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*Medicines and Medical Devices*

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cc: J. McGuire  
**RECEIVED**

JUN 29 2015

**State of California  
Office of Administrative Law**

by EXECUTIVE DIRECTOR'S OFFICE  
STATE BOARD OF EQUALIZATION

**In re:**  
**Board of Equalization**

**Regulatory Action:**

**Title 18, California Code of Regulations**

**Adopt sections:**

**Amend sections: 1591**

**Repeal sections:**

**NOTICE OF APPROVAL OF REGULATORY  
ACTION**

**Government Code Section 11349.3**

**OAL Matter Number: 2015-0513-02**

**OAL Matter Type: Regular (S)**

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This rulemaking action by the Board of Equalization (BOE) revises section 1591 of title 18 of the California Code of Regulations to clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, are included in the definition of "medicines." This rulemaking action also clarifies the type of United States Food and Drug Administration (FDA) approval that is required in order for a medical device to qualify as a "medicine." Additionally, this rulemaking action clarifies the relationship between subdivisions (b) and (c) of the regulations as they pertain to the definition of "medicines."

OAL approves this regulatory action pursuant to section 11349.3 of the Government Code. This regulatory action becomes effective on 10/1/2015.

Date: June 25, 2015

  
Lindsey S. McNeill  
Attorney

For: DEBRA M. CORNEZ  
Director

Original: Cynthia Bridges  
Copy: Richard Bennion

**OFFICE OF ADMINISTRATIVE LAW**

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**DEBRA M. CORNEZ**  
Director

**MEMORANDUM**

TO: Richard Bennion  
FROM: OAL Front Desk  
DATE: 6/25/2015  
RE: Return of Approved Rulemaking Materials  
OAL File No. 2015-0513-02S

OAL hereby returns this file your agency submitted for our review (OAL File No. 2015-0513-02S regarding Medicines and Medical Devices).

If this is an approved file, it contains a copy of the regulation(s) stamped “ENDORSED APPROVED” by the Office of Administrative Law and “ENDORSED FILED” by the Secretary of State. The effective date of an approved regulation is specified on the Form 400 (see item B.5). **Beginning January 1, 2013**, unless an exemption applies, Government Code section 11343.4 states the effective date of an approved regulation is determined by the date the regulation is filed with the Secretary of State (see the date the Form 400 was stamped “ENDORSED FILED” by the Secretary of State) as follows:

- (1) **January 1** if the regulation or order of repeal is filed on September 1 to November 30, inclusive.
- (2) **April 1** if the regulation or order of repeal is filed on December 1 to February 29, inclusive.
- (3) **July 1** if the regulation or order of repeal is filed on March 1 to May 31, inclusive.
- (4) **October 1** if the regulation or order of repeal is filed on June 1 to August 31, inclusive.

If an exemption applies concerning the effective date of the regulation approved in this file, then it will be specified on the Form 400. The Notice of Approval that OAL sends to the state agency will contain the effective date of the regulation. The history note that will appear at the end of the regulation section in the California Code of Regulations will also include the regulation’s effective date. Additionally, the effective date of the regulation will be noted on OAL’s Web site once OAL posts the Internet Web site link to the full text of the regulation that is received from the state agency. (Gov. Code, secs. 11343 and 11344.)

**Please note this new requirement:** Unless an exemption applies, Government Code section 11343 now requires:

1. **Section 11343(c)(1):** Within 15 days of OAL filing a state agency’s regulation with the Secretary of State, the state agency is required to post the regulation on its Internet Web site in an easily marked and identifiable location. The state agency shall keep the regulation posted on its Internet Web site for at least six months from the date the regulation is filed with the Secretary of State.
2. **Section 11343(c)(2):** Within five (5) days of posting its regulation on its Internet Web site, the state agency shall send to OAL the Internet Web site link of each regulation that the agency posts on its Internet Web site pursuant to section 11343(c)(1).

OAL has established an email address for state agencies to send the Internet Web site link to for each regulation the agency posts. Please send the Internet Web site link for each regulation posted to OAL at [postedregslink@oal.ca.gov](mailto:postedregslink@oal.ca.gov).

**NOTE ABOUT EXEMPTIONS.** Posting and linking requirements do not apply to emergency regulations; regulations adopted by FPPC or Conflict of Interest regulations approved by FPPC; and regulations not subject to OAL/APA review. However, an exempt agency may choose to comply with these requirements, and OAL will post the information accordingly.

**DO NOT DISCARD OR DESTROY THIS FILE**

Due to its legal significance, you are required by law to preserve this rulemaking record. Government Code section 11347.3(d) requires that this record be available to the public and to the courts for possible later review. Government Code section 11347.3(e) further provides that "...no item contained in the file shall be removed, altered, or destroyed or otherwise disposed of." See also the State Records Management Act (Government Code section 14740 et seq.) and the State Administrative Manual (SAM) section 1600 et seq.) regarding retention of your records.

If you decide not to keep the rulemaking records at your agency/office or at the State Records Center, you may transmit it to the State Archives with instructions that the Secretary of State shall not remove, alter, or destroy or otherwise dispose of any item contained in the file. See Government Code section 11347.3(f).

Enclosures

**NOTICE PUBLICATION/REGULATIONS SUBMISSION**

**REGULAR**

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

<b>OAL FILE NUMBERS</b>	NOTICE FILE NUMBER <b>Z-2015-0212-01</b>	REGULATORY ACTION NUMBER <b>2015-0513-025</b>	EMERGENCY NUMBER
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**ENDORSED - FILED**  
in the office of the Secretary of State  
of the State of California

**JUN 25 2015**

3:37 pm

2015 MAY 13 AM 9:13  
OFFICE OF ADMINISTRATIVE LAW

For use by Office of Administrative Law (OAL) only

NOTICE	REGULATIONS
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**AGENCY WITH RULEMAKING AUTHORITY**  
State Board of Equalization

AGENCY FILE NUMBER (If any)

**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE	TITLE(S)	FIRST SECTION AFFECTED	2. REQUESTED PUBLICATION DATE
3. NOTICE TYPE <input type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other	4. AGENCY CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)
<b>OAL USE ONLY</b> <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn	ACTION ON PROPOSED NOTICE	NOTICE REGISTER NUMBER <b>2015, 92</b>	PUBLICATION DATE <b>2/27/2015</b>

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S) Medicines and Medical Devices	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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2. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

<b>SECTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)</b>	ADOPT
	AMEND 1591
TITLE(S) 18	REPEAL

3. TYPE OF FILING

<input checked="" type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify) _____	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input checked="" type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify) _____
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify) _____		

7. CONTACT PERSON Richard E. Bennion	TELEPHONE NUMBER (916) 445-2130	FAX NUMBER (Optional) (916) 324-3984	E-MAIL ADDRESS (Optional) rbennion@boe.ca.gov
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

SIGNATURE OF AGENCY HEAD OR DESIGNEE <i>Joann Richmond</i>	DATE May 11, 2015
TYPED NAME AND TITLE OF SIGNATORY Joann Richmond, Chief, Board Proceedings Division	

For use by Office of Administrative Law (OAL) only

ENDORSED APPROVED

JUN 25 2015

Office of Administrative Law

**Final Text of Proposed Amendments to**  
**California Code of Regulations, Title 18, Section 1591**

**1591. Medicines and Medical Devices.**

(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, and also includes “clinic” as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that “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.

(B) Section 1200 of the Health and Safety Code provides that “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. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that “clinic” also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in

the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics 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.

(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 & 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 & Professions Code, when acting within the scope of that section.

(9) Medicines. “Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent 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.

For purposes of subdivision (a)(9)(A), products “approved by the United States Food and Drug Administration” means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.

Medicines are further defined in subdivisions (b) and (c) below.

(b) “Medicines.” In addition to the definition set forth in subdivision (a)(9) of this ~~regulation~~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. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 or mark the location of a medical condition, 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, including the ear implant’s interdependent internal and external components. 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 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, 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 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). 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 cuffs, 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; 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 to be 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)(5)), 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, nor 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 sSection 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

(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 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) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) ~~of Regulation 1591.~~

(8) 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.

Pursuant to sSection 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 sSection 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.

Note: Authority cited: Section 7051, Revenue and Taxation Code. Reference: Sections 6006 and 6369, Revenue and Taxation Code; and Sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

[Comments@oehha.ca.gov](mailto:Comments@oehha.ca.gov) with “NOIL — 1–Bromo-propane” in the subject line. Comments submitted in paper form may be mailed, faxed, or delivered in person to the addresses below:

**Mailing**

Address: Ms. Esther Barajas–Ochoa  
Office of Environmental Health  
Hazard Assessment  
P.O. Box 4010, MS–12B  
Sacramento, California  
95812–4010

Fax: (916) 323–2265

**Street**

Address: 1001 I Street  
Sacramento, California 95814

Comments received during the public comment period will be posted on the OEHHA web site after the close of the comment period. Electronic files submitted should not have any form of encryption.

If you have any questions, please contact Esther Barajas–Ochoa at [esther.barajas-ochoa@oehha.ca.gov](mailto:esther.barajas-ochoa@oehha.ca.gov) or at (916) 445–6900.

**References**

National Toxicology Program (NTP, 2011). National Toxicology Program. Toxicology and Carcinogenesis Studies of 1–Bromopropane (CAS No. 106–94–5) in F344/N Rats and B6C3F1 Mice (Inhalation Studies). Technical Report Series No. 564. NIH Publication No. 11–5906. U.S. Department of Health and Human Services, NTP, Research Triangle Park, NC. Available at URL: [http://ntp.niehs.nih.gov/ntp/htdocs/lt\\_rpts/tr564.pdf](http://ntp.niehs.nih.gov/ntp/htdocs/lt_rpts/tr564.pdf).

National Toxicology Program (NTP, 2014). Report on Carcinogens, Thirteenth Edition, U.S. Department of Health and Human Services, Public Health Service, NTP, Research Triangle Park, North Carolina. Available at URL: <http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html>.

**SUMMARY OF REGULATORY  
ACTIONS**

**REGULATIONS FILED WITH  
SECRETARY OF STATE**

This Summary of Regulatory Actions lists regulations filed with the Secretary of State on the dates indicated. Copies of the regulations may be obtained by contacting the agency or from the Secretary of State, Archives, 1020 O Street, Sacramento, CA 95814, (916)

653–7715. Please have the agency name and the date filed (see below) when making a request.

File# 2015–0528–01

**BOARD OF BARBERING AND COSMETOLOGY**

Text and Reference Books for Students

The National Interstate Council of State Boards of Cosmetology (the “NIC”) currently develops the Board of Barbering and Cosmetology’s (the “Board”) examination for licensure. Through this regular rulemaking, the Board amended section 961 in Title 16 of the California Code of Regulations to transfer responsibility to approve educational materials, including text and reference books, from the Board to the NIC. Additionally, the Board added the use of on–line training programs — in lieu of text books — as an acceptable form of teaching materials.

Title 16

California Code of Regulations

AMEND: 961

Filed 06/29/2015

Effective 10/01/2015

Agency Contact: Kevin Flanagan (916) 575–7104

File# 2015–0513–01

**BOARD OF EQUALIZATION**

Application for Equalization by Member, Alternate Member, or Hearing

In this rulemaking action, the Board of Equalization is amending section 308.6 of title 18 of the California Code of Regulations regarding hearings by alternate assessment appeals boards.

Title 18

California Code of Regulations

AMEND: 308.6

Filed 06/25/2015

Effective 10/01/2015

Agency Contact:

Richard E. Bennion (916) 445–2130

File# 2015–0513–02

**BOARD OF EQUALIZATION**

Medicines and Medical Devices

This rulemaking action by the Board of Equalization (BOE) revises section 1591 of title 18 of the California Code of Regulations to clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, are included in the definition of “medicines.” This rulemaking action also clarifies the type of United States Food and Drug Administration (FDA) approval that is required in order for a medical device to qualify as a “medicine.” Additionally, this rulemaking action clarifies the relationship between subdivisions (b) and (c) of the regulations as they pertain to the definition of “medicines.”

Title 18  
 California Code of Regulations  
 AMEND: 1591  
 Filed 06/25/2015  
 Effective 10/01/2015  
 Agency Contact:  
 Richard E. Bennion (916) 445-2130

File# 2015-0512-04  
 COMMISSION ON PEACE OFFICER STANDARDS  
 AND TRAINING  
 Training and Testing Specifications

This action amends Learning Domains throughout the Training and Testing Specifications for Peace Officer Basic Courses publication which is used for course instruction and training for law enforcement officers who are employed as peace officers or enrolled in a training academy.

Title 11  
 California Code of Regulations  
 AMEND: 1005, 1007, 1008  
 Filed 06/24/2015  
 Effective 08/01/2015  
 Agency Contact: Cheryl Smith (916) 227-0544

File# 2015-0522-01  
 DEPARTMENT OF FOOD AND AGRICULTURE  
 Setting The Commercial Feed License Fee

In this regulatory action, the Department is amending section 2751 of title 3 of the California Code of Regulations to increase the annual commercial fee license from four hundred dollars to five hundred dollars, effective July 1, 2015.

Title 3  
 California Code of Regulations  
 AMEND: 2751(b)  
 Filed 06/24/2015  
 Effective 07/01/2015  
 Agency Contact: Maria Tenorio (916) 900-5022

File# 2015-0619-01  
 DEPARTMENT OF FOOD AND AGRICULTURE  
 Phytosanitary Certification

In this regulatory action, the Department amends Title 3 of the California Code of Regulations, section 4603, which relates to the Departments schedule of charges for providing non-regulatory services related to Phytosanitary Certification services. The amendment removes the sunset clause of July 1, 2015, found in subdivision (i) to allow the Department to continue to recover its costs for providing such services.

Title 3  
 California Code of Regulations  
 AMEND: 4603(i)  
 Filed 07/01/2015  
 Effective 07/01/2015  
 Agency Contact: Stephen S. Brown (916) 654-0317

File# 2015-0623-01  
 DEPARTMENT OF FOOD AND AGRICULTURE  
 Asian Citrus Psyllid Interior Quarantine

This emergency regulatory action by the Department of Food and Agriculture expands the quarantine area for the Asian Citrus Psyllid (ACP) (*Diaphorina citri*) by approximately 13 square miles in the San Jose area of Santa Clara County and into Alameda County. The effect of the emergency action provides authority for the state to perform quarantine activities against ACP within this additional area, along with the existing regulated areas.

Title 3  
 California Code of Regulations  
 AMEND: 3435(b)  
 Filed 06/24/2015  
 Effective 06/24/2015  
 Agency Contact: Sara Khalid (916) 403-6625

File# 2015-0615-02  
 DEPARTMENT OF HEALTH CARE SERVICES  
 Managed Care Information Sharing

This emergency rulemaking by the Department of Health Care Services (the "Department") adopts section 50188 in title 22 of the California Code of Regulations. Section 50188 is adopted to address the matter of describing how and under what circumstances updated Medi-Cal beneficiary contact information shall be reported, which the Department is required to do through an emergency rulemaking no later than July 1, 2015. (See Health & Saf. Code, § 14005.36, subd. (e).)

Title 22  
 California Code of Regulations  
 ADOPT: 50188  
 Filed 06/24/2015  
 Effective 06/24/2015  
 Agency Contact: Jordan Espey (916) 445-1514

File# 2015-0515-03  
 DEPARTMENT OF INSURANCE  
 Travel Insurance Agent Licensing

The Department of Insurance in this rulemaking action is adopting nine new sections in Title 10 of the California Code of Regulations. These sections implement AB2354 (CH 257, Statutes of 2012) by establishing travel insurance agent licensing. These regulations also set the license application and renewal fees and

Rulemaking File Index  
Title 18. Public Revenue  
Sales and Use Tax

Regulation 1591,  
*Medicines and Medical Devices*

1. [Final Statement of Reasons](#)
2. [Updated Informative Digest](#)
3. [Business Tax Committee Minutes, November 19, 2014](#)
  - Minutes
  - Deputy Director memo dated November 7, 2014
  - BTC Agenda
  - Formal Issue Paper Number 14-006
  - Exhibit 1 Revenue Estimate
  - Exhibit 2 Text Regulation 1591
  - Exhibit 3 Submission from Downey Smith & Fier
  - Exhibit 4 Submission from Equity Recovery Solutions Inc..
4. [Reporter's Transcript Business Taxes Committee, November 19, 2014](#)
5. [Estimate of Cost or Savings, February 12, 2015](#)
6. [Economic and Fiscal Impact Statements, February 11, 2015](#)
7. [Notice of Publications](#)
  - Form 400 and Notice, Publication Date February 27, 2015
  - Email sent to Interested Parties, February 27, 2015
  - CA Regulatory Notice Register 2015, Volume No. 9-Z
8. [Notice to Interested Parties, February 27, 2015](#)

The following items are exhibited:

  - Notice of Hearing
  - Initial Statement of Reasons
  - Proposed Text of Regulation 1591
  - Regulation History
9. [Statement of Compliance](#)
10. [Reporter's Transcript, Item F2, April 28, 2015](#)
11. [Draft Minutes, April 28, 2015, and Exhibits](#)
  - Notice of Proposed Regulatory Action
  - Initial Statement of Reasons
  - Proposed Text of Regulation 1591
  - Regulation History

VERIFICATION

I, Richard E. Bennion, Regulations Coordinator of the State Board of Equalization, state that the rulemaking file of which the contents as listed in the index is complete, and that the record was closed on May 11, 2015 and that the attached copy is complete.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

May 11, 2015

A handwritten signature in black ink, appearing to read "Richard E. Bennion", written over a horizontal line.

Richard E. Bennion  
Regulations Coordinator  
State Board of Equalization

**Final Statement of Reasons for the Adoption of the  
Proposed Amendments to California Code of Regulations,  
Title 18, Section 1591, *Medicines and Medical Devices***

Update of Information in the Initial Statement of Reasons

The State Board of Equalization (Board) held a public hearing regarding the proposed amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, on April 28, 2015. During the public hearing, the Board unanimously voted to adopt the proposed amendments to Regulation 1591 without making any changes. The Board did not receive any written comments regarding the proposed regulatory action and no interested parties appeared at the public hearing on April 28, 2015, to comment on the proposed regulatory action.

The factual basis, specific purpose, and necessity for, the problem to be addressed by, and the anticipated benefits from the adoption of the proposed amendments to Regulation 1591 are the same as provided in the initial statement of reasons. The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by Revenue and Taxation Code section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The adoption of the proposed amendments to Regulation 1591 is not mandated by federal law or regulations. There is no previously adopted or amended federal regulation that is identical to Regulation 1591 or the proposed amendments to Regulation 1591.

The Board did not rely on any data or any technical, theoretical, or empirical study, report, or similar document in proposing or adopting the proposed amendments to Regulation 1591 that was not identified in the initial statement of reasons, or which was otherwise not identified or made available for public review prior to the close of the public comment period.

In addition, the factual basis has not changed for the Board's initial determination that the proposed regulatory action will not have a significant adverse economic impact on business, the Board's determination that the proposed regulatory action is not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000, and the Board's economic impact assessment, which determined that the Board's proposed regulatory action:

- 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; and

- Will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

The proposed amendments to Regulation 1591 may affect small business.

#### No Mandate on Local Agencies or School Districts

The Board has determined that the adoption of the proposed amendments to Regulation 1591 does not impose a mandate on local agencies or school districts.

#### No Public Comments

The Board did not receive any written comments regarding the proposed regulatory action and no interested parties appeared at the public hearing on April 28, 2015, to comment on the proposed regulatory action.

#### Determinations Regarding Alternatives

By its motion on April 28, 2015, the Board determined that no alternative to the proposed amendments to Regulation 1591 would be more effective in carrying out the purpose for which the amendments are proposed, would be as effective and less burdensome to affected private persons than the adopted amendments, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provisions of law.

The Board did not reject any reasonable alternatives to the proposed amendments to Regulation 1591 that would lessen any adverse impact the proposed amendments may have on small business.

No reasonable alternatives have been identified and brought to the Board's attention that would lessen any adverse impact the proposed action may have on small business, be more effective in carrying out the purposes for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

**Updated Informative Digest for the  
State Board of Equalization's Adoption of Proposed Amendments to  
California Code of Regulations, Title 18, Section 1591,  
*Medicines and Medical Devices***

The State Board of Equalization (Board) held a public hearing regarding the proposed amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, on April 28, 2015. During the public hearing, the Board unanimously voted to adopt the proposed amendments to Regulation 1591 without making any changes.

The Board did not receive any written comments regarding the proposed regulatory action and no interested parties appeared at the public hearing on April 28, 2015, to comment on the proposed regulatory action. There have not been any changes to the applicable laws or the effect of, the objective of, and anticipated benefits from the adoption of the proposed amendments to Regulation 1591 described in the informative digest included in the notice of proposed regulatory action. The informative digest included in the notice of proposed regulatory action provides:

Summary of Existing Laws and Regulations

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (RTC, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (RTC, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (RTC, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (RTC, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 6202.)

RTC section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the

definition of medicines, including “(2) [a]rticles 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 or the component parts and accessories thereof.” Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term “medicines” means and includes “[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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.”

Regulation 1591 implements, interprets, and makes specific RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. Regulation 1591, subdivision (a)(9), currently defines “medicines” as follows:

“Medicines” means:

- (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 or the component parts and accessories thereof. . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses, and in some cases, subdivision (b) also identifies specific items that are included in or

excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant’s interdependent internal and external components. 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.

Also, as relevant here, the Board’s Legal Department has previously determined, as early as 1965, that diagnostic “opaques and dyes” are medicines as defined in RTC section 6369. (See Sales and Use Tax Annotation 425.0580 (9/1/65)). Furthermore, the FDA’s website explains that:

- “The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.”
- “Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order ‘clears’ the device for commercial distribution.”

Effect, Objective, and Benefit of the Proposed Amendments to Regulation 1591

During the Board’s February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

#### *Interested Parties Process*

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues discussed above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369 and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph]

would be subject to tax, if intended for temporary placement.” Mr. Bholat also included an attachment with his proposed changes.

*November 19, 2014, BTC Meeting*

In response to the interested parties’ concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term “medicines” is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties’ recommendations to amend subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat’s language would have actually narrowed the definition by removing the phrase “for all uses,” which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat’s comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat’s recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties’ proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board’s November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff’s recommended amendments to Regulation 1591; the interested parties primarily wanted more specific clarification

regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2). The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issues with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The Board has performed an evaluation of whether the proposed amendments to Regulation 1591 are inconsistent or incompatible with existing state regulations and determined that the proposed amendments are not inconsistent or incompatible with existing state regulations. This is because there are no other sales and use tax regulations that specifically prescribe the application of the sales and use tax exemption provided by RTC section 6369 to medicines and medical devices. In addition, the Board has determined that there are no comparable federal regulations or statutes to Regulation 1591 or the proposed amendments to Regulation 1591.



**BOARD OF EQUALIZATION**  
**BUSINESS TAXES COMMITTEE MEETING MINUTES**  
HONORABLE MICHELLE STEEL, COMMITTEE CHAIR  
450 N STREET, SACRAMENTO  
MEETING DATE: NOVEMBER 19, 2014, TIME: 10:00 A.M.

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**ACTION ITEMS & STATUS REPORT ITEMS**

**Agenda Item No: 1**

**Title: Proposed Amendments to Regulation 1574, *Vending Machine Operators***

**Issue:**

Whether the Board should amend Sales and Use Tax Regulation 1574, *Vending Machine Operators*, to update the tax rates in the example, table, and formula, and provide uniformity in rounding in the computation of the cold food factor percentage.

**Committee Discussion:**

This item was removed from the agenda.

**Committee Action:**

No action taken.

**Agenda Item No: 2**

**Title: Proposed Amendments to Regulations 1533.2, *Diesel Fuel Used in Farming Activities or Food Processing*, and 1598.1, *Diesel Fuel Prepayment Exemption*.**

**Issue:**

Whether the Board should amend Regulations 1533.2, *Diesel Fuel Used in Farming Activities or Food Processing*, and 1598.1, *Diesel Fuel Prepayment Exemption*.

**Committee Discussion:**

There was no discussion of this item.

**Committee Action:**

Upon motion by Ms. Yee and seconded by Mr. Runner, without objection, the Committee approved and authorized for publication the proposed amendments to Regulations 1533.2, *Diesel Fuel Used in Farming Activities or Food Processing*, and 1598.1, *Diesel Fuel Prepayment Exemption*. Copies of the proposed amendments to Regulations 1533.2 and 1598.1 are attached.

**Agenda Item No: 3****Title: Proposed Amendments to Regulation 1685.5, *Calculation of Estimated Use Tax – Use Tax Table*****Issue:**

Whether the Board should amend Sales and Use Tax Regulation 1685.5, *Calculation of Estimated Use Tax – Use Tax Table*, to update the definition of the average state, local, and district sales and use tax rate by removing the specific reference to “Section 35” of article XIII of the California Constitution.

**Committee Discussion:**

There was no discussion of this item.

**Committee Action/Recommendation/Direction:**

Upon motion by Mr. Horton, seconded by Ms. Yee, without objection, the Committee approved and authorized for publication the proposed amendments to Regulation 1685.5, *Calculation of Estimated Use Tax – Use Tax Table*. A copy of the proposed amendments to Regulation 1685.5 is attached.

**Agenda Item No: 4****Title: Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*****Issue:**

Whether the Board should amend Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*, to clarify that the definition of “medicines” includes devices implanted to mark the location of a medical condition.

**Committee Discussion:**

Staff introduced the amendments to Regulation 1591 explaining the four action items included one area of agreement and three areas where alternative language was suggested by interested parties. Mr. Wade Downey of Downey, Smith & Fier thanked staff for the language regarding the breast tissue markers and clarification of FDA approval. He stated his goal throughout this process was to clarify subdivisions (a)(9)(A) and (c)(2) as they relate to fully implanted items. Mr. Roderick Calub of Downey, Smith & Fier requested the Board adopt language to include in the definition of medicines fully implanted devices that are FDA approved but do not assist the functioning of the human body. Mr. Jacob Bholat of Equity Recovery Solutions, Inc., also thanked staff for addressing the complex and difficult process of dealing with medicines. However, citing four examples where the Board has allowed a broader interpretation of the definition, he believes staff has continued to apply a narrow interpretation.

Staff continued the discussion by stating that the existing language in subdivision (c)(2) is taken directly from statute.

Questions involving port-a-caths were brought up by Board Members. Staff clarified that their recommendation to remove a sentence in subdivision (b)(2) was done so that articles listed in the subdivision may qualify as a medicine under a different section. Staff also explained the use of port-a-caths in the revenue estimate was appropriate as the language proposed for both

alternatives to staff's recommendation would allow the port-a-caths to be exempt under subdivision (a)(9)(A).

Ms. Yee stated that the intent of the regulation was to define medicines and not to provide an exhaustive list of devices. She added that staff's recommendations helped provide a good road map to clarify what constitutes a medicine. Mr. Runner expressed his concern that we may be missing the opportunity to create greater clarification and staff's recommended amendments may not reduce future appeals cases. Mr. Horton stated the statute was clear and suggested the audit staff could be provided additional guidance in the audit manual.

A consensus was reached amongst Board Members, staff, and the interested parties in attendance regarding staff's recommendations for action items 1 through 3. It was further discussed that no action should be taken on item 4. It was also suggested that the audit manual could be updated to provide guidance to staff on the application of Regulation 1591 and the interrelationship of subdivisions (a), (b), and (c) defining medicines.

**Committee Action/Direction:**

Upon motion by Ms. Yee, seconded by Mr. Runner, without objection, the Committee approved and authorized publication of staff's recommended amendments with respect to Action Items 1, 2 and 3. The committee further directed staff to provide guidance in the audit manual on the application of Regulation 1591 and the interrelationship of subdivisions (a), (b), and (c) defining medicines. No action was taken on Item 4.

A copy of the proposed amendments to Regulation 1591 is attached.



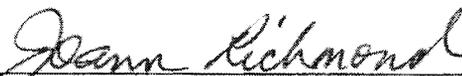
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Honorable Michelle Steel, Committee Chair



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Cynthia Bridges, Executive Director

BOARD APPROVED

at the 12/18/14 Board Meeting



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Joann Richmond, Chief  
Board Proceedings Division

**Sales and Use Tax Regulation 1533.2. *Diesel Fuel Used in Farming Activities or Food Processing.***

(a) General. Commencing on and after September 1, 2001, section 6357.1 of the Revenue and Taxation Code partially exempts from sales and use tax the sale of, and the storage, use, or other consumption in this state, of diesel fuel used in farming activities or food processing. The terms “farming activities” and “food processing” are defined below.

For the period commencing on September 1, 2001, and ending on December 31, 2001, the partial exemption applies to the taxes imposed by sections 6051 and 6201 of the Revenue and Taxation Code (4.75%), but does not apply to the taxes imposed pursuant to sections 6051.2 and 6201.2 of the Revenue and Taxation Code, the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, or section 35 of article XIII of the California Constitution.

For the period commencing on January 1, 2002, and ending on June 30, 2004, the partial exemption applies to the taxes imposed by sections 6051, 6051.3, 6201, and 6201.3 of the Revenue and Taxation Code (5%), but does not apply to the taxes imposed pursuant to sections 6051.2 and 6201.2 of the Revenue and Taxation Code, the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, or section 35 of article XIII of the California Constitution.

For the period commencing on July 1, 2004, and ending on March 31, 2009, the partial exemption applies to the taxes imposed by sections 6051, 6051.3, 6051.5, 6201, 6201.3, and 6201.5 of the Revenue and Taxation Code (5.25%), but does not apply to the taxes imposed or administered pursuant to sections 6051.2 and 6201.2 of the Revenue and Taxation Code, the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, or section 35 of article XIII of the California Constitution.

For the period commencing on April 1, 2009, and ending on June 30, 2011, the partial exemption applies to the taxes imposed by sections 6051, 6051.3, 6051.5, 6051.7, 6201, 6201.3, 6201.5, and 6201.7 of the Revenue and Taxation Code (6.25%), but does not apply to the taxes imposed or administered pursuant to sections 6051.2 and 6201.2 of the Revenue and Taxation Code, the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, or section 35 of article XIII of the California Constitution.

For the period commencing on July 1, 2011, and ending on December 31, 2012, the partial exemption applies to the taxes imposed by sections 6051, 6051.3, 6051.5, 6051.8, 6201, 6201.3, 6201.5, and 6201.8 of the Revenue and Taxation Code, but does not apply to the taxes imposed or administered pursuant to sections 6051.2 and 6201.2 of the Revenue and Taxation Code, the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, or section 35 of article XIII of the California Constitution.

For the period commencing on January 1, 2013, the partial exemption applies to the taxes imposed by section 36 of article XIII of the California Constitution and sections 6051, 6051.3, 6051.5, 6051.8, 6201, 6201.3, 6201.5, and 6201.8 of the Revenue and Taxation Code, but does not apply to the taxes imposed or administered pursuant to sections 6051.2 and 6201.2 of the Revenue and Taxation Code, the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, or section 35 of article XIII of the California Constitution.

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Given the varying rates of the taxes imposed by sections 6051.8 and 6201.8, the partial exemption applies to the following cumulative sales and use tax rates:

- (1) 7.12 percent for the period July 1, 2011, through June 30, 2012;
- (2) 7.42 percent for the period July 1, 2012, through December 31, 2012;
- (3) 7.67 percent for the period January 1, 2013 through June 30, 2013;
- (4) 7.44 percent for the period July 1, 2013, through June 30, 2014; and
- (5) 7.25 percent on or after July 1, 2014.

(b) Definitions. For purposes of this regulation:

(1) "Farming activities" mean a trade or business involving the cultivation of land or the raising or harvesting of any agricultural or horticultural commodity that may be legally sold to or offered for sale to others. These include the trade or business of operating a nursery or sod farm; the raising or harvesting of trees bearing fruit or nuts, or of other crops (e.g., grains, vegetables, or cotton); the raising of ornamental trees (other than evergreen trees that are more than six years old at the time they are severed from their roots); and the raising, shearing, feeding, caring for, training, and management of animals. The raising of animals includes the delivery of feed to the animal feeding operation, whether by the owner or the supplier of the feed. Operating a garden plot, orchard, or farm for the purpose of growing plants or animals for a person's own use shall not be considered a farming activity. Harvesting involves the gathering of any agricultural or horticultural commodity and includes activities such as crop drying, cotton ginning, and fruit ripening. Harvesting an agricultural commodity also includes the washing of the agricultural commodity, the inspection and grading of the agricultural commodity or livestock, and the packaging of the agricultural commodity for shipment as well as those activities delineated in Codes 0723 and 0724 of the Standard Industrial Classification Manual published by the United States Office of Management and Budget, 1987 edition (hereafter SIC Manual). For purposes of this regulation, merely buying and reselling plants or animals grown or raised entirely by another is not raising an agricultural or horticultural commodity. A person is engaged in raising a plant or animal, rather than the mere selling of a plant or animal, if the plant or animal is held for further cultivation and development prior to sale. In determining whether a plant or animal is held for further cultivation and development prior to sale, consideration will be given to all of the facts and circumstances, including: the value added by a person to the plant or animal through agricultural or horticultural processes; the length of time between the person's acquisition of the plant or animal and the time that the person makes the plant or animal available for sale; and in the case of a plant, whether the plant is kept in the container in which purchased, replanted in the ground, or replanted in a series of larger containers as it is grown to a larger size.

Farming activities also include the transportation and delivery of the agricultural or horticultural commodity, as described herein, from the trade or business that cultivated, raised or harvested the commodity to the marketplace, as described in subdivision (b)(5), and any empty haul related to the transportation of that agricultural or horticultural commodity.

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Farming activities do not include food processing or transportation and delivery of processed food products to the marketplace.

Example A: A commercial hauler travels from its company yard to Grower A's field to pick up a load of tomatoes. The tomatoes are hauled to a processing plant. The hauler returns to the field with empty trailers. The sale of diesel fuel to the commercial hauler for use in this activity is partially exempt from tax.

Example B: A commercial hauler travels from its company yard to Grower A's field to pick up a load of fresh bell peppers. The bell peppers are sold to a grocery store and are delivered to the grocery store's distribution center. At the distribution center, the hauler picks up a load of pallets to deliver to another customer. The sale of diesel fuel to the commercial hauler for use from the yard to the field and from the field to the grocery store's distribution center is partially exempt from tax. The sale of diesel fuel to the commercial hauler for use in delivering the pallets is not partially exempt from tax.

Example C: A nursery owner transports its horticultural products to a distribution center. After delivering the product, the nursery owner makes two stops. The first stop is to pick up fertilizer for use at the nursery. The second stop is personal business unrelated to the nursery operation. The sale of diesel fuel to the nursery owner for use in this example is partially exempt from tax up to and including the first stop.

(2) "Plants" mean an agricultural or horticultural commodity produced in a farming activity which includes, but is not limited to, trees bearing fruit or nuts, other crops, an ornamental tree, a vine, a bush, or sod. Sea plants are produced in a farming activity if they are tended and cultivated as opposed to merely harvested.

(3) "Animals" mean a life form produced in a farming activity which includes, but is not limited to, any livestock, poultry or other bird, and fish or other sea life. Fish and other sea life are produced in a farming activity if they are raised on a fish farm. A fish farm is an area where fish or other sea life are grown or raised as opposed to merely caught or harvested.

(4) "Food processing" means the activities described in Industry Groups 201, 202, 203, 204, and 207, or Codes 2068 and 2084 of the SIC Manual. Food processing activities also includes transporting raw product, supplies and materials to the processing facility, transporting partially processed food products between various divisions of the same food processing entity for further processing operations, and any empty hauls related to the transportation of that product. Food processing does not include transportation and delivery of processed food products to the marketplace. A food processor is not required to be engaged 50 percent or more of the time in such activities as described herein.

Example A: A for-hire carrier, contracted for by a cheese plant, transports unprocessed milk from a dairy farm to the cheese plant for processing and then returns to the carrier's truck yard. The diesel used in this example is eligible for the partial sales tax exemption.

Example B: A flour mill transports flour sacks from a bag manufacturer to the mill's facility, and then transports those sacks to other flour mills owned by the same entity. The diesel used to transport the sacks in this example is eligible for the partial sales tax exemption, but the transportation of flour is not.

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Example C: Cannery A and Cannery B are different divisions of the same food processing entity. Cannery A processes unprocessed tomatoes into tomato paste and then transports the paste to Cannery B for further processing. Cannery B processes the paste into tomato soup which is then transported to a grocery distribution warehouse. From the distribution warehouse the processed product is transported by the buyer to individual grocery stores and other distribution warehouses. Only the movement of paste from Cannery A to Cannery B is eligible for the partial sales tax exemption. The subsequent movement of product to the first distribution center and to retail stores and other warehouses is not eligible for the exemption.

(5) "Marketplace" means the place where a commodity is sold for resale, at retail or for consumption at an animal feeding operation, notwithstanding any intervening activities to prepare the product for sale in the marketplace. Such preparation activities include, but are not limited to, cooling, sorting, inspection, grading, drying, packing, handling, washing, slaughtering and butchering (except as otherwise described in Codes 2011 and 2015 of the SIC Manual), candling, sterilizing, freezing, pasteurizing, homogenizing, and packaging. Producers of agricultural or horticultural products may prepare and market their products through a cooperative, joint venture, corporation or partnership in which they have a financial interest, or other such enterprises, and the diesel used in these enterprises to transport products to the marketplace is eligible for the sales tax exemption.

(6) "Diesel fuel" means, for purposes of this regulation only, any liquid fuel that is commonly or commercially known, or sold or represented as a diesel fuel that is suitable for use in a diesel-powered highway vehicle. A liquid meets this requirement if, without further processing or blending, the liquid has practical and commercial fitness for use in the engine of a diesel-powered highway vehicle.

However, a liquid does not possess this practical and commercial fitness solely by reason of its possible or rare use as a fuel in the engine of a diesel-powered vehicle.

