



STATE OF CALIFORNIA

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January 20, 2006

Dear Interested Party :

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for the January 31, 2006 Business Taxes Committee meeting. This meeting will address the proposed amendments to Regulation 1591, *Medicines and Medical Devices*.

Action 1 on the Agenda concerns revising Regulation 1591 to clarify that certain products approved by the U.S. Food and Drug Administration to treat medical conditons be included within the definition of "medicines."

If you are interested in other topics to be considered by the Business Taxes Committee, you may refer to the "Board Meetings and Committee Information" page on the Board's Internet web site (<http://www.boe.ca.gov/meetings/meetings.htm#two>) for copies of Committee discussion or issue papers, minutes, a procedures manual and calendars arranged according to subject matter and by month.

Thank you for your input on these issues and I look forward to seeing you at the Business Taxes Committee meeting at **9:30 a.m.** on **January 31, 2006** in Room 121 at the address shown above.

Sincerely,

Randie L. Henry, Deputy Director  
Sales and Use Tax Department

RLH:llw

Enclosures

cc: (all with enclosures)

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Ms. Leila Khabbaz (MIC 50)  
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Mr. Peter Horton (MIC 50)



**AGENDA — January 31, 2006 Business Taxes Committee Meeting**  
**Regulation 1591, Medicines and Medical Devices**

<b>Action Item</b>	<b>Alternative 1 - Amend Regulation 1591 - Staff and Petitioner’s Proposed Regulatory Language</b>	<b>Alternative 2 – Do Not Amend Regulation 1591 – Issue Legal Opinion Regarding Botox® and Botox® Cosmetic</b>
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<b>Action 1 -</b>		
<b>“Medicines” as provided in RTC section 6369</b>	<p>(a)(9) MEDICINES. “Medicines” means:  <u>(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, or</u>  <u>(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.</u>          The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p> <p>(b) <u>“MEDICINES.” In addition to the definition set forth in subdivision (a)(9) of this section, the term “medicines” means and includes the following items:</u></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, “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</p>	Do not amend Regulation 1591. Issue an opinion from the Legal Department stating that sales of Botox® and Botox® Cosmetic fall within the definition of medicines as provided in RTC section 6369.

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**Regulation 1591, Medicines and Medical Devices**

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	<p>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. An article is considered to be permanently implanted if its removal is not otherwise anticipated. Tax does not apply to the sale or use of articles permanently implanted in the human body to assist the functioning of any natural organ, artery, vein or limb and which remain or dissolve in the body when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are</p>	

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	<p>permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>Implantable articles that do not qualify as “permanently” implanted medicines include, but are not limited to, Chemoport implantable fluid systems; Port-a-Cath systems used for drug infusion purposes; disposable urethral catheters; temporary myocardial pacing leads used during surgery and recovery; and defibrillator programmer and high voltage stimulator used with an implanted defibrillator. The sale or use of these items is subject to tax.</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, other than orthodontic devices, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such</p>	

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	<p>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 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</p>	

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**Regulation 1591, Medicines and Medical Devices**

<p align="center"><b>Action Item</b></p>	<p align="center"><b>Alternative 1 - Amend Regulation 1591 - Staff and Petitioner's Proposed Regulatory Language</b></p>	<p align="center"><b>Alternative 2 – Do Not Amend Regulation 1591 – Issue Legal Opinion Regarding Botox® and Botox® Cosmetic</b></p>
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	<p>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 replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes</p>	
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	<p>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 cuff, dacron grafts, heart valves, orbital implant, nerve cups, rhinoplasty prosthesis, neuromuscular electrical stimulators, transcutaneous nerve stimulators, urinary incontinent devices, and wigs and hairpieces prescribed by a physician or podiatrist.</p> <p>Prosthetic devices that do not qualify as “medicines,” include, but are not limited to, air compression pumps and pneumatic garments; noninvasive, temporary pace makers; and vacuum/constriction devices used to treat male impotency; auditory, ophthalmic and ocular devices or appliances; and dental prosthetic devices and materials such as dentures, removable or fixed bridges, crowns, caps, inlays, artificial teeth, and other dental prosthetic materials and devices. Sales of such items are subject to tax in the same manner as any other sale of tangible personal property.</p> <p>(6) DRUG INFUSION DEVICES. Programmable drug infusion devices worn on or implanted in the human body which automatically cause the infusion of measured quantities of a drug on an intermittent or continuous basis at variable dose rates and at high or low fluid volume into the body of the wearer of the device qualify as medicines under Revenue and Taxation Code section 6369(c)(6). The sale or use of the qualifying infusion device is not subject to tax when the device is sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6).</p> <p>(c) EXCLUSIONS FROM THE DEFINITION OF “MEDICINES.”</p>	

