method of manufacture and materials used and regardless of its individual character.

(5) **PROSTHETIC DEVICES.** Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of

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subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). ~~For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.~~

Prosthetic devices that are considered medicines when worn on or in the patient include, but are not limited to, acetabular cups, atrial valves, cervical cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.

Prosthetic devices that do not qualify as "medicines," include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.

(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(c) EXCLUSIONS FROM THE DEFINITION OF "MEDICINES."

Except as otherwise provided in subdivision (b), the following items are specifically excluded from the definition of medicines. Sales of these items are subject to tax in the same manner as any other sale of tangible personal property.

(1) Orthodontic, prosthetic (except as described in subdivision (b)(56)), auditory, ophthalmic or ocular devices or appliances.

(2) 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. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

(3) Any alcoholic beverage the manufacture, sale, purchase, possession or transportation of which is licensed and regulated by the Alcoholic Beverage Control Act (Division 9, commencing with section 23000, of the Business and Professions Code).

(d) APPLICATION OF TAX – IN GENERAL.

Tax applies to retail sales, including over-the-counter sales of drugs and medicines, and other tangible personal property by pharmacists and others. However, tax does not apply to the sale or use of medicines when sold or furnished under one of the following conditions:

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- (1) ~~P~~rescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or
- (2) ~~F~~urnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or
- (3) ~~F~~urnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or
- (4) ~~S~~old to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or
- (5) ~~S~~old to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or
- (6) ~~E~~ffective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) SPECIFIC TAX APPLICATIONS.

- (1) **PRESCRIPTIONS.** No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.
- (2) **LICENSED PHYSICIAN, DENTIST OR PODIATRIST.** Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patients for the medicines furnished.
- (3) **HEALTH FACILITY.** Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.
- (4) **PHARMACEUTICAL MANUFACTURER OR DISTRIBUTOR.** Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant

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to the order of the licensed physician. "Clinical trial medicines" do not include placebos. Placebos are not used for the treatment of a human being and, as such, do not qualify for the exemption provided under this subdivision. Thus, the use of placebos is subject to tax.

(5) **ANTIMICROBIAL AGENTS USED BY HOSPITAL PERSONNEL.** Tax does not apply to the sale or use of substances or preparations, such as antiseptic cleansers or scrubs, when such substances or preparations qualify as medicines and are used by hospital personnel on the patient or by hospital personnel on their own bodies to benefit the patient, and which constitute a critical component of the patient's treatment. Qualifying medicines used on the bodies of hospital personnel include antimicrobial agents used for preoperative scrubbing or hand cleansing prior to any patient contact such as Accent Plus Skin Cleanser; Accent Plus Perinal Cleanser; Bacti-Stat; Betadine; and Medi-Scrub. However, antimicrobial agents such as Accent Plus 1 Skin Lotion; Accent Plus 2 Body Massage; Accent Plus 2 Skin Crème; and Accent Plus Total Body Shampoo applied to the body of hospital personnel are not considered used in the treatment of the patient and the sale or use of these products is subject to tax.

(6) **VITAMINS, MINERALS, HERBS, AND OTHER SUCH SUPPLEMENTS.** In general, sales of vitamins, minerals, herbs and other such supplements are subject to tax. However, when vitamins, minerals, herbs and other such supplements are used in the cure, mitigation, treatment or prevention of disease, and are commonly recognized as a substance or preparation intended for such use, they will qualify as medicines for the purposes of Revenue and Taxation Code section 6369. As such, their sale or use is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6).

(7) **DIAGNOSTIC SUBSTANCES, TEST KITS, AND EQUIPMENT.** Tax applies to the sale or use of diagnostic substances applied to samples of cells, tissues, organs, or bodily fluids and waste after such samples have been removed, withdrawn, or eliminated from the human body. Diagnostic substances are applied to the samples outside the living body ("in vitro") in an artificial environment. They are not administered in the living body ("in vivo"). As the substances are not applied internally or externally to the body of the patient, they do not qualify as medicines under Revenue and Taxation Code section 6369.

Except as provided in Regulation 1591.1(b)(45), tax applies to the sale or use of test-kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(8) CPM MACHINES. A continuous passive motion machine (CPM) is an orthotic device whose sale or use is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).