~~No. 1-D or No. 2-D, pursuant to the specifications in American Society for Testing and Materials Standard Specification for Diesel Fuel Oils ("ASTM") D 975-81, which is incorporated herein by reference. Diesel fuel, for purposes of this regulation only, also includes Environmental Protection Agency-rated diesel fuel commonly known as "federal fuel" sold for use in locomotives, or which is used in generators, pumps, dehydrators and any other equipment used in the conduct of farming and food processing activities.~~

~~"Diesel fuel" does not include gasoline, kerosene, liquefied petroleum gas, natural gas in liquid or gaseous form, or alcohol, aviation fuel, except diesel fuel sold for use in aircraft designed for agricultural aerial applications that meets the specifications of ASTM D 1655, jet fuel, bunker fuel, or other like substance used as a fuel. Qualifying diesel fuel shall be identified accordingly on the invoice of sale.~~

(7) "Qualified activity" means farming activities as defined in subdivision (b)(1) or food processing, as defined in subdivision (b)(4).

(c) Partial Exemption Certificates.

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(1) In General. A person who purchases diesel fuel for use in a qualified activity from an in-state retailer, or an out-of state retailer obligated to collect use tax, must provide the retailer with a partial exemption certificate in order for the retailer to claim the partial exemption. If the retailer takes a partial exemption certificate timely and in good faith, as defined in subdivision (c)(5), from a person who purchases diesel fuel for use in a qualified activity, the partial exemption certificate relieves the retailer from the liability for the sales tax subject to partial exemption under this regulation or the duty of collecting the use tax subject to partial exemption under this regulation. A partial exemption certificate will be considered timely if it is taken any time before the retailer bills the purchaser for the diesel fuel, any time within the retailer's normal billing or payment cycle, any time at or prior to delivery of the diesel fuel to the purchaser, or no later than 15 days after the date of purchase. A partial exemption certificate which is not taken timely will not relieve the retailer of the liability for tax excluded by the partial exemption; however the retailer may present satisfactory evidence to the Board that the retailer sold the diesel fuel to a person that used it in a qualified activity. A partial exemption from the sales and use tax under this part shall not be allowed unless the retailer claims the partial exemption on its sales and use tax return for the reporting period during which the transaction subject to the partial exemption occurred. Where the retailer fails to claim the partial exemption as set forth above, the retailer may file a claim for refund as set forth in subdivision (e).

The partial exemption certificate form set forth in Appendix A may be used to claim the partial exemption.

(2) Blanket Partial Exemption Certificates. In lieu of requiring a partial exemption certificate for each transaction, a person who purchases diesel fuel for use in a qualified activity may issue a blanket partial exemption certificate. The partial exemption certificate form set forth in Appendix A may be used as a blanket partial exemption certificate. Appendix A may also be used as a specific partial exemption certificate if the purchaser provides the purchase order or sales invoice number and a precise description of the property being purchased. A person who purchases diesel fuel for use in a qualified activity must include in the partial exemption certificate how much or what percentage of the diesel fuel purchased will be used in a qualified activity. If purchasing diesel fuel not qualifying for the partial exemption, the purchaser must clearly state in documents such as a written purchase order, sales agreement, or contract that the sale or purchase is not subject to the blanket partial exemption certificate.

(3) Form of Partial Exemption Certificate. Any document, such as a letter or purchase order, timely provided by the purchaser to the seller will be regarded as a partial exemption certificate with respect to the sale or purchase of diesel fuel if it contains all of the following essential elements:

(A) The signature of the purchaser, purchaser's employee, or authorized representative of the purchaser.

(B) The name, address and telephone number of the purchaser.

(C) The number of the seller's permit held by the purchaser. If the purchaser is not required to hold a permit because the purchaser sells only property of a kind the retail

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sale of which is not taxable, e.g., food products for human consumption, or because the purchaser makes no sales in this state, the purchaser must include on the certificate a sufficient explanation as to the reason the purchaser is not required to hold a California seller's permit in lieu of a seller's permit number.

(D) A statement of how much or what percentage of the diesel fuel purchased will be used in a qualified farming or food processing activity.

(E) Date of execution of document.

(4) **Retention and Availability of Partial Exemption Certificates.** A retailer must retain each partial exemption certificate received from a person who purchases diesel fuel for use in a qualified activity for a period of not less than four years from the date on which the retailer claims a partial exemption based on the partial exemption certificate.

While the Board will not normally require the filing of the partial exemption certificate with a sales and use tax return, when necessary for the efficient administration of the Sales and Use Tax Law, the Board may, on 30 days' written notice, require a retailer to commence filing with its sales and use tax returns copies of all partial exemption certificates. The Board may also require, within 45 days of the Board's request, retailers provide the Board access to any and all partial exemption certificates, or copies thereof, accepted for the purposes of supporting the partial exemption.

(5) **Good Faith.** A seller will be presumed to have taken a partial exemption certificate in good faith in the absence of evidence to the contrary. A seller, without knowledge to the contrary, may accept a partial exemption certificate in good faith where the purchaser states that a certain percentage of the diesel fuel purchased will be used in farming activities or food processing. However, a partial exemption certificate cannot be accepted in good faith where the seller has knowledge that the diesel fuel is not subject to a partial exemption, or will not be otherwise used in a partially exempt manner.

(d) **Partial Exemption Certificate for Use Tax.** The partial exemption certificate must be completed by a person who purchases diesel fuel for use in a qualified activity to claim a partial exemption from use tax from an out-of-state retailer not obligated to collect the use tax. A partial exemption from the use tax shall not be allowed unless the purchaser or retailer claims the partial exemption on its individual use tax return, sales and use tax return, or consumer use tax return for the reporting period during which the transaction subject to the partial exemption occurred. Where the purchaser or retailer fails to claim the partial exemption as set forth above, the purchaser or retailer may file a claim for refund as set forth in subdivision (e).

The purchaser who files an individual use tax return must attach a completed partial exemption certificate to the return. The purchaser who is registered with the Board as a retailer or consumer and files a sales and use tax return or consumer use tax return must, within 45 days of the Board's request, provide the Board access to any and all documents that support the claimed partial exemption.

The partial exemption certificate form set forth in Appendix A may be used to claim the partial exemption.

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(e) Refund of Partial Exemption.

(1) For the period commencing on September 1, 2001, and ending on April 30, 2002, a person who purchases diesel fuel for use in a qualified activity may claim the partial exemption on qualified purchases from an in-state retailer or an out-of-state retailer obligated to collect the use tax by furnishing the retailer with a partial exemption certificate on or before July 31, 2002. The retailer must refund the tax or tax reimbursement directly to a purchaser of diesel fuel for use in a qualified activity or, at the purchaser's sole option, the purchaser may be credited with such amount.

(2) A retailer who paid sales tax on a qualified sale or a person who paid use tax on a qualified purchase and who failed to claim the partial exemption as provided by this regulation may file a claim for refund equal to the amount of the partial exemption that he or she could have claimed pursuant to this regulation. The procedure for filing a claim shall be the same as for other claims for refund filed pursuant to Revenue and Taxation Code section 6901. For transactions subject to use tax, a person who purchases diesel fuel for use in a qualified activity filing a claim for refund of the partial exemption has the burden of establishing that he or she was entitled to claim the partial exemption with respect to the amount of refund claimed under this part. For transactions subject to sales tax, a person filing a claim for refund of the partial exemption has the burden of establishing that the purchaser of the diesel fuel otherwise met all the requirements of a person who purchases diesel fuel for use in a qualified activity at the time of the purchase subject to the refund claimed under this part.

(f) Improper Use of Partial Exemption. Notwithstanding subdivision (a), tax applies to any sale of, and the storage, use, or other consumption in this state of diesel fuel that is used in a manner not qualifying for the partial exemption under this regulation.

(g) Purchaser's Liability for the Payment of Sales Tax.

(1) If a purchaser timely submits a copy of a partial exemption certificate to the retailer or partial exemption certificate for use tax to the Board, and then uses the diesel fuel in a manner not qualifying for the partial exemption, the purchaser shall be liable for payment of the sales tax, with applicable interest, to the same extent as if the purchaser were a retailer making a retail sale of the diesel fuel at the time the diesel fuel was so removed, converted, or used.

(2) A purchaser providing a partial exemption certificate accepted in good faith by the retailer or a partial exemption certificate for use tax to the Board for diesel fuel that does not qualify for the partial exemption is liable for payment of the sales tax, with applicable interest, to the same extent as if the purchaser were a retailer making a retail sale of the diesel fuel at the time the diesel fuel was purchased.

(h) Records. Adequate and complete records must be maintained by the person who purchases diesel fuel for use in a qualified activity as evidence that the diesel fuel purchased was used in a qualified activity.

(i) Operative Date. This regulation is operative as of September 1, 2001.

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**Appendix A**

PARTIAL EXEMPTION CERTIFICATE

STATE BOARD OF EQUALIZATION

**Qualified Sales and Purchases of Diesel and Farm Equipment and Machinery**

NOTE: This is an exemption only from the state general fund portion of the sales and use tax rate. You are not relieved from your obligations for the local and district taxes on this transaction. This partial exemption also does not apply to any tax levied pursuant to Section 6051.2 and 6201.2 of the Revenue and Taxation Code, or pursuant to Section 35 of article XIII of the California Constitution. This partial exemption also applies to lease payments made on or after September 1, 2001, for tangible personal property even if the lease agreement was entered into prior to September 1, 2001.

SELLER'S/LESSOR'S NAME
SELLER'S/LESSOR'S ADDRESS (Street, City, State, Zip Code)

**Diesel Fuel Used in Farming Activities or Food Processing\*** - I as the undersigned purchaser, hereby certify that of the diesel purchased, \_\_\_\_\_ % will be used in qualified farming activities or food processing in accordance with Revenue and Taxation Code Section 6357.1.

**Farm Equipment and Machinery (or parts<sup>1</sup> thereof)\*** - I as the undersigned purchaser, hereby certify I am engaged in an agricultural business described in Codes 0111 to 0291 of the Standard Industrial Classification (SIC) Manual, or I perform an agricultural service described in Codes 0711 to 0783 of the SIC Manual for such classified persons. The property purchased or leased will be used primarily in producing and harvesting agricultural products in accordance with Revenue & Taxation Code Section 6356.5.<sup>2</sup>

Type of Farm Equipment and Machinery (or parts thereof) \_\_\_\_\_

\*If you also want this certificate to be used as a blanket certificate for future purchases, describe generally the type of property you will be purchasing and ask your vendor to keep this certificate on file. If this is a specific partial exemption certificate, provide the purchase order or sales invoice number and a precise description of the property being purchased.

I understand that if such property is not used in the manner qualifying for the partial exemption, or if I am not a qualified person, as applicable, that I am required by the Sales and Use Tax Law to report and pay the state tax measured by the sales price/rentals payable of the property to/by me. I also understand that this partial exemption certificate is in effect as of the date shown below and will remain in effect until revoked in writing.

PURCHASER'S NAME OR COMPANY NAME (if applicable)		DATE
SIGNATURE (signature of the purchaser, purchaser's employee, or authorized representative of the purchaser)		TELEPHONE NUMBER
TITLE		PERMIT NUMBER (if applicable) <sup>3</sup>
ADDRESS	CITY	STATE, ZIP

<sup>1</sup> If you are purchasing oil, grease, or lubricating or other qualifying fluids, indicate what percentage will be used in farm equipment and machinery performing qualified producing and harvesting activities.  
<sup>2</sup> Vehicles that qualify as farm equipment and machinery, as defined in Regulation 1533.1(b)(1)(B), must be used exclusively in producing and harvesting agricultural products.  
<sup>3</sup> If you are not required to hold a seller's permit, please enter "Not Applicable."

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**Sales and Use Tax Regulation 1598.1. Diesel Fuel Prepayment Exemption.**

## (a) Definitions.

- (1) "Bulk deliveries" mean transfers of diesel fuel into storage tanks holding 500 gallons or more.
- (2) "Cardlock, keylock, or other unattended mechanism" means an unattended, completely automated fueling station at which a purchaser obtains diesel fuel through use of a coded card or key and an access code. Charges for sales of diesel fuel to customers are usually consolidated at a central location and periodically invoiced to the purchaser.
- (3) A "diesel fuel consumer" or "diesel fuel consumers" mean a person or persons that use diesel fuel in a manner that qualifies for the partial sales and use tax exemption set forth in Revenue and Taxation Code section 6357.1 and Regulation 1533.2, Diesel Fuel Used in Farming Activities or Food Processing.
- (4) "Diesel fuel," for purposes of the imposition of the prepayment of sales tax, is defined in Revenue and Taxation Code section 6480(c) (by reference to Revenue and Taxation Code section 60022) and means any liquid that is commonly or commercially known or sold as a fuel that is suitable for use in a diesel-powered highway vehicle. A liquid meets this requirement if, without further processing or blending, the liquid has practical and commercial fitness for use in the engine of a diesel-powered highway vehicle. However, a liquid does not possess this practical and commercial fitness solely by reason of its possible or rare use as a fuel in the engine of a diesel-powered highway vehicle.

Diesel fuel does not include gasoline, kerosene, liquefied petroleum gas, natural gas in liquid or gaseous form, or alcohol.

~~Diesel fuel does not include the water in a diesel fuel and water emulsion of two immiscible liquids of diesel fuel and water, which emulsion contains an additive that causes the water droplets to remain suspended within the diesel fuel, provided the diesel fuel emulsion meets standards set by the California Air Resources Board.~~

- (5) "Qualified retailer" means a person who meets the requirements of subdivisions (b)(1) through (b)(5).
- (6) "Seller" means either the supplier or the wholesaler, as those terms are defined in Revenue and Taxation Code section 6480(c), that sells diesel fuel to a qualified retailer.
- (7) "Total taxable sales" means the gross receipts from the sale of tangible personal property subject to tax, including sales of diesel fuel.

(b) Application of Tax. Commencing on and after October 9, 2002, a seller of diesel fuel is not required to collect the prepayment of sales tax on that percentage of diesel fuel specified in the retailer's diesel fuel prepayment exemption certificate that is otherwise required by Revenue and Taxation Code section 6480.1, provided the diesel fuel is sold to a retailer who:

- (1) Will resell the diesel fuel in the ordinary course of business,

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- (2) Issues a diesel fuel prepayment exemption certificate to the seller as set forth in subdivision (c),
- (3) Sells diesel fuel to a diesel fuel consumer.
- (4) During the calendar year immediately preceding any purchases of diesel fuel, sold diesel fuel to diesel fuel consumers in which the gross receipts from such sales exceeded 25 percent of that retailer's total taxable sales, and
- (5) Sold more than 50% of its diesel fuel through bulk deliveries or through a cardlock, keylock, or other unattended mechanism, or both.

For purposes of calculating the percentage set forth in subdivision (b)(4) above, the numerator shall be the sum total of amounts ~~entered on Form BOE 401GS line 10(e)(4) (Amount \$subject to the partial state tax exemption for Diesel fuel used in farming and food processing exemption)~~ for each return filed during the preceding calendar year and the denominator shall be the sum total of amounts ~~entered on line 14(a) (Transactions \$subject to County Tax)~~ for each return filed during the preceding calendar year.

(c) Prepayment Exemption Certificate.

(1) In General. A seller of diesel fuel who takes a diesel fuel prepayment exemption certificate timely and in good faith, as defined in subdivision (c)(5), from a qualified retailer, is relieved from the liability for the sales tax prepayment subject to the exemption under this regulation, or the duty of collecting the sales tax prepayment subject to exemption under this regulation. A diesel fuel prepayment exemption certificate will be considered timely if it is taken any time before the seller bills the qualified retailer for the diesel fuel, any time within the seller's normal billing or payment cycle, or any time at or prior to delivery of the diesel fuel to the qualified retailer. A diesel fuel prepayment exemption certificate which is not taken timely will not relieve the seller of the liability for the sales tax prepayment excluded by the exemption; however, the seller may present satisfactory evidence to the Board that the seller sold the diesel fuel to a qualified retailer. A diesel fuel prepayment exemption under this part shall not be allowed unless the seller claims the exemption on its sales and use tax return for the reporting period during which the transaction subject to the diesel fuel prepayment exemption occurred. The diesel fuel prepayment exemption certificate form set forth in the Appendix may be used to claim the diesel fuel prepayment exemption.

(2) Blanket Prepayment Exemption Certificate. In lieu of requiring a diesel fuel prepayment exemption certificate for each transaction, a qualified retailer may issue a blanket diesel fuel prepayment exemption certificate. The diesel fuel prepayment exemption certificate form set forth in the Appendix may be used as a blanket diesel fuel prepayment exemption certificate. The diesel fuel prepayment exemption certificate in the Appendix may also be used as a specific diesel fuel prepayment exemption certificate if the qualified retailer provides the purchase order or sales invoice number and a precise description of the property being purchased. A blanket diesel fuel prepayment exemption certificate is only valid during the calendar year in which it is provided to the seller.

(3) Form of Prepayment Exemption Certificate. Any document, such as a letter or purchase order, timely provided by the qualified retailer to the seller will be regarded as a diesel fuel prepayment

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exemption certificate with respect to the sale of diesel fuel if it contains all of the following essential elements:

- (A) The signature of the qualified retailer, qualified retailer's employee, or authorized representative of the qualified retailer.
- (B) The name, address and telephone number of the qualified retailer.
- (C) The number of the seller's permit held by the qualified retailer.
- (D) A statement setting forth the requirements of subdivisions (b)(1) through (b)(5).
- (E) A statement of what percentage of total diesel fuel purchases will be resold to diesel fuel consumers.
- (F) Date of execution of document.

(4) Retention and Availability of Prepayment Exemption Certificates. A seller must retain each diesel fuel prepayment exemption certificate received from a qualified retailer who purchases diesel fuel for resale to diesel fuel consumers for a period of not less than four years from the date on which the qualified retailer claims an exemption for sales tax prepayment based on the diesel fuel prepayment exemption certificate. The Board may require, within 45 days of the Board's request, sellers to provide the Board access to any and all diesel fuel prepayment exemption certificates, or copies thereof, accepted for the purposes of supporting the diesel fuel prepayment exemption.

(5) Good Faith. A seller will be presumed to have taken a diesel fuel prepayment exemption certificate in good faith in the absence of evidence to the contrary. However, a diesel fuel prepayment exemption certificate cannot be accepted in good faith where the seller has knowledge that the diesel fuel will not be sold to a retailer who meets the requirements of subdivisions (b)(1) through (b)(5), will not otherwise be used by diesel fuel consumers, or that the percentage listed on the exemption certificate for sales tax prepayment is inaccurate. A blanket diesel fuel prepayment exemption certificate utilized for sales occurring in a subsequent calendar year in which the blanket diesel fuel prepayment exemption certificate was initially provided to the seller is not accepted in good faith for sales occurring in that subsequent calendar year.

(d) Retailer's Liability for the Payment of Tax.

(1) A qualified retailer providing a diesel fuel prepayment exemption certificate pursuant to subdivision (c) is liable for the taxes imposed by the Bradley-Burns Uniform Local Sales and Use Tax Law, the Transactions and Use Tax Law, and the tax that is imposed under Revenue and Taxation Code section 6051.2 or 6201.2, or under section 35 of article XIII of the California Constitution on the sale of diesel fuel to diesel fuel consumers.

(2) A qualified retailer providing a diesel fuel prepayment exemption certificate pursuant to subdivision (c) is liable for sales tax on any portion of the gross receipts derived from the sale of diesel fuel that is not sold to diesel fuel consumers.

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(3) A qualified retailer that is liable for the tax under the provisions of subdivisions (d)(1) or (d)(2) shall report and pay that tax with the sales and use tax return filed for the reporting period during which the qualified retailer sells the diesel fuel.

(e) **Improper Use of Prepayment Exemption Certificate.** Any person who gives a diesel fuel prepayment exemption certificate pursuant to this regulation for the purpose of evading the prepayment of sales tax on sales of diesel fuel that he or she knows at the time of sale do not qualify for the diesel fuel prepayment exemption is guilty of a misdemeanor punishable as provided in Revenue and Taxation Code section 7153. In addition, such person shall be liable to the state for a penalty of one thousand dollars (\$1,000) for each diesel fuel prepayment exemption certificate issued for personal gain or to evade the prepayment of sales tax.

(f) **Records.** Adequate and complete records must be maintained by the seller and qualified retailer as evidence that the diesel fuel qualifies for the diesel fuel prepayment exemption.

(g) **Operative Date.** This regulation is operative as of October 9, 2002.

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**DIESEL FUEL PREPAYMENT EXEMPTION CERTIFICATE  
SECTION 6480.3**

**Please Note:** This is an exemption only from the prepayment of sales tax required by Revenue and Taxation Code (RTC) section 6480.1. This exemption applies only to the prepayment of the sales tax on sales of diesel fuel that you purchase for resale to persons qualifying for the partial exemption from sales and use tax on the sale or use of diesel fuel pursuant to RTC section 6357.1 and Regulation 1533.2, Diesel Fuel Used in Farming Activities or Food Processing. You are not relieved of your obligation to report and pay sales tax on the non-exempt portion of your partially exempt diesel fuel sales or on other retail sales.

.....  
DIESEL FUEL SELLER'S NAME

.....  
DIESEL FUEL SELLER'S ADDRESS (street, city, state, zip code)

I, the undersigned diesel fuel retailer, hereby certify that, of the diesel fuel purchased for resale from the above diesel fuel seller, I reasonably expect that \_\_\_\_\_ % will be sold to consumers engaged in farming activities or food processing who qualify for the diesel fuel partial exemption pursuant to RTC section 6357.1 and Regulation 1533.2, Diesel Fuel Used in Farming Activities or Food Processing. I further certify that:

1. During the calendar year immediately preceding my purchases of diesel fuel, I sold diesel fuel to consumers that qualified for the RTC section 6357.1 and Regulation 1533.2 partial sales and use tax exemption and that these sales were in excess of 25% of my total taxable sales; and,
2. More than 50% of my diesel fuel sales occur through deliveries into storage tanks of 500 gallons or more, or through a cardlock, keylock, or other unattended mechanism, or both.

By signing below, I acknowledge I am liable for the taxes imposed under the Bradley-Burns Uniform Local Sales and Use Tax Law or imposed by the Transactions and Use Tax Law, and for the taxes imposed under RTC section 6051.2 or 6201.2, or under section 35 of Article XIII of the California Constitution. I also acknowledge I am liable for all sales taxes on any portion of the gross receipts derived from the sale of diesel fuel not sold in a manner that qualifies for the partial exemption under RTC section 6357.1 and Regulation 1533.2, Diesel Fuel Used in Farming Activities or Food Processing. I further acknowledge that I am required to report and pay these taxes with the return for the reporting period in which I sell the diesel fuel.

I understand that any person who gives this diesel fuel prepayment exemption certificate for the purpose of evading the prepayment of sales tax on sales of diesel fuel that he or she knows at the time of purchase do not qualify for the diesel fuel prepayment exemption is guilty of a misdemeanor punishable as provided in RTC section 7153. I also understand that such person shall be liable to the state for a penalty of one thousand dollars (\$1,000) for each diesel fuel prepayment exemption certificate issued for personal gain or to evade the prepayment or payment of taxes.

**Important:** This diesel fuel prepayment exemption certificate constitutes a blanket diesel fuel prepayment exemption certificate for future purchases and is only valid during the calendar year in which it is provided to the diesel fuel seller unless the diesel fuel prepayment exemption certificate is otherwise specified as a specific diesel fuel prepayment exemption certificate. The diesel fuel seller shall require a retailer to provide a new blanket diesel fuel prepayment exemption certificate for any future purchases of diesel fuel in each subsequent calendar year. If this is a specific diesel fuel prepayment exemption certificate, provide the purchase order or sales invoice number in the following space:

RETAILER'S NAME OR COMPANY NAME	DATE
SIGNATURE (signature of the retailer, retailer's employee, or authorized representative of the retailer)	TELEPHONE NUMBER ( )
TITLE	PERMIT NUMBER
ADDRESS (STREET, CITY, STATE, ZIP CODE)	CUSTOMER ACCOUNT NUMBER

**Appendix**

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**REGULATION 1685.5 CALCULATION OF ESTIMATED USE TAX—USE TAX TABLE.**

**(a) IN GENERAL.**

(1) ESTIMATED USE TAX AND USE TAX TABLE. The Board of Equalization (BOE) is required to annually calculate the estimated amount of use tax due according to a person's adjusted gross income (AGI) and make such amounts available to the Franchise Tax Board (FTB), by July 30 of each year, in the form of a use tax table for inclusion in the instructions to the FTB's returns.

(2) WHO IS ELIGIBLE TO USE BOE USE TAX TABLES.

(A) Consumers may elect to use the use tax tables included in the instructions to their FTB returns to report their estimated use tax liabilities for one or more single nonbusiness purchases of individual items of tangible personal property each with a sales price of less than one thousand (\$1,000) on their FTB returns. However, eligible consumers may still calculate their actual use tax liabilities using the worksheets in the instructions to their FTB returns and report their actual use tax liabilities on their FTB returns. Consumers are not required to use the use tax tables included in the instructions to their FTB returns.

(B) The use tax table may not be used to estimate use tax liabilities for business purchases, including purchases made by businesses required to hold a seller's permit or to register with the BOE under the Sales and Use Tax Law and report their use tax liabilities directly to the BOE.

(3) SAFE HARBOR. If eligible consumers use the use tax tables included in the instructions to their FTB returns to estimate their use tax liabilities for qualified nonbusiness purchases and correctly report their estimated use tax liabilities for their qualified nonbusiness purchases in accordance with their AGI ranges, then the BOE may not assess the difference, if any, between the estimated use tax liabilities reported in accordance with the use tax tables and the consumers' actual use tax liabilities for qualified nonbusiness purchases.

**(b) DEFINITIONS AND DATA SOURCES.**

(1) AGI RANGES. The use tax table shall be separated into fifteen (15) AGI ranges as follows:

(A) AGI less than \$10,000

(B) AGI of \$10,000 to \$19,999

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- (C) AGI of \$20,000 to \$29,999
- (D) AGI of \$30,000 to \$39,999
- (E) AGI of \$40,000 to \$49,999
- (F) AGI of \$50,000 to \$59,999
- (G) AGI of \$60,000 to \$69,999
- (H) AGI of \$70,000 to \$79,999
- (I) AGI of \$80,000 to \$89,999
- (J) AGI of \$90,000 to \$99,999
- (K) AGI of \$100,000 to \$124,999
- (L) AGI of \$125,000 to \$149,999
- (M) AGI of \$150,000 to \$174,999
- (N) AGI of \$175,000 to \$199,999
- (O) AGI more than \$199,999

(2) USE TAX LIABILITY FACTOR OR USE TAX TABLE PERCENTAGE. For the 2011 calendar year the use tax liability factor or use tax table percentage shall be 0.070 percent (.0007). On June 1, 2012, the BOE shall calculate the use tax liability factor or use tax table percentage for the current calendar year by multiplying the percentage of income spent on taxable purchases for the preceding calendar year by 0.37, multiplying the product by the average state, local, and district sales and use tax rate, and then rounding the result to the nearest thousandth of a percent. On June 1, 2013, and each June 1 thereafter, the BOE shall calculate the use tax liability factor or use tax table percentage for the current calendar year by multiplying the percentage of income spent on taxable purchases for the preceding calendar year by 0.23, multiplying the product by the average state, local, and district sales and use tax rate, and then rounding the result to the nearest thousandth of a percent.

(3) TOTAL PERSONAL INCOME. Total personal income shall be determined by reference to the most current personal income data published by the United States Bureau of Economic Analysis.

(4) TOTAL SPENDING AT ELECTRONIC SHOPPING AND MAIL ORDER HOUSES. Total spending at electronic shopping and mail order houses shall be determined by reference

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to the most current electronic shopping and mail order house spending data published by the United States Census Bureau.

(5) TOTAL SPENDING ON TAXABLE PURCHASES. Total spending on taxable purchases shall be determined by:

(A) Determining the percentage, rounded to the nearest tenth of a percent, of total spending at electronic shopping and mail order houses that are not included in the following categories of items, by reference to the most current retail trade product lines statistics by kind of business data published by the United States Census Bureau:

- (i) Groceries and other foods for human consumption off premises, excluding bottled, canned, or packaged soft drinks;
- (ii) Prescriptions;
- (iii) Video Content Downloads;
- (iv) Audio Content Downloads;
- (v) Prepackaged computer software, including software downloads; and
- (vi) All nonmerchandise receipts.

(B) Adding ten billion dollars (\$10,000,000,000) to the total spending at electronic shopping and mail order houses to account for spending that is not included in the spending data published by the United States Census Bureau; and

(C) Multiplying the sum calculated in (B) by the percentage of total spending at electronic shopping and mail order houses that are not included in the categories of items listed in (A) above so that the result does not include spending on nontaxable purchases, and then rounding the result to the nearest tenth of a percent.

(6) PERCENTAGE OF INCOME SPENT ON TAXABLE PURCHASES. The percentage of income spent on taxable purchases during a calendar year shall be calculated by dividing the total spending on taxable purchases for that year by the total personal income for that year, multiplying the result by 100, and rounding the result to the nearest tenth of a percent.

(7) AVERAGE STATE, LOCAL, AND DISTRICT SALES AND USE TAX RATE. The average state, local, and district sales and use tax rate for a calendar year shall be the total of:

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(A) The rates of the statewide sales and use taxes imposed under ~~section 35~~ of article XIII of the California Constitution and the Sales and Use Tax Law (Rev. & Tax. Code, § 6001 et seq.) in effect on January 1 of that year;

(B) The statewide rate of local tax imposed under the Bradley-Burns Uniform Local Sales and Use Tax Law (Rev. & Tax. Code, § 7200 et seq.) in effect on January 1 of that year; and

(C) The weighted average rate of the district taxes imposed under the Transactions and Use Tax Law (Rev. & Tax Code, § 7251 et seq.) in effect in the various jurisdictions throughout the state on January 1 of that year after taking into account the proportion of the total statewide taxable transactions (by dollar) reported for each jurisdiction during the fourth quarter of the calendar year that is two years prior to the calendar year for which the calculation is made. For example, the total reported taxable transactions (by dollar) for the fourth quarter of 2010 shall be used to determine the weighted average rate of the district tax rates in effect on January 1, 2012, to calculate the weighted average rate of district taxes for calendar year 2012.

**(c) CALCULATION OF THE ESTIMATED USE TAX LIABILITY.**

(1) The estimated use tax liability for the AGI range described in subdivision (b)(1)(A) shall be determined by multiplying \$5,000 by the use tax liability factor or use tax table percentage and then rounding the result to the nearest whole dollar.

(2) The estimated use tax liability for the AGI ranges described in subdivision (b)(1)(B) through (N) shall be determined by multiplying the midpoint of each AGI range by the use tax liability factor or use tax table percentage and then rounding the result to the nearest whole dollar.

(3) The estimated use tax liability for the AGI range described in subdivision (b)(1)(O) shall be determined by multiplying each range members actual AGI by the use tax liability factor or use tax table percentage and then rounding the result to the nearest whole dollar.

**(d) USE TAX TABLE FORMAT.**

(1) The use tax table for calendar year 2011 shall provide as follows:

Adjusted Gross Income (AGI) Range:	Use Tax Liability
Less Than \$20,000	\$7

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\$20,000 to \$39,999	\$21
\$40,000 to \$59,999	\$35
\$60,000 to \$79,999	\$49
\$80,000 to \$99,999	\$63
\$100,000 to \$149,999	\$88
\$150,000 to \$199,999	\$123
More than \$199,999 - Multiply AGI by 0.070% (.0007)	

(2) The use tax tables for calendar year 2012 and subsequent years shall utilize the same format as follows:

Adjusted Gross Income (AGI) Range	Use Tax Liability
Less Than \$10,000	\$
\$10,000 to \$19,999	\$
\$20,000 to \$29,999	\$
\$30,000 to \$39,999	\$
\$40,000 to \$49,999	\$
\$50,000 to \$59,999	\$
\$60,000 to \$69,999	\$
\$70,000 to \$79,999	\$
\$80,000 to \$89,999	\$
\$90,000 to \$99,999	\$
\$100,000 to \$124,999	\$
\$125,000 to \$149,999	\$
\$150,000 to \$174,999	\$
\$175,000 to \$199,999	\$
More than \$199,999 - Multiply AGI by ___% (.000__)	

Note: Authority cited: Section 7051, Revenue and Taxation Code. Reference: Section 6452.1, Revenue and Taxation Code.

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## REGULATION 1591. MEDICINES AND MEDICAL DEVICES.

### (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, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "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.

(B) Section 1200 of the Health and Safety Code provides that "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. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or

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contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of ~~d~~Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(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 & 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

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California and includes an unlicensed person lawfully practicing medicine pursuant to §Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(9) Medicines. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~ United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent 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.

For purposes of subdivision (a)(9)(A), products, "approved by the United States Food and Drug Administration" means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.

Medicines are further defined in subdivisions (b) and (c) below.

(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

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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. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of "medicines," permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 or mark the location of a medical condition, 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, including the ear implant's interdependent internal and external components. 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 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).

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(4) Orthotic Devices. Orthotic devices and their replacement parts, 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.

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(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). 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 cuffs, 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; 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 to be 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

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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)(5)), 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, nor 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

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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 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) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject

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to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) 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.

(i) 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.

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(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 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.

*Authority cited: Section 7051, Revenue and Taxation Code. Reference: Sections 6006 and 6369, Revenue and Taxation Code; and Sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.*

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Executive Director

November 7, 2014

Dear Interested Party:

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for proposed amendments to Regulation 1591, *Medicines and Medical Devices*, which will be discussed at the Business Taxes Committee meeting on November 19, 2014. The proposed amendments will add devices that are implanted in the human body to mark the location of a medical condition to the definition of medicines.

Please feel free to publish this information on your website or otherwise distribute it to your associates, members, or other persons that may be interested in this issue.

Thank you for your input on these issues and I look forward to seeing you at the Business Taxes Committee meeting at **10:00 a.m.** on **November 19, 2014** in Room 121 at the address shown above.