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**Regulation 1591, Medicines and Medical Devices**

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	<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)(6)), auditory, ophthalmic or ocular devices or appliances.</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, or foot orthoses.</p> <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 section 23000, of the Business and Professions Code).</p>	

Issue Paper Number **05-013**



BOARD OF EQUALIZATION  
**KEY AGENCY ISSUE**

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

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## **Proposed Revisions to Regulation 1591, *Medicines and Medical Devices*, Regarding Products Approved by the FDA to Treat Medical Conditions**

### **I. Issue**

Should the definition of “medicines” in Regulation 1591, *Medicines and Medical Devices*, be revised to clarify that certain products approved by the U.S. Food and Drug Administration (FDA) to treat medical conditions are included within the definition?

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

As agreed upon by staff and petitioners, staff proposes to amend subdivisions (a)(9) and (b) of Regulation 1591 to clarify the application of tax to certain sales of medical products. The proposed amendments would provide:

(a)(9) MEDICINES. “Medicines” means:

(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) “MEDICINES.” In addition to the definition set forth in subdivision (a)(9) of this section, The the term “medicines” means and includes the following items...

A copy of staff’s proposed amendments is illustrated in Exhibit 2. See Issue Paper (IP) pages 5-9, and agenda action item 1.

### **III. Other Alternative(s) Considered**

Alternative 2 – Do not amend Regulation 1591. Issue an opinion from the Legal Department stating that sales of Botox® and Botox® Cosmetic fall within the definition of “medicines” as provided in Revenue and Taxation Code (RTC) section 6369. See IP page 9.

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#### IV. Background

In September 2005 the California Society of Dermatology and Dermatologic Surgery, the California Society of Plastic Surgery, the California Academy of Ophthalmology, and the California Medical Association (hereafter, collectively, petitioners) filed a petition with the Board of Equalization (Board) to amend subdivisions (a)(9) and (b) of Regulation 1591 to revise the definition of “medicines.” The petition proposed that the following revisions be made:

(a)(9) MEDICINES. “Medicines” means (a) any product approved to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition by the U.S. Food and Drug Administration, or (b) any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) “MEDICINES.” In addition to the definition set forth in subdivision (a)(9) of this section, the ~~The~~ term “medicines” means and includes the following items:

The petitioners are of the opinion that the revisions are needed because Board auditors are erroneously assessing tax on sales of prescription drugs used to treat medical conditions. Specifically, auditors have questioned non-taxed sales of Botox® and Botox® Cosmetic when the eventual application of the product is to treat skin wrinkles.

The Board heard the petition at the October 25, 2005 Board meeting. (The petition is available on the Board’s Web site at <http://www.boe.ca.gov/meetings/pdf/OCT25PAN.pdf> under item J2.) In reply to the petition, staff stated that the proposed language provided a reasonable basis on which to resolve the issue. The Board referred the issue to the Business Taxes Committee (BTC) to work on the proposed regulatory language through an expedited interested parties process.

On November 23, 2005, staff distributed its discussion paper on this issue. After review of industry’s petition, staff agreed that Botox® and Botox® Cosmetic fall within the definition of “medicines” as provided in RTC section 6369. However, the paper expressed concerns that since the FDA approves a variety of products, including devices, appliances, equipment and other medical-related products, the revisions proposed by the petitioners could be interpreted more broadly than intended. Accordingly, to clarify the effect of the proposed regulatory revisions, staff recommended replacing the petitioner’s proposed phrase “any product approved” with “any drug approved.” At the November 30, 2005 interested parties meeting, representatives from industry expressed various concerns with this revision. After discussion of the issue, staff and industry agreed to address staff and industry concerns by retaining the term “product” but beginning subdivision (a)(9) with the phrase, “except as provided in subdivision (c).” The addition of this phrase clarifies that while certain products are approved by the FDA, they are excluded from the definition of “medicine” as designated by the legislature and listed in subdivision (c).