(9) ENTERAL FEEDING, TPN, IDPN DEVICES. Tax does not apply to the sale or use of the following prosthetic devices when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. Tax does not apply to sales of needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

(f) INSURANCE PAYMENTS

(1) **MEDICAL INSURANCE AND MEDI-CAL.** The exemption of retail sales of medicines is not affected by the fact that charges to the person for whom the medicine is furnished may be paid, in whole or in part, by an insurer. This is so even though a joint billing may be made by the retailer in the name of both the person and the insurer.

(2) **MEDICARE**

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of

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medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

(B) Medicare Part B. Tax applies to sales of items to a person in which payment is made pursuant to Part B of the Medicare Act. Sales made under Part B do not qualify as exempt sales to the United States Government even though the patient may assign the claim for reimbursement to the seller and payment is made by a carrier administering Medicare claims under contract with the United States Government. Under Part B, the seller does not have a contract with the United States Government. The contract is between the patient and the United States Government. Unless the sale is otherwise exempt (such as a sale of a medicine under subdivision (d)), the sale is subject to tax.

(3) **EMPLOYER MEDICAL CONTRACTS.** Certain employers have contracted with their employees to provide the latter with medical, surgical, and hospital benefits in a hospital operated by or under contract with the employer for a fixed charge. Usually the charge is by payroll deduction. These contracts are not insurance plans; rather, they are agreements to furnish specified benefits under stated conditions, one of which may be that no charge is to be made to the employee for prescribed medicines. The agreements may provide for making a charge for medicines furnished to out-patients but not to in-patients. This in no way affects the exemption of sales of medicines.

(g) RECORDS.

Any pharmacy whether in a health facility or not must keep records in support of all deductions claimed on account of medicines. Section 4081 of the Business and Professions Code requires that all prescriptions filled shall be kept on file and open for inspection by duly constituted authorities.

Pursuant to section 4081 of the Business and Professions Code, physicians and surgeons and podiatrists must keep accurate records of drugs furnished by them. Any deduction on account of sales of medicines shall be supported by appropriate records.

(1) The following written information constitutes acceptable documentation for retailers in those cases where sales are made of supplies which are "deemed to be dispensed on prescription" within the meaning of Revenue and Taxation Code section 6369:

- Name of purchaser
- Name of doctor
- Date of sale
- Item sold
- The sale price

(2) **"DOUBLE DEDUCTION" UNAUTHORIZED.** The law does not, of course, permit a double deduction for sales of exempt medicines. For example, if an exemption is claimed on account of a sale of a prescription medicine, no additional deduction for the same sale may be taken as a sale to the United States Government under the Medicare Program.

(3) Persons making purchases of items in which their sale or use is exempt under this regulation should give their suppliers an exemption certificate pursuant to Regulation 1667.

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BEFORE THE BOARD OF EQUALIZATION
OF THE STATE OF CALIFORNIA

In the Matter of the Late Protest
Under the Sales and Use Tax Law of:

Action Medical Products, Inc.
Account: SR FH 97-309543
Case ID: 57424

Appearances:

For Petitioner: Jacqueline Reynolds, President
For Sales and Use Tax Department: David Levine, Tax Counsel IV
For Appeals Section: John Abbott, Tax Counsel IV

MEMORANDUM OPINION

This opinion considers the merits of a late protest for the period May 10, 1991, through December 31, 1998. At the Board hearing, taxpayer protested a determination measured by \$865,982 for leases of certain types of continuous passive motion machines, leased in the same form as acquired and purchased ex-tax from out-of-state vendors. A physician must order the use of these machines. Patients use the machines for the treatment of injuries and, post-operatively, to deter stiffness and loss of range of motion in joints such as knees and hips. The affected limbs of these patients are strapped into the machines. Powered by electricity, the machines move the affected joints through a controlled range of motion. The taxpayer contended that these continuous passive motion machines qualify as medicines, specifically, orthotic devices exempt under Revenue and Taxation Code section 6369, subdivision (c)(3)(A). If so, the leases are exempt from tax.