Sincerely,

Susanne Buehler, Chief  
Tax Policy Division  
Sales and Use Tax Department

SB:map

Enclosures

cc: (all with enclosures)

Honorable Jerome E. Horton, Chairman, Fourth District

Honorable Michelle Steel, Vice Chair, Third District

Honorable Betty T. Yee, Member, First District (MIC 71)

Senator George Runner (Ret.), Member, Second District (via email)

Honorable John Chiang, State Controller, c/o Ms. Marcy Jo Mandel

(via email)

Mr. David Hunter, Board Member's Office, Fourth District  
Ms. Jaelyn Appleby, Board Member's Office, Fourth District  
Mr. Neil Shah, Board Member's Office, Third District  
Mr. Tim Treichel, Board Member's Office, Third District  
Mr. Alan LoFaso, Board Member's Office, First District  
Ms. Yvette Stowers, Board Member's Office, First District  
Mr. Ramon Salazar, Board Member's Office, First District  
Mr. Sean Wallentine, Board Member's Office, Second District  
Mr. James Kuhl, Board Member's Office, Second District  
Mr. Lee Williams, Board Member's Office, Second District  
Mr. Alan Giorgi, Board Member's Office, Second District  
Ms. Tanya Vandrick, Board Member's Office, Second District  
Ms. Natasha Ralston Ratcliff, State Controller's Office  
Ms. Cynthia Bridges (MIC 73)  
Mr. Randy Ferris (MIC 83)  
Mr. David Gau (MIC 101)  
Mr. Marc Alviso (MIC 101)  
Mr. Chris Lee (MIC 101)  
Mr. John Thiella (MIC 73)  
Mr. Jeffrey L. McGuire (MIC 43)  
Mr. Robert Tucker (MIC 82)  
Mr. Bradley Heller (MIC 82)  
Mr. Lawrence Mendel (MIC 82)  
Mr. Scott Claremon (MIC 82)  
Ms. Kirsten Stark (MIC 50)  
Mr. Clifford Oakes (MIC 50)  
Mr. Bradley Miller (MIC 92)  
Mr. Robert Wilke (MIC 50)  
Mr. Michael Patno (MIC 50)

**AGENDA — November 19, 2014 Business Taxes Committee Meeting**  
**Regulation 1591, Medicines and Medical Devices**

<p><b>Action 1 – Agreed upon items</b>          Agenda, pages 2 - 16</p>	<p>Approve and authorize publication of proposed revisions to Regulation 1591 as agreed upon by interested parties and staff (except as indicated in Actions 2 - 4).</p>
<p><b>Action 2 — Definition of Medicines - 1591(a)(9)(A)</b>          Agenda, page 17</p>	<p>Approve and authorize publication of:</p> <p>Staff's recommendation that language be inserted at the end of Regulation 1591(a)(9) clarifying that medicines are further defined in subdivisions (b) and (c).</p> <p align="center"><b>OR</b></p> <p>The recommendation from Downey Smith &amp; Fier (DSF) which clarifies the definition of medicines by placing the opening phrase referencing subdivision (c), along with suggested edits to Regulation 1591(a)(9)(A), at the end of the subsection.</p> <p align="center"><b>OR</b></p> <p>The recommendation from Equity Recovery Solutions Inc. (ERS) which amends the definition of medicines by placing the opening phrase referencing subdivision (c), along with suggested edits to Regulation 1591(a)(9)(A), at the end of the subsection.</p>
<p><b>Action 3 — “Permanently Implanted Articles” - 1591(b)(2) Paragraph 3</b>          Agenda, pages 17 - 18</p>	<p>Approve and authorize publication of:</p> <p>Staff's recommendation to delete the last sentence in the last paragraph of subdivision (b)(2).</p> <p align="center"><b>OR</b></p> <p>ERS's recommendation to add language stating that specified devices are taxable only if intended to be implanted in the human body on a temporary basis.</p>
<p><b>Action 4 — Exclusions from the Definition of Medicines - 1591(c)(2)</b>          Agenda, pages 18 - 19</p>	<p>Approve and authorize publication of:</p> <p>Staff's recommendation to leave Regulation 1591(c)(2) intact.</p> <p align="center"><b>OR</b></p> <p>DSF's recommendation to add the parenthetical language that articles which are fully implanted would not be excluded from the definition of medicines.</p> <p align="center"><b>OR</b></p> <p>ERS's recommendation to add language stating that articles which are fully and permanently implanted or their fully worn components would not be excluded from the definition of medicines.</p>

**AGENDA — November 19, 2014 Business Taxes Committee Meeting**  
**Regulation 1591, Medicines and Medical Devices**

<b>Action Item</b>	<b>Proposed Regulation 1591 as agreed upon by interested parties and staff</b>
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<b>Action 1 — Agreed Upon Items</b>	<p>(a) Definitions.</p> <p>(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.</p> <p>(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.</p> <p>(3) Furnish. “Furnish” means to supply by any means, by sale or otherwise.</p> <p>(4) Health Facility. “Health Facility” as used herein has the meaning ascribed to the term in sSection 1250 of the Health and Safety Code, and also includes “clinic” as defined in sections 1200 and 1200.1 of the Health and Safety Code.</p> <p>(A) Section 1250 of the Health and Safety Code provides that “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>(B) Section 1200 of the Health and Safety Code provides that “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 <del>an</del> incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for</p>
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	<p>purposes of this subdivision.</p> <p>(C) Section 1200.1 of the Health and Safety Code provides that “clinic” also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of dDivision 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.</p> <p>(5) Pharmacist. “Pharmacist” means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of sSection 4200 of the Business &amp; Professions Code, except as specifically provided otherwise in Chapter 9 of the Pharmacy Law.”</p> <p>(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 sSection 4037 of the Business and Professions Code.</p> <p>(7) Prescription. “Prescription” means an oral, written, or electronic transmission order that is issued by a physician,</p>
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	<p>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:</p> <p>(A) The name or names and address of the patient or patients.</p> <p>(B) The name and quantity of the drug or device prescribed and the directions for use.</p> <p>(C) The date of issue.</p> <p>(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.</p> <p>(E) A legible, clear notice of the conditions for which the drug is being prescribed, if requested by the patient or patients.</p> <p>(F) If in writing, signed by the prescriber issuing the order.</p> <p>(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 sSection 2065 of the Business &amp; Professions Code, when acting within the scope of that section.</p> <p>(9) Medicines. “Medicines” means: <b>[See Action 2, page 17 for proposed amendments]</b></p> <p>(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the</p>
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	<p>human body, or any drug or any biologic, when such are approved by the <u>U.S. United States</u> Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, or</p> <p>(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.</p> <p>The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p> <p><u>For purposes of subdivision (a)(9)(A), products, “approved by the United States Food and Drug Administration” means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.</u></p> <p><u>Medicines are further defined in subdivisions (b) and (c) below.</u></p> <p>(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:</p> <p>(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).</p> <p>“Preparations and similar substances” include, but are not limited to, drugs such as penicillin, and other antibiotics,</p>
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	<p>“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.</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. <u>In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines.</u> An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 <u>or mark the location of a medical condition,</u> 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</p>

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	<p>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, including the ear implant's interdependent internal and external components. 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 align="center"><b>[See Action 3, Page 17 for proposed amendments to the last paragraph (#3) of (b)(2)]</b></p> <p>(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).</p> <p>(4) Orthotic Devices. Orthotic devices and their replacement parts, 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).</p> <p>Orthotic devices worn on the body of the person include, but are not limited to, abdominal binders and supports, ace</p>

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	<p>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.</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>“Custom-made biomechanical foot orthosis” do not include:</p> <p>(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;</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</p>
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	<p>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.</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, breast tissue expanders and tissue expanders, cervical cuffs, 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; 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>
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	<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>(6) Drug Infusion Devices. Programmable drug infusion devices to be 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).</p> <p>(c) Exclusions from the Definition of “Medicines.”</p> <p>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.</p> <p>(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.</p> <p align="center"><b>[See Action 4, Page 18, for proposed amendments to (c)(2)]</b></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 seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.</p>
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	<p>(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 sSection 23000, of the Business and Professions Code).</p> <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.</p>
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	<p>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>(e) Specific Tax Applications.</p> <p>(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.</p> <p>(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.</p> <p>(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.</p> <p>(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,</p>
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	<p>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.</p> <p>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.</p> <p>(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</p>
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	<p>the treatment of the patient and the sale or use of these products is subject to tax.</p> <p>(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).</p> <p>(7) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.</p> <p>(8) 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.</p> <p>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.</p>
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	<p>(f) Insurance Payments</p> <p>(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.</p> <p>(2) Medicare</p> <p>(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.</p> <p>(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.</p> <p>(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.</p>
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	<p>(g) Records.</p> <p>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.</p> <p>Pursuant to sSection 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.</p> <p>(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 sSection 6369:</p> <p>Name of purchaser</p> <p>Name of doctor</p> <p>Date of sale</p> <p>Item sold</p> <p>The sale price</p> <p>(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.</p> <p>(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</p>
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**Regulation 1591, Medicines and Medical Devices**

Action Item	Alternative 1 – Staff Recommendation	Alternative 2 – Regulatory Language Proposed by Downey Smith & Fier	Alternative 3 – Regulatory Language Proposed by Equity Recovery Solutions Inc.
<p><b>Action 2 — Definition of Medicines - 1591(a)(9)(A)</b></p>	<p>(a)(9) <i>[beginning after subdivisions (a)(9)(A) and (a)(9)(B), as the third paragraph]</i></p> <p><u>Medicines are further defined in subdivisions (b) and (c) below.</u></p>	<p>(9) Medicines. “Medicines” means:</p> <p>(A) <del>Except where taxable for all uses as provided in subdivision (e),</del> <u>Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses, or</u></p>	<p>(9) Medicines. “Medicines” means:</p> <p>(A) <del>Except where taxable for all uses as provided in subdivision (e),</del> <u>Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, except where taxable as provided in subdivision (c), or</u></p>
<p><b>Action 3 — “Permanently Implanted Articles” - 1591(b)(2) Paragraph 3</b></p>	<p>(b)(2) <i>[beginning at paragraph 3]</i></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 the surgery and</p>	<p>[No alternative language provided for this section.]</p>	<p>(b)(2) <i>[beginning at paragraph 3]</i></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 the surgery and</p>

**AGENDA — November 19, 2014 Business Taxes Committee Meeting**  
**Regulation 1591, Medicines and Medical Devices**

Action Item	Alternative 1 – Staff Recommendation	Alternative 2 – Regulatory Language Proposed by Downey Smith & Fier	Alternative 3 – Regulatory Language Proposed by Equity Recovery Solutions Inc.
<b>Action 3 — (Continued) “Permanently Implanted Articles” - 1591(b)(2) Paragraph 3</b>	recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. <del>The sale or use of these items is subject to tax.</del>		recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax, <u>if intended for temporary placement.</u>
<b>Action 4 — Exclusions from the Definition of Medicines - 1591(c)(2)</b>	[No alternative language is recommended by staff for this section.]	(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 <u>(unless the product is fully implanted into the human body)</u> 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	(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 <u>that are fully and permanently implanted or their fully worn components.</u> “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,

**AGENDA — November 19, 2014 Business Taxes Committee Meeting**  
*Regulation 1591, Medicines and Medical Devices*

<b>Action Item</b>	<b>Alternative 1 – Staff Recommendation</b>	<b>Alternative 2 – Regulatory Language Proposed by Downey Smith &amp; Fier</b>	<b>Alternative 3 – Regulatory Language Proposed by Equity Recovery Solutions Inc.</b>
<p><b>Action 4 — (Continued)</b>  <b>Exclusions from the Definition of Medicines - 1591(c)(2)</b></p>		<p>than those fully worn on the patient), thermophore pads, nor foot orthoses.</p>	<p>traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.</p>

Issue Paper Number 14-006



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

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## Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*

### I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that the definition of “medicines” includes devices implanted to mark the location of a medical condition?

### II. Alternative 1 - Staff Recommendation

Staff recommends that the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines and to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval. In addition, it is recommended that language be inserted in subdivision (a)(9) clarifying that medicines are further defined in subdivisions (b) and (c) and that the last sentence of subdivision (b)(2) be removed to clarify that the specific articles that do not qualify as permanently implanted medicines under subdivision (b)(2) may meet the definition of medicines under a different subdivision.

### III. Other Alternative(s) Considered

Staff received comments from Downey, Smith & Fier (DSF) and Equity Recovery Solutions, Inc. (ESR) in response to staff’s second discussion paper. (See Exhibits 3 & 4, respectively.) Their proposed language is presented as Alternatives 2 and 3.

#### Alternative 2 – DSF Recommendation

DSF submitted proposed language for two subdivisions. They recommend altering and relocating language in subdivision (a)(9)(A), specifically the reference to subdivision (c). They also add parenthetical language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for fully implanted articles. (See Exhibit 3 and Agenda, Action Items 2 and 4.)

#### Alternative 3 – ERS Recommendation

ERS submitted proposed language for three subdivisions. They also recommend altering and relocating language in subdivision (a)(9)(A). In addition, ERS proposes to add language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for articles which are “fully and permanently implanted or their fully worn components.” Lastly, ERS proposes adding the language “if intended for temporary placement” to the end of the last sentence in subdivision (b)(2). (See Exhibit 4 and Agenda, Action Items 2, 3 and 4.)

## IV. Background

### General

Revenue and Taxation Code section (section) 6369, as interpreted and implemented by Regulation 1591, provides that the sale or use of medicines is not subject to tax if they are sold or otherwise transferred under specified circumstances. Section 6369, subdivision (b), defines “medicines” as “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.” It further provides that certain items are excluded from the definition of medicines, including “(2) 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 or the component parts and accessories thereof.” However, section 6369, subdivision (c), includes additional specific items that are, notwithstanding subdivision (b), considered to be medicines.

Regulation 1591 has been revised over the years to clarify the definition of “medicines,” but in general it closely resembles the structure of section 6369. Regulation 1591, subdivision (a)(9), defines “medicines” as follows:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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 include certain articles, devices, and appliances as described in subdivision (b) of this regulation.

Subdivision (b), in addition to defining and providing examples of preparations and similar substances, includes several categories of articles, devices and appliances which are included in the definition of medicines, either generally or for specific uses and provides examples of specific items that are included in or excluded from those categories. Additional exclusions from the definition of medicines are identified in subdivision (c).

### February 2014 Board Meeting

During the February 2014 Board Meeting, the Members heard a sales and use tax appeal hearing involving breast tissue markers (BTMs). At issue was whether BTMs are medicines and therefore exempt from tax when sold or furnished under the prescribed conditions. The BTMs discussed in the hearing were purchased from an out-of-state vendor. The hospital paid use tax to the Board and then filed claims for refund for the use tax paid.

BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. A doctor inserts the BTM in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site so that it can be accurately identified by ultrasound, MRI or other imaging methods at a future date.

**FORMAL ISSUE PAPER 14-006**

During the hearing, the taxpayer's representative stated the BTMs are devices that are fully implanted in a person and are approved for marketing by the FDA to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition, and therefore meet the definition of medicines provided in Regulation 1591, subdivision (a)(9)(A). The taxpayer's representative also stated that the BTMs were not articles excluded from the definition of medicine by subdivision (c)(2).

Conversely, staff stated that BTMs are "devices" which are "articles" excluded under subdivision (c)(2). Furthermore, though they are permanently implanted in the human body and aid patients during their medical treatments, BTMs do not assist the functioning of any organ, artery, vein or limb as currently specified by subdivision (b)(2), *Permanently Implanted Articles*, as a requirement to be deemed exempt. Finally, staff contended that BTMs were not "approved" by the FDA.

The Board unanimously voted in favor of the claimant. During the discussion, it was recommended that staff provide a narrow clarification of Regulation 1591 to explore the possibility of not having to apply tax to these types of articles. The Board directed the Business Taxes Committee (BTC) staff to clarify the provisions of Regulation 1591 as it relates to Class II medical devices that are fully implanted.

## V. Discussion

### Does the definition of medicines contained in subdivision (a)(9) need clarification?

At the February 2014 Board meeting, the Board discussed the definition of medicines as it pertains to medical devices and the complicated nature of FDA classifications of those medical devices. Pursuant to the Board's instructions, in the first discussion paper, staff suggested altering the wording of the phrase "Except where taxable for all uses as provided in subdivision (c)" found at the beginning of subdivision (a)(9)(A) and moving it to the end of the subdivision. Staff also added language to subdivision (a)(9) that would clarify the meaning of the term "approved by United States Food and Drug Administration."

During the first interested parties meeting in June, DSF contended that subdivision (a)(9)(A) is confusing, specifically, that it is not clear to taxpayers that they must look to subdivisions (b) and (c) to determine if a product qualifies as a medicine under subdivision (a)(9)(A). They further stated that moving the phrase "Except where taxable for all uses as provided in subdivision (c)" to the end of the subdivision did not improve its clarity. DSF submitted alternative language.

In the second discussion paper, the proposed revision to subdivision (a)(9)(A) was removed. Staff instead recommended that a single sentence be added to the end of subdivision (a)(9) indicating that medicines are further defined in subdivisions (b) and (c). Staff believes the inclusion of the sentence will emphasize that subdivisions (a), (b), and (c) all need to be considered when determining whether a product meets the definition of medicines.

Most medical devices are deemed Class II devices by the FDA. They generally are subject to Section 510(k) of the Food, Drug and Cosmetic Act, which requires the device manufacturers to notify the FDA of their intent to market a medical device. This is known as "premarket notification" and demonstrates that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR § 807.92(a)(3)) that is not subject to premarket approval. Generally, a new device that contains new materials or differs in design from products already on the market requires premarket approval by the FDA.

At the February 2014 Board meeting, it was noted that a device may not require pre-market approval when similar devices, which may have required premarket approval, are already on the market. Additionally, it was noted that although Class II devices are generally subject to premarket notification,

and Class III devices are generally subject to premarket approval, such is not always the case. As a result, staff's position that "approved by the U.S. Food and Drug Administration" refers only to premarket approval, could exclude devices of the type that the Board intended to include in the definition of medicine and that met all of the other elements of subdivision (a)(9)(A). Therefore, staff recommends the inclusion of language that defines "approved by the U.S. Food and Drug Administration" at the end of subdivision (a)(9), to provide needed clarity. No opposition to this language was received from interested parties.

Should permanently implanted articles that mark the location of a medical condition be included in the definition of medicines?

The BTM manufacturer's marketing materials indicated that BTMs could remain in the human body for an indefinite amount of time, therefore staff considers them to be permanently implanted. Staff proposed a revision to include permanently implanted articles that mark a location of a medical condition in the definition of medicines. Staff determined that the appropriate placement for revised language is in Regulation 1591, subdivision (b)(2), *Permanently Implanted Articles*. Staff also included BTMs as a specific example of a device that performs such a function. This recommendation is supported by interested parties.

Does the definition of medicines contained in subdivision (b)(2) need clarification?

The final paragraph of subdivision (b)(2) lists articles that "do not qualify as "permanently" implanted medicines," and states: "The sale or use of these items is subject to tax." During the interested parties process, ERS contended that such items may meet the definition of medicines under a different subdivision. Staff agreed with ERS that some devices, while determined not to be permanently implanted medicines, may meet the definition of medicines under a different part of subdivision (b). Believing the confusion stems from the final sentence in (b)(2), staff proposes deleting the sentence entirely. Staff presented this amendment at the second interested parties meeting held in September.

ERS submitted language to amend the subdivision. Instead of removing the final sentence, their proposal modified the subdivision to state:

The sale or use of these types of items would be subject to tax, if intended for temporary placement.

Staff considered the language proposed, but concluded that it should not be added. The addition of the phrase to the existing sentence would create confusion and even nullify the preceding language regarding "permanently" implanted articles contained within subdivision (b)(2). For instance, some of the items listed in the paragraph fail to meet the definition of medicine contained in subdivision (b)(2), not because they are not permanently implanted, but because they do not assist the functioning of a natural organ, artery, vein or limb. Additionally, the use of the word "intended" would expand the definition of medicine by implying that an item would need only to be intended for permanent use to meet the definition. Adding an intent element would also add ambiguity and make it difficult for audit staff to determine if an article was considered permanently implanted.

Should an exception for fully implanted or fully and permanently implanted articles be added to the exclusion from the definition of medicines contained in subdivision (c)(2)?

Both DSF and ERS have concerns with existing language used in subdivision (c)(2) and have submitted revisions for consideration. During the last interested parties meeting, DSF indicated they believe fully implanted products were ruled exempt by the Board, at the February 2014 Board meeting. DSF's

language adds an exception for articles excluded from medicines if “the product is fully implanted into the human body.” ERS proposes additional language to be inserted at the end of a list of articles excluded from the definition of medicines. Language from ERS provides an exception if the articles “are fully and permanently implanted or their fully worn components.”

Staff cannot incorporate either submission because they would expand the definition of medicine in conflict with the plain language of the statute. The language used in subdivision (c)(2) is taken directly from section 6369, subdivision (b)(2). Thus the interested parties are seeking to add an exception that does not exist under the statutory language. The revisions would effectively include in the definition of medicines all products fully implanted but section 6369, subdivision (c)(2), specifically states that only permanently implanted articles that “assist the functioning of any natural organ, artery, vein, or limb” are medicines. Accordingly, the proposed language would expand the definition of medicine beyond the statute, making redundant the narrower definition of medicines set forth in Regulation 1591, subdivision (b)(2). Both alternatives could also have a material negative impact on state revenues, as the revenue impact report shows in Exhibit 1.

## **VI. Alternative 1 - Staff Recommendation**

### **A. Description of Alternative 1**

Staff recommends that the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines, to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval, to insert language in subdivision (a)(9) indicating that medicines are further defined in subdivisions (b) and (c) and to delete the final sentence in subdivision (b)(2) to clarify that articles that do not qualify as a permanently implanted medicine may meet the definition of medicines under a different subdivision.

### **B. Pros of Alternative 1**

The proposed revisions narrowly clarify that permanently implanted devices that mark the location of a medical condition are included in the definition of medicines. Staff believes its recommendations also provide clarity with regard to the application of subdivision (a)(9)(A) and remove language from subdivision (b)(2) that could cause confusion with regard to the application of tax to certain items.

### **C. Cons of Alternative 1**

Interested parties disagree with staff’s decision not to add language to subdivisions (c)(2) and (b)(2) regarding articles “fully” or “fully and permanently” implanted. Interested parties believe the changes sought are in keeping with the Board’s unanimous decision at the February 2014 appeals hearing and its direction to staff to clarify Regulation 1591 as it relates to fully implanted devices.

### **D. Statutory or Regulatory Change for Alternative 1**

No statutory change is required. However, staff’s alternative will require a regulatory change.

### **E. Operational Impact of Alternative 1**

Staff will publish the proposed amendments to Regulation 1591 and thereby begin the formal rulemaking process. Once proposed amendments are approved by the Office of Administrative Law,

staff will update the Board of Equalization (BOE) website information, Publication 27, *Drug Stores* and Publication 45, *Hospitals and Other Medical Facilities*.

#### **F. Administrative Impact of Alternative 1**

##### **1. Cost Impact**

The workload associated with publishing the regulation is considered routine. Any corresponding cost would be absorbed within the Board's existing budget.

##### **2. Revenue Impact**

Negligible. See Revenue Estimate (Exhibit 1).

#### **G. Taxpayer/Customer Impact of Alternative 1**

Staff believes its proposal clarifies the definition of medicines for taxpayers. Staff will update the BOE website and publications that provide information regarding Regulation 1591 to taxpayers.

#### **H. Critical Time Frames of Alternative 1**

None.

### **VII. Alternative 2 – DSF Recommendation**

#### **A. Description of Alternative 2**

DSF recommends that subdivision (a)(9)(A) be revised by amending the reference to subdivision (c) and moving it to the end of the paragraph. In addition, they suggest language for subdivision (c)(2) to state that products, fully implanted in the human body, would be an exception to the exclusion contained in the subdivision.

#### **B. Pros of Alternative 2**

- This alternative provides that products which are fully implanted in the human body would not be excluded from the definition of medicines.
- DSF believes these revisions are consistent with the Board's decision favoring their client in the appeals case involving BTMs.

#### **C. Cons of Alternative 2**

- Staff believes that the DSF proposed revision to subdivision (c) is not supported by section 6369. The language currently used in subdivision (c) is taken directly from the statute.
- Staff believes the change would expand the definition of medicine beyond the statute to include all fully implanted items and have a negative revenue impact.
- Staff believes that amending the reference to subdivision (c) and moving it to the end of subdivision (a)(9)(A) would make it harder for a taxpayer to understand that they must look to subdivision (c) when applying subdivision (a)(9)(A).

#### **D. Statutory or Regulatory Change for Alternative 2**

A statutory change would be required to make the regulatory revision to subdivision (c)(2) being sought by DSF because this revision would expand the definition of medicine to include all fully implanted products.

**E. Operational Impact of Alternative 2**

Same as Alternative 1.

**F. Administrative Impact of Alternative 2**

**1. Cost Impact**

Same as Alternative 1.

**2. Revenue Impact**

Sizable economic impact. See Revenue Estimate (Exhibit 1).

**G. Taxpayer/Customer Impact of Alternative 2**

DSF believes that their alternative properly includes fully implanted products in the definition of medicines and would be in keeping with the Board's decision during the February 2014 Board Meeting.

**H. Critical Time Frames of Alternative 2**

None.

**VIII. Alternative 3 – ERS Recommendation**

**A. Description of Alternative 3**

ERS recommends that subdivision (a)(9)(A) be revised by moving the reference to subdivision (c) to the end of the paragraph and removing from it the phrase "for all uses." In addition, ERS proposes adding a phrase to the final sentence of subdivision (b)(2) indicating that the items specified as not constituting permanently implanted medicines are taxable only if intended for temporary implantation. Finally, ERS suggests language for subdivision (c)(2) to state that products, fully and permanently implanted in the human body, would be an exception to the exclusions in the subdivision.

**B. Pros of Alternative 3**

- ERS believes their provisions provide that products which are fully and permanently implanted in the human body would not be excluded from the definition of medicines.
- ERS believes their revisions will allow staff to use their judgment, when appropriate, in working with taxpayers to analyze medical products.

**C. Cons of Alternative 3**

- Staff believes that the ERS proposed revision to subdivision (c) is not supported by section 6369. The language currently used in subdivision (c) is taken directly from the statute.
- Staff believes the change would expand the definition of medicine beyond the statute to include all fully implanted items and have a negative revenue impact.
- Staff believes that moving the reference to subdivision (c) to the end of subdivision (a)(9)(A) would make it harder for a taxpayer to understand that they must look to subdivision (c) when applying subdivision (a)(9)(A). Additionally, removing the phrase "for all uses" will actually narrow the definition of medicines in conflict with the intent of the subdivision.

- Staff believes the change to subdivision (b)(2) would create contradictions within the subdivision, would expand the definition and make it more ambiguous by adding an intent element, and would create unnecessary complexity.

**D. Statutory or Regulatory Change for Alternative 3**

A statutory change is required to make the regulatory revisions being sought by ERS.

**E. Operational Impact of Alternative 3**

Same as Alternative 1.

**F. Administrative Impact of Alternative 3**

**1. Cost Impact**

Same as Alternative 1.

**2. Revenue Impact**

A material economic impact. See Revenue Estimate (Exhibit 1).

**G. Taxpayer/Customer Impact of Alternative 3**

ERS believes that their alternative properly includes fully and permanently implanted products in the definition of medicines. They also consider that their revisions clarify confusing language that incorrectly implies specific products are taxable for all uses.

**H. Critical Time Frames of Alternative 3**

None.

**Preparer/Reviewer Information**

Prepared by: Tax Policy Division, Sales and Use Tax Department

Current as of: 10/30/14

REVENUE ESTIMATE

STATE OF CALIFORNIA  
BOARD OF EQUALIZATION



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## Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*

### I. Issue

Should Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that the definition of “medicines” includes devices implanted to mark the location of a medical condition?

### II. Alternative 1 - Staff Recommendation

Staff recommends the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines and to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval. In addition, it is recommended that language be inserted in subdivision (a)(9) clarifying that medicines are further defined in subdivisions (b) and (c) and that the last sentence of subdivision (b)(2) be removed to clarify that the specific articles that do not qualify as being permanently implanted medicines under subdivision (b)(2) may meet the definition of medicines under a different subdivision.

### III. Other Alternative(s) Considered

Staff received comments from Downey, Smith & Fier (DSF) and Equity Recovery Solutions, Inc. (ERS) in response to staff’s second discussion paper. (See Exhibits 3 and 4, respectively.) The suggested revisions to staff’s proposed language which staff did not include in its recommendations are presented as Alternatives 2 and 3.

#### Alternative 2 – DSF Recommendation

DSF recommends altering and relocating the language used in subdivision (a)(9)(A), specifically the reference to subdivision (c). They also add parenthetical language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for fully implanted articles

#### Alternative 3 – ERS Recommendation

ERS also recommends altering and relocating the language used in subdivision (a)(9)(A) which references subdivision (c). In addition, ERS proposes to add language to the list of products excluded from the definition of medicines in subdivision (c)(2) which would create an exception for articles which are “fully and permanently implanted or their fully worn components.” Lastly, ERS

proposes adding the language “if intended for temporary placement” to the end of the last sentence to subdivision (b)(2).

## **Background, Methodology, and Assumptions**

### **Alternative 1 – Staff Recommendation**

Staff recommendation would have a relatively insignificant impact on revenue. Staff recommends the Board approve and authorize publication of the proposed amendments to Regulation 1591, to provide that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines and to clarify that approval by the United States Food and Drug Administration (FDA) means any device for which the FDA cleared a premarket notification or approved an application for premarket approval. In addition, it is recommended that language be inserted in subdivisions (b) and (c) and the last sentence of (b)(2) be removed to clarify that the specific articles that do not qualify as permanently implanted medicines under subdivision (b)(2) may meet the definition of medicines under a different subdivision.

Staff recommendation would expand the number of permanently implanted devices included in the definition of medicines in a limited manner when they are used to mark the location of a medical condition. Staff believes their recommendation also provides clarity with regard to the application of subdivision (a)(9)(A) and removes language from subdivision (b)(2) that could cause confusion with regard to the application of tax to certain items.

Staff recommendation could have a negligible impact on revenue in the thousands of dollars based on the amount of refund claims the Board of Equalization has processed within the last eight months.

### **Other Alternatives Considered**

#### **Alternative 2 – DSF Recommendation**

The DSF recommendations would have a significant impact on revenue. DSF recommends that the (a)(9)(A) definition of medicines be revised by amending the reference to subdivision (c) and moving it to the end of the paragraph. In addition, they suggest language for subdivision (c)(2) to state that products, fully implanted in the human body, would be an exception to the exclusions in the subdivision.

This provision provides that products which are fully implanted in the human body would not be excluded from the definition of medicines. In addition, DSF believes these revisions to be what the Board indicated in their decision favoring their client in their case involving BTMs.

However, staff contends that the revision to subdivision (c) is not supported by Revenue and Taxation Code section 6369 as the language used in subdivision (c) is taken directly from the statute. Further, staff believes the change would also expand the definition of medicines beyond the statute to include all fully implanted items and have a negative revenue impact.

Alternative 2 will have a significant impact on revenues in the millions of dollars, based on a pending claim for refund of \$35,000 for portacath implants from one hospital over an audit period of 2 ½ years. A portacath is currently excluded from the definition for medicines. A portacath is a small medical appliance that is installed beneath the skin and used for hemodialysis patients, and for

administering medication such as chemotherapy. If we extrapolate the claim total of \$35,000 to a population of over 500 hospitals in California the annual revenue impact could be as much as \$7 million ( $\$35,000 / 30 \text{ months} \times 12 \text{ months} \times 500 \text{ hospitals} = \$7 \text{ million}$ ).

### **Alternative 3 – ERS Recommendation**

Alternative 3 would have a significant impact on revenue. ERS recommends that subdivision (a)(9)(A) be revised by moving the reference to subdivision (c) to the end of the paragraph and removing the phrase “for all uses.” In addition, ERS proposes adding a phrase to the final sentence of subdivision (b)(2) indicating items specified as not constituting permanently implanted medicines are taxable only if intended for temporary implantation. Finally, ERS suggests language for subdivision (c)(2) to state that products, fully and permanently implanted in the human body, would be an exception to the exclusions in the subdivision.

This provision provides that products which are fully and permanently implanted in the human body would not be excluded from the definition of medicines. ERS believes their revisions will allow staff to use their judgment, when appropriate, in working with taxpayers to analyze medical products.

However, staff contends that the revision to subdivision (c) is not supported by section 6369. The language currently used in subdivision (c) is taken directly from the statute. Further, staff believes the change would also expand the definition of medicines beyond the statute to include all fully implanted items and have a negative revenue impact.

The ESR recommendations will have a significant impact on revenues in the millions of dollars, based on a pending claim for refund of \$35,000 for portacath implants from one hospital over an audit period of 2 ½ years. As with the DSF recommendation, if we extrapolate the claim total of \$35,000 to a population of over 500 hospitals in California the annual revenue impact could be as much as \$7 million ( $\$35,000 / 30 \text{ months} \times 12 \text{ months} \times 500 \text{ hospitals} = \$7 \text{ million}$ ).

### **Revenue Summary**

Alternative 1 – staff recommendation will have relatively insignificant revenue impact of thousands of dollars annually.

Alternative 2 – DSF recommendation will have a significant impact on revenue in the millions of dollars annually.

Alternative 3 – ERS recommendation will also have a significant impact on revenue in the millions of dollars annually.

### **Preparation**

Mr. Bill Benson, Jr., Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. This estimate has been reviewed by Mr. Mark Durham, Manager, Research and Statistics Section, Legislative and Research Division, and Ms. Susanne Buehler, Chief, Tax Policy Division, Sales and Use Tax Department. For additional information, please contact Mr. Benson at (916) 445-0840.

Current as of October 30, 2014

§ 1591. Medicines and Medical Devices.

(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 ~~s~~Section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "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.

(B) Section 1200 of the Health and Safety Code provides that "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. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or

contributions which may be in the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under Chapter 6.6 (commencing with section 2900) of ~~d~~Division 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(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 & 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 & Professions Code, when acting within the scope of that section.

(9) Medicines. “Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent 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.

For purposes of subdivision (a)(9)(A), products, “approved by the United States Food and Drug Administration” means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.

Medicines are further defined in subdivisions (b) and (c) below.

(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. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 or mark the location of a medical condition, 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, including the ear implant's interdependent internal and external components. 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 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, 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 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). 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 cuffs, 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; 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 to be 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)(5)), 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, nor 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

(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 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) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) 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.

Pursuant to sSection 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 sSection 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.

*Authority cited: sSection 7051, Revenue and Taxation Code. Reference:sSections 6006 and 6369, Revenue and Taxation Code; and sSections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.*

*Note: Text is from the website of the Office of Administrative Law as of 5/14/14. History was removed for ease of review.*

**Patno, Michael**

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**From:** Wade Downey <Wade.Downey@dsfgroup.com>  
**Sent:** Thursday, August 28, 2014 4:49 PM  
**To:** Patna, Michael  
**Cc:** Royd Baik; Roderick Calub; Jim Fier  
**Subject:** RE:Interested Parties Meeting - Regulation 1591 - Agenda and handouts  
**Attachments:** DSF Proposed Revisions to 1591\_August2014\_final.docx

Michael,

I am back from vacation and finally have some language for you. As discussed, I had hoped to get this out before I left but ran out of time, so I apologize for the delay.

Anyways, after reflecting on the goal and discussing with our group, we think the required changes are pretty simple. See attached proposed language/changes to (a)(9)(A) and (c)(2). As recap, we like the idea of the reference to (c) being moved to the end of the sentence as Staff originally proposed. It just reads better, which I think we discussed. Also, we think adding a parenthetical reference to (c)(2) should clarify that "or article" is not intended to include fully implanted products consistent with Board decisions. During the appeals process, the language of (c)(2), specifically "or article", caused the greatest confusion. Adding a parenthetical, similar to other parts of (c)(2), stating...(unless product is fully implanted into the human body) would eliminate such confusion while maintaining the referencing and integrity of the regulation.

Beyond our proposed language, we wanted to point out and staff can decide how to address, that the proposed language may leave open whether fully implanted products of a temporary nature are covered by (a)(9)(A). The temporary aspect was not address in the BTM case and I am not aware of any other cases or Board decisions that have applied (a)(9)(A) to exempt temporary implants. We would be okay if Staff recommended or decided to include the term "permanently" (defined in annotation to be longer than 6 months) somewhere in the proposed (c)(2) parenthetical; either as "fully/permanently implanted" or "permanently and fully implanted".

If you would like to discuss further or want me to finalize in a letter with the comments let me know.

Thanks

Wade Downey

**Downey, Smith & Fier**

Direct: 562.249.6002

(9) Medicines. "Medicines" means:

(A) ~~Except where taxable for all uses as provided in subdivision (c), a~~Any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent disease, illness or medical condition regardless of ultimate use, ~~or~~ **unless the item is specifically excluded from the definition of medicine under subdivision (c) for all uses.**

(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)(5)), 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 (unless product is fully implanted into the human body) 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, nor 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).

**From:** Jacob Bholat  
**To:** Patno, Michael  
**Subject:** RE: Interested Parties Discussion - Regulation 1591  
**Date:** Wednesday, September 03, 2014 8:14:10 PM

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Hi Michael,

As part of the continued discussion we would propose the following edits to Regulation 1591. We don't believe that the minor revision proposed by staff clears up the continued confusion in the regulation.

Suggested revisions to (a)(9)(A)

(9) MEDICINES. "Medicines" means:

(A) Any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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, except where taxable as provided in subdivision (c) or

Suggested revisions to (b)(2)

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 types of items would be subject to tax, if intended for temporary placement.

Suggested revisions to (c)(2)

(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 that are not fully and permanently implanted or their fully worn components. "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.

Please let me know if you would like any clarification or discussion regarding our suggestions.

Thank you,

**Jacob Bholat**  
*Partner*  
*Equity Recovery Solutions Inc.*

1215 N. Red Gum St.  
Suite B  
Anaheim, CA 92806  
949.295.1899  
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**From:** Jacob Bholat [mailto:jbholat@equityrs.com]  
**Sent:** Monday, August 11, 2014 9:50 AM  
**To:** 'michael.patno@boe.ca.gov'  
**Subject:** RE: Interested Parties Discussion - Regulation 1591

Hi Michael,

We greatly appreciate the opportunity to work with the BOE as you tackle potential revisions to help clarify the application of Regulation 1591. As discussed, below you will find our proposed language revision to 1591(b)(2) in bold and underlined. Rather than deal with each of the issues we presented in our original submission, we propose language that allows staff to use their judgment, when needed in working with taxpayers to analyze individual product types. Please forward to legal and staff to see if this might be an option to help clarify language and give staff the ability to deal with actual usage and changes in technology.

Thank you,

Regulation 1591(b)(2)

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, **unless they are permanently implanted or the product use qualifies under another section in this regulation.**

**Jacob**  
949.295.1899  
1215 N. Red Gum St. Suite B  
Anaheim, CA 92806

BEFORE THE CALIFORNIA STATE BOARD OF EQUALIZATION

450 N STREET

SACRAMENTO, CALIFORNIA

REPORTER'S TRANSCRIPT

NOVEMBER 19, 2014

BUSINESS TAXES COMMITTEE

REPORTED BY: Kathleen Skidgel

CSR NO. 9039

Juli Price Jackson

CSR NO. 5214

P R E S E N T

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For the Committee:

Michelle Steel  
Chair

Betty T. Yee  
Member

Jerome E. Horton  
Member

George Runner  
Member

Marcy Jo Mandel  
Appearing for John  
Chiang, State Controller  
(per Government Code  
Section 7.9)

Joann Richmond  
Chief, Board Proceedings  
Division

For Board of  
Equalization Staff:

Susanne Buehler  
Chief, Tax Policy Division

Kevin Smith  
Tax Counsel III  
Legal Department

Bradley Heller  
Tax Counsel IV  
Legal Department

Scott Claremon  
Tax Counsel  
Legal Department

Lawrence Mendel  
Tax Counsel III  
Legal Department

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1 450 N STREET  
2 SACRAMENTO, CALIFORNIA  
3 NOVEMBER 19, 2014

4 ---oOo---

5 MR. HORTON: Members, let us call the  
6 meeting of the Board of Equalization to order.

7 Ms. Richmond, what is our first matter?

8 MS. RICHMOND: Good morning, Chairman and  
9 Board Members.

10 Our first item on this morning's agenda is  
11 the Business Taxes Committee. Ms. Steel is the  
12 Chair of that committee.

13 Ms. Steel.

14 MS. STEEL: I call the Business Taxes  
15 Committee meeting to order. And I have staff coming  
16 up. And we have three items here.

17 MS. BUEHLER: Good morning. I am Susanne  
18 Buehler with the Sales and Use Tax Department.

19 We have three agenda items for your  
20 consideration today. We will take each agenda item  
21 and their respective action item separately before  
22 moving to the next.

23 With me for Agenda Item 2 is Mr. Kevin  
24 Smith from our Legal Department.

25 For this agenda item we request your  
26 approval and authorization to publish proposed  
27 amendments to Sales and Use Tax Regulations 1533.2,  
28 Diesel Fuel Used in Farming Activities or Food

1 Processing, and 1598.1, Diesel Fuel Prepayment  
2 Exemption.

3 Staff's recommended amendments revise the  
4 definition of diesel fuel to be consistent with the  
5 definition in the Diesel Fuel Tax Law.

6 We would be happy to answer any questions  
7 you may have on this topic.

8 MS. STEEL: Any comments?

9 Members, there is a motion.

10 MS. YEE: Move to approve and authorize  
11 publication.

12 MR. RUNNER: Second.

13 MR. HORTON: Sec --

14 MS. STEEL: Okay. Member Yee moved and  
15 Member Runner second.

16 So it's been moved.

17 So next item.

18 MS. BUEHLER: Okay. With me for Agenda  
19 Item 3 will be Mr. Bradley Heller from our Legal  
20 Department.

21 For this agenda item we request your  
22 approval and authorization to publish proposed  
23 amendments to Sales and Use Tax Regulation 1685.5,  
24 Calculation of Estimated Use Tax - Use Tax Table.