Following the interested parties meeting, staff received submissions from Mr. John Valencia, representing the petitioners (see Exhibit 4) and Dr. Malcolm Paul, representing the California Society of Plastic Surgeons (CSPS) (see Exhibit 5) supporting the staff recommendation. There is, however, disagreement about the effect of the revisions on implanted devices. (See the Description of Staff

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Recommendation section (page 5) for a discussion of the different interpretations of the proposed revisions.) In addition to the submissions from Mr. Valencia and CSPA, staff received 43 submissions from interested parties expressing general support that sales of prescription drugs, specifically Botox® and Botox® Cosmetic, should not be taxed.

### Current Application of Tax

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

RTC section 6369, interpreted and implemented by Regulation 1591, provides that sales or other transfers of medicines as defined in the statute are not subject to tax if they are sold or otherwise transferred pursuant to the requirements set forth in the statute. In section 6369, subdivision (b), the Legislature has provided that the term “medicines” means “any substance or preparation *intended for use* by external or internal application to the human body *in the diagnosis, cure, mitigation, treatment, or prevention of disease* and commonly recognized as a substance or preparation intended for that use [emphasis supplied].” Thus, the intent (or professional judgment) of the qualified person (e.g., doctors) ultimately prescribing or furnishing the substance or preparation for treatment is an essential element to the statutory definition of “medicines.” Assuming all the other requirements for exemption are met, the Legislature has set up a statutory scheme where the professional judgment of doctors is deferred to regarding whether they have prescribed or furnished the substance or preparation for use in the treatment of a disease or for some other purpose (e.g., for a purpose that is purely cosmetic and wholly unrelated to the treatment of a medical condition).

While acknowledging that sales of Botox® are not subject to tax when the product is used to treat physical maladies like cervical dystonia (i.e., a muscle disorder leading to an abnormal positioning of the head), field audit staff questioned the taxability of sales of Botox® and Botox® Cosmetic when the products were used for what they considered to be cosmetic purposes (i.e., merely improving physical appearance). The audit staff believed that the products did not meet the definition of “medicines” as provided in Regulation 1591. The audit staff’s position on sales of Botox® and Botox® Cosmetic under such circumstances is consistent with staff’s handling of implanted devices that are used for cosmetic purposes, such as collagen that is injected under a patient’s skin to smooth the appearance of wrinkles. However, after further review of the issue, staff now agrees that it is unnecessary to question the professional judgment of the doctors who had determined that their use of Botox® and Botox® Cosmetic was intended to treat medical conditions.

### Medicines in General

In order for the sale of a medicine to be exempt from California Sales and Use Tax, the item must (1) meet the definition for “medicines,” and (2) be sold or furnished under one of the conditions described in subdivision (d) of Regulation 1591. Specifically, in relevant part, subdivision (d) requires that the medicine be:

- prescribed for the treatment of a human being by a person authorized to prescribe medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

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- furnished by a licensed physician, dentist or podiatrist to his or her own patient for treatment of the patient, or
- furnished by a health facility for treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist, or
- sold to a licensed physician, dentist, podiatrist or health facility for the treatment of a human being.

See Exhibit 3 for the full provisions of Regulation 1591, subdivision (d).

Neither staff nor industry recommends revision to subdivision (d). Therefore, to be exempt, the sale of any product that meets a revised definition of “medicines” would still need to meet the requirements of subdivision (d).

#### General Audit Procedures for Verifying Exempt Sales of Medicines

It should be noted that staff’s position does not require nor permit auditors to review personal patient records to verify whether an item was prescribed or furnished to treat a medical condition. While Regulation 1698, *Records*, provides that retailers must provide documentation to support claimed exemptions, staff agrees that auditors should not examine a patient’s personal medical records. Auditors can, and do, exercise other verification methods that do not involve the auditor examining patients’ personal medical records. For example:

- When auditing a manufacturer of medical products, an auditor will verify claimed exemptions for sales of medicines by examining the manufacturer’s file of exemption certificates. If the manufacturer does not maintain exemption certificates for tested sales, the auditor can have the manufacturer send letters to their customers (e.g., doctors) asking if the products were used in a manner that would qualify for exemption. Accepting that doctors have an ethical responsibility to honestly respond to the Board’s inquiry and acknowledging that the Legislature has mandated by statute that the judgment of qualified medical professionals is controlling with respect to the intended use of the products, such statements by doctors would be accepted without further investigation.
- When auditing a doctor or hospital, auditors rely on the information provided by the doctor and professional medical staff to determine if the procedure was performed for medical or cosmetic purposes. To the extent the information provided is incomplete or is otherwise unreliable, the auditor can also ask if the item was used in a procedure covered by insurance. The auditor can assume that the product was used in the diagnosis, cure, mitigation, treatment or prevention of disease if the procedure was covered by the patient’s health insurance. Auditors can verify payment by reviewing billing records between doctors or hospitals and insurance companies by procedure/insurance codes with the patient’s name omitted. Such redacted billing records are not part of patients’ personal medical records.

To the extent the Board would like staff to examine and modify our procedures regarding the verification of claimed exempt sales of medicines, staff is certainly open to revising these procedures as needed.

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## V. Alternative 1 - Staff Recommendation

### A. Description of the Staff Recommendation

Staff and petitioners propose amending subdivisions (a)(9) and (b) of Regulation 1591 to provide:

(a)(9) MEDICINES. “Medicines” means:

(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

(b) “MEDICINES.” In addition to the definition set forth in subdivision (a)(9) of this section, The the term “medicines” means and includes the following items:

An overview of how Regulation 1591 is organized may help understand the scope of the recommended language and why staff believes it covers the sales and use of a product like Botox® and Botox® Cosmetic.

Subdivision (a) provides general definitions of terms used in the regulation. Paragraph 9 defines “medicines.”

Subdivision (b) provides the classifications and examples of products that qualify as medicines under specified conditions.

Subdivision (c) provides the statutory exclusions from the definition of “medicines.” A product excluded from “medicines” under (c) is also excluded from “medicines” under (a), unless it satisfies the listed conditions provided in (b).

For example, a prosthetic device is a product specifically excluded from the definition of “medicines” in subdivision (c). As such, the prosthetic device is not a medicine under the general definition provided in subdivision (a), unless it meets the conditions specified in (b). Namely, the prosthetic device is designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body. A prosthetic device that is not worn on or in the patient, or is worn for a purpose other than to replace or assist the functioning of a natural part of the human body, would not meet the statutory definition of “medicines.”

The revisions proposed by staff and petitioners properly interpret the definition of “medicines” as defined in RTC section 6369, subdivision (b), and will include substances and preparations such as Botox® and Botox® Cosmetic within the definition of “medicines.” When Botox® and Botox® Cosmetic are sold or furnished as provided in subdivision (d) of Regulation 1591, no tax will be due on those transactions. This is so because staff accepts that doctors only give patients injections of Botox® and Botox® Cosmetic when, in the professional judgment of the doctors, they are treating a medical condition.

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In addition, staff interprets the phrase, “Except as provided in subdivision (c)” to mean that the provisions of Regulation 1591, subdivision (c), must be considered before applying the language in proposed subdivision (a)(9)(A). Subdivision (c) of Regulation 1591 provides in relevant part:

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

(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. “Medicines” does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

Thus, staff believes that although the FDA Center for Devices and Radiological Health may approve<sup>1</sup> devices such as implants for treatment of medical conditions, those items are excluded from the definition of “medicines” except as provided in subdivision (b) of Regulation 1591.

For example, dermal implants like collagen are Class III devices approved by the FDA for the correction of soft tissue contour deficiencies such as wrinkles and acne scars. Staff believes dermal implants are devices excluded in Regulation 1591, subdivision (c), from the definition of “medicines” except as provided in subdivision (b). Regulation 1591, subdivision (b)(2), provides that tax does not apply to the sale or use of “[a]rticles 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 [emphasis added]” when such articles are sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Staff has interpreted this to mean that when collagen is used for an aesthetic purpose such as smoothing the appearance of lines and wrinkles from aging, the collagen does not qualify as a medicine. This is so because collagen injected for aesthetic purposes is not *assisting* the functioning of a natural organ or limb, but is merely affecting the appearance of an otherwise healthy and properly functioning part of the body. However, collagen would qualify as a medicine when used in a corrective procedure such as assisting in the functioning of a qualified part of the body (including restoration of appearance)

