



STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION

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March 3, 2006

TO INTERESTED PARTIES:

**NOTICE OF PROPOSED REGULATORY ACTION
BY THE
STATE BOARD OF EQUALIZATION**

**PROPOSED AMENDMENT TO SALES AND USE TAX
REGULATION 1591, MEDICINES AND MEDICAL DIVICES**

NOTICE IS HEREBY GIVEN

The State Board of Equalization, pursuant to the authority vested in it by section 15606(a) of the Government Code, proposes to amend Regulation 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, of the California Code of Regulations, relating to sales and use tax. A public hearing on the proposed regulation will be held in Room 121, 450 N Street, Sacramento, at 1:30 p.m., or as soon thereafter as the matter may be heard, on April 18, 2006. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by April 18, 2006.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Current law, Revenue and Taxation Code section 6369, provides that sales of tangible personal property defined as "medicines" by that statute are not subject to tax if the medicines are sold or otherwise transferred in one of the ways specified in the statute.

Regulation 1591, Medicines and Medical Devices, is proposed to be amended to interpret, implement and make specific Revenue and Taxation Code (RTC) section 6369. Amendments are proposed to amend Regulation 1591 to clarify the application of tax to certain sales of medical products. The proposed amendments would provide that, subject to certain qualifications, the term "medicines" includes any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition.

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments and regulations do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5(a)(8), the Board of Equalization made an initial determination that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendment to this regulation and the proposed regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendment to the regulation as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulation may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulation 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6369 Revenue and Taxation Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed to Ms. Lisa Andrews (916) 322-5989, at 450 N Street, Sacramento, CA 95814, e-mail Lisa.Andrews@boe.ca.gov or MIC:50, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0050.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Diane Olson, Regulations Coordinator, telephone (916) 322-9569, fax (916) 324-3984, e-mail Diane.Olson@boe.ca.gov or Ms. Chelsea Carlock, Analyst, telephone (916) 322-3084, e-mail Chelsea.Carlock@boe.ca.gov or by mail at State Board of Equalization, Attn: Diane Olson Chelsea Carlock, MIC:80, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

ALTERNATIVES CONSIDERED

The Board must determine that no reasonable alternative considered by it or that has been otherwise identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed, or be as effective and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's web site <http://www.boe.ca.gov>.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's web site following its public hearing of the proposed regulation. It is also available for your inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Ms. Richmond. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.

Sincerely,



Deborah Pellegrini, Chief
Board Proceedings Division

DP:dgo
Attachments

INITIAL STATEMENT OF REASONS
OVERVIEW/NON-CONTROLLING SUMMARY

TITLE 18. PUBLIC REVENUE
REGULATION 1591, MEDICINES AND MEDICAL DEVICES

Regulation 1591 interprets and explains the application of sales and use tax to sales or other transfers of medicines, as defined. It explains when such sales are subject to sales and use tax and when they are not.

Specific Purpose

The purpose of the proposed amendments is to interpret, implement, and make specific Revenue and Taxation Code section 6369. These amendments are necessary to provide guidance to that portion of the public which is affected by this statute.

Factual Basis

The California Sales and Use Tax Law imposes either a sales or use tax on all retail sales of tangible personal property to California consumers, unless otherwise exempted by statute or type of transaction. Generally, doctors are considered consumers of products they use in performance of their medical services. The sale of these products to doctors is taxable unless the item qualifies for exemption, such as the exemption for medicines provided in RTC section 6369.

RTC section 6369, interpreted and implemented by Regulation 1591, provides that sales or other transfers of medicines as defined in the statute are not subject to tax if they are sold or otherwise transferred pursuant to the requirements set forth in the statute. In section 6369, subdivision (b), the Legislature has provided that the term "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 commonly recognized as a substance or preparation intended for that use [emphasis supplied]." Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of "medicines." Assuming all the other requirements for exemption are met, the Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease or for some other purpose (i.e., for a purpose that is wholly unrelated to the treatment of a medical condition). The same deference to the professional judgment of doctors and other qualified persons is also required for devices and articles prescribed or furnished under subdivision (c) of RTC section 6369.

The Board has concluded that revisions are needed because Board auditors are erroneously assessing tax on sales of prescription drugs used to treat medical conditions. Specifically, auditors have questioned non-taxed sales of certain substances that have a medical purpose when the eventual application of the specific product sold is for cosmetic purposes. The Board has concluded that to make the determination as to whether or not a product is sold for an exempt purpose when it has a dual use would require auditors to investigate doctors' practices and to examine patient records, thus violating the doctor-patient privilege.