25 Staff's recommended amendments update the  
26 definition of the average state, local and district  
27 sales and use tax rate by removing the specific  
28 reference to Section 35 of Article XIII of the

1 California Constitution, to make the language  
2 consistent with the statute.

3 No interested parties meetings were held on  
4 this issue since staff's recommended amendments are  
5 technical in nature.

6 We would be happy to answer any questions  
7 you may have on this topic.

8 MR. HORTON: Move adoption.

9 MS. YEE: Second.

10 MS. STEEL: Perfect. Okay.

11 Mr. Chair made a motion, and then second by  
12 Ms. Yee. And it's been moved.

13 And next one we have actually three  
14 speakers. So all the speakers please come up.

15 And could you introduce?

16 MS. BUEHLER: Certainly.

17 With me for Agenda Item 4 are Mr. Larry  
18 Mendel and Mr. Scott Claremon from our Legal  
19 Department.

20 For this agenda item we request your  
21 approval and authorization to publish proposed  
22 amendments to Sales and Use Tax Regulation 1591,  
23 Medicines and Medical Devices.

24 We have four action items; one concurred  
25 item and three which have alternate recommendations.  
26 I will be going through all four before we turn it  
27 over to our guest speakers.

28 In Action 1, it represents those areas

1 agreed upon by staff and interested parties and  
2 provides the following:

3           It clarifies that articles permanently  
4 implanted in the human body to mark the location of  
5 medical -- a medical condition are included in the  
6 definition of medicines, and clarifies that approval  
7 by the United States Food and Drug Administration  
8 means any device in which the agency cleared a  
9 pre-market notification or approved an application  
10 for pre-market approval.

11           In Action 2, we ask that the Board approve  
12 and authorize for publication either staff's  
13 recommendation to add language at the end of  
14 subdivision (a)(9), clarifying that medicines are  
15 further defined in subdivisions (b) and (c);

16           Or, Alternative 2 from Downey, Smith and  
17 Fier which deletes the opening phrase, quote,  
18 "except where taxable for all uses as provided in  
19 subdivision (c)," end quote, from subdivision  
20 (a)(9)(A) and inserts, quote, "unless this item is  
21 specifically excluded from the definition of  
22 medicine under subdivision (c) for all uses," end  
23 quote, at the end of the subdivision;

24           Or, Alternative 3 from Equity Recovery  
25 Solutions, Incorporated which also deletes the  
26 opening phrase of subdivision (a)(9)(A) but inserts,  
27 quote, "except where taxable as provided in  
28 subdivision (c)" at the end of the subdivision.

1           In Action 3 we ask that the Board approve  
2 and authorize for publication either staff's  
3 recommendation to delete the last sentence in  
4 subdivision (b)(2) which states "implantable  
5 articles that do not qualify as permanently  
6 implanted medicines are subject to tax when sold or  
7 used."

8           Or, the recommendation from Equity Recovery  
9 Solutions, Incorporated which adds language to the  
10 last sentence of subdivision (b)(2) that stated  
11 specific -- "specified devices are taxable only if  
12 intended to be implanted in the human body on a  
13 temporary basis."

14           Lastly, in Action 4 we ask that the Board  
15 approve and authorize for publication either staff's  
16 recommendation to make no changes to the existing  
17 language of subdivision (c)(2) which is based on the  
18 fact that the current language is taken from  
19 statute;

20           Or, Alternative 2 from Downey, Smith and  
21 Fier which recommends adding parenthetical language  
22 to subdivision (c)(2) that articles which are fully  
23 implanted would not be excluded from the definition  
24 of medicines;

25           Or, Alternative 3 from Equity Recovery  
26 Solutions, Incorporated which recommends adding  
27 language to subdivision (c)(2) that articles which  
28 are fully and permanently implanted or they're fully

1 worn components would not be excluded from the  
2 definition of medicines.

3 Please note that page 18 of the agenda  
4 erroneously omitted the word "not" from the  
5 underlying sentence; it should read, quote, "that  
6 are not fully and permanently implanted or they're  
7 fully worn components," end quote. And that is part  
8 of Alternative 3 from Equity Recovery Solutions,  
9 Incorporated.

10 We have speakers on the action items, and  
11 we would be happy to answer any questions you may  
12 have after their presentations.

13 MS. STEEL: Sure. It seems like we have  
14 four speakers.

15 No, actually -- three, because one recorded  
16 two times.

17 Okay. Mr. Wade Downey. Go ahead.

18 ---oOo---

19 WADE DOWNEY

20 ---oOo---

21 MR. DOWNEY: Great. My name's Wade Downey.  
22 I'm a partner with Downey, Smith and Fier, state and  
23 local tax consulting firm.

24 First of all, I wanted to make sure that  
25 the Board has received the letter that we issued  
26 relative to the misstatement, I guess, of the  
27 revenue impact related to the changes that we're  
28 proposing.

1           Our proposal has no change to the treatment  
2 of the Port-a-Cath as reported in the information.

3           So Chairman and Members of the Board, thank  
4 you for the opportunity to present related to  
5 proposed Regulation 1591 changes.

6           DSF has participated in each of the  
7 interested party discussions. We'd like to thank  
8 staff and -- for their work, specifically to address  
9 breast tissue markers, and their leadership  
10 throughout this process.

11           I'd also like to thank staff, the Policy  
12 Group and the Legal Department, for not mistaking my  
13 passion and boisterous expression at times for  
14 anything other than dedication to this process and  
15 the goal to come up with a regulation that is  
16 clearer than we have today.

17           I truly believe, at the most basic level,  
18 we're all here with a common goal to clarify this  
19 regulation that causes so much confusion.

20           Our goal in participating in interested  
21 party process was not limited to adding BTMs to the  
22 regulation; that's the easy part. It was -- it was  
23 a much loftier goal. And that was to actually  
24 clarify the language of 1591(a)(9)(A) to be  
25 consistent with Board's decision, the statute, and  
26 how industry reads and applies that section.

27           Whether the adopted language includes or  
28 excludes any specific medical product, the

1 regulation language needs to be clear, unambiguous,  
2 and not contain underlining interpretations as are  
3 currently the case.

4 To reject Alternative 2 -- that is, only  
5 addressing the specific BTM product -- does not  
6 resolve the disconnect between the Board's decisions  
7 and how staff applies this regulation. It also  
8 continues the patchwork nature of the regulation,  
9 provides little guidance to address emerging  
10 technology and new advances in diagnostic implants.

11 It leaves ambiguous the treatment of  
12 FDA-approved implants that are to diagnose,  
13 mitigate, treat or prevent disease. Implants that  
14 are covered by 6369(c), those that specifically  
15 replace a body function, are already clearly  
16 addressed in the regulation. We're not dealing with  
17 those.

18 At the beginning of this process we  
19 reflected on the BT -- BTM appeal and attempted to  
20 frame the specific elements of the regulation that  
21 were unclear or caused confusion during the audit  
22 and appeals process. And we've provided Exhibit  
23 A -- hopefully everyone has a copy -- that lays out  
24 those. And they're summarized, the FDA approval,  
25 and staff has done a nice job of addressing that.

26 The second is the application of (c)(2) as  
27 it relates to fully implanted items and  
28 clarification as to whether (a)(9)(A) provides an

1 independent definition of medicines separate from  
2 the alliance -- reliance on little (b).

3 It's our understanding, based on the  
4 decision and providence, that the Board sought the  
5 same clarification. The decision specifically  
6 stated:

7 "Clarify the provisions of 1591 as it  
8 relates to Class II medical devices that  
9 are fully implanted."

10 We've not addressed -- or Alternative 1  
11 certainly clarifies FDA approval and specifically  
12 includes BTMs. However, the proposed language does  
13 not address points two and three.

14 Staff's recommended sentence -- "medicines  
15 are further defined in subdivision (b) and (c)" --  
16 does little to clarify the asserted dependency on  
17 little (b).

18 Further defined in that section or added by  
19 staff, coupled with subdivision (b) that begins "in  
20 addition to the definition set forth in (a)(9)"  
21 creates an ambiguity as to whether (a)(9) provides  
22 an independent definition of medicine. Such  
23 ambiguity -- ambiguous language is concerning.

24 Throughout the appeal and this interested  
25 party process, staff has maintained that (a)(9) does  
26 not create an independent definition of medicine  
27 separate from (b). However, they have been  
28 unwilling, when we proposed, to include any specific

1 language to inform taxpayers of this position,  
2 leaving uncertainty and unwary taxpayers to apply  
3 (a)(9) incorrectly based on its plain language which  
4 says:

5 "Medicines include fully implanted  
6 FDA-approved devices used to diagnose,  
7 cure, mitigate, treat and prevent disease."

8 The second component of staff's underlying  
9 interpretation involves the scope of little (c),  
10 specifically (c)(2), as it relates to implanted  
11 products.

12 During the BTM appeal process, staff reads  
13 this section that includes the term "article" to  
14 clearly exclude fully implanted products that are  
15 FDA-approved to diagnose, cure, mitigate disease.  
16 However, the Board rejected that interpretation.

17 The Alternative 2 language was at the  
18 request of staff, and that was simply to just make  
19 clear where it says "or article," which is so  
20 ambiguous, just to say that does not include a fully  
21 implanted product that we've already defined in  
22 (a)(9)(A). And that's -- that's it. It's simple.  
23 It's clear.

24 And we would propose if -- if staff wants  
25 to tax those, or if the Board wants to tax implants  
26 of that nature, then we should say the opposite in  
27 that section. And it doesn't matter to us whether  
28 they tax them or don't tax them, we just need to be

1 clear in terms of what the Board's position is.  
2 Because the way staff reads the regulation and how  
3 the Board has ruled in a number of -- of opinions,  
4 are the exact opposite. And I think that's been the  
5 biggest challenge throughout this process is that we  
6 have a disconnect that we each disagree in terms of  
7 what that section says.

8 In closing -- I also have other comments,  
9 but in closing, you know, we believe the language of  
10 Alternative 2 provides a long-needed clarity to  
11 (a)(9)(A) and (a)(9)(B), provides an independent  
12 definition of medicines that are supported by  
13 6369(b) which include "diagnose, cure, mitigate,  
14 treat, prevent disease by internal or external  
15 application to the human body."

16 And we've attached Exhibit B. And so if we  
17 look at Exhibit B, we have the statute on the left  
18 and we have the regulation on the right. And the  
19 statute, 6369(b) says "medicines means," and it  
20 includes the language "diagnose, cure, mitigate,  
21 treat or prevent disease."

22 When we look at the regulation, the --  
23 the -- the comparable part of the regulation is  
24 (a)(9)(A) and (a)(9)(B) which both use the same  
25 exact language "diagnose, cure, mitigate, treat or  
26 prevent disease."

27 So, we believe that that definition stands  
28 on its own. So if you look at the bottom, 6369(c),

1 which is not dependent on (b) above, is where we get  
2 the exemption for only implants that assist a body  
3 function. However, that's not dependent on (b)  
4 above. When you get the regulation, the comparable  
5 section is little (b) and staff is saying, well,  
6 that is dependent on the -- on (a)(9)(A).

7 And I don't know if I just confused the  
8 heck out of it, but that's -- that's my best  
9 attempt.

10 Note, the more restrictive language that  
11 defines implants as an item that replaces a body  
12 function are clearly listed in 6369(c) and clearly  
13 listed in little (b). That's not the section that  
14 we're looking at.

15 The issue that needs to be resolved and the  
16 issue in the appeal is (a)(9)(A) and whether that is  
17 intended to exclude implants that are not otherwise  
18 listed in (b). And if it is, then we should just  
19 say it excludes -- unless you can find your implant  
20 in (b), it's excluded in (c).

21 MS. STEEL: Thank you very much.

22 MR. DOWNEY: Thanks.

23 MS. STEEL: We're going to go all the  
24 speakers before staff respond.

25 And second person is Roderick Calub.

26 If I mispronounced your name, sorry. But  
27 go ahead.

28 ---oOo---

1                   RODERICK CALUB

2                   ---oOo---

3           MR. CALUB: That's okay.

4           MS. STEEL: Yeah.

5           MR. CALUB: Good morning. My name is  
6 Roderick Calub, senior manager at Downey, Smith and  
7 Fier, and help lead our healthcare practice.

8                   A very large portion of my responsibilities  
9 include assisting our clients with assigning tax  
10 codes to the various products that they either sell  
11 or purchase. And this is almost a daily activity as  
12 more and more products are being added.

13                   As background, vendors -- medical  
14 vendors -- and health facilities administer and  
15 maintain their taxability based on a class or a  
16 bucket of products. And, as such, we believe that  
17 the regulation should be something that would apply  
18 to similar type products within that same class or  
19 category.

20                   Recently, I've been concerned about the --  
21 providing accurate guidance to my clients because  
22 there are -- or I'm concerned with advising -- or  
23 properly advising on the class of products that are  
24 fully implanted, used to cure, mitigate, prevent  
25 disease, as these, to me, clearly meet the  
26 definition in (a)(9)(A), consistent with the  
27 decision in the breast tissue marker case and  
28 consistent with all the materials distributed when

1 (a)(9) was adopted. But I'm hesitant because staff  
2 continues to say that in order for an item to meet  
3 the definition of medicine, it must meet the  
4 requirements in subdivision (b).

5 With emerging technology, there has been  
6 development of new products fully implanted, used to  
7 treat patients by diagnosing, monitoring medical --  
8 medical conditions. Again, to me, this meets the  
9 definition of a medicine under (a)(9)(A) but staff  
10 would assert that they wouldn't because they don't  
11 replace or assist a body function.

12 As such, I respectfully ask the Board to  
13 adopt language to clarify whether a fully implanted  
14 FDA-approved article to cure, mitigate, prevent,  
15 treat disease but does not replace or assist a body  
16 function meet the definition of a medicine. And I  
17 believe this can be achieved by addressing the two  
18 elements that Mr. Downey just discussed; and that  
19 is, does (a)(9)(A) provide a separate, distinct  
20 definition separate from those in little (b) and the  
21 subdivision (c) exclusions include permanently  
22 implanted items.

23 MS. STEEL: Okay, thank you.

24 MR. CALUB: Thank you.

25 MS. STEEL: Mr. Jacob Bholat.

26 ---oOo---

27 JACOB BHOLAT

28 ---oOo---

1 MR. BHOLAT: Correct.

2 Hi. My name is Jacob Bholat. I am a  
3 partner with Equity Recovery Solutions.

4 I -- first, I'd like to thank the staff as  
5 well, the Interested Parties Committee, and this  
6 Board for the opportunity to collaborate to help  
7 clarify portions of Regulation 1591.

8 I think we can all agree that this area is  
9 complex and always changing. And overall, staff, I  
10 think, does a good job of evaluating most products.

11 Apparently, I guess in my recommendations  
12 of language I guess I created a little bit of a  
13 stir, and -- and -- but that wasn't my intention. I  
14 was just trying to provide some clarity, or at least  
15 try to help provide clarity.

16 Our position -- and I'll try to keep this a  
17 little simple. Our position is basically over the  
18 last many years this Board has had several different  
19 types of implanted products brought before it. And  
20 consistently, the Board has ruled that these types  
21 of implanted products are exempt. And staff has  
22 always brought various arguments of why these  
23 particular implants should be taxable.

24 Examples of the four major ones that come  
25 to mind were the cochlear implants, the dental bone  
26 screws, the reconstructive cosmetic implants, and  
27 then now, just recently, with the BTMs, tissue  
28 markers.

1           Consistently, you guys have provided, or  
2 the Board has provided guidance that an item  
3 implanted into the patient meets the definition of a  
4 medicine under Regulation 1591 and Regulation -- and  
5 law section 6369. Consistently, staff has taken  
6 these rulings away and very narrowly applied them.  
7 Their proposed revisions to 1591 continue this  
8 approach.

9           The -- the one thing that I would like to  
10 address is the specific ruling on the Port-a-Cath  
11 because that's something that I actually added to  
12 the -- or recommended to the language.

13           In that particular ruling that was  
14 provided, the staff again took an implanted item and  
15 said, we know it's permanently implanted, we  
16 understand it meets all the criteria of being  
17 permanently implanted; however, we believe that it  
18 doesn't meet based on certain regulation -- or on  
19 the law section, and we're excluding this por -- the  
20 section from section (a) and (c) and not applying it  
21 to (b).

22           Based on this historical trend of the Board  
23 consistently ruling that -- that implanted products  
24 are exempt, we ask the Board to help provide clear  
25 guidance so that staff can be more comfortable with  
26 their decisions.

27           Our recommendation on section (b) pertains  
28 to permanently implanted items. In that section, as

1 you read the different descriptions of the different  
2 products, the beginning of that law section -- or  
3 that paragraph talks about "permanently implanted,"  
4 and then they go in and they describe three or four  
5 different products. And in those different  
6 products, some of those items are permanently  
7 implanted.

8 So that's where the confusion in my mind  
9 comes in, from that particular paragraph, and that's  
10 why we recommended those changes.

11 Our goal and overall objection is to  
12 provide -- or our recommendation's for the following  
13 premise: That all items fully implanted fall under  
14 the jurisdiction of Regulation -- that -- that fall  
15 under the Regulation 1591 should be exempt. Our  
16 goal is not to expand the regulation. Rather, we  
17 would like to help audit staff to provide consistent  
18 and accurate application of the law and regulation.

19 That being said, I would like to make a  
20 couple comments. First, we agree that anything  
21 that's temporarily implanted doesn't meet the  
22 definition of a permanent implant and should remain  
23 taxable as currently structured.

24 Second, we don't believe that our  
25 recommendations alter the spirit of the law or any  
26 of your previous rulings. Permanent implants should  
27 be exempt when placed in the patient under a  
28 hospital or doctor care.

1 Third, the -- the question or comment that  
2 we had relates to the financial impact that was put  
3 into that recent discussion paper. We believe that  
4 that estimate is highly overstated.

5 The particular claim that they're citing is  
6 coming from a very large medical center, probably  
7 two to four times overstated, somewhere in that  
8 neighborhood. We don't know exactly, but we do  
9 believe it's overstated.

10 That -- that facility is a very large  
11 facility, so multiplying that by the number of  
12 hospitals doesn't really make sense.

13 Finally, the value of the financial impact,  
14 we believe, shouldn't be a deterrent to the  
15 decision.

16 Our goal, and hopefully everybody -- and I  
17 believe staff and your goal is to provide clarity.  
18 And we are only seeking consistent treatment. And  
19 we seem to continue to have the Board rule, staff  
20 narrowly apply the rule and we go back to the  
21 circle. And -- and it's been three or four times  
22 over the many years. And so hopefully we can  
23 provide some clarity.

24 Thank you.

25 MS. STEEL: Thank you.

26 It seems like there's four action items.  
27 And Action Item 1 is everybody agreed, right? So  
28 all the speakers.

1           So let's, you know, clarify a little bit  
2 about, you know, what these speakers want. Just,  
3 you know, can you answer that some of those requests  
4 of the temporary ones, it's taxable and permanent  
5 ones?

6           MR. CLAREMON: I could respond to the --  
7 the ele -- the items laid out in Exhibit A,  
8 specifically Mr. Downey's concern with the  
9 application of Regulation 1591 section (c)(2).

10           That is -- that is language that is taken  
11 directly from the statute which excludes from the  
12 definition of medicine all articles, including  
13 devices.

14           So staff reads that as to exclude all  
15 devices --

16           MS. STEEL: Mm-hmm.

17           MR. CLAREMON: -- unless there -- there's  
18 an exception to that general exclusion contained in  
19 subdivision (b) of the regulation which -- and there  
20 are several categories of items or devices that  
21 are -- that are in those -- in subdivision (b). And  
22 those, too, those categories are also taken directly  
23 from the statute.

24           So staff reads it as a device, based on the  
25 statute, is excluded from the definition of medicine  
26 unless it falls within one of those categories.

27           So, there is no general -- there's no  
28 exception to that general exclusion for fully

1 implanted items that treat, mitigate, prevent  
2 disease. So to add that language to (c)(2) or to  
3 add language -- an exception to that language,  
4 anywhere in the regulation, would go beyond what  
5 the statute -- how the statute defines medicines.  
6 So that is -- that's how we would respond to -- to  
7 that item.

8           With regard to the Number 3 -- does  
9 Regulation 1591(a)(9)(A) create an independent  
10 definition of medicine -- well, staff looks at the  
11 plain language of (a)(9)(A), and this is why we  
12 actually wanted to leave the plain language in  
13 place.

14           And it starts with the statement that  
15 "except where taxable for all uses as provided in  
16 subdivision (c)..." That's the very first thing in  
17 (a)(9)(A). So immediately the answer is no, it is  
18 not independent of (c). It specifically says that  
19 it's reliant on "except where taxable for all uses  
20 in (c)."

21           And if you go to (c), the very first  
22 sentence of (c) states "except as otherwise provided  
23 in subdivision (b)." So right there you have the  
24 framework that staff follows that (a)(9)(A) is  
25 dependent on (c) which is -- has exceptions to that  
26 general exclusion from -- in (b).

27           So that is why staff doesn't want to move  
28 that first sentence. They want it to be clear to

1 taxpayers that they need to look at (c). And that's  
2 why staff wants to add that last sentence which says  
3 you need to look at (b) and (c) as well, just to  
4 reinforce that.

5 MS. STEEL: Thank you.

6 Any comments, Members?

7 Member Yee.

8 MS. YEE: Mm-hmm.

9 Thank you, Madam Chairman.

10 Just a question for staff. I just wanted  
11 to understand this a little bit better with respect  
12 to the speaker's assertion about the Port-a-Cath  
13 product.

14 So is there a disagreement about how that  
15 was treated under the proposed language by staff?

16 MR. CLAREMON: I mean, I don't -- I don't  
17 know --

18 MS. YEE: Or maybe comment on their  
19 alternative that they proposed. I guess there was  
20 some suggestion that it would have a revenue impact.  
21 And I thought that the application of tax was not  
22 going to change in the alternative that they  
23 proposed. And so I'm just trying to understand what  
24 the revenue impact was about.

25 MR. CLAREMON: So there's Action Item 3,  
26 which is in subdivision (b)(2), which specifically  
27 relates to that statement that Port-a-Caths are not  
28 a medicine.

1 MS. YEE: Yeah.

2 MR. CLAREMON: In that action item we  
3 believe that we're trying to reach the same goal,  
4 which is to say that if they are a medicine in some  
5 other subdivision --

6 MS. YEE: Right.

7 MR. CLAREMON: -- that this wouldn't  
8 exclude them from being a medicine. And that's why  
9 we just want to -- we think the best way to do that  
10 is to remove that statement, "The sale or use of  
11 these items is subject to tax."

12 But going to Action Item 4, we believe that  
13 the recommended language from both interested  
14 parties, Alternative 2 and Alternative 3, if you  
15 were to add this language, which we feel isn't  
16 within the statute, excepting a fully or a fully and  
17 permanently implanted article -- device from (c)(2),  
18 what that would do is it would -- it would allow  
19 Port-a-Caths to be considered a medicine under  
20 (a)(9)(A).

21 MS. YEE: Oh, I see. Okay.

22 MR. CLAREMON: So we do think that the  
23 language in either alternative in Action Item 4  
24 would make a Port-a-Cath a medicine under  
25 (a)(9)(A).

26 MS. YEE: Okay. Okay.

27 MS. MANDEL: Can I just ask him to clarify  
28 something?

1 MS. YEE: Yeah.

2 MS. MANDEL: At the beginning when you were  
3 talking about the (c) provision and taking out the  
4 last sentence that talked about taxable --

5 MR. CLAREMON: Mm-hmm.

6 MS. MANDEL: -- I thought -- I thought what  
7 you were saying was that the items that are  
8 specifically listed in (c), whatever it is --

9 MR. MENDEL: Within (b).

10 MR. CLAREMON: -- (b) -- (b)(2).

11 MS. MANDEL: Oh, it's (b)(2).

12 MR. CLAREMON: Yeah.

13 MS. MANDEL: Okay, wait a second.

14 MR. CLAREMON: It's the last sentence of  
15 (b)(2).

16 MS. MANDEL: I feel like I'm -- and  
17 sometimes this regulation makes me feel like that  
18 Monty Python, my head is stuck in a cupboard and my  
19 brain hurts.

20 I thought what I heard was that there was  
21 some possibility -- maybe I just read it  
22 somewhere -- that the items -- the articles that are  
23 specifically listed, under some circumstances might  
24 be exempt.

25 MR. CLAREMON: Yeah, we agreed with  
26 interested parties. And we believe this is what  
27 they were stating, was that what (b)(2) says is that  
28 it does not meet this definition of medicine, but

1 that it could meet a different definition of  
2 medicine. For instance, it could be a prosthetic  
3 device or an orthotic device.

4 MS. MANDEL: Okay.

5 MR. CLAREMON: So that -- that last  
6 sentence is ambiguous, that we want to remove, in  
7 the sense that it implies that it could not meet  
8 another definition of medicine. And we agree that  
9 it should be removed.

10 MS. MANDEL: And is that the provision  
11 where -- where's the -- which is the provision that  
12 had -- that has "Port-a-Cath" in it?

13 MR. CLAREMON: It's the -- it's that same  
14 paragraph.

15 MS. MANDEL: Oh, okay.

16 MR. CLAREMON: Yeah.

17 MS. MANDEL: Then I just was remembering  
18 the wrong --

19 MR. CLAREMON: Yeah.

20 MS. MANDEL: Okay. So you -- so -- because  
21 when I was looking at this I was thinking, well,  
22 whatever it said in the revenue analysis, the  
23 Port-a-Cath claim is not in front of us. If it ever  
24 comes before the Board, you know, the -- our office  
25 sort of looks at all of the facts and circumstances  
26 in each case, and I was concerned about a ruling one  
27 way or the other.

28 You know, I don't know anything about

1 Port-a-Caths, so I wasn't really prepared to say a  
2 Port-a-Cath is in or a Port-a-Cath is out under  
3 particular circumstances.

4 So you are saying that the staff  
5 recommended change to that paragraph that mentions  
6 Port-a-Caths and all the other things that it  
7 mentions, that you're not -- you're not necessarily  
8 saying that under every single circumstance all of  
9 those things forever are taxable because they might  
10 fit under some other provision.

11 MR. CLAREMON: Absolutely, yes.

12 MS. MANDEL: Including the Port-a-Cath.

13 MR. CLAREMON: Yes.

14 MS. MANDEL: Okay. Thanks.

15 MS. YEE: Mr. Downey?

16 MR. DOWNEY: I -- I was just going to say,  
17 if -- I have a couple comments on the other things.  
18 But if the Port-a-Cath fits some other definition  
19 under (b), then it's exempt under (a)(9)(A) for all  
20 uses.

21 So that doesn't -- if the Board thinks that  
22 there is an exempt use of that product under --  
23 under (b), then it should be exempt under (a)(9)(A)  
24 because that's what the plain language says. It's  
25 exempt for all uses if you have one exempt use.

26 MS. YEE: Get staff to comment on that?

27 MR. CLAREMON: That -- that would -- if  
28 that were the case, that would create somewhat of an

1 ambiguity. Because that's correct, (a)(9)(A) would  
2 make it exempt for all uses but you have a use  
3 that's specifically cited as not a medicine.

4 But the point is that we -- we don't know  
5 of any use, for instance, of a Port-a-Cath that  
6 meets the definition of medicine at this point. If  
7 you were to make the changes recommended in Action  
8 Item 4, Alternative 2 or 3, it -- that would create  
9 -- it would create that -- that use and it would  
10 make a Port-a-Cath a medicine, arguably, for all  
11 uses.

12 MR. DOWNEY: (c) says "except as otherwise  
13 stated in (b)." If (b) specifically says it's  
14 taxable --

15 MR. RUNNER: It's taxable.

16 MR. DOWNEY: -- what's the unclarity?  
17 What's -- what's unclear?

18 MR. CLAREMON: The clar -- yeah.

19 MR. MENDEL: (b) doesn't say it's taxable,  
20 (b) just says Port-a-Caths, when used in these  
21 fashions, are not included in the definition of  
22 medicine.

23 Consistent with (a)(9)(A), in staff's  
24 opinion, that that was overreaching, that there is a  
25 possibility that all of those items listed might be  
26 used in a different fashion that would come within  
27 another section in (b) that would make them a  
28 medicine. And we just didn't want to absolutely

1 preclude that.

2 MS. MANDEL: And -- and the reason -- I  
3 mean he's raising his hand again. But because  
4 you're suggesting taking out -- you're recommending  
5 taking out the sentence that says "sales of such  
6 items are subject to the tax."

7 MR. MENDEL: Yes, exactly. We're -- we're  
8 trying to make it broader, not --

9 MS. YEE: Right.

10 MR. MENDEL: -- not limit it such that  
11 Port-a-Caths will never ever be considered a  
12 medicine no matter how used or how defined.  
13 We're -- we're making it more consistent with the  
14 rest of the regulation which simply defines what is  
15 or is not a medicine rather than setting down "These  
16 are taxable, period."

17 MS. STEEL: Mr. Bholat?

18 Is that okay?

19 Yeah, go ahead.

20 MR. DOWNEY: I was just going to say  
21 isn't -- isn't the whole proposal here that we're  
22 going to specifically address BTMs and we're going  
23 to add BTMs because that's the latest opinion, doing  
24 the exact opposite of what was just discussed?

25 He's saying we don't -- we don't want to  
26 have a specific rule in (b), but all we have are  
27 specific rules in (b). We have all kinds of  
28 products that are specific in (b). And -- and we're

1 proposing to add BTMs to (b), to be specific.

2 MS. STEEL: Let's give --

3 MR. DOWNEY: So it doesn't make sense.

4 MS. STEEL: -- Mr. Bholat a chance to  
5 speak.

6 MR. DOWNEY: Yeah.

7 MR. BHOLAT: From a personal note, I  
8 actually have a nephew who has a Port-a-Cath  
9 implanted in him. And just to give Mrs. Mandel's  
10 question earlier about how it works, basically what  
11 happens is is that there's a catheter  
12 placed inside -- implanted inside the patient of the  
13 body and then it's connected to a vein or a --  
14 usually a large vein.

15 And the reason why it's placed -- and my  
16 nephew has it because he has a serious condition.  
17 And the reason why it's placed is because he  
18 consistently goes through various types of  
19 treatments. And when they do those accesses  
20 consistently, what happens is is that the blood  
21 vessels in the arm or in the leg, wherever they  
22 access it from, gets damaged. So the -- the patient  
23 then has to go through significant pain, difficulty,  
24 and it's damaging the patient.

25 So the Port-a-Cath is put in to assist and  
26 facilitate the blood system so that it isn't damaged  
27 during the treatment process. So there is a  
28 component of what it does.

1           The other thing that I would like to add  
2 is -- which is confusing, and -- and this is the  
3 struggle that I've had. Because in dealing with --  
4 when we prepared this claim -- and it's being held  
5 under abeyance currently because we're waiting for  
6 this -- this decision. Staff and the refund section  
7 has basically said, well -- and they went back and  
8 forth in this whole process. They were -- first,  
9 they were saying, "Yes, we believe it's exempt."  
10 Then they were saying, "No, we don't." Then they  
11 were saying, "Yes." And then they were "No." Then  
12 they said, "We don't know."

13           The challenge is that when you list a  
14 specific item in the regulation, in the implant  
15 section, and say that doesn't meet the definition of  
16 a permanent implant, if you only read part of that  
17 sentence and you only read that specific product,  
18 which is what the confusion comes about, then staff  
19 is going to say, well, we don't really know, so  
20 therefore we're going to treat it as taxable.

21           Because if you read the sentence or that  
22 paragraph, those items are specifically included.  
23 And when you have that item that's permanently  
24 implanted in that permanent implant paragraph, it  
25 creates a circular, a circular reference. And  
26 what's the answer? We don't really know.

27           And that's what we -- that was our  
28 objective in adding that portion in the bottom of

1 (b) was to say that this section only applies to  
2 items that are temporarily implanted or not fully or  
3 permanently implanted. And that was our  
4 objection -- or our objective.

5           Maybe there's a way to improve the language  
6 that staff can live with, but we see this problem  
7 and -- and going about their resolution of saying,  
8 well, it may qualify under some potential, possible  
9 exemption later on, is going to be counter-intuitive  
10 to what staff and what the field auditors are going  
11 to do.

12           MS. YEE: Madam Chair.

13           MS. STEEL: Yes, Ms. Yee. Member Yee.

14           MS. YEE: I think the confusion arises from  
15 the intent of these -- well, actually the intent of  
16 this regulation is to define what constitutes  
17 medicine for then the application of tax. It's not  
18 meant to be an exhaustive listing of products to  
19 which we would then say tax is applied or not.

20           And I think what staff has done is actually  
21 quite -- I think it's to your favor in terms of  
22 really trying to preserve some ability to look at  
23 perhaps some use of the Port-a-Cath that may not be  
24 subject to tax down the road.

25           And I guess as I'm looking at some of the  
26 proposed changes, I just want to have us keep in  
27 mind that this really is about what constitutes  
28 medicine. And as we look then at reading

1 subdivision (a) paragraph (9) subparagraph (A) and  
2 how we've placed -- and directed really the --  
3 whoever's going to read the regulation about how to  
4 determine what constitutes a medicine, I think it's  
5 a pretty good roadmap with respect to how you look  
6 and relate the various subdivisions.

7           So I'm -- I'm a little concerned about some  
8 of the suggestions that I believe adds confusion.  
9 But I think if we keep a mind of what we're trying  
10 to do here is to really clarify what constitutes  
11 medicine and then really -- and I think the staff  
12 took it a step further in terms of whatever's -- our  
13 latitude under the statute in terms of then  
14 understanding that there could be some use of  
15 particular products that may be exempt from tax down  
16 the road.

17           So I do believe the staff alternative  
18 accomplishes all that and some of the concerns I've  
19 had about the alternative language really buries, I  
20 think, the -- some elements of the roadmap that  
21 would lead one to read this regulation to where they  
22 really do have to kind of dig into a particular  
23 subdivision before understanding that, oh, we've got  
24 to look at another related subdivision to see  
25 whether, you know, that really is more instructive  
26 than the initial (a)(9)(A).

27           So I'm -- I'm -- I'm going to support the  
28 staff regulation. But I think the -- my main

1 concern was really whether there was a  
2 misunderstanding with respect to how we're looking  
3 at the Port-a-Cath product and the application of  
4 tax currently. But that wasn't really the intent of  
5 the -- of this rule change after the hearing. It  
6 was really to reflect our decision with respect to  
7 the breast tissue markers. And, again, this is a  
8 regulation that -- that guides us with respect to  
9 what constitutes medicine, and I think it works with  
10 respect to the interaction between the various  
11 subdivisions.

12 MS. STEEL: Thank you.

13 Any more comments?

14 MS. MANDEL: Yeah.

15 MS. STEEL: Member Mandel.

16 MS. MANDEL: I just have one sort of  
17 language question. And I know you lump all of the  
18 Downey languages, you know, sort of like it was one  
19 alternative, but I have a question about the  
20 (a)(9)(A). And I thought I had -- that -- that --  
21 where some of this started was that there -- that  
22 the existing language which you all would leave, the  
23 staff would leave -- "except where taxable for all  
24 uses as provided in subdivision (c)" -- I thought  
25 someone had said somewhere along the line that that  
26 was a little bit -- that that phrase was a little  
27 confusing.

28 And if (c) is a "these things are

1 specifically excluded," my question was kind of  
2 why -- whether you put it at the beginning of the  
3 sentence so that somebody will stop reading and go  
4 down to (c) first, or at the end of the sentence so  
5 they'll remember to go down to (c) and read (c)?  
6 Why the language about "unless an item is  
7 specifically excluded from the definition under  
8 subdivision (c)" -- I don't know about this "for all  
9 uses" -- I was just wondering if it was a -- if you  
10 had some issue with more clear language on that  
11 phrasing or if you think that -- if you gave thought  
12 to changing the words?

13 MR. CLAREMON: We -- we did actually. And  
14 I think staff's first recommendation was to move  
15 it.

16 MS. MANDEL: But you were just moving the  
17 same words.

18 MR. CLAREMON: We were. And I'd have to go  
19 back and look, but we may have actually changed it  
20 from "except" to "unless."

21 But there were actually during, I think,  
22 the first interested parties meeting it seemed to  
23 create more confusion moving it than leaving it  
24 where it was. And it seemed to create the  
25 impression that we were changing it and we weren't  
26 trying to change it.

27 And that's why, leading up to the second  
28 interested parties meeting -- and -- and we actually

1 thought we were in agreement on that point with  
2 interested parties. But that's why leading into the  
3 second interested parties meeting we thought we  
4 would leave it where it was because it was as clear  
5 as it could be.

6 MS. MANDEL: So you -- you didn't -- did --

7 I guess my question on words is whether  
8 you -- you gave thought to saying, um --

9 Oh, I see. So you're just saying that you  
10 were concerned that if you changed the words at all  
11 even if you changed it to make -- to say  
12 "specifically excluded from definition of medicines  
13 under (c)," that people would think somehow that was  
14 materially different --

15 MR. CLAREMON: That what we've seen --

16 MS. MANDEL: -- than what was there before,  
17 and so that you were just better off leaving it the  
18 way it was.

19 MR. CLAREMON: We didn't want to signal  
20 that there was a change. Yeah.

21 MS. MANDEL: Okay, okay. I think that that  
22 was the only other question that I had.

23 Yeah, okay. Thank you.

24 MS. STEEL: Member Runner.

25 MR. RUNNER: Yeah, let me -- let me start  
26 with the -- again, this whole discussion is trying  
27 to figure out -- well, I find it interesting our  
28 concern is that we don't want to create ambiguities.

1 And it seems to me that's what this session is all  
2 about in regards to ambiguities that we're  
3 struggling with that were already existing.

4 And so my concern is that are we actually  
5 missing an opportunity to give greater clarity  
6 long-term? And I'm concerned about if we are  
7 parsing and piecemealing this too tightly, that  
8 all's it's gonna do is just add for a series of  
9 future appeals and us clarifying issues one at a  
10 time. And, you know, I don't think that does us any  
11 good. I don't think it does the state any good, and  
12 it certainly doesn't -- think it does folks who are  
13 trying to interpret and understand the, uh -- the  
14 law and the regulation any good.