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<sup>1</sup> The Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act established three regulatory classes for medical devices. Class I devices present minimal potential for harm to the user and are often simpler in design than Class II and III devices. Examples of Class I devices are elastic bandages and examination gloves. Most Class I devices are exempt from FDA clearance or approval. Class II devices pose more risk and are subject to more FDA controls. Examples of Class II devices are infusion pumps and urinary catheters. Class II devices may not require specific FDA approval. For example, if a manufacturer can demonstrate to the FDA that a device is substantially equivalent to a device already on the market (i.e., is as safe and effective), the FDA can clear the product for marketing without going through the FDA approval process. Class II devices may also be exempt from FDA clearance or approval under certain circumstances. Class III devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Dermal implants and breast implants are examples of Class III devices. Generally, new Class III devices require premarket approval by the FDA. (See article, “Learn if a Medical Device Has Been Cleared by FDA for Marketing,” [www.fda.gov/cdrh/consumer/geninfo.html](http://www.fda.gov/cdrh/consumer/geninfo.html).)

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when used to treat atrophy or scarring from disease or trauma, skin graft or other surgically induced irregularity.

In another example, saline-filled breast implants are Class III devices approved by the FDA. Again, staff believes breast implants are devices excluded in Regulation 1591, subdivision (c), from the definition of “medicines” except as provided in subdivision (b). Regulation 1591, subdivision (b)(5), provides that “[p]rosthentic 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 [emphasis added]” are medicines under RTC section 6369, subdivision (c)(4). Staff has interpreted this to mean that when a breast implant is sold in connection with a reconstructive surgical procedure to treat the loss of a breast (such as following a mastectomy), the implant constitutes a prosthetic device designed to be worn in the person of the user to **replace** a natural part of the human body. Under those circumstances, the implant qualifies as a medicine under subdivision (b)(5). However, when a breast implant is sold as part of a purely cosmetic procedure to merely **enhance or augment** the size of existing breasts, staff believes that those implants are not used to replace or assist the functioning of a natural part of the human body. Therefore, those implants do not constitute medicines within the meaning of subdivision (b)(5) and their sales are not exempt. This interpretation of the proposed amendments significantly differs from interpretation of the California Society of Plastic Surgeons (CSPS).

In its interested party letter of December 7, 2005, CSPS points out that breast implants are commonly used to treat multiple medical conditions including but not limited to breast reconstruction, breast asymmetry, Poland’s Syndrome,<sup>2</sup> and congenital underdevelopment of the breasts. CSPS believes that because the FDA approves breast implants to treat medical conditions, breast implants will always qualify as medicines under subdivision (a)(9). While staff agrees that breast implants used to treat medical conditions would be replacing or assisting the function of a natural part of the human body, staff does not agree that breast implants used solely for cosmetic augmentation (i.e., wholly unrelated to medical treatment) qualify as medicines.

Staff does not believe that RTC section 6369, subdivision (b), supports a blanket exemption to items classified as devices. With certain exceptions, the Legislature specifically excluded prosthetic devices from the provisions of RTC section 6369. Unless a device meets those exceptions as interpreted in subdivision (b) of Regulation 1591, the product cannot be considered a medicine under the statute. In addition, staff has long considered devices such as breast and dermal implants to be outside the definition of “medicines” when used in cosmetic procedures. To attempt at this time to redefine those items as medicines under Regulation 1591 would be outside the scope of the petition filed before the Board and the resulting staff recommendation to revise the regulation. Such re-interpretation would also result in refunds of previously reported tax. When the Board directed that this issue be handled through an expedited BTC process, staff understood that the proposed revisions were a revenue neutral clarification of Regulation 1591. If the Board wishes to examine the issue of which implanted devices should be included in the definition of “medicines,” staff believes that a significant revenue impact may exist and that the issue would be better considered as a separate BTC matter with a full interested parties process.

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<sup>2</sup> Poland’s Syndrome is a congenital cause of breast asymmetry. Poland’s Syndrome causes underdevelopment of one breast and its underlying musculature along with anomalies of the ipsilateral (same side) hand.