The Sales and Use Tax Department contended that, while the machines met all other requirements of a medicine as defined in California Code of Regulations, title 18, section 1591, the machines were orthotic devices that patients did not fully wear on their bodies. Instead, the machines' support stands rested on the floor. The Department contended that it has long been Board policy that, in order to qualify as a medicine, orthotic devices must be fully worn on the body. By amendments to subdivision (b)(4) of section 1591, effective March 10, 2000 and applicable retroactively, the Board clarified that "If any part of the orthotic device is not worn on the person, the device is not a medicine for the purposes of this regulation." However, the Department allowed the medicine exemption for taxpayer's leases of continuous passive motion machines that served the identical medical rehabilitation purpose for other joints, such as elbow and shoulder joints, but were fully worn on the body.

OPINION

Revenue and Taxation Code section 6369 provides in relevant part:

“(c)... ‘medicines,’ as used in this section means and includes any of the following:

¶...¶

(3)(A) Orthotic devices... designed to be worn on the person of the user as a brace, support, or correction for the body structure....”

Some continuous passive motion machines leased by the taxpayer were exempt, but others were classified as taxable, even though all the machines served the identical medical rehabilitation purpose. We conclude that the continuous passive motion machines at issue in this case qualify as orthotic devices pursuant to section 6369, subdivision (c)(3)(A), although they were not fully worn on the body. Grant the late protest with respect to the disputed transactions.

Adopted at Sacramento, California, on April 18, 2002.

Dean F. Andal _____, Member

Claude Parrish _____, Member

Marcy Jo Mandel* _____, Member

*For Dr. Kathleen Connell, pursuant to Government Code section 7.9.

NIELSEN, MERKSAMER, PARRINELLO,
MUELLER & NAYLOR, LLP
Eric Miethke, (State Bar No. 133224)

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Attorneys for Taxpayer McGhan Medical Corporation

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BEFORE THE BOARD OF EQUALIZATION OF THE STATE OF CALIFORNIA

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In the Matter of the)
Appeal of the Determination)
of Sales Tax Against McGhan)
Medical Corporation)
SR AR 15-707037)

Appeal No. 27128

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Declaration of
Debra Johnson, M.D.,F.A.C.S.

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I, Debra Johnson, M.D., do hereby declare the following:

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1. I am a currently a physician specializing in plastic surgery. Since October, 1989, I have been a partner at the Plastic Surgery Center, 95 Scripps Drive, Sacramento, California 95825.

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2. My educational background is as follows. I have a Bachelor of Science Degree in Biology from the University of California, Irvine (1977). I received my M.D. degree from Stanford University in 1981. For 1981 and from 1984-1989, I remained at Stanford University Hospital through my internship, a residency in General Surgery and a residency in plastic surgery. Also during my tenure at Stanford University Hospital, I had residencies in aesthetic surgery at Clinica Planas in Barcelona, Spain in 1987 and in hand and microsurgery in 1988 at Institut Francais de la Main in Paris France. During 1982-

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1 1984 I worked as a National Health Service Corps physician at Native American Clinics
2 in Northern California. In 1989, I became Chief Resident at Stanford University
3 Hospital, and remained in that capacity until I joined my current group.

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5 3. I have received several awards and published several articles during my career. I
6 am also a member of several professional and medical specialty organizations. These are
7 noted in my Curriculum Vitae, which is attached to this declaration.

8

9 4. My current practice now concerns almost exclusively reconstructive plastic
10 surgery. A significant portion of these procedures are breast reconstructions involving
11 the use of implants and tissue expanders. In an average year, I perform approximately
12 100 breast reconstructions.

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14 5. Tissue expanders are strictly regulated by federal law and can only be sold to and
15 prescribed by a licensed physician or medical facility. In breast reconstruction surgery,
16 their use is inextricably entwined with the implant itself. By that, I mean that a breast
17 implant is rarely used for its intended purpose unless a tissue expander were part of the
18 procedure as well. The size and shape of the implant and the size of the patient dictate
19 the size and shape of the tissue expander, but they are almost always used together. For
20 example, in a mastectomy, once the breast is removed, there is insufficient skin to cover a
21 permanent prosthesis. The tissue expander is surgically inserted in the patient and its
22 purpose is to increase the surface skin area through gradual inflation of the expander (a
23 balloon-like device) with saline solution. Once there is sufficient skin area to cover the
24 prosthesis, the tissue expander is removed from the patient and the prosthesis is

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1 implanted. In short, without the tissue expander the implant would not be usable;
2 conversely, the tissue expander has no other use other than in conjunction with
3 reconstructive surgery. Tissue expanders are "single-use" and are not approved for reuse.