15 Let's -- let's start with the idea of the  
16 statute. Because clearly the bedrock of what the  
17 concern is, is this is extra -- this just goes  
18 beyond the intent of the statute.

19 I've got -- point -- can you help  
20 me find -- point to me where you believe this is --  
21 goes beyond statute in regards to if we were to  
22 accept the language that is -- is -- has been  
23 recommended.

24 MR. MENDEL: In the statute, in subpart (b)  
25 of the statute --

26 MR. RUNNER: Okay, (b), uh-huh.

27 MR. MENDEL: -- starts about discussing  
28 substances of preparations. And then the last line

1 of (b) says:

2 "However, medicines does not include  
3 any of the following..."

4 And (2) of that reads:

5 "Articles that are in the nature of  
6 splints, bandages, pads, compresses,  
7 supports, dressings, instruments,  
8 apparatus, contrivances, appliances,  
9 devices or other mechanical electronic  
10 optical or physical equipment or article or  
11 the component, parts or accessories  
12 thereof."

13 MR. RUNNER: Okay.

14 MR. MENDEL: And then it goes down to (c),  
15 similar to the way the regulation is set up,  
16 notwithstanding what I just read.

17 MR. RUNNER: Mm-hmm.

18 MR. MENDEL: "Medicines as used in the  
19 section includes any of the following ..."

20 And --

21 MR. RUNNER: Okay.

22 MR. MENDEL: -- number two is:

23 "Bone screws, bone pins, pacemakers and  
24 other articles, other than dentures,  
25 permanently implanted in the human body to  
26 assist the functioning of any natural  
27 organ."

28 And then down again in (4) "Prosthetic

1 devices and replacement parts" --

2 MR. RUNNER: Okay.

3 MR. MENDEL: -- "for those devices designed  
4 to be worn on or in the body of the user to replace  
5 or assist the functioning of the nature of a natural  
6 part of the human body."

7 MR. RUNNER: Okay.

8 MR. MENDEL: Those two phrases are what we  
9 see as being the key restriction.

10 MR. RUNNER: Well, wouldn't this, under  
11 your definition then, make our decision in regards  
12 to the -- the markers outside the definition of the  
13 law?

14 MR. MENDEL: We are inter -- trying to  
15 interpret the definition of markers narrowly based  
16 more on their function, that they are -- as was  
17 discussed at the Board hearing; that in fact they  
18 are a technological advance that is replacing  
19 something that used to be done with dyes and other  
20 substances that were injected. And so rather than  
21 say, well, we have to change the --

22 MR. RUNNER: Are you trying to artfully get  
23 through how to make markers work?

24 MR. MENDEL: Yes. We are trying to  
25 artfully get through how to make markers work.  
26 However --

27 MR. RUNNER: Within the statute.

28 MR. MENDEL: With the statute.

1 MR. RUNNER: Okay.

2 MR. MENDEL: We felt that global changes to  
3 (c) that were suggested by the interested parties  
4 would simply eliminate those restrictions in the  
5 statute.

6 MR. RUNNER: But isn't the -- I guess my  
7 concern is, and that's why I'm concerned that we're  
8 opening up the door for a series of appeals.  
9 Because I think the Board has pretty consistently  
10 dealt with these permanently implanted medical  
11 devices. And it seems to me every time we've been  
12 including them. And so I'm concerned that the next  
13 time you're going to have to artfully do it again.

14 MR. MENDEL: I'm -- I'm afraid that to  
15 avoid artfully doing it would require a -- a  
16 legislative change to actually --

17 MR. RUNNER: So what line was -- hold it.  
18 So the next one that comes that we're going to ask  
19 you to do creates a legislative -- a statute  
20 dilemma. This -- the -- the last one we did didn't.

21 MR. MENDEL: That was our opinion, yes.

22 MR. RUNNER: So is it just by the number of  
23 'em we ask you to look at?

24 MR. MENDEL: No. It's -- it's in the  
25 nature of medical devices. Each --

26 I mean when we look at a device, we look at  
27 that very specific device. We look at how it's  
28 used, what it's used for. We look at whether it's

1 simply replacing something that has already been  
2 found to be a medicine. We have traditionally tried  
3 to move the statute and regulation along with  
4 technology the best we can without violating the  
5 statute, by not reading the statute so literally  
6 that a technological advance will, every time,  
7 require a legislative change.

8 MR. RUNNER: Okay. Let me go back to the  
9 taxpayers or the representatives here in terms of  
10 that and -- and ask specifically in regards to --  
11 because, again, I -- I mean it seems to me I see  
12 room in the statute for some broader definitions  
13 than what it is that I'm hearing from the staff.

14 So help -- from -- from your perspective,  
15 why would you believe the staff is too narrowly  
16 interpreting the statute, going back to the statute?

17 MR. DOWNEY: I think that it's the use of  
18 "diagnose, cure, treat, mitigate, prevent disease,"  
19 that that broad language of a product that does that  
20 as -- as defined in (a)(9)(A) defines medicine. And  
21 that definition is something that we should be able  
22 to rely on in determining taxability.

23 And, you know, one thing that hit me is  
24 they were reading the list of products in little (c)  
25 and one point of confusion we had is what -- as we  
26 discussed this issue with -- with all of you and  
27 staff, there's nothing in that list that tells us or  
28 tells a taxpayer that we're trying to exclude an

1 implant.

2 MR. RUNNER: Right.

3 MR. DOWNEY: There's nothing there. It  
4 actually is all external things. It's all things  
5 used to treat, etcetera.

6 So, that's one of the challenges we have is  
7 that really it looks like (a)(9)(A); statutory basis  
8 is 6369(b). And there's a couple products --  
9 there's a -- there's a product -- there are a  
10 handful of products currently that fit within this  
11 definition.

12 One of the ones we've seen recently are not  
13 being taxed by medical manufacturers, they're not  
14 being taxed by hospitals, and they're a diagnostic  
15 product that is implanted into the patient to  
16 monitor heart failure. And that product tracks  
17 blood flow, tracks heart rate, tracks all of these  
18 things to help physicians diagnose. And so unlike a  
19 pacemaker that would zap the heart when it stopped  
20 working, it sends the information to a physician and  
21 it says, hey, it's time to replace that valve  
22 because we're not getting the flow that we need.  
23 There's a stroke that's coming. There's a --  
24 there's a heart attack that's coming. And -- and so  
25 it seems like, as --

26 Is it "Larry"?

27 MR. MENDEL: Yes.

28 MR. DOWNEY: Yes. So it seemed like as

1 Larry defined the statute, he would say, well,  
2 clearly we could fit that under the regulation  
3 because that's a medical advance, right, that --  
4 that is changing something that we've done in the  
5 past. We -- we would, you know, do an angioplasty  
6 which is exempt, or we would replace a valve which  
7 is exempt. But this -- this diagnostic unit that  
8 doesn't assist the body function but helps us to  
9 make sure and diagnose when it's failing, that that  
10 product would be taxable and I don't think that is  
11 the case.

12 And Larry would say, well, if it came  
13 before of you, you probably would argue it's exempt  
14 because that's a technological advance that would  
15 have otherwise been an exempt product if we would  
16 have done it differently than we're doing it today.  
17 And I think that's the concern.

18 So that's one of the products that's out  
19 there. There are two, maybe three, other products  
20 that we can come --

21 I represent one of the largest medical  
22 supply vendors. They sell a hundred thousand  
23 different products. And we're talking about --  
24 we're broadening the regulation to exempt three or  
25 four products that -- that they sell? How -- how  
26 broad are we making this?

27 And the -- the one thing that with our  
28 clarity is that we're okay if the Board wants to tax

1 an implant that does not assist a body function,  
2 let's just say that in little (c). Add a sentence  
3 and say, hey, guys, you're reading this and I know  
4 it's talking about hospital beds, etcetera, but we  
5 really intended this to cover implants that don't  
6 assist a body function and are not covered by (b).  
7 And staff said, well, we wouldn't add that because  
8 that's not what the Board wants to do, or at least  
9 that's the way I interpret it. And that's where the  
10 confusion and maybe frustration came throughout this  
11 process.

12 MR. RUNNER: Okay. I mean my -- my concern  
13 is that, again, it seems to me that the first part  
14 of the definition of medicines give us some pretty  
15 broad ability to do some interpretation. And  
16 clearly, apparently so does -- so -- so -- so does  
17 Legal and the Department because you were able to  
18 tuck in the breast markers into that -- into it.

19 And so I'm having -- struggling with the  
20 idea as to why it is that the next one goes too far  
21 when it is that we've already defined some -- our  
22 ability to interpret it legally to include those --  
23 the markers.

24 I'm much more comfortable with a much --  
25 with a broader understanding of "permanently  
26 implanted." I think that's gives clear definition.  
27 I think it fits under the -- under -- under the  
28 definition of medicines in -- in -- in little (b).

1 I think -- and, again, I get the idea, although I  
2 don't agree with it, quite frankly, the Port-a-Cath  
3 is an interesting issue.

4 I do believe that it's -- I -- I -- I find  
5 it curious that we would go ahead and add it to the  
6 economic analysis even though the regulation  
7 excludes it. You know. And with the idea that  
8 said, well, we must have to include it then if we  
9 change that.

10 MR. DOWNEY: Well --

11 MR. RUNNER: No, then we'd have to go back  
12 and change that. I -- I -- I think. Wouldn't we  
13 have to actually change the regulation to --

14 MR. MENDEL: The way -- the way we read  
15 their change to (c) --

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1 MR. RUNNER: Huh-uh.

2 MR. MENDEL: To include all permanently  
3 implanted articles as medicines we believe would  
4 simply make most of those restrictions in B moot  
5 because --

6 MR. RUNNER: But doesn't -- isn't  
7 Port-a-Cath specifically called out, though, later?

8 MR. MENDEL: No. Port-a-Caths are  
9 listed -- Port-a-Caths, as used in certain  
10 applications, are listed as not being a medicine  
11 under one part of B. However, if you change C -- if  
12 you fundamentally change C to include all  
13 permanently implanted devices, it essentially makes  
14 B moot because it says regardless --

15 MR. RUNNER: We wouldn't have the ability  
16 to actually create that broader and then list  
17 exceptions? That would be wrong?

18 MR. MENDEL: Not the way it's currently  
19 written.

20 MR. RUNNER: I mean --

21 MR. MENDEL: We would have to restructure  
22 the -- the -- we would have restructure the  
23 regulation.

24 MR. RUNNER: Okay. I can -- it's -- I  
25 mean, again -- it's an interesting reach. I'm not  
26 sure I'm there with you.

27 Quite frankly, I'm -- I have a basic issue  
28 with the Port-a-Cath issue because you all know

1 Sharon, she's got a Port-a-Cath. It's very clear  
2 it's part of her medical treatment. It's part --  
3 it's a medicine. She has to live with it.

4 So, the whole idea that it's excluded and  
5 separate to me doesn't even make sense. I intend to  
6 say it's a pretty fundamental part of what I would  
7 to go the definition of medicine of medicine and to  
8 try to nuance that it seems to me a bit trivial.

9 So, anyhow, let me -- let me just -- let me  
10 ask this question just to clarify because we have --  
11 we have two different proposals with some language.

12 And for myself, I'd like to kind of get an  
13 idea with the DSF language, that -- and the  
14 difference, the DSF language, and then also then the  
15 language from -- I'm sorry --

16 MR. BHOLAT: Equity.

17 MR. RUNNER: -- Equity, yes.

18 What is the unique nuances between those --  
19 that language and -- and can -- how -- I mean, I  
20 think one of it goes down to the specific issue of  
21 the Port-a-Cath anyhow.

22 So, let me -- let me just ask --

23 MR. BHOLAT: Our proposed language is, I  
24 think on (a)(9)(A) and on C, our language is fairly  
25 similar. The words are slightly tweaked  
26 differently.

27 In Section B, what -- what our proposal is  
28 is to provide clarity that when you're listing --

1 that when the Board lists those products in that  
2 regulation, that that section only applies to  
3 temporarily implanted items.

4 MR. RUNNER: Okay.

5 MR. BHOLAT: Because when you read the  
6 paragraph it says, "permanently implanted items,  
7 exclude this, this and this."

8 MR. RUNNER: Okay.

9 MR. BHOLAT: And then it says, "Sales tax  
10 applies to these items."

11 Staff, when we're dealing with auditors and  
12 staff in the field, they read that and they say,

13 "Well, sorry, Jacob, this item  
14 is specifically listed in the regulation.  
15 There is no way that this product is  
16 exempt, period."

17 Without even further analyzing it.

18 And that -- that's the reason why we  
19 proposed the language to add, when -- the sales tax  
20 is not applied or sales tax would apply, or however  
21 we want to structure it -- that when it's  
22 permanently implanted that it meets the definition.

23 MR. RUNNER: Okay.

24 MR. DOWNEY: Our proposal does not  
25 contemplate any change to little (b).

26 MR. RUNNER: Uh-huh.

27 MR. DOWNEY: And our participation in this  
28 process was not trying to exempt any particular

1 product.

2 MR. RUNNER: Okay.

3 MR. DOWNEY: But it was to come here to  
4 clarify it.

5 So, if you look at C, C starts, "as  
6 provided" -- "except as provided in B."

7 Well, if it's already provided in B that  
8 it's taxable, there is no uncertainty.

9 But what does become uncertain, and what we  
10 think needs to be clarified, is as you read on,  
11 there's nothing in C(2) that tells you we're  
12 intending to exclude an FDA-approved implant that is  
13 used to diagnose, cure, mitigate or prevent disease.

14 And, so, whether you -- whether you want  
15 that to be taxable or you -- or you don't or you  
16 want it to cover it or not, we think that there  
17 should be language added to that section to take  
18 away that uncertainty.

19 Because I don't know if you remember --

20 MR. RUNNER: That's good.

21 MR. DOWNEY: -- yeah.

22 MR. RUNNER: That's fine.

23 MR. DOWNEY: Yeah.

24 MR. RUNNER: So, let's just ask this  
25 broader question, and this is what -- again, I had  
26 mentioned my concern and that is that I'm concerned  
27 that if we again adopt specifically the staff  
28 language -- recommended language, that we create

1 additional ambiguities that are going to create  
2 additional appeals and we're going to be talking  
3 about these things, you know, many, many times in  
4 the future.

5           You represent -- you -- you all provide,  
6 you know, tax consultation and representation on  
7 these issues for these kinds of devices.

8           How do you see that? Do we have a chance  
9 to create clarity here? Or if -- that would -- that  
10 would make it easier and better for those taxpayers  
11 in the field to actually know what the law says? Or  
12 if we -- or are we actually opening the door for  
13 additional time and appeals and --

14           MR. DOWNEY: I think the real issue here --

15           MR. RUNNER: -- ambiguities?

16           MR. DOWNEY: -- the real issue here is  
17 clarifying how industry and vendors are applying  
18 (a)(9)(A).

19           You look at the major vendors that sell  
20 medical products that don't replace a body function  
21 but are implanted, they read (a)(9)(A) and they  
22 exempt those products and the sale of those  
23 products.

24           And, so -- and that's -- that's what we  
25 see.

26           And, so, what we're creating is a situation  
27 that -- where -- how everybody reads this regulation  
28 that that's not the way staff is reading it.

1 And, so --

2 MR. RUNNER: Okay.

3 MR. DOWNEY: -- you're going to have a  
4 series of appeals.

5 MR. RUNNER: Again here my concern is that  
6 again I think there's a concern about creating a  
7 broader interpretation.

8 I think there's a concern as to whether or  
9 not it's within statute authority.

10 But I also believe what we're going to find  
11 is -- if I was to guess, based upon what's come  
12 before us so far, what came before us -- before this  
13 Board before I was here, we usually end up finding  
14 and expanding the intent -- or finding -- finding  
15 reason to -- to -- to include these devices.

16 I think the nature of the Board would  
17 probably be that in the future and I think it's  
18 unfortunate, though, that if we don't have this  
19 opportunity now to clarify the language, we're going  
20 to end up with a series of piecemeal attempts in the  
21 future to try to fit them into the statute.

22 So, thank you.

23 MS. STEEL: Mr. Bholat.

24 MR. BHOLAT: Yeah, I think -- to answer the  
25 question that you asked earlier --

26 MR. RUNNER: Uh-huh.

27 MR. BHOLAT: -- as far as our  
28 recommendation to simplify the language or the

1 approach and that is when -- when -- when a  
2 hospital, a retailer of medical products, determines  
3 the taxability, generally what they do is they put  
4 them into different categories.

5 And the broader the category -- some  
6 products fit into multiple categories, but a very  
7 broad category is a permanent implant.

8 And if the Board here can decide that we're  
9 going to either -- we can provide an exemption for  
10 anything that's permanently implanted, it's  
11 obviously got -- in order to qualify under 1591,  
12 it's got to be under a doctor's orders, it's got to  
13 be under prescription, it's got to meet all those  
14 definitions.

15 So, we still are working within a  
16 hospital/doctor setting. Anything that's  
17 permanently implanted into a patient is exempt. And  
18 that's the simplest way to approach it.

19 MR. RUNNER: Yeah, thank you.

20 MS. STEEL: Thank you.

21 Chairman Horton.

22 MR. HORTON: Members, I think what we face  
23 here is a historical challenge that the Board has  
24 had dating back to when the regulation was initially  
25 passed.

26 And the inherent challenge is whenever we  
27 begin to delineate specific items as being exempt,  
28 we run into a potential file of -- of -- going

1 beyond our authority in doing so and after counter  
2 interpreting the statute in itself, which brings  
3 concerns to me as to whether or not the Office of  
4 Administrative Law is going to approve a regulation  
5 that actually specifically exempts anything.

6 Because the law -- the statute itself  
7 intentionally set forth conditions in which an item  
8 would be considered medicine.

9 And I, quite frankly, think the Board was  
10 correct in its interpretation of the statute. And  
11 therein is the inherent challenge that we face,  
12 because the statute, in my mind, is very, very  
13 clear.

14 It is when the facts and the functionality  
15 of the item before us, whether it fits within the  
16 statute or not, is the determination that we have to  
17 make.

18 And, so, what seems to have happened in the  
19 case before us is is that staff in the field failed  
20 to look at the essence of the law and possible --  
21 you know, my thoughts was is that we would give  
22 staff additional directions that would basically say  
23 is that staff -- Section 6369 governs, irrespective  
24 of whether this is -- irrespective of what the  
25 regulation says.

26 And when we get into these specitivities  
27 (sic), we run into an a challenge of running into --  
28 afoul of the statute itself.

1           Why -- you know, part of me is saying what  
2 we really need here is clarification in the audit  
3 manual. And that whenever we embark upon adding and  
4 subtracting things to the regulation, all we're  
5 really -- without going in and saying, well, as long  
6 as this -- as long as it's -- it does what is  
7 prescribed in the statute, it diagnoses, cures,  
8 mitigates, is a treatment, it's prevention of a  
9 disease and lah di dah di dah, we're still  
10 referencing back to that language, even in the  
11 regulation, which is the language -- the inherent  
12 intent of the statute.

13           And, so, years ago when the Board  
14 started -- came up with pamphlet, I believe 61, and  
15 tried to delineate all these different things that  
16 are medicine and not medicine, they recognized that  
17 they were -- they were running into this problem  
18 articulated by Mr. Runner that every time an item  
19 comes up we have to try to determine if this item is  
20 medicine or not, when that is not the determination.

21           The determination, I think, is whether or  
22 not it functions as a medicine as prescribed in the  
23 statute.

24           And, so, these templates are going to cause  
25 these problems. And every time we add something  
26 it's just going to have an inherent problem in the  
27 field.

28           As Mr. Downey indicated, there's another

1 million products. So, do we list all of those  
2 products in the regulation? Quite frankly, I think  
3 we don't.

4 I think we -- I think the statute is clear.  
5 I think if we want to give guidance to the staff, we  
6 give it to them, as we have traditionally done, in  
7 the audit manual. And that guidance is basically to  
8 go back to the statute.

9 And, if -- and evaluate the facts and how  
10 this particular item functions. And if it functions  
11 in accordance with the statute, then it's exempt.  
12 If it doesn't, it's taxable.

13 And, so, you know I'd ask staff to take  
14 another look at this altogether and -- and --  
15 because, I mean, I read both -- all three  
16 alternatives and they're all concerning to me as to,  
17 you know, they all create more confusion when, in  
18 fact, the statute is just very, very clear, you  
19 know, as to when something is considered a medicine.

20 I think industry practice creates a problem  
21 because they seek to establish these templates that  
22 says, oh, here's a list of items. If it falls in  
23 this category, it's easy.

24 Interpreting the law was never meant to  
25 eliminate professional judgment in the process.  
26 And, so, I think we stay with that professional  
27 judgment, stay with that evaluation and stay with  
28 the statute and just bring some clarity in the audit

1 manual to make sure that the auditors are aware of  
2 the cases that have come before the Board of  
3 Equalization and where that distinction has occurred  
4 is not the law.

5 I think we are clear on the law. I don't  
6 think you have to figure out a way to justify what  
7 the Board has said. I think we're clear. We said  
8 that this -- this item is part of the diagnostic  
9 process that leads to the cure and mitigation of a  
10 disease, cancer. That's it, that's all we do.

11 And we said -- also said that the staff's  
12 interpretation of the statute was wrong and their  
13 application was wrong.

14 And, so, that's where we need the  
15 clarification and those types of clarifications  
16 occur in the audit manual and not the regulation.

17 I see everyone nodding their head, so, that  
18 would be my advice.

19 MR. DOWNEY: I -- that right there provides  
20 more clarity than any proposal that we have.

21 And I think we were talking before this  
22 meeting that the direction of what the -- what the  
23 Board wants and how they want to apply to products  
24 is what we, trying to interpret this, needed to  
25 hear.

26 And that explanation of, look, if a product  
27 is used in the diagnostic process, implanted,  
28 et cetera then, you know, we can't just say, hey, it

1 says article in C and it's excluded.

2 And that's our only purpose of coming here  
3 is that we don't want this "or article" held over  
4 our head and I think that provides clarity.

5 MR. HORTON: Yeah. Mr. Downey, at the rate  
6 we're going, it won't be implanted, it won't be on  
7 the outside, it will up in the stars somewhere, you  
8 know, that is helping these patients as they walk  
9 around. You know, but even when that occurs, this  
10 statute will be sufficient, if properly  
11 interpreted.

12 MS. STEEL: So, Mr. Chairman, what you're  
13 suggesting you want staff to go back and bring it  
14 back with the broader definition of this regulation,  
15 proposed regulation? Or what your exactly  
16 suggestion -- your suggestion is?

17 MS. YEE: May I?

18 MS. STEEL: Yes, Member Yee.

19 MS. YEE: I concur with Mr. Chairman's  
20 approach about -- and certainly understanding the  
21 speakers concerns about how our audit staff will be  
22 interpreting, applying this regulation.

23 But I do think where that guidance should  
24 occur is in our audit manual and to perhaps use that  
25 as a means of providing our audit staff with more  
26 clarity about the application of -- of this  
27 particular regulation.

28 I -- I hope you weren't suggesting,

1 Mr. Chairman, that we bring this entire process  
2 back --

3 MR. HORTON: No.

4 MS. YEE: -- because I'm prepared to adopt  
5 the staff recommendation, but direct staff to really  
6 look at where there are opportunities to provide  
7 that clarity in the audit manual.

8 MS. MANDEL: Yeah, because the taxpayers  
9 are going to look at the regulation first.

10 MS. YEE: Uh, I --

11 MS. MANDEL: That was part of the purpose  
12 was to --

13 MS. YEE: -- yes.

14 MS. MANDEL: -- right?

15 MS. YEE: Yes, yeah.

16 And I believe the regulation in terms of  
17 how it's structured and how the different  
18 subdivisions interact with one another is clear.

19 I also think the staff really stretched to  
20 the extent possible under the statute to really  
21 preserve the option of how some of these products  
22 may be characterized with respect to the application  
23 of tax going forward.

24 So, I'm -- I think we've gotten that  
25 flexibility. And I know it may not feel that way  
26 for the speakers, but I think they really did try to  
27 address that issue.

28 But I think where the clarity is and where

1 we don't want to see, frankly, additional appeals  
2 over just the ambiguity of how this is going to be  
3 applied is by providing that guidance to our staff  
4 through the audit manual.

5 MR. HORTON: Well -- thank you, Member Yee.

6 I -- I could adopt staff's recommendation,  
7 but I think we're continuing down that path of  
8 modifying the regulation every time a situation  
9 comes and sort confuses staff.

10 MS. YEE: Yeah.

11 MR. HORTON: And, quite frankly, I don't  
12 think we need to touch it.

13 And that that clarification can be provided  
14 in the audit manual. And I think subsequent  
15 training of our staff, as it relates to interpreting  
16 the law and the regulation, might be helpful as well  
17 is that you have to interpret it in its entirety.

18 And my experience in the field -- and I'm  
19 sure many others as well -- is that it takes -- you  
20 know, it isn't until you're seasoned a little bit  
21 that you -- that you begin to look at the essence of  
22 the law and the regulation and -- in your  
23 interpretation. And if they're taught to do that  
24 earlier on in their careers, it might be helpful.

25 And I just harken back to all those changes  
26 over the years to the definition of medicine and  
27 this is included that's not included. And I really  
28 think that created -- got us to where we are today.

1           And, so, it's a double-edged sword whether  
2 we continue along those lines or just leave the  
3 regulation alone would be my advice and just to --  
4 'cause it's not an issue of law, in my opinion.

5           In my opinion this is an issue of facts,  
6 whether it is function -- whether it functions in  
7 accordance with the statute or not. And it's fact  
8 driven, not legally driven.

9           And I would imagine that the only reason  
10 there is like one of these cases before us is  
11 because a whole lot of other auditors and  
12 supervisors and District reviewers and Appeals folks  
13 got it right when it came before them.

14           This one they just got it wrong and it just  
15 got through the system because it was so unique and  
16 so new in the minds of our team. And, for some  
17 reason, we got off the statute, but --

18           MS. MANDEL: Well --

19           MR. HORTON: -- that would be my --

20           MS. STEEL: Member Runner.

21           MR. RUNNER: Well, again, I don't have any  
22 issues with the idea of trying to get clarity in the  
23 audit manuals.

24           The only trouble is I don't think an audit  
25 -- clarity in the audit manual changes somebody's  
26 decision to appeal, based upon what they believe is  
27 incorrect interpretation of either the -- or  
28 application of either the regulation or the statute.

1           So, I think that's really what we're  
2 talking about. So, I -- I don't have any issue with  
3 us stepping back, taking another look at this.

4           You know what -- if -- does this actually  
5 solve a problem or does it create a broader problem?  
6 And just -- and just try to re-examine it, asking  
7 the broader questions again.

8           Because, again, I'm concerned about us  
9 adopting a regulation right now that again creates  
10 greater angst and ambiguity rather than clarity.

11           And I couldn't tell you right now if we --  
12 I mean, if indeed the current law -- regulation  
13 is -- doesn't need to be changed and there's enough  
14 room for interpretation given what's there and can  
15 be clarified in the audit manual, I don't know.

16           But maybe a broader steep back would be --  
17 and a little more time on this could be helpful.

18           Comment?

19           MS. STEEL: Chairman Horton.

20           MR. HORTON: Mr. Runner.

21           MR. RUNNER: I think he had a comment  
22 on it.

23           MR. DOWNEY: I was just going to say that I  
24 think with the advice and direction that you gave  
25 that one of the challenges that both of our sides  
26 have had during this interested parties discussion  
27 is that I don't think we were certain on what your  
28 direction was.

1           And I think it is interpreted to be a  
2 little bit different than where we each were. And,  
3 so, it's hard to reach language when you both  
4 disagree.

5           I am -- I don't see anything that you said  
6 that is inconsistent with what our objectives are to  
7 clarify this reg. And, so, it would seem like we  
8 could reach -- we could work together to come up  
9 with language, unless the Board is saying -- or  
10 unless staff is saying, no, absolutely everything  
11 you said is exactly consistent with what we proposed  
12 here.

13           And then I'd say, "Well, should probably  
14 adopt Alternative 2 because nothing's going to  
15 change."

16           MS. STEEL: Chairman Horton.

17           MR. HORTON: Well, I think, we -- I mean,  
18 we are very fortunate to see the exceptions that  
19 happens out there in the world -- in the audit  
20 world. We see the exceptions.

21           I mean, I have personally conducted these  
22 audits and personally thought that many of the items  
23 that were not where listed in pamphlet 51 -- 61 and  
24 not listed somewhere in the regulation, was exempt  
25 because it met the definition of medicine and that  
26 that was what was governed.

27           And I would, quite frankly, say that  
28 relative -- we don't have a whole lot of appeals

1 coming because folks are doing it right out there  
2 and that they are interpreting it right.

3 And I believe the parties can work  
4 together. But where we position this clarification  
5 of facts and interpretation -- we're not talking  
6 about changing the law -- I think everyone is in  
7 agreement that the law is clear. We all understand  
8 it. We all understand the law.

9 The interpretation of the facts is where  
10 we've got a problem. And, so, we're trying to  
11 somehow codify something that tells folks what set  
12 of facts will lead to a certain conclusion. When,  
13 in fact, we all know that facts is one of the things  
14 that change on a regular basis.

15 And, so, I don't know, Members, I just am  
16 very careful not to govern based on the exception  
17 and try to govern based on the rule.

18 MS. MANDEL: Ms. Steel?

19 MS. STEEL: Yes, Member Mandel.

20 MS. MANDEL: It's -- it is a complicated  
21 regulation. And my recollection was that part of  
22 when the regulation came out in this long way that  
23 it is was that there were a lot of annotations and  
24 that it was, in part, to try to get things out of  
25 the annotations and into the regulations so that  
26 everybody would know -- you're nodding yes, I  
27 remember something correctly today, yay.

28 And my sense of what staff was trying to do

1 in what they're recommending is clear up some things  
2 that -- that the discussion and interested parties  
3 meeting made staff realize that there were areas  
4 that could be clarified. Like we talked about you  
5 guys recommending dropping the forever taxable  
6 language because it wasn't quite accurate and some  
7 of the discussions of interested parties meetings  
8 and things that staff has seen through looking at  
9 products meets that.

10 People do write in and ask for advice on  
11 new products. I think they're probably continuing  
12 to do that, in large part, you know, because of  
13 6596. They want to know.

14 So, I -- I don't -- it doesn't -- and I  
15 thought that the Board had wanted to see the tissue  
16 markers specifically added because the Board had, in  
17 fact, made that decision.

18 And that is how a couple of the things that  
19 got specifically added came in because they were  
20 things where staff wasn't quite ready to go there  
21 and they came to hearing and the Board decided, then  
22 they were put in the regs.

23 So, I'm not sure that there is anything  
24 necessarily wrong with the suggested clarifications.

25 And -- and in terms of the (a)(9)(A), I  
26 know the Controller's original concern on that  
27 language in (a)(9)(A) was how broad was it? What --  
28 what did it really cover approved by FDA? You know,

1 that was a little bit of his concern and there was  
2 some discussion at that time at the BTC about it.

3 So, it sounds like what staff's trying to  
4 do is just -- bad words coming to my brain -- a  
5 surgical strike on the tissue markers.

6 But that doesn't mean that further guidance  
7 to audit staff in the manual isn't appropriate. I  
8 just don't know what all that would be.

9 You know, we have a tendency to look at the  
10 facts of the case as it becomes before us, 'cause  
11 that's when we see it and we look at the reg and we  
12 look at the statute and see if it -- if we believe  
13 that that product fits the definitions as ultimately  
14 they go back to the statute.

15 Where -- where staff looking at it thought  
16 not, but that's -- that's how you get -- that's just  
17 the nature the dispute resolution process. I don't  
18 know that you can answer every single question that  
19 might come up.

20 MR. RUNNER: Just --

21 MS. STEEL: Let's go to Chairman Horton  
22 first and then --

23 MR. HORTON: Members, I wasn't proposing we  
24 answer every specific question. I was just  
25 proposing that we give guidance on how to interpret  
26 this law in -- you know, which is consistent with  
27 the statute and they just stay consistent with the  
28 statute and that this is fact based, functional

1 base, irrespective of whether it's included or  
2 excluded, every item that is included as a medicine  
3 could, depending on how it's functionally used, not  
4 be a medicine, you know, and could be used for  
5 purposes not intended to even cure somebody.

6 So, it's always going back to just the  
7 fundamental interpretation of the law. As it  
8 relates to staff's alternative, I mean, I think by  
9 staff's own admissions, that they were trying to  
10 craft something to address what they perceived to be  
11 the Board's intent to delineate a specific item  
12 as -- and clarify, as opposed to approaching this  
13 problem and saying how can we -- how can we assure  
14 that the statute is properly interpreted?

15 And I also believe that Member Mandel is  
16 absolutely correct that there are segments of the  
17 correction that this process had been a good  
18 process.

19 And whenever you say something is forever  
20 taxable, you are just fundamentally wrong, you know  
21 what I mean, and that just shouldn't be anywhere,  
22 you know what I mean? And, so, those things  
23 probably did need to be cleaned up and we probably  
24 can clean those up.

25 But when you start itemizing an item and --  
26 you can do it, but you are going to find that you're  
27 going to say, "if this item, if consistent with the  
28 statute, if for cure of a disease, if for mitigation

1 of a disease," you know.

2           Anyway, that's -- so, I think they can go  
3 back and eliminate all that.

4           But if you want to do it, I'm okay with  
5 saying okay, well, let's do it this one more time.

6           But when it comes up again, we're going to  
7 do it one more time -- therein is the confusion.  
8 You get auditors looking for lists instead of  
9 looking at the law and interpreting the intent and  
10 the essence of law.

11           When we do that, we're going to get it  
12 right.

13           MS. STEEL: Member Runner.

14           MR. HORTON: It won't come before us.

15           MR. RUNNER: My -- I was going to suggest,  
16 I think the -- you know, going back to what Member  
17 Mandel was talking about, I think -- you know,  
18 Action 1, I think is a clarification of the FDA  
19 issue, which I think everybody is -- understands and  
20 that makes -- that makes sense at that point.

21           MR. HORTON: Yeah.

22           MR. RUNNER: I'm wondering if, indeed,  
23 there isn't at least a path for us to go ahead and  
24 understand that that is a good -- we move forward  
25 with that issue.

26           And then at least on the -- on the other  
27 issues, which seem to be the point of contention at  
28 this point, you know, just go back and ask the staff

1 to come back with some -- some clarity or, you know,  
2 try to address it in the audit manual.

3 MR. HORTON: I second that if that's a  
4 motion.

5 MR. RUNNER: Okay, I'll make that as a  
6 motion.

7 MS. STEEL: You mean all the action items?

8 MS. YEE: All the action items?

9 MR. RUNNER: No, I'm sorry, approve Action  
10 Item 1.

11 MS. STEEL: Okay.

12 MS. MANDEL: Well -- and staff's other -- I  
13 know there was alternative language in Action  
14 Item 3, but --

15 MR. RUNNER: Was there an agreement -- was  
16 there agreement -- I think there was agreement on  
17 Action Item 3.

18 MS. MANDEL: Yes, on Action Item 3 --

19 MS. STEEL: Member Yee.

20 MS. YEE: Let Ms. Mandel finish.

21 MS. MANDEL: -- well, I'm just looking at  
22 the little agenda thing and Action Item -- oh, okay,  
23 yeah, I think there would be -- I don't know --  
24 Action Item 3, staff is taking out that last  
25 sentence about the sale or use is subject to tax?

26 MR. RUNNER: Yeah, maybe --

27 MS. MANDEL: And there was alternative  
28 language only from the equity recovery people.

1 MR. RUNNER: Yeah.

2 MS. MANDEL: But if staff's -- maybe they  
3 don't disagree if -- if that sentence is taken out?

4 The gentleman on the end?

5 MR. BHOLAT: Yeah, I don't think we don't  
6 object to removing that.

7 MS. MANDEL: Okay.

8 MR. BHOLAT: We're in agreement with  
9 removing.

10 MR. RUNNER: So, let me restate the  
11 motion.

12 MS. STEEL: Okay.

13 MR. RUNNER: That we would approve --

14 MS. STEEL: Okay.

15 MR. HORTON: Wait, Madam Chair --

16 MS. STEEL: Member Yee.

17 MS. YEE: I'm getting a little nervous.

18 My suggestion would be to -- I mean, these  
19 amendments are before us because with the Appeals  
20 matter that we heard, I thought the action of this  
21 Board was directing staff to clarify the permanently  
22 implanted device, in this case the breast tissue  
23 expander, which helped identify the -- or mark the  
24 location of the medical condition because it was  
25 actually a device rather than the injected dyes or  
26 inks or whatever, that this what gave rise to us  
27 wanting to have this incorporated in the regulation.

28 What I'm hearing is a discussion that goes

1 beyond. And I -- I really hope that we can start a  
2 separate effort to really look at broader expansion  
3 of what constitutes medicine, because I do think  
4 that some of the devices, if we're going to think  
5 about devices -- and our speakers very concerned  
6 about that thousands of their clients are  
7 manufacturing or producing or providing -- but I  
8 also am concerned about how -- how far can we  
9 actually reach under the statute and -- without  
10 really requiring a statutory change.

11 MS. STEEL: Right.

12 MS. YEE: And I'm not so sure that our  
13 friends up the street are going to be all that  
14 enamored if take a broad sweep and start to exempt  
15 the application of tax on a whole range of products  
16 without looking at a potential statutory change that  
17 has broader authority to do that.

18 We've been doing this case by case because,  
19 you know, new products are coming into the  
20 marketplace. And we're acknowledging that they do  
21 fit into the definition of medicine, given the  
22 parameters of the statute.

23 But I think our charge today with respect  
24 to what's before us was the direction we gave to  
25 staff subsequent to our action on the matter  
26 regarding breast tissue markers.

27 So, I would really like to take action on  
28 this. I like the idea that we can always use the

1 audit manual to provide guidance to the staff and I  
2 would recommend that we do that in this regard.

3 But also then start a separate effort with  
4 respect to our speakers here of what else you  
5 believe we ought to be examining and then having  
6 staff really do the evaluation as to whether we have  
7 the authority to look at expanding the regulation to  
8 encompass that.