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Staff also understands that, under the legal principle that “[p]articular expressions qualify those that are general” (Civ. Code, § 3534), the proposed changes to subdivisions (a)(9) and (b) of Regulation 1591 would have no effect on the application of Regulations 1591.1, 1591.2, 1591.3, 1591.4, 1602, etc., and that the particular expressions set forth in other regulations would be controlling with respect to any transactions subject to those regulatory provisions. In other words, staff does not believe the proposed amendments to Regulation 1591 would affect the application of tax to transactions governed by other provisions of the Sales and Use Tax Law.

In addition to the proposed revisions discussed above, staff will also correct a typographical error in the regulation by deleting the end quotation marks at the end of Regulation 1591, subdivision (a)(5) (see Exhibit 3).

### **B. Pros of the Staff Recommendation**

- Addresses the petitioners’ concerns regarding the application of tax to sales of Botox® and Botox® Cosmetic.
- Clarifies the definition of “medicines” within Regulation 1591.

### **C. Cons of the Staff Recommendation**

- Amended language could be misinterpreted to include implants and other devices beyond what is provided in RTC section 6369.

### **D. Statutory or Regulatory Change**

No statutory change needed. However, the recommendation will require amendment of Regulation 1591.

### **E. Administrative Impact**

- Requires notification of Board staff explaining the effect of amendments on current audit procedures.
- Staff will notify taxpayers of the amendments through an article in the Tax Information Bulletin (TIB).

### **F. Fiscal Impact**

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

The workload associated with publishing the regulation and TIB article is considered routine and any corresponding cost would be absorbed within the Board’s existing budget.

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

None. See Revenue Estimate (Exhibit 1).

### **G. Taxpayer/Customer Impact**

This action would resolve audits where assessing tax on sales of Botox® and Botox® Cosmetic was under consideration. Because Board staff would interpret the change as not affecting sales of prosthetic and implanted devices, staff is not aware of any refund claims that would result from this

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action. There would be no change in the application of tax to sales and use of other medical products.

#### **H. Critical Time Frames**

None. The amended regulation will become effective 30 days after approval by the Office of Administrative Law.

### **VI. Alternative 2**

#### **A. Description of the Alternative**

Do not amend Regulation 1591. Issue an opinion from the Legal Department stating that sales of Botox® and Botox® Cosmetic are exempt sales of medicines as provided in RTC section 6369.

#### **B. Pros of the Alternative**

- Addresses the petitioners' concerns regarding the application of tax to sales of Botox® and Botox® Cosmetic.
- Resolves the issue without going through the rulemaking process.

#### **C. Cons of the Alternative**

- Clarifying language is not provided in Regulation 1591.

#### **D. Statutory or Regulatory Change**

None.

#### **E. Administrative Impact**

- Requires notification of Board staff explaining the effect of the opinion on current audit procedures.

#### **F. Fiscal Impact**

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

None.

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

None. See Revenue Estimate (Exhibit 1).

#### **G. Taxpayer/Customer Impact**

This action would resolve audits where assessing tax on sales of Botox® and Botox® Cosmetic was under consideration. Board staff is not aware of any refund claims that would result from this action. There would be no change in the application of tax to sales of other medical products.

#### **H. Critical Time Frames**

None.

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

Current as of: January 20, 2006



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PROPOSED REVISIONS TO REGULATION 1591, *MEDICINES AND MEDICAL DEVICES*, REGARDING PRODUCTS APPROVED BY THE FDA TO TREAT MEDICAL CONDITIONS

**Alternative 1 - Staff Recommendation**

As agreed upon by staff and petitioners, staff proposes to amend subdivisions (a)(9) and (b) of Regulation 1591 to clarify the application of tax to certain sales of medical products. The proposed amendments would provide:

(a)(9) **MEDICINES.** “Medicines” means:

(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, 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.

(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...

A copy of staff’s proposed amendments is illustrated in Exhibit 2. See Issue Paper (IP) pages 5-9, and agenda action item 1.

**Other Alternative(s) Considered**

**Alternative 2**

Do not amend Regulation 1591. Issue an opinion from the Legal Department stating that sales of Botox® and Botox® Cosmetic fall within the definition of “medicines” as provided in Revenue and Taxation Code (RTC) section 6369.