4

5 6. I have reviewed a April 11, 1997 memorandum from John Waid to J.W. Cornelius
6 regarding "tissue expanders" and "breast expanders", and find it makes several erroneous
7 conclusions, based on several inaccurate assumptions and inadequate facts.

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9 7. First, the memorandum's conclusion are based solely on what appears to be a
10 marketing brochure which does not begin to adequately describe the medical uses of
11 tissue expanders. For instance, a tissue expander (as that term is used in the
12 memorandum) that is not used in conjunction with breast reconstruction is probably being
13 predominantly used either to replace skin tissue lost as the result of a catastrophic burn or
14 other wound. I disagree with the memorandum's conclusion on page 2 that "the tissue
15 expander does not stimulate the growth of skin to promote healing on an injury at the site
16 where the expander is placed." In fact, in the case of a burn or catastrophic wound, the
17 expander is placed immediately proximate to the burn or wound, and the tissue is
18 expanded until it is sufficiently stretched to cover the burn or wound. In that sense, it is
19 directly related to promote healing and the production of new skin at the place where the
20 expander is used.

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22 8. Next, the memorandum makes the assumption that tissue expanders and breast
23 expanders are not implants because they are not implanted in the human body for greater
24 than six months. As a medical fact, this is not correct. Tissue expanders are left in place

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1 for as long as it takes for sufficient skin area to be created for the particular use. For
2 instance, in breast reconstruction surgeries, it is not uncommon for tissue expanders to be
3 implanted for six months; in fact I have personally had a case where a tissue expander
4 was left in place for 3 years.

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6 Finally, I disagree with the comparison on page 2 of the letter of the use of a tissue
7 expander to the production of artificial skin outside the body. Tissue expanders are used
8 to help the body repair itself by generating tissue to cover a wound, or as an integral part
9 of a permanent breast implant to replace tissue that has been removed due to disease.

10 There simply is no comparison to a machine that manufactures artificial skin outside the
11 body for uses that may be completely unknown at the time of manufacture.

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103 I declare under penalty of perjury that the foregoing is true and correct, and was executed
14 on the ___ day of September, 2001 in Sacramento, California.

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DEBRA JOHNSON, M.D., F.A.C.S.

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21 NIELSEN, MERKSAMER, PARRINELLO,
22 MUELLER & NAYLOR, LLP
23 Eric Miethke, (State Bar No. 133224)
24 770 L Street, Suite 800
25 Sacramento, CA 95814
26 Telephone: (916) 446-6752
27 Telecopier: (916) 446-6106

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1 Attorneys for Taxpayer McGhan Medical Corporation

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3 BEFORE THE BOARD OF EQUALIZATION OF THE STATE OF CALIFORNIA

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5	In the Matter of the)	Appeal No. 27128
6	Appeal of the Determination)	
7	of Sales Tax Against McGhan)	Supplemental Declaration of
	Medical Corporation)	Debra Johnson, M.D.,F.A.C.S.
	SR AR 15-707037)	
	_____)	

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9

10 I, Debra Johnson, M.D., do hereby declare the following:

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12 1. In my previous declaration, I have stated that tissue expanders are left in place for
13 as long as it takes for sufficient skin area to be created for the particular use. For
14 instance, in breast reconstruction surgeries, it is not uncommon for tissue expanders to be
15 implanted for six months; in fact I have personally had a case where a tissue expander
16 was left in place for 3 years.

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18 2. Based on the totality of my practice, which involves about an average of 100
19 breast reconstructions per year, the median (average) amount of time tissue expanders are
20 left inside the patient's body is six months.

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22 3. The shortest I have ever left a tissue expander in place as part of a breast
23 reconstruction procedure is about three months; however, for every case that a tissue
24 expander was left in place for 3-6 months, I have had at least as many cases where the

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1 expander was left in place from 6-9 months. Thus, I conclude six months to be an
2 appropriate estimate of average placement.

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4 4. I declare under penalty of perjury that the foregoing is true and correct, and was
5 executed on the ____ day of October, 2001 in Sacramento, California.

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DEBRA JOHNSON, M.D., F.A.C.S.

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