9 And my nervousness is that I think with --  
10 if the list gets very, very broad, we are going to  
11 have some revenue impact. And we really need to be  
12 conscious of what that is as we look at amending the  
13 regulation.

14 MR. RUNNER: Just to clarify the motion.

15 MS. STEEL: Okay, Member Mandel.

16 MS. MANDEL: Oh, he can -- he can --

17 MS. STEEL: So, he can -- okay.

18 MS. MANDEL: -- he can clarify.

19 MR. RUNNER: Yeah, I just want to make sure  
20 we understand what we're -- again because there was  
21 some further discussion on -- on Action 3.

22 So, I think the intent of the motion would  
23 be to approve Action 1 and Action 3 and then ask  
24 that the -- there be -- the issues that have been  
25 discussed here then be -- be attempted to get  
26 resolved with a -- within -- within -- clarity  
27 within the audit manual.

28 That would be the intent of the motion.

1 I'm not sure if that's the same thought as --

2 MS. MANDEL: Well --

3 MR. RUNNER: -- Mr. Horton seconded, I'm  
4 not -- I just want to make clear, see if that's  
5 truly what's on the table or not so that we know  
6 what we're discussing.

7 MR. HORTON: Uhm --

8 MS. YEE: Could we maybe have staff walk  
9 through it if we were to adopt?

10 MR. RUNNER: Can we just finish up with the  
11 motion? Just make sure -- I'm confused right now  
12 what we're discussing, I guess. And my concern is  
13 more procedural at this point.

14 MS. YEE: All right.

15 MS. STEEL: Okay, motion is Action 1 and  
16 Action 3 --

17 MS. MANDEL: Yeah, staff recommendation.

18 MS. STEEL: -- staff recommendation.

19 MS. MANDEL: Right.

20 MS. STEEL: And then Action 2 and Action 4  
21 that we going to have little more broader definition  
22 and staff is going to --

23 MR. RUNNER: No, no, I don't think it's --  
24 again that's why I'm going to clarify.

25 It's not the idea of broadening the  
26 definition, it's the idea of seeing if the issues  
27 can be addressed under statute by -- within the  
28 audit manual.

1           So, I'm not -- I don't -- my intent of the  
2 motion isn't to broaden as much as it is can we --  
3 can the audit manual actually seek to solve that  
4 problem of the ambiguity that we seem to have there.  
5 That's all.

6           So, not -- not to -- not to purposefully  
7 broaden it, to just see if the problem can be solved  
8 within the audit manual.

9           MS. STEEL: Clarified?

10          MR. RUNNER: Clarified, right.

11          So, that's the motion. I don't know if  
12 that motion worded that way is actually on the table  
13 or not with a second, that's all.

14          MS. YEE: Is there a second for discussion?

15          MR. HORTON: I -- I think what I'm hearing,  
16 Mr. Runner, is that your motion is to adopt Action  
17 Item No. --

18          MS. YEE: 1.

19          MS. STEEL: 1.

20          MR. HORTON: -- adopt revision under Action  
21 Item No. 1 and adopt staff recommendation on 2, 3  
22 and 4?

23          MR. RUNNER: No.

24          MS. MANDEL: 2 --

25          MR. HORTON: Oh, okay.

26          MS. STEEL: 2 and 4.

27          MS. MANDEL: -- 2, the staff recommendation  
28 is just to add a sentence that medicines are further

1 defined in B and C.

2 MR. RUNNER: Uh-huh.

3 MS. MANDEL: And 4, staff didn't recommend  
4 any alternative language. Their recommendation was  
5 leave the reg as it is.

6 MS. YEE: Uh-huh.

7 MR. HORTON: Yeah.

8 MS. MANDEL: Right?

9 MR. HORTON: I'm clear on that.

10 MR. RUNNER: So, the motion is just  
11 Action 3, which is the staff -- excuse me, Action 1,  
12 which is the staff recommendation.

13 MS. MANDEL: Which everybody agrees.

14 MR. RUNNER: Right.

15 And then -- and then also the motion is  
16 Action 3, which everybody agrees, staff  
17 recommendation.

18 And then try to address the other issues  
19 within clarity in the audit manual. That's the --  
20 that's -- that is the intent of the motion.

21 MR. HORTON: Madam Chair --

22 MS. STEEL: Yes.

23 THE COURT: -- may we hear from the parties  
24 to make sure that we have understanding -- being  
25 cognizant I wouldn't do anything personally, but --

26 MR. RUNNER: Well, we have a need,  
27 though --

28 MR. HORTON: -- given all of the -- all of

1 the -- the -- the concerns of my colleagues, I would  
2 certainly adhere to the majority.

3 MR. RUNNER: -- can I just speak to the  
4 issue, especially in regards to Action -- Action 1  
5 is an issue of clarity with the FDA approval.

6 That's one that -- that's a very specific  
7 issue to -- which we struggled with, you know, in  
8 regards to what does it mean to have FDA approval.

9 So, I think that is just kind of a -- like  
10 a -- really clarifying so that we don't have such a  
11 narrow thought of what FDA approval means.

12 So --

13 MR. DOWNEY: Right.

14 MR. HORTON: Although, I think it should be  
15 in the audit manual.

16 MR. DOWNEY: Well, I was going to speak --  
17 I'm not -- and Jacob can reiterate after I state  
18 this, but I think we just talked about it.

19 I don't know that we're opposed to the  
20 language in Action 2 that staff is proposing. What  
21 we really seek is the relationship of C and B when  
22 you are referenced to those sections and not  
23 changing the reference, but what do those mean?

24 And that's where for issue 3 and item 3 and  
25 item -- article 4, that those should go to the  
26 audit -- audit manual.

27 We're not opposed to 2 if staff believes  
28 that -- that, you know, that that clarifies it, you

1 know, that we look at B and C and then we're going  
2 to, you know, go to the audit manual and clarify  
3 what B and C mean, great. We would be happy with  
4 that.

5 And we would accept their language in 2.  
6 And then go to the audit manual and clarify 3 and 4,  
7 which are, you know, all back and forth.

8 Jacob, I don't know if that -- is that  
9 accurate?

10 MR. BHOLAT: I think it can work.

11 MS. STEEL: Okay, let's --

12 MR. SMITH: I just wanted to --

13 MS. STEEL: -- yeah.

14 MR. SMITH: -- I just wanted to point out  
15 one thing.

16 Action Item 1 also includes the addition of  
17 the breast tissue marker language. So, I just want  
18 to be clear that it doesn't -- it's not just --

19 MR. RUNNER: Okay.

20 MS. YEE: That's --

21 MR. RUNNER: -- it solves -- it  
22 specifically speaks to the issue of that one item.

23 MR. SMITH: And then Action Item 4, if the  
24 intent is to not make any further changes to the  
25 regulation, that is Action Item 4 in terms of  
26 staff's recommendation.

27 So, adopting staff's recommendation with  
28 regard to Action Item 4 would be consistent with not

1 making a change to the regulation and addressing it  
2 with the -- in the audit manual.

3 MR. RUNNER: Okay.

4 MS. STEEL: Okay, so --

5 MR. DOWNEY: Right, but I'd like to see  
6 those changes to the audit manual first to see if  
7 they are answering that question.

8 MR. RUNNER: Well, there's a process for  
9 that.

10 MS. STEEL: Okay. So, Action 1 --

11 MR. DOWNEY: Hold on 4, that was it.

12 MS. STEEL: -- the motion is Action 1,  
13 everybody agrees here, so, the staff recommends --  
14 staff recommendation.

15 Action 3, everybody agrees, so we do staff  
16 recommendations.

17 And Action 2 that we are adding the breast  
18 tissue markers that coming -- oh, that's Action 1.

19 MS. YEE: That's Action 1.

20 MR. SMITH: That's part of our --

21 MS. YEE: Yeah.

22 MR. SMITH: -- Action 1.

23 MS. STEEL: You know, we bring this case --  
24 I mean, we decide to the proposed regulation  
25 amendment on this regulations because the tissue  
26 markers we started.

27 MS. YEE: Yeah, that's Action 1.

28 MS. STEEL: And that's the reason we had

1 interest parties.

2 MS. YEE: Right.

3 MS. STEEL: You know what, it seems like a  
4 new technology is coming in that, you know, we are  
5 having this trouble every time -- that after two  
6 months I'm going to be gone and you guys got stuck  
7 with it and --

8 MS. YEE: I'm not.

9 MS. STEEL: -- okay.

10 So, Action 4, that clarifies audit manual  
11 under the statute, that's clear?

12 So, we -- that's the motion that --

13 MR. HORTON: Madam Chair, if I may?

14 MS. STEEL: -- okay.

15 MR. HORTON: I would agree what staff  
16 articulated and ask that they do it one more time  
17 and we'll make that the motion and then -- and then  
18 we can discuss that.

19 MR. SMITH: Well, I just --

20 MS. STEEL: Can we discuss that without  
21 second?

22 We had a motion and nobody seconded yet.

23 MR. RUNNER: Well, I think, we -- I mean, I  
24 think staff basically walked through that motion,  
25 right?

26 Did I misunderstand something?

27 MR. SMITH: The only thing I was suggesting  
28 when referring to Action Item 4, is that I was just

1 suggesting that adopting Action Item 4 would be  
2 consistent with what you were saying, which is to  
3 not to make further changes to the regulation.

4 MS. MANDEL: Yeah.

5 MR. SMITH: But I'm not saying that's part  
6 of --

7 MR. RUNNER: Is it necessary, though?

8 MR. SMITH: I --

9 MR. RUNNER: I mean, if we're going to go  
10 ahead and refer to the audit -- have it addressed in  
11 the audit manual, is that a necessary action in  
12 order to do -- to do the step, which would be try to  
13 address it in the audit manual?

14 MS. YEE: I don't think the audit manual  
15 then takes the point.

16 MR. RUNNER: Just start there.

17 MR. MENDEL: No, I don't think it's  
18 necessary.

19 I think what he was trying to suggest is  
20 that simply accepting staff recommendation does  
21 everything you're talking about doing --

22 MR. RUNNER: Okay.

23 MR. MENDEL: -- and then having a separate  
24 item that recommends that we look at amending the  
25 audit manual to add clarification regarding how A, B  
26 and C are read together.

27 MS. YEE: Exactly.

28 MR. MENDEL: But that accepting staff

1 recommendation makes the 3 changes -- the FDA, the  
2 breast tissue markers --

3 MR. RUNNER: That's Action 1.

4 MR. MENDEL: -- and -- and the change to  
5 (a)(9)(A) that says medicines are further defined in  
6 B and C, and then eliminating that one sentence in  
7 (B)(2) --

8 MR. RUNNER: Which is 4.

9 MR. MENDEL: -- that said --

10 MS. STEEL: That's 3.

11 MR. MENDEL: -- no, that's 3.

12 MS. YEE: That's 3.

13 MR. RUNNER: That's 3, okay.

14 MR. MENDEL: 4 is actually to do nothing  
15 further.

16 MR. RUNNER: Okay, yeah.

17 MR. MENDEL: So, if you like 1, 2 and 3,  
18 you can simply accept staff recommendation. And  
19 then ask staff to do something in addition.

20 MR. HORTON: There you go.

21 MR. RUNNER: Well, let's -- let's -- I'd  
22 like to hear -- I mean, that's obviously what is  
23 before us and if everybody agreed with that,  
24 including the folks before us then we wouldn't be  
25 here.

26 MR. DOWNEY: The challenge I'm having is  
27 that we're compromising on 1, 2 and 3.

28 And by adopting 4 it's saying that we agree

1 that what it says is right and that isn't what I was  
2 hearing.

3 What I was hearing is that we need to look  
4 at clarifying that section. And if we put in the  
5 reg or the statute or we put in the audit manual,  
6 we're going to clarify something.

7 So, that's not accepting that --

8 MR. HORTON: Madam --

9 MR. DOWNEY: -- that we're not doing  
10 anything.

11 Or at least that's my -- that was our  
12 compromise.

13 MS. STEEL: Chairman Horton.

14 MR. HORTON: -- Madam Chair, I think staff  
15 said not accept 4.

16 MR. RUNNER: No, they said accept 4.

17 MR. HORTON: No, they said not.

18 They're right here.

19 MR. RUNNER: They said accept 4, which  
20 means --

21 MR. SMITH: Do not make any further  
22 changes.

23 MR. HORTON: Right, you're recommending  
24 that we accept 4?

25 MR. SMITH: Accept 4, but that we also --

26 MS. MANDEL: Are you saying A-C-C?

27 MR. HORTON: Yeah, the word that you're  
28 using --

1 MS. MANDEL: -- or E-X? I think you're --

2 MR. SMITH: I have a cold, so --

3 MS. MANDEL: -- no, I think's he's

4 hearing a different --

5 MR. SMITH: A-C-C, accept.

6 MR. RUNNER: Adopt.

7 MS. MANDEL: -- the staff recommendation.

8 MR. SMITH: Adopt --

9 MR. RUNNER: There you go.

10 MR. SMITH: -- recommendation and then add

11 that -- instruct --

12 MR. MENDEL: I think for clarification,  
13 staff's recommendation 4 is that there be no other  
14 changes made to the regulation.

15 It doesn't go beyond to say that there  
16 could be no other clarifications elsewhere in the  
17 audit manual.

18 It's simply -- is recommending that at this  
19 time no other changes be made to the regulation.

20 MS. MANDEL: And that's --

21 MS. STEEL: Clarify audit manual under the  
22 statute, that's what we been talking about.

23 MR. MENDEL: As a -- as a separate --

24 MS. STEEL: Right.

25 MR. MENDEL: -- direction to staff.

26 MS. STEEL: Right, right.

27 MS. YEE: Madam Chair.

28 MR. DOWNEY: If -- if we can't reach

1 agreement -- sorry, I don't know if it was my  
2 turn -- but if we can't reach agreement on what the  
3 audit manual says, then we should both bring back a  
4 proposed language related to this section.

5 I think if we say we accept this section  
6 then we're done this issue and I don't think  
7 we're -- the compromise on 1, 2 and 3 was because  
8 we're not done with 4, we're going to go look at 4.

9 And we're going to see if we can put it in  
10 the audit manual and if we can all agree, 'cause we  
11 have much better direction from you.

12 That's how I was taking it.

13 MS. STEEL: What's the next step and what's  
14 the process here?

15 When we ask you for Action Item 4 that  
16 clarify audit manual under the statute, then what  
17 kind of language you bring it? What's the process?

18 MS. BUEHLER: For the audit manual, we  
19 typically draft those as a result of policy memos.

20 We take a different objective with this, we  
21 can definitely work with our interested parties to  
22 draft language.

23 Once that has gone through our internal  
24 review, it is posted the internet for a 60-day  
25 comment period, where we can receive additional  
26 comments and feedback from interested parties.

27 And then it's brought before the Board,  
28 typically on consent, when we have agreement from

1 all parties.

2 MS. STEEL: Okay. So, there's a motion?

3 MR. RUNNER: The motion was what?

4 MS. STEEL: Staff already -- I am not going  
5 to --

6 MR. RUNNER: Staff doesn't make the  
7 motions.

8 MS. STEEL: -- yeah, no, no, staff  
9 recommended -- staff made it very clear there that  
10 Action 1 -- oh, my God, we're going to start all  
11 over again.

12 Action 1, that we going to put the tissue  
13 markers in it -- the language.

14 Okay?

15 MS. YEE: Madam Chair?

16 Okay. I don't think this is what I heard  
17 unanimously but my understanding of what is before  
18 us is to adopt Action 1, 2 and 3 and direct staff to  
19 provide guidance through the audit manual that  
20 speaks to the interaction between subdivisions A, B  
21 and C, in terms of its application. Share that with  
22 interested parties.

23 And if there is a broader effort that  
24 should arise out of the insufficiency of the  
25 guidance provided in the audit manual that that  
26 would be a separate effort coming back to the  
27 Board.

28 MR. RUNNER: Second.

1 MR. HORTON: Third.

2 MR. RUNNER: Fourth.

3 MS. STEEL: So, moved by Member Yee and  
4 second by Member Runner.

5 And it's been adopted.

6 And thank you very much. That concludes  
7 Business Tax Committee.

8 MS. BUEHLER: Thank you.

9 MR. DOWNEY: Thank you.

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REPORTER'S CERTIFICATE.

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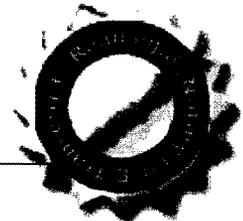
State of California )  
 ) ss  
County of Sacramento )

I, KATHLEEN SKIDGEL, Hearing Reporter for the California State Board of Equalization certify that on November 19, 2014 I recorded verbatim, in shorthand, to the best of my ability, the proceedings in the above-entitled hearing; that I transcribed the shorthand writing into typewriting; and that the preceding pages 1 through 46 constitute a complete and accurate transcription of the shorthand writing.

Dated: December 5, 2014

*Kathleen Skidgel*

KATHLEEN SKIDGEL  
Hearing Reporter





**ESTIMATE OF COST OR SAVINGS RESULTING  
FROM PROPOSED REGULATORY ACTION**

**Proposed Amendment of Sales and Use Tax Regulation 1591 *Medicines and Medical Devices***

STATEMENT OF COST OR SAVINGS FOR NOTICE OF PUBLIC HEARING

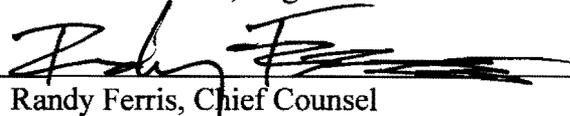
The State Board of Equalization has determined that the proposed action does not impose a mandate on local agencies or school districts. Further, the Board has determined that the action will result in no direct or indirect cost or savings to any State agency, any local agency or school district that is 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 cost or savings imposed on local agencies, or cost or savings in Federal funding to the State of California.

The cost impact on private persons or businesses will be insignificant. This proposal will not have a significant adverse economic impact on businesses.

This proposal will not be detrimental to California businesses in competing with businesses in other states.

This proposal will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand business in the State of California.

Statement Prepared by  Date 2-12-15  
Richard Bennion, Regulations Coordinator

Approved by  Date 2/12/15  
Randy Ferris, Chief Counsel

**If Costs or Savings are Identified, Signatures of Chief, Fiscal Management Division, and Chief, Board Proceedings Division, are Required**

Approved by \_\_\_\_\_ Date \_\_\_\_\_  
Chief, Financial Management Division

Approved by \_\_\_\_\_ Date \_\_\_\_\_  
Chief, Board Proceedings Division

**NOTE: SAM Section 6615 requires that estimates resulting in cost or savings be submitted for Department of Finance concurrence before the notice of proposed regulatory action is released.**

**ECONOMIC AND FISCAL IMPACT STATEMENT  
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

**ECONOMIC IMPACT STATEMENT**

DEPARTMENT NAME e Board of Equalization	CONTACT PERSON Richard E. Bennion	EMAIL ADDRESS rbennion@boe.ca.gov	TELEPHONE NUMBER 916-445-2130
DESCRIPTIVE TITLE FROM NOTICE REGISTER OR FORM 400 Title 18, Section 1591, Medicines and Medical Devices			NOTICE FILE NUMBER Z

**A. ESTIMATED PRIVATE SECTOR COST IMPACTS** *Include calculations and assumptions in the rulemaking record.*

1. Check the appropriate box(es) below to indicate whether this regulation:

- a. Impacts business and/or employees
- b. Impacts small businesses
- c. Impacts jobs or occupations
- d. Impacts California competitiveness
- e. Imposes reporting requirements
- f. Imposes prescriptive instead of performance
- g. Impacts individuals
- h. None of the above (Explain below):

Please see the attached .

***If any box in Items 1 a through g is checked, complete this Economic Impact Statement.  
If box in Item 1.h. is checked, complete the Fiscal Impact Statement as appropriate.***

2. The \_\_\_\_\_ estimates that the economic impact of this regulation (which includes the fiscal impact) is:  
(Agency/Department)

- Below \$10 million
- Between \$10 and \$25 million
- Between \$25 and \$50 million
- Over \$50 million *[If the economic impact is over \$50 million, agencies are required to submit a Standardized Regulatory Impact Assessment as specified in Government Code Section 11346.3(c)]*

3. Enter the total number of businesses impacted: \_\_\_\_\_

Describe the types of businesses (Include nonprofits): \_\_\_\_\_

Enter the number or percentage of total businesses impacted that are small businesses: \_\_\_\_\_

4. Enter the number of businesses that will be created: \_\_\_\_\_ eliminated: \_\_\_\_\_

Explain: \_\_\_\_\_

5. Indicate the geographic extent of impacts:  Statewide  
 Local or regional (List areas): \_\_\_\_\_

6. Enter the number of jobs created: \_\_\_\_\_ and eliminated: \_\_\_\_\_

Describe the types of jobs or occupations impacted: \_\_\_\_\_

7. Will the regulation affect the ability of California businesses to compete with other states by making it more costly to produce goods or services here?  YES  NO

If YES, explain briefly: \_\_\_\_\_

**ECONOMIC AND FISCAL IMPACT STATEMENT  
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

**ECONOMIC IMPACT STATEMENT (CONTINUED)**

**P ESTIMATED COSTS** *Include calculations and assumptions in the rulemaking record.*

1. What are the total statewide dollar costs that businesses and individuals may incur to comply with this regulation over its lifetime? \$ \_\_\_\_\_

a. Initial costs for a small business: \$ \_\_\_\_\_ Annual ongoing costs: \$ \_\_\_\_\_ Years: \_\_\_\_\_

b. Initial costs for a typical business: \$ \_\_\_\_\_ Annual ongoing costs: \$ \_\_\_\_\_ Years: \_\_\_\_\_

c. Initial costs for an individual: \$ \_\_\_\_\_ Annual ongoing costs: \$ \_\_\_\_\_ Years: \_\_\_\_\_

d. Describe other economic costs that may occur: \_\_\_\_\_

2. If multiple industries are impacted, enter the share of total costs for each industry: \_\_\_\_\_

3. If the regulation imposes reporting requirements, enter the annual costs a typical business may incur to comply with these requirements. *Include the dollar costs to do programming, record keeping, reporting, and other paperwork, whether or not the paperwork must be submitted.* \$ \_\_\_\_\_

4. Will this regulation directly impact housing costs?  YES  NO

If YES, enter the annual dollar cost per housing unit: \$ \_\_\_\_\_

Number of units: \_\_\_\_\_

5. Are there comparable Federal regulations?  YES  NO

Explain the need for State regulation given the existence or absence of Federal regulations: \_\_\_\_\_

Enter any additional costs to businesses and/or individuals that may be due to State - Federal differences: \$ \_\_\_\_\_

**C. ESTIMATED BENEFITS** *Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

1. Briefly summarize the benefits of the regulation, which may include among others, the health and welfare of California residents, worker safety and the State's environment: \_\_\_\_\_

2. Are the benefits the result of:  specific statutory requirements, or  goals developed by the agency based on broad statutory authority?

Explain: \_\_\_\_\_

3. What are the total statewide benefits from this regulation over its lifetime? \$ \_\_\_\_\_

4. Briefly describe any expansion of businesses currently doing business within the State of California that would result from this regulation: \_\_\_\_\_

**D. ALTERNATIVES TO THE REGULATION** *Include calculations and assumptions in the rulemaking record. Estimation of the dollar value of benefits is not specifically required by rulemaking law, but encouraged.*

List alternatives considered and describe them below. If no alternatives were considered, explain why not: \_\_\_\_\_

**ECONOMIC AND FISCAL IMPACT STATEMENT  
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

**ECONOMIC IMPACT STATEMENT (CONTINUED)**

2. Summarize the total statewide costs and benefits from this regulation and each alternative considered:

Regulation: Benefit: \$ \_\_\_\_\_ Cost: \$ \_\_\_\_\_

Alternative 1: Benefit: \$ \_\_\_\_\_ Cost: \$ \_\_\_\_\_

Alternative 2: Benefit: \$ \_\_\_\_\_ Cost: \$ \_\_\_\_\_

3. Briefly discuss any quantification issues that are relevant to a comparison of estimated costs and benefits for this regulation or alternatives: \_\_\_\_\_

4. Rulemaking law requires agencies to consider performance standards as an alternative, if a regulation mandates the use of specific technologies or equipment, or prescribes specific actions or procedures. Were performance standards considered to lower compliance costs?  YES  NO

Explain: \_\_\_\_\_

**E. MAJOR REGULATIONS** *Include calculations and assumptions in the rulemaking record.*

***California Environmental Protection Agency (Cal/EPA) boards, offices and departments are required to submit the following (per Health and Safety Code section 57005). Otherwise, skip to E4.***

1. Will the estimated costs of this regulation to California business enterprises exceed \$10 million?  YES  NO

***If YES, complete E2. and E3  
If NO, skip to E4***

Briefly describe each alternative, or combination of alternatives, for which a cost-effectiveness analysis was performed:

Alternative 1: \_\_\_\_\_

Alternative 2: \_\_\_\_\_

*(Attach additional pages for other alternatives)*

3. For the regulation, and each alternative just described, enter the estimated total cost and overall cost-effectiveness ratio:

Regulation: Total Cost \$ \_\_\_\_\_ Cost-effectiveness ratio: \$ \_\_\_\_\_

Alternative 1: Total Cost \$ \_\_\_\_\_ Cost-effectiveness ratio: \$ \_\_\_\_\_

Alternative 2: Total Cost \$ \_\_\_\_\_ Cost-effectiveness ratio: \$ \_\_\_\_\_

4. Will the regulation subject to OAL review have an estimated economic impact to business enterprises and individuals located in or doing business in California exceeding \$50 million in any 12-month period between the date the major regulation is estimated to be filed with the Secretary of State through 12 months after the major regulation is estimated to be fully implemented?

YES  NO

*If YES, agencies are required to submit a Standardized Regulatory Impact Assessment (SRIA) as specified in Government Code Section 11346.3(c) and to include the SRIA in the Initial Statement of Reasons.*

5. Briefly describe the following:

The increase or decrease of investment in the State: \_\_\_\_\_

The incentive for innovation in products, materials or processes: \_\_\_\_\_

The benefits of the regulations, including, but not limited to, benefits to the health, safety, and welfare of California residents, worker safety, and the state's environment and quality of life, among any other benefits identified by the agency: \_\_\_\_\_

**ECONOMIC AND FISCAL IMPACT STATEMENT  
(REGULATIONS AND ORDERS)**

STD 399 (REV 12/2013)

**FISCAL IMPACT STATEMENT**

**A. FISCAL EFFECT ON LOCAL GOVERNMENT** *Indicate appropriate boxes 1 through 6 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

1. Additional expenditures in the current State Fiscal Year which are reimbursable by the State. (Approximate)  
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

\$ \_\_\_\_\_

a. Funding provided in \_\_\_\_\_  
Budget Act of \_\_\_\_\_ or Chapter \_\_\_\_\_, Statutes of \_\_\_\_\_.

b. Funding will be requested in the Governor's Budget Act of \_\_\_\_\_  
Fiscal Year: \_\_\_\_\_

2. Additional expenditures in the current State Fiscal Year which are NOT reimbursable by the State. (Approximate)  
(Pursuant to Section 6 of Article XIII B of the California Constitution and Sections 17500 et seq. of the Government Code).

\$ \_\_\_\_\_

*Check reason(s) this regulation is not reimbursable and provide the appropriate information:*

a. Implements the Federal mandate contained in \_\_\_\_\_

b. Implements the court mandate set forth by the \_\_\_\_\_ Court.

Case of: \_\_\_\_\_ vs. \_\_\_\_\_

c. Implements a mandate of the people of this State expressed in their approval of Proposition No. \_\_\_\_\_

Date of Election: \_\_\_\_\_

d. Issued only in response to a specific request from affected local entity(s).

Local entity(s) affected: \_\_\_\_\_

e. Will be fully financed from the fees, revenue, etc. from: \_\_\_\_\_

Authorized by Section: \_\_\_\_\_ of the \_\_\_\_\_ Code;

f. Provides for savings to each affected unit of local government which will, at a minimum, offset any additional costs to each;

g. Creates, eliminates, or changes the penalty for a new crime or infraction contained in \_\_\_\_\_

3. Annual Savings. (approximate)

\$ \_\_\_\_\_

4. No additional costs or savings. This regulation makes only technical, non-substantive or clarifying changes to current law regulations.

5. No fiscal impact exists. This regulation does not affect any local entity or program.

6. Other. Explain \_\_\_\_\_

**ECONOMIC AND FISCAL IMPACT STATEMENT  
(REGULATIONS AND ORDERS)**

STD. 399 (REV. 12/2013)

**FISCAL IMPACT STATEMENT (CONTINUED)**

**B. FISCAL EFFECT ON STATE GOVERNMENT** *Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

1. Additional expenditures in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

*It is anticipated that State agencies will:*

a. Absorb these additional costs within their existing budgets and resources.

b. Increase the currently authorized budget level for the \_\_\_\_\_ Fiscal Year

2. Savings in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

3. No fiscal impact exists. This regulation does not affect any State agency or program.

4. Other. Explain \_\_\_\_\_

**C. FISCAL EFFECT ON FEDERAL FUNDING OF STATE PROGRAMS** *Indicate appropriate boxes 1 through 4 and attach calculations and assumptions of fiscal impact for the current year and two subsequent Fiscal Years.*

1. Additional expenditures in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

2. Savings in the current State Fiscal Year. (Approximate)

\$ \_\_\_\_\_

3. No fiscal impact exists. This regulation does not affect any federally funded State agency or program.

4. Other. Explain \_\_\_\_\_

FISCAL OFFICER SIGNATURE



DATE

February 11, 2015

*The signature attests that the agency has completed the STD. 399 according to the instructions in SAM sections 6601-6616, and understands the impacts of the proposed rulemaking. State boards, offices, or departments not under an Agency Secretary must have the form signed by the highest ranking official in the organization.*

AGENCY SECRETARY



DATE

February 11, 2015

*Finance approval and signature is required when SAM sections 6601-6616 require completion of Fiscal Impact Statement in the STD. 399.*

DEPARTMENT OF FINANCE PROGRAM BUDGET MANAGER

Exempt under SAM section 6615

DATE

**Attachment to Economic and Fiscal Impact**  
**Statement (STD. 399 (Rev. 12/2013)) for the Proposed Amendments to**  
**California Code of Regulations, Title 18, Section 1591,**  
***Medicines and Medical Devices***

As explained in more detail in the initial statement of reasons, California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (Rev. & Tax. Code, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (Rev. & Tax. Code, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (Rev. & Tax. Code, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (Rev. & Tax. Code, 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (Rev. & Tax. Code, § 6202.)

Revenue and Taxation Code (RTC) section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." It further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

The State Board of Equalization (Board) adopted California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, to implement, interpret, and make specific the exemption provided by RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. As relevant here, Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

"Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 or the component parts and accessories thereof . . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses, and, in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant’s interdependent internal and external components. 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.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. This determination is found in Sales and Use Tax Annotation 425.0580, which provides as follows:

**Opaques and Dyes.** Opaques and dyes used by hospitals and doctors in examination of patients are given internally to the patients and facilitate the taking of diagnostic x-ray photographs. Since such opaques and dyes are intended for use by internal application to the human body in diagnosis of disease they qualify as medicines under section 6369 of the Revenue and Taxation Code. 9/1/65.

Furthermore, as relevant here, the United States Food and Drug Administration's (FDA's) website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices."
- "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution."

Finally, during the Board's February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applier as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during

surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that there were issues (or problems within the meaning of Gov. Code, § 11346.2, subd. (b)) because Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

As explained in more detail in the initial statement of reasons, the proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that products approved by the FDA means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, to make the regulation consistent with the FDA's "approval processes" (discussed above) and the Board's February 2014 decision (discussed above). The proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that medicines are further defined in subdivisions (b) and (c) of the regulation. The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines under Regulation 1591, subdivision (b)(2), to be consistent with the Board's historical treatment of opaques and dyes and the Board's February 2014 decision. The proposed amendments also make Regulation 1591, subdivision (b)(2), consistent with current law, by clarifying that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision. In addition, the proposed amendments make non-substantive changes to make the regulation grammatically correct and internally consistent.

The proposed amendments do not change the requirements for FDA approval in Regulation 1591, subdivision (a)(9), because the Board determined in its February 2014 decision that the provisions requiring "approval" by the FDA were not intended to be narrowly interpreted to mean pre-market approval. The proposed amendments to Regulation 1591, subdivision (a)(9), stating that medicines are further defined in subdivisions (b) and (c) do not change the application of any of the regulation's provisions because, currently, subdivisions (b) and (c) do further define the term medicines.

The proposed amendments to Regulation 1591, subdivision (b)(2), clarifying that articles permanently implanted in the human body to mark the location of a medical condition, such as

BTMs, qualify as medicines do not change the meaning of the term medicines as used in RTC section 6369 and Regulation 1591 because the Board has historically treated opaques and dyes as medicines, the devices being added to subdivision (b)(2) perform the same function as opaques and dyes, and the Board previously determined that BTMs are medicines in its February 2014 decision. The proposed amendments clarifying that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision do not change current law. This is because current law does permit specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), to qualify as medicines under other provisions in Regulation 1591.

As a result, there is nothing in the proposed amendments to Regulation 1591 that would significantly change how retailers and consumers of medical devices would generally behave in the absence of the proposed amendments. The proposed amendments to Regulation 1591 do not require that individuals and businesses do anything that is not currently required by RTC section 6369 or Regulation 1591, and do not impose any costs on any persons. And, the proposed amendments will have an insignificant or negligible revenue impact.

Furthermore, the Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation's provisions.

Therefore, based upon the foregoing information and all of the information in the rulemaking file, 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 regulatory action, and the Board has determined that the proposed amendments to Regulation 1591:

- Will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states;
- 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;
- Will not have a significant effect on housing costs;
- Will result in no direct or indirect cost or savings to any state agency, no cost to any local agency or school district that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code, no other non-discretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State of California; and
- Will not impose a mandate on local agencies or school districts, including a mandate that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code.

The Board has also determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000, because the Board has estimated that the proposed amendments will not have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars (\$50,000,000) during any 12-month period.

Finally, Regulation 1591 does not regulate the health and welfare of California residents, worker safety, or the state's environment. Therefore, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

**NOTICE PUBLICATION/REGULATIONS SUBMISSION**

(See instructions on reverse)

For use by Secretary of State only

STD. 400 (REV. 01-2013)

OAL FILE NUMBERS	NOTICE FILE NUMBER <b>Z-2015-0212-01</b>	REGULATORY ACTION NUMBER	EMERGENCY NUMBER
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For use by Office of Administrative Law (OAL) only

RECEIVED FOR FILING PUBLICATION DATE

FEB 12 '15      FEB 27 '15

Office of Administrative Law

NOTICE

REGULATIONS

AGENCY WITH RULEMAKING AUTHORITY  
State Board of Equalization

AGENCY FILE NUMBER (if any)

**A. PUBLICATION OF NOTICE (Complete for publication in Notice Register)**

1. SUBJECT OF NOTICE Medicines and Medical Devices		TITLE(S) 18	FIRST SECTION AFFECTED 1591	2. REQUESTED PUBLICATION DATE February 27, 2015
3. NOTICE TYPE <input checked="" type="checkbox"/> Notice re Proposed Regulatory Action <input type="checkbox"/> Other		4. AGENCY CONTACT PERSON Richard E. Bennion	TELEPHONE NUMBER (916) 445-2130	FAX NUMBER (Optional) (916) 324-3984
OAL USE ONLY	ACTION ON PROPOSED NOTICE <input type="checkbox"/> Approved as Submitted <input type="checkbox"/> Approved as Modified <input type="checkbox"/> Disapproved/Withdrawn		NOTICE REGISTER NUMBER	PUBLICATION DATE

**B. SUBMISSION OF REGULATIONS (Complete when submitting regulations)**

1a. SUBJECT OF REGULATION(S)	1b. ALL PREVIOUS RELATED OAL REGULATORY ACTION NUMBER(S)
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3. SPECIFY CALIFORNIA CODE OF REGULATIONS TITLE(S) AND SECTION(S) (Including title 26, if toxics related)

ACTION(S) AFFECTED (List all section number(s) individually. Attach additional sheet if needed.)	ADOPT
	AMEND
	REPEAL
TITLE(S)	

3. TYPE OF FILING

<input type="checkbox"/> Regular Rulemaking (Gov. Code §11346)	<input type="checkbox"/> Certificate of Compliance: The agency officer named below certifies that this agency complied with the provisions of Gov. Code §§11346.2-11347.3 either before the emergency regulation was adopted or within the time period required by statute.	<input type="checkbox"/> Emergency Readopt (Gov. Code, §11346.1(h))	<input type="checkbox"/> Changes Without Regulatory Effect (Cal. Code Regs., title 1, §100)
<input type="checkbox"/> Resubmittal of disapproved or withdrawn nonemergency filing (Gov. Code §§11349.3, 11349.4)	<input type="checkbox"/> Resubmittal of disapproved or withdrawn emergency filing (Gov. Code, §11346.1)	<input type="checkbox"/> File & Print	<input type="checkbox"/> Print Only
<input type="checkbox"/> Emergency (Gov. Code, §11346.1(b))		<input type="checkbox"/> Other (Specify) _____	

4. ALL BEGINNING AND ENDING DATES OF AVAILABILITY OF MODIFIED REGULATIONS AND/OR MATERIAL ADDED TO THE RULEMAKING FILE (Cal. Code Regs. title 1, §44 and Gov. Code §11347.1)

5. EFFECTIVE DATE OF CHANGES (Gov. Code, §§ 11343.4, 11346.1(d); Cal. Code Regs., title 1, §100)

<input type="checkbox"/> Effective January 1, April 1, July 1, or October 1 (Gov. Code §11343.4(a))	<input type="checkbox"/> Effective on filing with Secretary of State	<input type="checkbox"/> §100 Changes Without Regulatory Effect	<input type="checkbox"/> Effective other (Specify)
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6. CHECK IF THESE REGULATIONS REQUIRE NOTICE TO, OR REVIEW, CONSULTATION, APPROVAL OR CONCURRENCE BY, ANOTHER AGENCY OR ENTITY

<input type="checkbox"/> Department of Finance (Form STD. 399) (SAM §6660)	<input type="checkbox"/> Fair Political Practices Commission	<input type="checkbox"/> State Fire Marshal
<input type="checkbox"/> Other (Specify) _____		

7. CONTACT PERSON	TELEPHONE NUMBER	FAX NUMBER (Optional)	E-MAIL ADDRESS (Optional)
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8. I certify that the attached copy of the regulation(s) is a true and correct copy of the regulation(s) identified on this form, that the information specified on this form is true and correct, and that I am the head of the agency taking this action, or a designee of the head of the agency, and am authorized to make this certification.