Revenue Estimate

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

### **Alternative 1 - Staff Recommendation**

Staff asserts that the proposed revisions by staff and petitioners meet the definition of “medicine” as defined in RTC section 6369(b) and will include substances and preparations such as Botox® and Botox® Cosmetic within the definition of medicine. When Botox® and Botox® Cosmetic are sold or furnished as provided in subdivision (d) of Regulation 1591 no tax will be due on those transactions. In addition, staff interprets the phrase, “Except as provided in subdivision (c)” to mean that the provisions of Regulation 1591, subdivision (c), must be considered before applying the language in subdivision (a)(9)(A).

There is nothing in the proposed amendment to Regulation 1591 (a)(9) and (b) that would impact revenue. The amendments only clarify existing law governing the application of tax to sales of medicine pursuant to the RTC section 6369(b). Since Botox® and Botox® Cosmetic have been approved by the U.S. Food and Drug Administration to treat medical conditions that are included within the definition, this proposed amendment to Regulation 1591 does not impact revenue.

### **Alternative 2**

Alternative 2 would not amend the current Regulation 1591. The Board’s Legal Department would issue an opinion stating that Botox® and Botox® Cosmetic fall within the definition of medicines as provided in RTC section 6369. The Legal Department’s opinion would provide guidance to the Board’s audit staff while conducting field audits of taxpayers providing medicinal products and services using Botox® and Botox® Cosmetic. There is nothing in Alternative 2 that would impact revenue.

## **Revenue Summary**

Alternative 1 - The staff recommendation does not have a revenue impact.

Alternative 2 – The alternative does not have a revenue impact.

## **Preparation**

Bill Benson, Jr., Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. Mr. Dave Hayes, Manager, Research and Statistics Section, Legislative and Research Division, and Mr. Jeff McGuire, Tax Policy Manager, Sales and Use Tax Department, reviewed this revenue estimate. For additional information, please contact Mr. Benson at (916) 445-0840.

Current as of January 17, 2006

cc: Ms. Leila Khabbaz

Ms. Lynn Whitaker

**Regulation 1591, Medicines and Medical Devices**  
**Comparison of Current and Proposed Language**  
 Current as of January 11, 2006

Action Item	Current Regulatory Language	Alternative 1: Regulatory Language Proposed by Staff	Summary Comments
<b>ACTION 1 -</b>			
Amend subdivisions (a)(9) and (b) of Regulation 1591 to clarify	<p>Regulation 1591, <i>Medicines and Medical Devices</i></p> <p>(a) Definitions.                      (9) MEDICINES. “Medicines” means any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p> <p>(b) “MEDICINES.” The term “medicines” means and includes the following items:</p>	<p>Regulation 1591, <i>Medicines and Medical Devices</i></p> <p>(a) Definitions.                      (9) MEDICINES. “Medicines” means:</p> <p><u>(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, or</u></p> <p><u>(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.</u></p> <p>The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.</p> <p>(b) “MEDICINES.” <u>In addition to the definition set forth in subdivision (a)(9) of this section,</u> <del>The</del>the term “medicines” means and includes the following items:</p>	<p>Staff and petitioners agree on the proposed revisions. However, staff and the California Society of Plastic Surgeons (CSPS) disagree how the language should be interpreted.</p> <p>CSPS believes that because the FDA approves breast implants to treat medical conditions, all breast implants will qualify as medicines. Staff believes breast implants are prosthetic devices that must still meet the provisions of Regulation 1591, subdivision (b), to qualify as “medicines.”</p>

**REGULATION 1591. MEDICINES AND MEDICAL DEVICES.**

*Reference:* Sections 6006 and 6369 Revenue and Taxation Code.

**(a) DEFINITIONS.**

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

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

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

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

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

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

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

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

**(A)** The name or names and address of the patient or patients.

**(B)** The name and quantity of the drug or device prescribed and the directions for use.

**(C)** The date of issue.

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

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

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

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

(9) MEDICINES. "Medicines" means:

(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, or

(B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment or prevention of disease and which is commonly recognized as a substance or preparation intended for that use.

The term medicines also includes certain articles, devices, and appliances as described in subdivision (b) of this regulation.

**(b) "MEDICINES."** In addition to the definition set forth in subdivision (a)(9) of this section, the term "medicines" means and includes the following items:

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

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

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

Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.