Subdivision (a)(9)- new subdivision (a)(9)(A) added to clarify that any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition is considered a medicine, except for devices excluded from the term “medicine in subdivision (c)(2); current language of subdivision (a)(9) transferred to new subdivision (a)(9)(B) with word “any” capitalized accordingly. Subdivision (b)(1)- phrase “In . . . The” added to clarify that the definition of “medicine” in subdivision (a)(9) is in addition o the definitions of “medicines” contained in subdivision (b).

Pursuant to Government Code section 11346.5(a)(8), the Board of Equalization finds that the adoption of the proposed amendments will not have a significant adverse economic impact on private businesses or persons. The amendments are proposed to interpret, implement, and make specific the authorizing statutes in the context covered by the regulation for greater ease of understanding and to conform the regulation to recent legislation. These changes will clarify the interpretation or administration of the sales and use tax laws. Therefore, the Board has determined that these changes will not have a significant adverse economic impact on private businesses or persons.

REGULATION 1591. MEDICINES AND MEDICAL DEVICES.

Reference: 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:

"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:

(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.

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(9) MEDICINES. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or

(B) 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." In addition to the definition set forth in subdivision (a)(9) of this section, 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; 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; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. 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

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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. 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 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, breast tissue expanders and tissue expanders, 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)(6)), 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:

(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

(2) furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or

(3) furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or

(4) sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being, or

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(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

(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.

(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 patient 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 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

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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)(4), 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.

(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 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.

The proposed amendments contained in this document may not be adopted. Any revisions that are adopted may differ from this text.

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.

The proposed amendments contained in this document may not be adopted. Any revisions that are adopted may differ from this text.

Regulation History

Type Of Regulation:	Sales and Use Tax
Regulations:	1591
Title:	<i>Medicines and Medical Devices</i>
Preparation:	Lynn Whitaker/Peter Horton
Legal Contact:	Randy Ferris/Trecia Nienow

In September 2005, the Board was petitioned to amend the definition of “medicines” in Regulation 1591, subdivision (a)(9). Revenue and Taxation Code section (Section) 6369, interpreted and implemented by Regulation 1591, provides that sales or other transfers of medicines as defined in the statute are not subject to tax if they are sold or otherwise transferred pursuant to the requirements set forth in the statute. In Section 6369, subdivision (b), the Legislature has provided that the term “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 commonly recognized as a substance or preparation intended for that use [emphasis supplied].” Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of “medicines.” Assuming all the other requirements for exemption are met, the Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease or for some other purpose (i.e., for a purpose that is wholly unrelated to the treatment of a medical condition). The same deference to the professional judgment of doctors and other qualified persons is also required for devices and articles prescribed or furnished under subdivision (c) of Section 6369.

The Board has concluded that revisions are needed because Board auditors were erroneously assessing tax on nontaxable sales of prescription drugs, devices and articles approved by the U.S. Food and Drug Administration (FDA) for the treatment of medical conditions. Confusion on the correct application of tax arose when such FDA-approved products could be used either to treat a medical condition or for purely cosmetic purposes. The Board has concluded that to make the determination as to whether or not a product is sold for an exempt purpose, when the product is susceptible to a dual use, would require auditors to investigate unnecessarily doctors’ practices and to examine patient records, thus violating the doctor-patient privilege.

The amendments clarify that except where taxable for all purposes as provided in Regulation 1591, subdivision (c), “medicines” include any product approved by the FDA to treat medical conditions. Regulation 1591, subdivision (c), provides that except as otherwise provided in subdivision (b) of 1591, certain items (including various medical devices and articles) are specifically excluded from the definition of “medicines.”

History of Amendments

April 18, 2006:	Public hearing.
April 17, 2006:	45-Day public comment period ends.
March 4, 2006:	45-Day public comment period begins.
March 3, 2006:	Notice of public hearing published in California Regulatory Notice Register, Register 2006, No. 9-Z, e-mailed and US mail to interested parties.
January 31, 2006:	Business Taxes Committee Meeting, (Vote 5-0)
November 30, 2005:	Interested Parties Meeting
November 1, 2005:	Topic Placed on Business Taxes Committee Calendar

Sponsor: Petitioners: California Society of Dermatology and Dermatologic Surgery, California Society of Plastic Surgery, California Academy of Ophthalmology, California Medical Association

Support: Petitioners
Forty-three letters received from various interested parties

Oppose: None expressed.