For use by Office of Administrative Law (OAL) only

SIGNATURE OF AGENCY HEAD OR DESIGNEE	DATE
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TYPED NAME AND TITLE OF SIGNATORY

## TITLE 18. BOARD OF EQUALIZATION

### **The State Board of Equalization Proposes to Adopt Amendments to California Code of Regulations, Title 18, Section 1591, *Medicines and Medical Devices***

NOTICE IS HEREBY GIVEN that the State Board of Equalization (Board), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to adopt amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*. The proposed amendments clarify Regulation 1591, subdivision (a)(9), by providing that products approved by the United States Food and Drug Administration (FDA) means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, and by providing that medicines are further defined in subdivisions (b) and (c). The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, are included in the definition of medicines under Regulation 1591, subdivision (b)(2). The proposed amendments clarify that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision of Regulation 1591. In addition, the proposed amendments make non-substantive changes to the regulation to make the regulation grammatically correct and internally consistent.

#### PUBLIC HEARING

The Board will conduct a meeting in Room 121 at 450 N Street, Sacramento, California on April 28-30, 2015. The Board will provide notice of the meeting to any person who requests that notice in writing and make the notice, including the specific agenda for the meeting, available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov) at least 10 days in advance of the meeting.

A public hearing regarding the proposed regulatory action will be held at 9:30 a.m. or as soon thereafter as the matter may be heard on April 28, 29, or 30, 2015. At the hearing, any interested person may present or submit oral or written statements, arguments, or contentions regarding the adoption of the proposed amendments to Regulation 1591.

#### AUTHORITY

RTC section 7051

#### REFERENCE

RTC sections 6006, 6369, and Health and Safety Code sections 1200, 1200.1, 1204.1 and 1250.

## INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

### Summary of Existing Laws and Regulations

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (RTC, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (RTC, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (RTC, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (RTC, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 6202.)

RTC section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

Regulation 1591 implements, interprets, and makes specific RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

"Medicines" means:

- (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 or the component parts and accessories thereof. . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses, and in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant’s interdependent internal and external components. 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.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. (See Sales and Use Tax Annotation 425.0580 (9/1/65)). Furthermore, the FDA's website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices."
- "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution."

#### Effect, Objective, and Benefit of the Proposed Amendments to Regulation 1591

During the Board's February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

#### *Interested Parties Process*

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues discussed above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr.

Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369 and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph] would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

#### *November 19, 2014, BTC Meeting*

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' recommendations to amend subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff

also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2). The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issues with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the

type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The Board has performed an evaluation of whether the proposed amendments to Regulation 1591 are inconsistent or incompatible with existing state regulations and determined that the proposed amendments are not inconsistent or incompatible with existing state regulations. This is because there are no other sales and use tax regulations that specifically prescribe the application of the sales and use tax exemption provided by RTC section 6369 to medicines and medical devices. In addition, the Board has determined that there are no comparable federal regulations or statutes to Regulation 1591 or the proposed amendments to Regulation 1591.

#### NO MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will not impose a mandate on local agencies or school districts, including a mandate that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code.

#### NO COST OR SAVINGS TO ANY STATE AGENCY, LOCAL AGENCY, OR SCHOOL DISTRICT

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will result in no direct or indirect cost or savings to any state agency, no cost to any local agency or school district that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code, no other non-discretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State of California.

#### NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS

The Board has made an initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The adoption of the proposed amendments to Regulation 1591 may affect small business.

#### NO COST IMPACTS TO PRIVATE PERSONS 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.

#### RESULTS OF THE ECONOMIC IMPACT ASSESSMENT REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

The Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000. Therefore, the Board has prepared the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1), and included it in the initial statement of reasons. The Board has determined that the adoption of the proposed amendments to Regulation 1591 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. Furthermore, the Board has determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

#### NO SIGNIFICANT EFFECT ON HOUSING COSTS

The adoption of the proposed amendments to Regulation 1591 will not have a significant effect on housing costs.

#### DETERMINATION REGARDING ALTERNATIVES

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 the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

#### CONTACT PERSONS

Questions regarding the substance of the proposed amendments should be directed to Bradley M. Heller, Tax Counsel IV, by telephone at (916) 323-3091, by e-mail at [Bradley.Heller@boe.ca.gov](mailto:Bradley.Heller@boe.ca.gov), or by mail at State Board of Equalization, Attn: Bradley Heller, MIC:82, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0082.

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 Mr. Rick Bennion, Regulations Coordinator, by telephone at (916) 445-2130, by fax at (916) 324-3984, by e-mail at [Richard.Bennion@boe.ca.gov](mailto:Richard.Bennion@boe.ca.gov), or by mail at State Board of Equalization, Attn: Rick Bennion, MIC:80, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0080.

#### WRITTEN COMMENT PERIOD

The written comment period ends at 9:30 a.m. on April 28, 2015, or as soon thereafter as the Board begins the public hearing regarding the adoption of the proposed amendments to Regulation 1591 during the April 28-30, 2015, Board meeting. Written comments

received by Mr. Rick Bennion at the postal address, email address, or fax number provided above, prior to the close of the written comment period, will be presented to the Board and the Board will consider the statements, arguments, and/or contentions contained in those written comments before the Board decides whether to adopt the proposed amendments to Regulation 1591. The Board will only consider written comments received by that time.

#### AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an underscored and strikeout version of the text of Regulation 1591 illustrating the express terms of the proposed amendments. The Board has also prepared an initial statement of reasons for the adoption of the proposed amendments to Regulation 1591, which includes the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1). These documents and all the information on which the proposed amendments are 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 amendments and the initial statement of reasons are also available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

#### SUBSTANTIALLY RELATED CHANGES PURSUANT TO GOVERNMENT CODE SECTION 11346.8

The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. If a sufficiently related change is made, the Board will make the full text of the proposed regulation, with the change clearly indicated, available to the public for at least 15 days before adoption. The text of the resulting regulation will be mailed to those interested parties who commented on the original proposed regulation orally or in writing or who asked to be informed of such changes. The text of the resulting regulation will also be available to the public from Mr. Bennion. The Board will consider written comments on the resulting regulation that are received prior to adoption.

#### AVAILABILITY OF FINAL STATEMENT OF REASONS

If the Board adopts the proposed amendments to Regulation 1591, the Board will prepare a final statement of reasons, which will be made available for inspection at 450 N Street, Sacramento, California, and available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

## Bennion, Richard

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**From:** BOE-Board Meeting Material  
**Sent:** Friday, February 27, 2015 9:06 AM  
**To:** Alonzo, Mary Ann (Legal); Angeja, Jeff (Legal); Appleby, Jaclyn; Armenta, Christopher; Asprey, Kathryn E; Bartolo, Lynn; Bennion, Richard; Benson, Bill; Bisauta, Christine (Legal); Blake, Sue; Block, Susan; BOE-Board Meeting Material; Boyle, Kevin; Bridges, Cynthia; Brown, Michele C; Chung, Sophia (Legal); Cruz, Giovan; Davis, Toya P.; Dixon, Camille; Duran, David; Durham, Mark; Epolite, Anthony (Legal); Ferris, Randy (Legal); Folchi, Gino; Ford, Ladeena L; Garcia, Laura; Gau, David; Gilman, Todd; Hamilton, Tabitha; Harrison, Michelle; Harvill, Mai; Heller, Bradley (Legal); Hellmuth, Leila; Herrera, Cristina; Holmes, Dana; Hughes, Shellie L; Jacobson, Andrew; Kinkle, Sherrie L; Kinst, Lynne; Kruckenber, Kendra; Kuhl, James; Lambert, Gary; Lambert, Robert (Legal); Lee, Chris; Levine, David H. (Legal); Lopez, Claudia; Lowery, Russell; Matsumoto, Sid; Matthies, Ted; McGuire, Jeff; Miller, Brad; Moon, Richard (Legal); Morquecho, Raymond; Nienow, Trecia (Legal); Oakes, Clifford; Pielsticker, Michele; Ralston, Natasha; Richmond, Joann; Riley, Denise (Legal); Schultz, Glenna; Shah, Neil; Silva, Monica (Legal); Singh, Sam; Smith, Kevin (Legal); Smith, Rose; Stowers, Yvette; Tran, Mai (Legal); Treichel, Tim; Tucker, Robert (Legal); Vandrick, Tanya; Vena, Emily (Legal); Wallentine, Sean; Whitaker, Lynn; White, Sharon; Wiggins, Brian; Williams, Lee; Zivkovich, Robert  
**Subject:** State Board of Equalization - Announcement of Regulatory Change 1591

The State Board of Equalization proposes to adopt amendments to Regulation 1591, *Medicines and Medical Devices*. A public hearing regarding the proposed amendments will be held in Room 121, 450 N Street, Sacramento, California on April 28-30, 2015.

The proposed amendments clarify the meaning of "approved by the United States Food and Drug Administration" and include medical devices implanted in the human body to mark the location of a medical condition, such as breast tissue markers, in the definition of medicines.

To view the notice of hearing, initial statement of reasons, proposed text, and history click on the following link:  
[http://www.boe.ca.gov/reg/reg\\_1591\\_2015.htm](http://www.boe.ca.gov/reg/reg_1591_2015.htm).

Questions regarding the substance of the proposed amendments should be directed to Mr. Bradley Heller, Tax Counsel IV, at 450 N Street, MIC:82, Sacramento, CA 94279-0082, email [Bradley.Heller@boe.ca.gov](mailto:Bradley.Heller@boe.ca.gov), telephone (916) 323-3091, or FAX (916) 323-3387.

Written comments for the Board's consideration, notices of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed regulatory action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445-2130, fax (916) 324-3984, e-mail [Richard.Bennion@boe.ca.gov](mailto:Richard.Bennion@boe.ca.gov) or by mail to: State Board of Equalization, Attn: Rick Bennion, MIC: 80, P.O. Box 942879-0080, Sacramento, CA 94279-0080.

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## **Bennion, Richard**

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**From:** State Board of Equalization - Announcement of Regulatory Change  
<Legal.Regulations@BOE.CA.GOV>  
**Sent:** Friday, February 27, 2015 10:31 AM  
**To:** BOE\_REGULATIONS@LISTSERV.STATE.CA.GOV  
**Subject:** State Board of Equalization - Announcement of Regulatory Change 1591

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no cost to any local agency or school district for which Government Code Sections 17500–17630 require reimbursement, no cost or savings to any state agency, nor costs or savings in federal funding to the state; (4) will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses or create or expand businesses in the State of California; and (5) will not have a significant statewide adverse economic impact directly affecting businesses including the ability of California businesses to compete with businesses in other states.

**Benefits of the Proposed Action:** The proposed regulation updating safe stops designated for carriers transporting explosives will continue to provide benefits which include a nonmonetary benefit to the protection of public health and safety for residents and workers, and the protection to the environment by providing a regulatory basis for enforcement efforts as they relate to safety compliance ratings.

The regulated community is encouraged to respond during the comment period of this regulatory process if significant impacts are identified.

#### COST IMPACTS ON REPRESENTATIVE PRIVATE PERSONS OR BUSINESSES

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

#### EFFECT ON SMALL BUSINESSES

The CHP has determined the proposed regulatory action may affect small businesses. If a business can no longer meet the requirements for safety, they will be deleted from the list of safe stopping and safe parking places. However, due to the very limited amount of highway commercial vehicles transporting explosives on the designated routes in the state, no foreseeable economic impact is projected for the small business to be removed from the list.

#### ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the CHP must determine that no reasonable alternative considered by the CHP, or otherwise identified and brought to the attention of the CHP, would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in imple-

menting the statutory policy or other provision of law. The CHP invites interested parties to present statements or arguments with respect to alternatives to the proposed regulations during the written comment period.

#### AUTHORITY

This regulatory action is being taken pursuant to Sections 31611 and 31616, CVC.

#### REFERENCE

This action implements, interprets, or makes specific Sections 31303, 31304, 31601, 31602, 31607, 31611, 31614, and 31616, CVC.

### TITLE 18. BOARD OF EQUALIZATION

#### **The State Board of Equalization Proposes to Adopt Amendments to California Code of Regulations, Title 18, Section 1591, *Medicines and Medical Devices***

NOTICE IS HEREBY GIVEN that the State Board of Equalization (Board), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to adopt amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*. The proposed amendments clarify Regulation 1591, subdivision (a)(9), by providing that products approved by the United States Food and Drug Administration (FDA) means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, and by providing that medicines are further defined in subdivisions (b) and (c). The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, are included in the definition of medicines under Regulation 1591, subdivision (b)(2). The proposed amendments clarify that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision of Regulation 1591. In addition, the proposed amendments make non-substantive changes to the regulation to make the regulation grammatically correct and internally consistent.

#### PUBLIC HEARING

The Board will conduct a meeting in Room 121 at 450 N Street, Sacramento, California on April 28–30, 2015.

The Board will provide notice of the meeting to any person who requests that notice in writing and make the notice, including the specific agenda for the meeting, available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov) at least 10 days in advance of the meeting.

A public hearing regarding the proposed regulatory action will be held at 9:30 a.m. or as soon thereafter as the matter may be heard on April 28, 29, or 30, 2015. At the hearing, any interested person may present or submit oral or written statements, arguments, or contentions regarding the adoption of the proposed amendments to Regulation 1591.

#### AUTHORITY

RTC section 7051.

#### REFERENCE

RTC sections 6006, 6369, and Health and Safety Code sections 1200, 1200.1, 1204.1 and 1250.

#### INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

##### Summary of Existing Laws and Regulations

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (RTC, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (RTC, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (RTC, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (RTC, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 6202.)

RTC section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivisions (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

Regulation 1591 implements, interprets, and makes specific RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

"Medicines" means:

- (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof. . . ." Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses,

and in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 subdivisions (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, including the ear implant’s interdependent internal and external components. 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.

Also, as relevant here, the Board’s Legal Department has previously determined, as early as 1965, that diagnostic “opaques and dyes” are medicines as defined in RTC section 6369. (See Sales and Use Tax Annotation

425.0580 (9/1/65)). Furthermore, the FDA’s website explains that:

- “The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.”
- “Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order ‘clears’ the device for commercial distribution.”

Effect, Objective, and Benefit of the Proposed Amendments to Regulation 1591

During the Board’s February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x–ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic reso-

nance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rule-making process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

#### *Interested Parties Process*

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues discussed above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's pre-market approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and contended that it is not clear to taxpayers, from the current text of subdivision

(a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369 and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of

the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the “sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph] would be subject to tax, if intended for temporary placement.” Mr. Bholat also included an attachment with his proposed changes.

*November 19, 2014, BTC Meeting*

In response to the interested parties’ concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term “medicines” is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties’ recommendations to amend subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat’s language would have actually narrowed the definition by removing the phrase “for all uses,” which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat’s comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat’s recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties’ proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14–006 and distributed it to the Board Members for consideration at the Board’s November 19, 2014, BTC meeting. Formal Issue Paper 14–006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14–006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested

parties were not necessarily opposed to staff’s recommended amendments to Regulation 1591; the interested parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2). The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issues with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The Board has performed an evaluation of whether the proposed amendments to Regulation 1591 are inconsistent or incompatible with existing state regulations and determined that the proposed amendments are not inconsistent or incompatible with existing state regulations. This is because there are no other sales and use tax regulations that specifically prescribe the application of the sales and use tax exemption provided by RTC section 6369 to medicines and medical devices. In addition, the Board has determined that there are no comparable federal regulations or statutes to Regulation 1591 or the proposed amendments to Regulation 1591.

#### NO MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will not impose a mandate on local agencies or school districts, including a mandate that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code.

**NO COST OR SAVINGS TO ANY STATE  
AGENCY, LOCAL AGENCY, OR  
SCHOOL DISTRICT**

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will result in no direct or indirect cost or savings to any state agency, no cost to any local agency or school district that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code, no other non-discretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State of California.

**NO SIGNIFICANT STATEWIDE ADVERSE  
ECONOMIC IMPACT DIRECTLY  
AFFECTING BUSINESS**

The Board has made an initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The adoption of the proposed amendments to Regulation 1591 may affect small business.

**NO COST IMPACTS TO PRIVATE PERSONS  
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.

**RESULTS OF THE ECONOMIC IMPACT  
ASSESSMENT REQUIRED BY GOVERNMENT  
CODE SECTION 11346.3, SUBDIVISION (b)**

The Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000. Therefore, the Board has prepared the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1), and included it in the initial statement of reasons. The Board has determined that the adoption of the proposed amendments to Regulation 1591 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. Furthermore, the Board has determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to

the health and welfare of California residents, worker safety, or the state's environment.

**NO SIGNIFICANT EFFECT ON  
HOUSING COSTS**

The adoption of the proposed amendments to Regulation 1591 will not have a significant effect on housing costs.

**DETERMINATION REGARDING  
ALTERNATIVES**

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 the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

**CONTACT PERSONS**

Questions regarding the substance of the proposed amendments should be directed to Bradley M. Heller, Tax Counsel IV, by telephone at (916) 323-3091, by e-mail at [Bradley.Heller@boe.ca.gov](mailto:Bradley.Heller@boe.ca.gov), or by mail at State Board of Equalization, Attn: Bradley Heller, MIC:82, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0082.

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 Mr. Rick Bennion, Regulations Coordinator, by telephone at (916) 445-2130, by fax at (916) 324-3984, by e-mail at [Richard.Bennion@boe.ca.gov](mailto:Richard.Bennion@boe.ca.gov), or by mail at State Board of Equalization, Attn: Rick Bennion, MIC:80, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0080.

**WRITTEN COMMENT PERIOD**

The written comment period ends at 9:30 a.m. on April 28, 2015, or as soon thereafter as the Board begins the public hearing regarding the adoption of the proposed amendments to Regulation 1591 during the April 28-30, 2015, Board meeting. Written comments received by Mr. Rick Bennion at the postal address, email address, or fax number provided above, prior to the close of the written comment period, will be presented

to the Board and the Board will consider the statements, arguments, and/or contentions contained in those written comments before the Board decides whether to adopt the proposed amendments to Regulation 1591. The Board will only consider written comments received by that time.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an underscored and strikethrough version of the text of Regulation 1591 illustrating the express terms of the proposed amendments. The Board has also prepared an initial statement of reasons for the adoption of the proposed amendments to Regulation 1591, which includes the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1). These documents and all the information on which the proposed amendments are 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 amendments and the initial statement of reasons are also available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

SUBSTANTIALLY RELATED CHANGES PURSUANT TO GOVERNMENT CODE SECTION 11346.8

The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. If a sufficiently related change is made, the Board will make the full text of the proposed regulation, with the change clearly indicated, available to the public for at least 15 days before adoption. The text of the resulting regulation will be mailed to those interested parties who commented on the original proposed regulation orally or in writing or who asked to be informed of such changes. The text of the resulting regulation will also be available to the public from Mr. Bennion. The Board will consider written comments on the resulting regulation that are received prior to adoption.

AVAILABILITY OF FINAL STATEMENT OF REASONS

If the Board adopts the proposed amendments to Regulation 1591, the Board will prepare a final statement of

reasons, which will be made available for inspection at 450 N Street, Sacramento, California, and available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

TITLE 18. FRANCHISE TAX BOARD

As required by section 11346.4 of the Government Code, the Franchise Tax Board hereby gives notice of its intention to adopt California Code of Regulations, title 18, section 18416.5, pertaining to the alternative electronic notification method.

Government Code section 15702, subdivision (b), provides for consideration by the three-member Franchise Tax Board of any proposed regulatory action if any person makes such request in writing.

PUBLIC HEARING

The Franchise Tax Board has not scheduled a public hearing on this proposed action. However, the Board will hold a hearing if it receives a written request for a public hearing from any interested person, or his or her authorized representative, no later than 15 days before the close of the written comment period indicated below. The request should be submitted to the agency officer named below.

WRITTEN COMMENT PERIOD

Written comments will be accepted until 5:00 p.m., April 13, 2015. All relevant matters presented will be considered before the proposed regulatory action is taken. Comments should be submitted to the agency officer named below.

AUTHORITY & REFERENCE

Section 18416.5 of the Revenue and Taxation Code authorizes the Franchise Tax Board to implement, by regulation, an alternative communication method that would allow the Franchise Tax Board, at the request of the taxpayer or the taxpayer's authorized representative, to provide notification to the taxpayer or taxpayer's authorized representative in a preferred electronic communication method designated by the taxpayer that a bill, notice, or other communication required under Part 10, Part 10.2, or Part 11 of the Revenue and Taxation Code is available for viewing on the Franchise Tax Board's limited access secure website. The proposed regulation also describes the manner in which a taxpayer or taxpayer's authorized representative may use an electronic method to submit a protest, notification, or other correspondence to FTB by way of the MyFTB folder. The proposed regulation by its terms shall apply to elections made and protests or other correspondence



STATE OF CALIFORNIA

**STATE BOARD OF EQUALIZATION**

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SEN. GEORGE RUNNER (RET.)  
First District, Lancaster

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Third District, Los Angeles County

DIANE L. HARKEY  
Fourth District, Orange County

BETTY T. YEE  
State Controller

CYNTHIA BRIDGES  
Executive Director

**February 27, 2015**

**To Interested Parties:**

**Notice of Proposed Regulatory Action**

**The State Board of Equalization Proposes to Adopt Amendments to  
California Code of Regulations, Title 18,  
Section 1591, *Medicines and Medical Devices***

**NOTICE IS HEREBY GIVEN** that the State Board of Equalization (Board), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to adopt amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*. The proposed amendments clarify Regulation 1591, subdivision (a)(9), by providing that products approved by the United States Food and Drug Administration (FDA) means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, and by providing that medicines are further defined in subdivisions (b) and (c). The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, are included in the definition of medicines under Regulation 1591, subdivision (b)(2). The proposed amendments clarify that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision of Regulation 1591. In addition, the proposed amendments make non-substantive changes to the regulation to make the regulation grammatically correct and internally consistent.

**PUBLIC HEARING**

The Board will conduct a meeting in Room 121 at 450 N Street, Sacramento, California on April 28-30, 2015. The Board will provide notice of the meeting to any person who requests that notice in writing and make the notice, including the specific agenda for the meeting, available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov) at least 10 days in advance of the meeting.

A public hearing regarding the proposed regulatory action will be held at 9:30 a.m. or as soon thereafter as the matter may be heard on April 28, 29, or 30, 2015. At the hearing, any interested

person may present or submit oral or written statements, arguments, or contentions regarding the adoption of the proposed amendments to Regulation 1591.

## **AUTHORITY**

RTC section 7051

## **REFERENCE**

RTC sections 6006, 6369, and Health and Safety Code sections 1200, 1200.1, 1204.1 and 1250.

## **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

### Summary of Existing Laws and Regulations

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (RTC, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (RTC, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (RTC, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (RTC, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 6202.)

RTC section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

Regulation 1591 implements, interprets, and makes specific RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

“Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 or the component parts and accessories thereof. . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses, and in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant's interdependent internal and external components. 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.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. (See Sales and Use Tax Annotation 425.0580 (9/1/65)). Furthermore, the FDA's website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices."
- "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution."

Effect, Objective, and Benefit of the Proposed Amendments to Regulation 1591

During the Board's February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

*Interested Parties Process*

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues discussed above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and

contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369 and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph] would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

*November 19, 2014, BTC Meeting*

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' recommendations to amend subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2). The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issues with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are

permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The Board has performed an evaluation of whether the proposed amendments to Regulation 1591 are inconsistent or incompatible with existing state regulations and determined that the proposed amendments are not inconsistent or incompatible with existing state regulations. This is because there are no other sales and use tax regulations that specifically prescribe the application of the sales and use tax exemption provided by RTC section 6369 to medicines and medical devices. In addition, the Board has determined that there are no comparable federal regulations or statutes to Regulation 1591 or the proposed amendments to Regulation 1591.

#### **NO MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS**

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will not impose a mandate on local agencies or school districts, including a mandate that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code.

#### **NO COST OR SAVINGS TO ANY STATE AGENCY, LOCAL AGENCY, OR SCHOOL DISTRICT**

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will result in no direct or indirect cost or savings to any state agency, no cost to any local agency or school district that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code, no other non-discretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State of California.

#### **NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS**

The Board has made an initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The adoption of the proposed amendments to Regulation 1591 may affect small business.

### **NO COST IMPACTS TO PRIVATE PERSONS 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.

### **RESULTS OF THE ECONOMIC IMPACT ASSESSMENT REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)**

The Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000. Therefore, the Board has prepared the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1), and included it in the initial statement of reasons. The Board has determined that the adoption of the proposed amendments to Regulation 1591 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. Furthermore, the Board has determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

### **NO SIGNIFICANT EFFECT ON HOUSING COSTS**

The adoption of the proposed amendments to Regulation 1591 will not have a significant effect on housing costs.

### **DETERMINATION REGARDING ALTERNATIVES**

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 the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

### **CONTACT PERSONS**

Questions regarding the substance of the proposed amendments should be directed to Bradley M. Heller, Tax Counsel IV, by telephone at (916) 323-3091, by e-mail at [Bradley.Heller@boe.ca.gov](mailto:Bradley.Heller@boe.ca.gov), or by mail at State Board of Equalization, Attn: Bradley Heller, MIC:82, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0082.

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 Mr. Rick Bennion, Regulations Coordinator, by telephone at (916) 445-2130, by fax at (916) 324-3984, by e-mail at [Richard.Bennion@boe.ca.gov](mailto:Richard.Bennion@boe.ca.gov), or by mail at State

Board of Equalization, Attn: Rick Bennion, MIC:80, 450 N Street, P.O. Box 942879,  
Sacramento, CA 94279-0080.

### **WRITTEN COMMENT PERIOD**

The written comment period ends at 9:30 a.m. on April 28, 2015, or as soon thereafter as the Board begins the public hearing regarding the adoption of the proposed amendments to Regulation 1591 during the April 28-30, 2015, Board meeting. Written comments received by Mr. Rick Bennion at the postal address, email address, or fax number provided above, prior to the close of the written comment period, will be presented to the Board and the Board will consider the statements, arguments, and/or contentions contained in those written comments before the Board decides whether to adopt the proposed amendments to Regulation 1591. The Board will only consider written comments received by that time.

### **AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION**

The Board has prepared an underscored and strikeout version of the text of Regulation 1591 illustrating the express terms of the proposed amendments. The Board has also prepared an initial statement of reasons for the adoption of the proposed amendments to Regulation 1591, which includes the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1). These documents and all the information on which the proposed amendments are 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 amendments and the initial statement of reasons are also available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

### **SUBSTANTIALLY RELATED CHANGES PURSUANT TO GOVERNMENT CODE SECTION 11346.8**

The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. If a sufficiently related change is made, the Board will make the full text of the proposed regulation, with the change clearly indicated, available to the public for at least 15 days before adoption. The text of the resulting regulation will be mailed to those interested parties who commented on the original proposed regulation orally or in writing or who asked to be informed of such changes. The text of the resulting regulation will also be available to the public from Mr. Bennion. The Board will consider written comments on the resulting regulation that are received prior to adoption.

February 27, 2015

**AVAILABILITY OF FINAL STATEMENT OF REASONS**

If the Board adopts the proposed amendments to Regulation 1591, the Board will prepare a final statement of reasons, which will be made available for inspection at 450 N Street, Sacramento, California, and available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

Sincerely,



Joann Richmond, Chief  
Board Proceedings Division

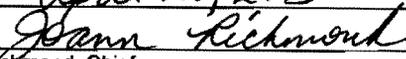
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**STATE BOARD OF EQUALIZATION**



BOARD APPROVED

At the April 28, 2015 Board Meeting

  
\_\_\_\_\_  
Joann Richmond, Chief  
Board Proceedings Division

**Initial Statement of Reasons for  
Proposed Amendments to California Code of Regulations,  
Title 18, Section 1591, *Medicines and Medical Devices***

SPECIFIC PURPOSE, PROBLEMS INTENDED TO BE ADDRESSED, NECESSITY, AND  
ANTICIPATED BENEFIT

Current Law

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (Rev. & Tax. Code, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (Rev. & Tax. Code, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (Rev. & Tax. Code, § 6012, subd. (a)(2).) Although sales tax is imposed on retailers, retailers may collect sales tax reimbursement from their customers if their contracts of sale so provide. (Civ. Code, § 1656.1; Cal. Code Regs., tit. 18, § 1700, subd. (a)(1).)

When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (Rev. & Tax. Code, 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (Rev. & Tax. Code, § 6202.) However, every retailer "engaged in business" in California that makes sales subject to California use tax is required to collect the use tax from its customers and remit it to the State Board of Equalization (Board), and such retailers are liable for California use tax that they fail to collect from their customers and remit to the Board. (Rev. & Tax. Code, § 6203; Cal. Code Regs., tit. 18, § 1684.)

Revenue and Taxation Code (RTC) section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

The Board adopted California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, to implement, interpret, and make specific the exemption provided by RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. As relevant here, Regulation 1591, subdivision (a)(9), currently defines “medicines” as follows:

“Medicines” means:

- (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 . . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)), which are included in the definition of medicines, either generally or for specific uses, and, in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

- (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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant's interdependent internal and external components. 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.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. This determination is found in Sales and Use Tax Annotation<sup>1</sup> 425.0580, which provides as follows:

**Opaques and Dyes.** Opaques and dyes used by hospitals and doctors in examination of patients are given internally to the patients and facilitate the taking of diagnostic x-ray photographs. Since such opaques and dyes are intended for use by internal application to the human body in diagnosis of disease they qualify as medicines under section 6369 of the Revenue and Taxation Code. 9/1/65.

Furthermore, as relevant here, the United States Food and Drug Administration's (FDA's) website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket

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<sup>1</sup> Annotations, which are published in the Business Taxes Law Guide, are summaries of conclusions reached in selected legal rulings by staff counsel, as applied to specific factual situations. Annotations do not embellish or interpret the legal rulings of counsel which they summarize and do not have the force and effect of law. (See, Cal. Code Regs., tit. 18, § 5700, *Annotations*.)

approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.”<sup>2</sup>

- “Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order ‘clears’ the device for commercial distribution.”<sup>3</sup>

### Proposed Amendments

Breast Tissue Markers (BTMs) are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI), or other imaging methods at a future date.

During the Board’s February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnosis breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA’s premarket approval process and did not receive the FDA’s premarket approval. Therefore, the Board determined that the BTMs at issue are “medicines” for purposes of the exemption provided by RTC section 6369. The Board also recognized that there were issues (or problems within the meaning of Gov. Code, § 11346.2, subd. (b)) because Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

### *Interested Parties Process*

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<sup>2</sup> The quoted information is available at:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>.

<sup>3</sup> The quoted information is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues described above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369, and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat, which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph], would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

*November 19, 2014, BTC Meeting*

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' suggested amendments to subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested

parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2) of the regulation. The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary for the specific purpose of addressing the issues (or problems) with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

In addition, the Board has determined that the proposed amendments are not mandated by federal law or regulations, and there are no federal regulations or statutes that are identical to Regulation 1591 or the proposed amendments to Regulation 1591.

#### DOCUMENTS RELIED UPON

The Board relied upon Formal Issue Paper 14-006, the exhibits to the issue paper, and the comments made during the Board's discussion of the issue paper during its November 19, 2014, BTC meeting in deciding to propose the amendments to Regulation 1591 described above.

#### ALTERNATIVES CONSIDERED

The Board considered whether to begin the formal rulemaking process to adopt the amendments to Regulation 1591 recommended by staff or the interested parties (discussed above), or some combination thereof, or, alternatively, whether to take no action at this time. The Board decided to begin the formal rulemaking process to propose to adopt staff's recommended amendments to Regulation 1591 at this time because the Board determined that the proposed amendments are reasonably necessary for the reasons set forth above.

The Board did not reject any reasonable alternative to the proposed amendments to Regulation 1591 that would lessen any adverse impact the proposed action may have on small business or that would be less burdensome and equally effective in achieving the purposes of the proposed action. No reasonable alternative has been identified and brought to the Board's attention that would lessen any adverse impact the proposed action may have on small business, be more effective in carrying out the purposes for which the action is proposed, would be as effective and

less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

INFORMATION REQUIRED BY GOVERNMENT CODE SECTION 11346.2,  
SUBDIVISION (b)(5) AND ECONOMIC IMPACT ASSESSMENT REQUIRED BY  
GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)

As previously explained, the proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that products approved by the FDA means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, to make the regulation consistent with the FDA's "approval processes" (discussed above) and the Board's February 2014 decision (discussed above). The proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that medicines are further defined in subdivisions (b) and (c) of the regulation. The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines under Regulation 1591, subdivision (b)(2), to be consistent with the Board's historical treatment of opaques and dyes and the Board's February 2014 decision. The proposed amendments also make Regulation 1591, subdivision (b)(2), consistent with current law, by clarifying that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision. In addition, the proposed amendments make non-substantive changes to make the regulation grammatically correct and internally consistent.

The proposed amendments do not change the requirements for FDA approval in Regulation 1591, subdivision (a)(9), because the Board determined in its February 2014 decision that the provisions requiring "approval" by the FDA were not intended to be narrowly interpreted to mean pre-market approval. The proposed amendments to Regulation 1591, subdivision (a)(9), stating that medicines are further defined in subdivisions (b) and (c) do not change the application of any of the regulation's provisions because, currently, subdivisions (b) and (c) do further define the term medicines.

The proposed amendments to Regulation 1591, subdivision (b)(2), clarifying that articles permanently implanted in the human body to mark the location of a medical condition, such as BTMs, qualify as medicines do not change the meaning of the term medicines as used in RTC section 6369 and Regulation 1591 because the Board has historically treated opaques and dyes as medicines, the devices being added to subdivision (b)(2) perform the same function as opaques and dyes, and the Board previously determined that BTMs are medicines in its February 2014 decision. The proposed amendments deleting the last sentence from the third paragraph in Regulation 1591, subdivision (b)(2), do not change current law, which does permit specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), to qualify as medicines under other provisions in Regulation 1591, and deleting the sentence removes any potential ambiguity.

Also, as previously explained, the Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity

with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation's provisions.

As a result, there is nothing in the proposed amendments to Regulation 1591 that would significantly change how retailers and consumers of medical devices would generally behave in the absence of the proposed amendments. In addition, the amendments to Regulation 1591 do not require that individuals and businesses do anything that is not currently required by RTC section 6369 or Regulation 1591, and do not impose any costs on any persons. And, the Research and Statistics Section of the Board's Legislative and Research Division determined that the proposed amendments will have an insignificant or negligible revenue impact. (See Exhibit 1 to Formal Issue Paper 14-006.) Therefore, the Board estimates that the proposed amendments will not have a measurable economic impact on individuals and business. And, the Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000, because the Board has estimated that the proposed amendments will not have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars (\$50,000,000) during any 12-month period.

Further, based on these facts and all of the information in the rulemaking file, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 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.

Furthermore, Regulation 1591 does not regulate the health and welfare of California residents, worker safety, or the state's environment. Therefore, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

The forgoing information also provides the factual basis for the Board's initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant adverse economic impact on business.

The proposed amendments to Regulation 1591 may affect small businesses.

**Text of Proposed Amendments to  
California Code of Regulations, Title 18, Section 1591**

**1591. Medicines and Medical Devices.**

(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, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "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.

(B) Section 1200 of the Health and Safety Code provides that "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. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in

the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under cChapter 6.6 (commencing with section 2900) of dDivision 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) Pharmacist. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of sSection 4200 of the Business & Professions Code, except as specifically provided otherwise in cChapter 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 sSection 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 ~~s~~Section 2065 of the Business & Professions Code, when acting within the scope of that section.

(9) Medicines. "Medicines" means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent 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.

For purposes of subdivision (a)(9)(A), products "approved by the United States Food and Drug Administration" means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.

Medicines are further defined in subdivisions (b) and (c) below.

(b) "Medicines." In addition to the definition set forth in subdivision (a)(9) of this ~~regulation~~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. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 or mark the location of a medical condition, 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, including the ear implant’s interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-reusable, 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 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, 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 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). 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 cuffs, 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; 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 to be 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)(5)), 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, nor 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 sSection 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

(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 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) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) 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.

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 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.

Note: Authority cited: Section 7051, Revenue and Taxation Code. Reference: Sections 6006 and 6369, Revenue and Taxation Code; and Sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

## Regulation History

**Type of Regulation:** Sales and Use Tax

Regulation: 1591

Title: *Medicines and Medical Devices*

**Preparation:** Bradley M. Heller

**Legal Contact:** Bradley M. Heller

The State Board of Equalization proposes to adopt amendments to Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*, to clarify the meaning of “approved by the United States Food and Drug Administration” and include medical devices implanted in the human body to mark the location of a medical condition, such as breast tissue markers, in the definition of medicines.

### History of Proposed Regulation:

April 28-30, 2015	Public Hearing
February 27, 2015	OAL publication date; 45-day public comment period begins; Interested Parties mailing
February 12, 2015	Notice to OAL
November 19, 2014	Business Tax Committee, Board Authorized Publication (Vote 5-0)

Sponsor: NA

Support: NA

Oppose: NA

## Statement of Compliance

The State Board of Equalization, in process of adopting Sales and Use Taxes Regulation 1591, *Medicines and Medical Devices*, did comply with the provision of Government Code section 11346.4(a)(1) through (4). A notice to interested parties was mailed on February 27, 2015, 60 days prior to the public hearing.

April 24, 2015

A handwritten signature in black ink, appearing to read "Richard Bennion", written over a horizontal line.

Richard Bennion  
Regulations Coordinator  
State Board of Equalization

BEFORE THE CALIFORNIA STATE BOARD OF EQUALIZATION  
450 N STREET  
SACRAMENTO, CALIFORNIA

REPORTER'S TRANSCRIPT

APRIL 28, 2015

F PUBLIC HEARING  
F2 PROPOSED ADOPTION OF AMENDMENTS TO  
REGULATION 1591, MEDICINES AND MEDICAL DEVICES

REPORTED BY: Kathleen Skidgel

CSR NO. 9039

P R E S E N T

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For the Board  
of Equalization:

Jerome E. Horton  
Chairman

Sen. George Runner (Ret.)  
Vice Chairman

Fiona Ma, CPA  
Member

Diane L. Harkey  
Member

Yvette Stowers  
Appearing for Betty T.  
Yee, State Controller  
(per Government Code  
Section 7.9)

Joann Richmond  
Chief  
Board Proceedings  
Division

For Staff:

Bradley Heller  
Tax Counsel IV  
Legal Department

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1 450 N STREET  
2 SACRAMENTO, CALIFORNIA  
3 APRIL 28, 2015

4 ---oOo---

5 MR. HORTON: Ms. Richmond, what's our next  
6 matter, please?

7 MS. RICHMOND: Our next public hearing is  
8 item F2, Proposed Adoption of Amendments to  
9 Regulation 1591, Medicines and Medical Devices.

10 MR. HORTON: As Mr. Heller settles in, we  
11 would ask that he commence his presentation once  
12 he's settled.

13 I understand there are no witnesses?

14 MS. RICHMOND: Correct.

15 MR. HELLER: Thank you, Chairman Horton,  
16 Members of the Board.

17 I'm Bradley Heller from the Board's Legal  
18 Department. And I'm here to request that the Board  
19 vote to adopt the proposed amendments to Regulation  
20 1591, Medicines and Medical Devices. The proposed  
21 amendments clarify the meaning of "approved by the  
22 United States Food and Drug Administration" and  
23 include medical devices implanted in the human body  
24 to mark the location of a medical condition, such as  
25 breast tissue markers, in the definition of  
26 medicines.

27 MR. HORTON: Thank you very much.

28 Discussion, Members?

1 Member Runner.

2 MR. RUNNER: Yeah, just a couple of quick  
3 observations.

4 One of the issues, the rest -- the rest of  
5 the -- the -- the motion that was made in regards to  
6 this was also to deal with the -- the Audit Manual.  
7 And, you know, one of the issues that concerns me a  
8 little bit is that, you know -- and I gue -- well, I  
9 think we're going to end up addressing this again in  
10 some appeals because I just -- I'm afraid -- I think  
11 we went -- I think we ended up being too narrow in  
12 regards to what I think the direction of the Board  
13 was. But I'm not too worried about that because I  
14 think we'll end up addressing it.

15 But I know, for instance, in -- we were --  
16 a couple of us were over in Houston for the opening  
17 of the office down there. And specifically talking  
18 with auditors there, two different auditors had  
19 issues in regards to clarity in regards to this reg.  
20 And particularly that I'm concerned about, in  
21 regards to the -- the Audit Manual and the direction  
22 that we give in clarity in the Audit Manual.

23 So, I'm going to make -- I guess I would  
24 like to make sure that, just as a reminder, and I  
25 think Member Harkey was there and heard some of this  
26 discussion, too, is that we work with the Business  
27 Taxes Committee to clarify on that -- on those -- on  
28 those issues that have been brought forward to us

1 and see if we can get enough clarity in the Audit  
2 Manual so we don't have to go back to the reg., I  
3 guess would be my concern.

4 Just my comment.

5 MR. HORTON: Member Harkey.

6 MS. HARKEY: I -- I concur. And I believe  
7 we are beginning to proceed a little bit in that  
8 direction. We were -- like Mr. Runner said, we were  
9 in -- in Houston and we met with the Chicago, New  
10 York, as well as the Houston staff and supervisor  
11 levels from the out-of-state.

12 And there was generally a concern over this  
13 regulation and -- and different parts of it. And  
14 they just -- the auditors want clarity. They want  
15 to know what to do and in what instances. And I  
16 think right now it's pretty subjective.

17 And so we will be coming back to this and  
18 we will be taking their advice on areas where we  
19 need to clarify, that would make their job easier  
20 and also have some -- a little more certainty for  
21 the business community.

22 Thank you.

23 MR. HORTON: Thank you very much.

24 Members, this process has been helpful in  
25 that there may be some -- may also be a need for  
26 legislative change. And to the extent that it does,  
27 possibly, with the permission of Madam Chair of the  
28 Legislative Committee, we could consider convening a

1 public hearing with all of the folks in the industry  
2 to discuss potential legislative change, over the --  
3 over the summer, over -- whatever's convenient for  
4 your schedule.

5 Be a nice opportunity to bring all of  
6 the -- all of the companies who are impacted by this  
7 together and discuss legislation that may be able to  
8 address their concerns.

9 MS. MA: Okay.

10 MR. HORTON: Further discussion, Members?

11 Member --

12 Mr. Heller, thank you so very much for your  
13 presentation.

14 Madam --

15 MS. RICHMOND: We need a motion.

16 MR. HORTON: I mean --

17 MR. RUNNER: Move to adoption.

18 MR. HORTON: Strike that.

19 Motion by Member Runner.

20 MS. HARKEY: Second.

21 MR. HORTON: Second by Member Harkey.

22 Without objection, Members, to adopt staff  
23 recommendations, such will be the order.

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REPORTER'S CERTIFICATE

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State of California )  
 ) ss  
County of Sacramento )

I, KATHLEEN SKIDGEL, Hearing Reporter for the California State Board of Equalization certify that on April 28, 2015 I recorded verbatim, in shorthand, to the best of my ability, the proceedings in the above-entitled hearing; that I transcribed the shorthand writing into typewriting; and that the preceding pages 1 through 6 constitute a complete and accurate transcription of the shorthand writing.

Dated: May 4, 2015

*Kathleen Skidgel*

KATHLEEN SKIDGEL  
Hearing Reporter



**2015 MINUTES OF THE STATE BOARD OF EQUALIZATION**

**Tuesday April 28, 2015**

**F2 Proposed Adoption of Amendments to Regulation 1591, *Medicines and Medical Devices***

Bradley Heller, Tax Counsel, Tax and Fee Programs Division, Legal Department, made introductory remarks regarding the proposed amendments clarifying the meaning of “approved by the United States Food and Drug Administration” and to include medical devices implanted in the human body to mark the location of a medical condition, such as breast tissue markers, in the definition of medicines (Exhibit 4.2).

Speakers were invited to address the Board, but there were none.

Action: Upon motion of Mr. Runner, seconded by Ms. Harkey and unanimously carried, Mr. Horton, Mr. Runner, Ms. Ma, Ms. Harkey and Ms. Stowers voting yes, the Board adopted the amendments to Regulation 1591, *Medicines and Medical Devices* as published.

**F3 Proposed Amendments to Property Tax Rule 308.6, *Application for Equalization by Member, Alternate Member, or Hearing Officer***

Bradley Heller, Tax Counsel, Tax and Fee Programs Division, Legal Department, made introductory remarks regarding the proposed amendments to clarify the current conflict of interest provisions applicable to county property tax assessment appeals (Exhibit 4.3).

Speakers were invited to address the Board, but there were none.

Action: Upon motion of Mr. Runner, seconded by Ms. Stowers and unanimously carried, Mr. Horton, Mr. Runner, Ms. Ma, Ms. Harkey and Ms. Stowers voting yes, the Board adopted the amendments to Property Tax Rule 308.6, *Application for Equalization by Member, Alternate Member, or Hearing Officer* as published.

**[B] CORPORATE FRANCHISE AND PERSONAL INCOME TAXES HEARINGS**

**B3 Todd Bentley and Kate Bentley, 593582**

2004, \$132,041.00 Assessment

2005, \$206,508.00 Assessment

For Appellants:

Todd Bentley, Taxpayer

For Franchise Tax Board:

Natasha Page, Tax Counsel

Fred Campbell-Craven, Tax Counsel

Contribution Disclosures pursuant to Government Code section 15626: None were disclosed.

Appellant's Exhibit: Net Revenue of Amazon.com from 2004 to 2014 (Exhibit 4.4)

Issue: Whether appellants have shown that respondent Franchise Tax Board erroneously assessed additional tax based on the sourcing to California of income arising from appellant-husband's settlement of a lawsuit with his former employer.



STATE OF CALIFORNIA

**STATE BOARD OF EQUALIZATION**

150 N STREET, SACRAMENTO, CALIFORNIA  
PO BOX 942879, SACRAMENTO, CALIFORNIA 94279-80  
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SEN. GEORGE RUNNER (RET.)  
First District, Lancaster

FIONA MA, CPA  
Second District, San Francisco

JEROME E. HORTON  
Third District, Los Angeles County

DIANE L. HARKEY  
Fourth District, Orange County

BETTY T. YEE  
State Controller

CYNTHIA BRIDGES  
Executive Director

**February 27, 2015**

**To Interested Parties:**

**Notice of Proposed Regulatory Action**

**The State Board of Equalization Proposes to Adopt Amendments to  
California Code of Regulations, Title 18,  
Section 1591, *Medicines and Medical Devices***

**NOTICE IS HEREBY GIVEN** that the State Board of Equalization (Board), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to adopt amendments to California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*. The proposed amendments clarify Regulation 1591, subdivision (a)(9), by providing that products approved by the United States Food and Drug Administration (FDA) means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, and by providing that medicines are further defined in subdivisions (b) and (c). The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, are included in the definition of medicines under Regulation 1591, subdivision (b)(2). The proposed amendments clarify that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision of Regulation 1591. In addition, the proposed amendments make non-substantive changes to the regulation to make the regulation grammatically correct and internally consistent.

**PUBLIC HEARING**

The Board will conduct a meeting in Room 121 at 450 N Street, Sacramento, California on April 28-30, 2015. The Board will provide notice of the meeting to any person who requests that notice in writing and make the notice, including the specific agenda for the meeting, available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov) at least 10 days in advance of the meeting.

A public hearing regarding the proposed regulatory action will be held at 9:30 a.m. or as soon thereafter as the matter may be heard on April 28, 29, or 30, 2015. At the hearing, any interested

person may present or submit oral or written statements, arguments, or contentions regarding the adoption of the proposed amendments to Regulation 1591.

## **AUTHORITY**

RTC section 7051

## **REFERENCE**

RTC sections 6006, 6369, and Health and Safety Code sections 1200, 1200.1, 1204.1 and 1250.

## **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

### Summary of Existing Laws and Regulations

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (RTC, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (RTC, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (RTC, § 6012, subd. (a)(2).) When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (RTC, §§ 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 6202.)

RTC section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

Regulation 1591 implements, interprets, and makes specific RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. Regulation 1591, subdivision (a)(9), currently defines "medicines" as follows:

“Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 or the component parts and accessories thereof. . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)) which are included in the definition of medicines, either generally or for specific uses, and in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant's interdependent internal and external components. 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.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. (See Sales and Use Tax Annotation 425.0580 (9/1/65)). Furthermore, the FDA's website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices."
- "Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order 'clears' the device for commercial distribution."

Effect, Objective, and Benefit of the Proposed Amendments to Regulation 1591

During the Board's February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI) or other imaging methods at a future date.

During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnose breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA's premarket approval process and did not receive the FDA's premarket approval. Therefore, the Board determined that the BTMs at issue are "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

*Interested Parties Process*

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues discussed above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

BTC staff subsequently provided its draft amendments to the interested parties and conducted an interested parties meeting on June 16, 2014. During the June 2014 meeting, the interested parties supported the proposed amendments to Regulation 1591 regarding FDA approval and BTMs. They did not agree, however, that staff's other proposed amendment would actually clarify subdivision (a)(9)(A) of the regulation. Moreover, Mr. Wade Downey of Downey, Smith & Fier disagreed with staff's analysis with regard to the application of subdivision (a)(9)(A) and

contended that it is not clear to taxpayers, from the current text of subdivision (a)(9)(A), that they must also look to subdivisions (b) and (c) to determine if a product qualifies as a medicine.

On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369 and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph] would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

*November 19, 2014, BTC Meeting*

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' recommendations to amend subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2). The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issues with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are

permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

The Board has performed an evaluation of whether the proposed amendments to Regulation 1591 are inconsistent or incompatible with existing state regulations and determined that the proposed amendments are not inconsistent or incompatible with existing state regulations. This is because there are no other sales and use tax regulations that specifically prescribe the application of the sales and use tax exemption provided by RTC section 6369 to medicines and medical devices. In addition, the Board has determined that there are no comparable federal regulations or statutes to Regulation 1591 or the proposed amendments to Regulation 1591.

#### **NO MANDATE ON LOCAL AGENCIES AND SCHOOL DISTRICTS**

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will not impose a mandate on local agencies or school districts, including a mandate that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code.

#### **NO COST OR SAVINGS TO ANY STATE AGENCY, LOCAL AGENCY, OR SCHOOL DISTRICT**

The Board has determined that the adoption of the proposed amendments to Regulation 1591 will result in no direct or indirect cost or savings to any state agency, no cost to any local agency or school district that is required to be reimbursed under part 7 (commencing with section 17500) of division 4 of title 2 of the Government Code, no other non-discretionary cost or savings imposed on local agencies, and no cost or savings in federal funding to the State of California.

#### **NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS**

The Board has made an initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant, statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states.

The adoption of the proposed amendments to Regulation 1591 may affect small business.

### **NO COST IMPACTS TO PRIVATE PERSONS 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.

### **RESULTS OF THE ECONOMIC IMPACT ASSESSMENT REQUIRED BY GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)**

The Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000. Therefore, the Board has prepared the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1), and included it in the initial statement of reasons. The Board has determined that the adoption of the proposed amendments to Regulation 1591 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. Furthermore, the Board has determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

### **NO SIGNIFICANT EFFECT ON HOUSING COSTS**

The adoption of the proposed amendments to Regulation 1591 will not have a significant effect on housing costs.

### **DETERMINATION REGARDING ALTERNATIVES**

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 the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

### **CONTACT PERSONS**

Questions regarding the substance of the proposed amendments should be directed to Bradley M. Heller, Tax Counsel IV, by telephone at (916) 323-3091, by e-mail at [Bradley.Heller@boe.ca.gov](mailto:Bradley.Heller@boe.ca.gov), or by mail at State Board of Equalization, Attn: Bradley Heller, MIC:82, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0082.

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 Mr. Rick Bennion, Regulations Coordinator, by telephone at (916) 445-2130, by fax at (916) 324-3984, by e-mail at [Richard.Bennion@boe.ca.gov](mailto:Richard.Bennion@boe.ca.gov), or by mail at State

Board of Equalization, Attn: Rick Bennion, MIC:80, 450 N Street, P.O. Box 942879,  
Sacramento, CA 94279-0080.

### **WRITTEN COMMENT PERIOD**

The written comment period ends at 9:30 a.m. on April 28, 2015, or as soon thereafter as the Board begins the public hearing regarding the adoption of the proposed amendments to Regulation 1591 during the April 28-30, 2015, Board meeting. Written comments received by Mr. Rick Bennion at the postal address, email address, or fax number provided above, prior to the close of the written comment period, will be presented to the Board and the Board will consider the statements, arguments, and/or contentions contained in those written comments before the Board decides whether to adopt the proposed amendments to Regulation 1591. The Board will only consider written comments received by that time.

### **AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION**

The Board has prepared an underscored and strikeout version of the text of Regulation 1591 illustrating the express terms of the proposed amendments. The Board has also prepared an initial statement of reasons for the adoption of the proposed amendments to Regulation 1591, which includes the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1). These documents and all the information on which the proposed amendments are 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 amendments and the initial statement of reasons are also available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

### **SUBSTANTIALLY RELATED CHANGES PURSUANT TO GOVERNMENT CODE SECTION 11346.8**

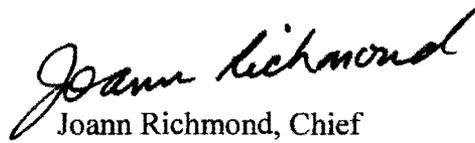
The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. If a sufficiently related change is made, the Board will make the full text of the proposed regulation, with the change clearly indicated, available to the public for at least 15 days before adoption. The text of the resulting regulation will be mailed to those interested parties who commented on the original proposed regulation orally or in writing or who asked to be informed of such changes. The text of the resulting regulation will also be available to the public from Mr. Bennion. The Board will consider written comments on the resulting regulation that are received prior to adoption.

February 27, 2015

**AVAILABILITY OF FINAL STATEMENT OF REASONS**

If the Board adopts the proposed amendments to Regulation 1591, the Board will prepare a final statement of reasons, which will be made available for inspection at 450 N Street, Sacramento, California, and available on the Board's Website at [www.boe.ca.gov](http://www.boe.ca.gov).

Sincerely,

  
Joann Richmond, Chief  
Board Proceedings Division

JR:reb

**Initial Statement of Reasons for  
Proposed Amendments to California Code of Regulations,  
Title 18, Section 1591, *Medicines and Medical Devices***

**SPECIFIC PURPOSE, PROBLEMS INTENDED TO BE ADDRESSED, NECESSITY, AND  
ANTICIPATED BENEFIT**

Current Law

California imposes sales tax on retailers for the privilege of selling tangible personal property at retail. (Rev. & Tax. Code, § 6051.) Unless an exemption or exclusion applies, the tax is measured by a retailer's gross receipts from the retail sale of tangible personal property in California. (Rev. & Tax. Code, §§ 6012, 6051.) The term "gross receipts" means the total amount of the sale price without any deduction for the cost of materials used, labor or service costs, interest paid, losses, or any other expense. (Rev. & Tax. Code, § 6012, subd. (a)(2).) Although sales tax is imposed on retailers, retailers may collect sales tax reimbursement from their customers if their contracts of sale so provide. (Civ. Code, § 1656.1; Cal. Code Regs., tit. 18, § 1700, subd. (a)(1).)

When sales tax does not apply, use tax is imposed, measured by the sales price of property purchased from a retailer for storage, use, or other consumption in California. (Rev. & Tax. Code, 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (Rev. & Tax. Code, § 6202.) However, every retailer "engaged in business" in California that makes sales subject to California use tax is required to collect the use tax from its customers and remit it to the State Board of Equalization (Board), and such retailers are liable for California use tax that they fail to collect from their customers and remit to the Board. (Rev. & Tax. Code, § 6203; Cal. Code Regs., tit. 18, § 1684.)

Revenue and Taxation Code (RTC) section 6369 provides an exemption from sales and use tax that applies to the sale or use of medicines that are dispensed, furnished, or sold under any of the circumstances prescribed by section 6369, subdivision (a)(1) through (6) (hereafter "statutorily prescribed circumstances"). As relevant here, section 6369, subdivision (b), defines "medicines" as "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." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) [a]rticles 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 or the component parts and accessories thereof." Subdivision (c) of section 6369 describes additional specific items that are medicines, notwithstanding subdivision (b), and subdivision (c)(2) of section 6369 expressly provides that the term "medicines" means and includes "[b]one screws, bone pins, pacemakers, and other articles, other than dentures, 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."

The Board adopted California Code of Regulations, title 18, section (Regulation) 1591, *Medicines and Medical Devices*, to implement, interpret, and make specific the exemption provided by RTC section 6369 and the structure of Regulation 1591 closely resembles the structure of RTC section 6369. As relevant here, Regulation 1591, subdivision (a)(9), currently defines “medicines” as follows:

“Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are 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.

Subdivision (c) of Regulation 1591 provides that certain items are excluded from the definition of medicines, including “(2) [a]rticles 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 . . . .” Notwithstanding subdivision (c), subdivision (b) of Regulation 1591 includes several categories of articles, devices and appliances (generally corresponding with those listed in RTC section 6369, subd. (c)), which are included in the definition of medicines, either generally or for specific uses, and, in some cases, subdivision (b) also identifies specific items that are included in or excluded from those categories. Currently, Regulation 1591, subdivision (b)(2), provides that “medicines” means and includes:

(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. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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, including the ear implant's interdependent internal and external components. 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.

Also, as relevant here, the Board's Legal Department has previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. This determination is found in Sales and Use Tax Annotation<sup>1</sup> 425.0580, which provides as follows:

**Opaques and Dyes.** Opaques and dyes used by hospitals and doctors in examination of patients are given internally to the patients and facilitate the taking of diagnostic x-ray photographs. Since such opaques and dyes are intended for use by internal application to the human body in diagnosis of disease they qualify as medicines under section 6369 of the Revenue and Taxation Code. 9/1/65.

Furthermore, as relevant here, the United States Food and Drug Administration's (FDA's) website explains that:

- "The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the act) established three regulatory classes for medical devices. The three classes are based on the degree of control necessary to assure that the various types of devices are safe and effective. The most regulated devices are in Class III. The amendments define a Class III device as one that supports or sustains human life or is of substantial importance in preventing impairment of human health or presents a potential, unreasonable risk of illness or injury. Insufficient information exists on a Class III device so that performance standards (Class II) or general controls (Class I) cannot provide reasonable assurance that the device is safe and effective for its intended use. Under Section 515 of the act, all devices placed into Class III are subject to premarket approval requirements. Premarket

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<sup>1</sup> Annotations, which are published in the Business Taxes Law Guide, are summaries of conclusions reached in selected legal rulings by staff counsel, as applied to specific factual situations. Annotations do not embellish or interpret the legal rulings of counsel which they summarize and do not have the force and effect of law. (See, Cal. Code Regs., tit. 18, § 5700, *Annotations*.)

approval by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices.”<sup>2</sup>

- “Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). . . . Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order ‘clears’ the device for commercial distribution.”<sup>3</sup>

### Proposed Amendments

Breast Tissue Markers (BTMs) are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. BTMs are placed in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site where the tissue sample was taken so that it can be accurately identified by ultrasound, magnetic resonance imaging (MRI), or other imaging methods at a future date.

During the Board’s February 2014 meeting, the Board heard a sales and use tax appeal concerning whether breast tissue markers (BTMs) are medicines and therefore exempt from tax under RTC section 6369 when sold or furnished under the statutorily prescribed circumstances. During the hearing, it was established that BTMs are fully implanted. BTMs are used to diagnosis breast cancer, and perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. And, the BTMs at issue were Class II medical devices that the FDA cleared under the 510(k) process discussed above, but the BTMs were not subject to the FDA’s premarket approval process and did not receive the FDA’s premarket approval. Therefore, the Board determined that the BTMs at issue are “medicines” for purposes of the exemption provided by RTC section 6369. The Board also recognized that there were issues (or problems within the meaning of Gov. Code, § 11346.2, subd. (b)) because Regulation 1591 does not specifically address medical devices that are permanently implanted to mark the location of a medical condition, and does not clearly explain what type of FDA approval is required in order for a medical device to qualify as a medicine. Therefore, to address the issues, the Board directed Board staff to initiate a rulemaking process to clarify the application of Regulation 1591 to Class II medical devices that are fully implanted.

### *Interested Parties Process*

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<sup>2</sup> The quoted information is available at:

<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm>.

<sup>3</sup> The quoted information is available at:

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/default.htm>.

Originally, the Board's Business Taxes Committee (BTC) staff prepared draft amendments to subdivisions (a)(9) and (b)(2) of Regulation 1591 to address the issues described above. The draft amendments suggested moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A). The draft amendment to subdivision (a)(9) also included language clarifying that products "approved" by the FDA include products for which an application for pre-market notification was cleared and products that received the FDA's premarket approval. The draft amendment to subdivision (b)(2) clarified that articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. The draft amendments also included non-substantive changes to the regulation to correct grammatical and formatting errors.

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On June 26, 2014, staff received letters from Mr. Downey and from Mr. Jacob Bholat of Equity Recovery Solutions, Inc. Mr. Downey's letter stated that staff's proposed changes did not resolve the confusing structure of Regulation 1591 and suggested that any product that is "approved" by the FDA and fully implanted or injected in a patient for a medical purpose should be exempt based on subdivision (a)(9)(A) of the regulation, alone. Mr. Bholat's letter suggested removing language that specifically excludes certain products (other than BTMs) from the definition of medicine in (b)(2).

In response to the interested parties' comments, staff decided not to pursue the proposed amendment moving and slightly amending the reference to subdivision (c) in subdivision (a)(9)(A) of Regulation 1591 because of the interested parties' belief that it did not clarify the regulation. Staff also decided to keep the reference to subdivision (c) in subdivision (a)(9)(A) because the removal of the reference to subdivision (c) would substantially change the meaning of subdivision (a)(9)(A) in a manner that would be inconsistent with RTC section 6369, and because there is no basis to delete the provisions of subdivision (c), which list items, including devices, that are specifically excluded from the definition of medicines.

On August 14, 2014, staff again met with the interested parties to discuss the draft amendments. The interested parties continued to disagree with staff regarding the application of subdivision (a)(9)(A) of Regulation 1591. The interested parties believed that the exclusion from the definition of medicine contained in subdivision (c)(2) of Regulation 1591 did not include all devices. Mr. Bholat also pointed out that the last sentence in subdivision (b)(2) of the regulation, stating that the sale of products specifically excluded from the definition of medicines under that subdivision are subject to tax, does not account for the possibility that such products could meet a different definition of medicine.

On August 28, 2014, staff received an email from Mr. Downey requesting that staff's original proposed amendment to subdivision (a)(9)(A) of Regulation 1591 be reinstated because it read better and that language should be added to the regulation to except fully implanted articles from the exclusion from the definition of medicine in subdivision (c)(2) of Regulation 1591. Mr. Downey included an attachment with his proposed changes. On September 3, 2014, staff received an email from Mr. Bholat, which also recommended revised language for subdivision (a)(9)(A) and an exception for fully and permanently implanted articles from the exclusion contained in subdivision (c)(2). Mr. Bholat also recommended adding a sentence to the end of the third paragraph in subdivision (b)(2) of Regulation 1591 stating that the "sale or use of [the] types of items [specifically excluded from the definition of medicine by that paragraph], would be subject to tax, if intended for temporary placement." Mr. Bholat also included an attachment with his proposed changes.

*November 19, 2014, BTC Meeting*

In response to the interested parties' concerns about clarity, BTC staff recommended inserting a final sentence at the end of subdivision (a)(9) of Regulation 1591 reiterating that the term "medicines" is further defined in subdivisions (b) and (c). Staff did not agree with either of the interested parties' suggested amendments to subdivision (a)(9)(A) because, as before, staff did not believe the amendments clarified the existing language and because Mr. Bholat's language would have actually narrowed the definition by removing the phrase "for all uses," which is currently in subdivision (a)(9)(A). Staff also agreed with Mr. Bholat's comment from the August 14, 2014, meeting that the items specifically excluded from the definition of medicine under subdivision (b)(2) of Regulation 1591 could meet a different definition of medicine. However, staff believed that Mr. Bholat's recommended amendment to subdivision (b)(2) (discussed above) would create contradictions within the subdivision, expand the definition of medicine, make the regulation more ambiguous by adding an intent element, and create unnecessary complexity. Accordingly, staff recommended simply removing the final sentence of subdivision (b)(2). In addition, staff did not agree with either of the interested parties' proposed changes to subdivision (c)(2) of Regulation 1591 because the changes would have expanded the definition of medicine in Regulation 1591 so that it conflicts with the plain language of RTC section 6369.

Subsequently, BTC staff prepared Formal Issue Paper 14-006 and distributed it to the Board Members for consideration at the Board's November 19, 2014, BTC meeting. Formal Issue Paper 14-006 recommended that the Board: (1) add the language regarding FDA approval and BTMs to Regulation 1591, subdivisions (a)(9) and (b)(2), respectively; (2) add the reference to subdivisions (b) and (c) to the end of Regulation 1591, subdivision (a)(9); (3) remove the final sentence from Regulation 1591, subdivision (b)(2); (4) make non-substantive amendments to make the regulation grammatically correct and internally consistent; and (5) make no changes to Regulation 1591, subdivision (c)(2).

The Board discussed Formal Issue Paper 14-006 during its November 19, 2014, BTC meeting. Mr. Downey and Mr. Bholat appeared in support of their respective proposals. However, during the November 19, 2014, BTC meeting, Mr. Downey clarified that the interested parties were not necessarily opposed to staff's recommended amendments to Regulation 1591; the interested

parties primarily wanted more specific clarification regarding the relationships between subdivisions (b) and (c) of the regulation; and that they would be satisfied if the Board provided the necessary clarification in its Audit Manual. At the conclusion of the discussion, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff and did not approve any changes to subdivision (c)(2) of the regulation. The Board also directed staff to draft guidance for inclusion in the Audit Manual that speaks to the interaction between subdivisions (a), (b), and (c) of the regulation, and share it with the interested parties.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary for the specific purpose of addressing the issues (or problems) with Regulation 1591, discussed above, by clarifying the application of tax to medical devices that are permanently implanted to mark the location of a medical condition, and clearly explaining the types of FDA approval that are required in order for a medical device to qualify as a medicine.

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation.

In addition, the Board has determined that the proposed amendments are not mandated by federal law or regulations, and there are no federal regulations or statutes that are identical to Regulation 1591 or the proposed amendments to Regulation 1591.

#### DOCUMENTS RELIED UPON

The Board relied upon Formal Issue Paper 14-006, the exhibits to the issue paper, and the comments made during the Board's discussion of the issue paper during its November 19, 2014, BTC meeting in deciding to propose the amendments to Regulation 1591 described above.

#### ALTERNATIVES CONSIDERED

The Board considered whether to begin the formal rulemaking process to adopt the amendments to Regulation 1591 recommended by staff or the interested parties (discussed above), or some combination thereof, or, alternatively, whether to take no action at this time. The Board decided to begin the formal rulemaking process to propose to adopt staff's recommended amendments to Regulation 1591 at this time because the Board determined that the proposed amendments are reasonably necessary for the reasons set forth above.

The Board did not reject any reasonable alternative to the proposed amendments to Regulation 1591 that would lessen any adverse impact the proposed action may have on small business or that would be less burdensome and equally effective in achieving the purposes of the proposed action. No reasonable alternative has been identified and brought to the Board's attention that would lessen any adverse impact the proposed action may have on small business, be more effective in carrying out the purposes for which the action is proposed, would be as effective and

less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law than the proposed action.

**INFORMATION REQUIRED BY GOVERNMENT CODE SECTION 11346.2,  
SUBDIVISION (b)(5) AND ECONOMIC IMPACT ASSESSMENT REQUIRED BY  
GOVERNMENT CODE SECTION 11346.3, SUBDIVISION (b)**

As previously explained, the proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that products approved by the FDA means any product for which the FDA cleared a premarket notification or approved an application for premarket approval, to make the regulation consistent with the FDA's "approval processes" (discussed above) and the Board's February 2014 decision (discussed above). The proposed amendments clarify the current provisions of Regulation 1591, subdivision (a)(9), by explaining that medicines are further defined in subdivisions (b) and (c) of the regulation. The proposed amendments clarify that articles permanently implanted in the human body to mark the location of a medical condition are included in the definition of medicines under Regulation 1591, subdivision (b)(2), to be consistent with the Board's historical treatment of opaques and dyes and the Board's February 2014 decision. The proposed amendments also make Regulation 1591, subdivision (b)(2), consistent with current law, by clarifying that the specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), may meet the definition of medicines under a different subdivision. In addition, the proposed amendments make non-substantive changes to make the regulation grammatically correct and internally consistent.

The proposed amendments do not change the requirements for FDA approval in Regulation 1591, subdivision (a)(9), because the Board determined in its February 2014 decision that the provisions requiring "approval" by the FDA were not intended to be narrowly interpreted to mean pre-market approval. The proposed amendments to Regulation 1591, subdivision (a)(9), stating that medicines are further defined in subdivisions (b) and (c) do not change the application of any of the regulation's provisions because, currently, subdivisions (b) and (c) do further define the term medicines.

The proposed amendments to Regulation 1591, subdivision (b)(2), clarifying that articles permanently implanted in the human body to mark the location of a medical condition, such as BTMs, qualify as medicines do not change the meaning of the term medicines as used in RTC section 6369 and Regulation 1591 because the Board has historically treated opaques and dyes as medicines, the devices being added to subdivision (b)(2) perform the same function as opaques and dyes, and the Board previously determined that BTMs are medicines in its February 2014 decision. The proposed amendments deleting the last sentence from the third paragraph in Regulation 1591, subdivision (b)(2), do not change current law, which does permit specific articles that do not qualify as medicines under the third paragraph in Regulation 1591, subdivision (b)(2), to qualify as medicines under other provisions in Regulation 1591, and deleting the sentence removes any potential ambiguity.

Also, as previously explained, the Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by providing clarity

with regard to the application of the exemption provided by RTC section 6369 to medical devices that are permanently implanted to mark the location of a medical condition, the type of FDA approval required by the regulation, and the interrelation between subdivisions (a) through (c) of the regulation's provisions.

As a result, there is nothing in the proposed amendments to Regulation 1591 that would significantly change how retailers and consumers of medical devices would generally behave in the absence of the proposed amendments. In addition, the amendments to Regulation 1591 do not require that individuals and businesses do anything that is not currently required by RTC section 6369 or Regulation 1591, and do not impose any costs on any persons. And, the Research and Statistics Section of the Board's Legislative and Research Division determined that the proposed amendments will have an insignificant or negligible revenue impact. (See Exhibit 1 to Formal Issue Paper 14-006.) Therefore, the Board estimates that the proposed amendments will not have a measurable economic impact on individuals and business. And, the Board has determined that the proposed amendments to Regulation 1591 are not a major regulation, as defined in Government Code section 11342.548 and California Code of Regulations, title 1, section 2000, because the Board has estimated that the proposed amendments will not have an economic impact on California business enterprises and individuals in an amount exceeding fifty million dollars (\$50,000,000) during any 12-month period.

Further, based on these facts and all of the information in the rulemaking file, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 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.

Furthermore, Regulation 1591 does not regulate the health and welfare of California residents, worker safety, or the state's environment. Therefore, the Board has also determined that the adoption of the proposed amendments to Regulation 1591 will not affect the benefits of Regulation 1591 to the health and welfare of California residents, worker safety, or the state's environment.

The forgoing information also provides the factual basis for the Board's initial determination that the adoption of the proposed amendments to Regulation 1591 will not have a significant adverse economic impact on business.

The proposed amendments to Regulation 1591 may affect small businesses.

**Text of Proposed Amendments to  
California Code of Regulations, Title 18, Section 1591**

**1591. Medicines and Medical Devices.**

(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, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

(A) Section 1250 of the Health and Safety Code provides that "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.

(B) Section 1200 of the Health and Safety Code provides that "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. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

(C) Section 1200.1 of the Health and Safety Code provides that "clinic" also means an organized outpatient health facility which provides direct psychological advice, services, or treatment to patients who remain less than 24 hours. As provided in section 1204.1 of the Health and Safety Code, such clinics serve patients under the direction of a clinical psychologist as defined in section 1316.5 of the Health and Safety Code, and are operated by a nonprofit corporation, which is exempt from federal taxation under paragraph (3), subsection (c) of section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, and which is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds, or contributions which may be in

the form of money, goods, or services. In such clinics, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. Such clinics may also provide diagnostic or therapeutic services authorized under cChapter 6.6 (commencing with section 2900) of dDivision 2 of the Business and Professions Code to patients in the home as an incident to care provided at the clinic facility.

(5) Pharmacist. "Pharmacist" means a person to whom a license has been issued by the California State Board of Pharmacy, under the provisions of sSection 4200 of the Business & Professions Code, except as specifically provided otherwise in cChapter 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 sSection 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 & Professions Code, when acting within the scope of that section.

(9) Medicines. “Medicines” means:

(A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the ~~U.S.~~United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent 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.

For purposes of subdivision (a)(9)(A), products “approved by the United States Food and Drug Administration” means any product for which a premarket notification was cleared by the United States Food and Drug Administration or for which an application for premarket approval was approved by the United States Food and Drug Administration.

Medicines are further defined in subdivisions (b) and (c) below.

(b) “Medicines.” In addition to the definition set forth in subdivision (a)(9) of this ~~regulation~~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. In addition, articles permanently implanted in the human body to mark the location of a medical condition, such as breast tissue markers, qualify as medicines. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Except for devices excluded from the definition of “medicines,” permanently implanted articles include the interdependent internal and external components that operate together as one device in and on the person in whom the device is implanted. 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 or mark the location of a medical condition, 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, including the ear implant’s interdependent internal and external components. 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 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, 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 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). 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 cuffs, 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; 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 to be 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)(5)), 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, nor 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

(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 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) Dietary Supplements and Adjuncts. Dietary supplements and adjuncts furnished to a patient as part of a medically supervised weight loss program to treat obesity qualify as medicines for the purposes of Revenue and Taxation Code section 6369 when the product does not otherwise qualify as a food product under Regulation 1602. The sale or use of such products is not subject to tax when sold or furnished under one of the conditions in subdivision (d)(1) through (d)(6) of Regulation 1591.

(8) 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.

Pursuant to sSection 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 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.

Note: Authority cited: Section 7051, Revenue and Taxation Code. Reference: Sections 6006 and 6369, Revenue and Taxation Code; and Sections 1200, 1200.1, 1204.1 and 1250, Health and Safety Code.

## Regulation History

**Type of Regulation:** Sales and Use Tax

Regulation: 1591

Title: *Medicines and Medical Devices*

**Preparation:** Bradley M. Heller

**Legal Contact:** Bradley M. Heller

The State Board of Equalization proposes to adopt amendments to Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*, to clarify the meaning of "approved by the United States Food and Drug Administration" and include medical devices implanted in the human body to mark the location of a medical condition, such as breast tissue markers, in the definition of medicines.

### History of Proposed Regulation:

April 28-30, 2015	Public Hearing
February 27, 2015	OAL publication date; 45-day public comment period begins; Interested Parties mailing
February 12, 2015	Notice to OAL
November 19, 2014	Business Tax Committee, Board Authorized Publication (Vote 5-0)

Sponsor: NA

Support: NA

Oppose: NA