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

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

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

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

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

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

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

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

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

(5) **PROSTHETIC DEVICES.** Prosthetic devices and their replacements parts designed to be worn on or in the patient to replace or assist the functioning of a natural part of the human body are medicines as provided under Revenue and Taxation Code section 6369(c)(4). The sale or use of prosthetic devices and their replacement parts is not subject to tax when sold or furnished under one of the conditions provided in subdivision (d)(1) through (d)(6). Prosthetic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, prosthetic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons are deemed to be dispensed on prescription within the meaning of subdivision (d)(1). For purposes of this regulation only, prosthetic devices include bags and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense enteral feeding to the patient, including: gastrostomy tubes (also called G tubes) which are used to deliver the nutrition directly into the stomach; jejunostomy tubes (also called J tubes) which are used to deliver the nutrition directly into the intestinal tract; and nasogastric tubes (also called NG tubes) which are used to deliver the nutrition directly through the nasal passage to the stomach. For purposes of this regulation only, prosthetic devices also include needles, syringes, cannulas, bags, and tubing, as well as filters, locks, tape, clamps, and connectors which are integral to the tubing, each of which is used to dispense TPN or IDPN to the patient, provided each of these items is used primarily to dispense the TPN or IDPN.

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

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

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

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

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

(1) Orthodontic, prosthetic (except as described in subdivision (b)(6)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, or foot orthoses.

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

**(d) APPLICATION OF TAX—IN GENERAL.**

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

(1) prescribed for the treatment of a human being by a person authorized to prescribe the medicines, and dispensed on prescription filled by a pharmacist in accordance with law, or

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

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

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

(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) **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 Revenue and Taxation Code section 6369:

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

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

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

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December 7, 2005

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**VIA E-MAIL FOLLOWED BY FACSIMILE (916) 322-4530**

Lynn Whitaker  
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450 N Street  
PO Box 942879  
Sacramento, CA 94279-0092

**Re: Interested Parties Meeting of 11/30/05 re Proposed Revisions to BOE  
Regulation 1591**

Dear Ms. Whitaker:

On behalf of Petitioners in the above referenced matter, we wanted, first, to thank the staff of the Board in fostering a productive exchange regarding the staff-generated discussion paper for the meeting.

Petitioners understanding of the outcome of this exchange is that there is concensus on the part of BOE staff, Petitioners and interested parties such as the manufacturer of Botox® and Botox Cosmetic® that:

(1) Petitioners' proposed language will be preceded by a phrase to the effect that Medicines means, "**(a) except those exclusions set forth in subdivision (c),...**" ; and,

(2) The grammatical repositioning of the reference to U.S. Food and Drug Administration is appropriate; and,

(3) The balance of Petitioners' proposed language will be retained as presented in the petition, as the newly-proposed cross-reference to subdivision (c) resolves staff concerns raised in its discussion paper.

Lynn Whitaker  
December 7, 2005  
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Thus, the proposed changes in their entirety would read, "Medicines" means (a) Except those exclusions set forth in subdivision (c), any product approved by the United States Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition, or (b)...." The following subsection would retain existing language that starts, "any substance or preparation intended for use by external or internal...."

Again, our appreciation is extended for all staff efforts and work in this regard.

Sincerely,

/s/

John R. Valencia

JRV:dr

cc: Jeffrey L. McGuire  
Chief, Tax Policy Division  
Sales and Use Tax Department

196265.2



December 7, 2005

Lynn Whitaker  
Board of Equalization  
State of California  
450 N Street  
PO Box 942879  
Sacramento, CA 94279-0092

**Re: Interested Parties' Meeting of 11/30/05 re Proposed Revisions to  
BOE Regulation 1591**

Dear Ms. Whitaker,

The California Society of Plastic Surgeons (CSPS) strongly urges you to approve the language that is being considered to change regulation 1591. This language would create a "bright line" test to determine whether a "medicine" is exempt from sales tax.

On November 30<sup>th</sup> at the "interested parties" meeting, the staff to the Board of Equalization discussed proposed amendments to Regulation 1591. At the conclusion of the meeting, the language that was discussed to be taken under consideration was as follows:

(9) MEDICINES. "Medicines" means:

(A) Except as provided in subdivision (c), any product approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat, or prevent any disease, illness or medical condition or

CSPS strongly supports this language and believes it will help clarify that not only should Botox and Botox Cosmetic be exempt from sales tax but also breast implants.

In the petition submitted by CSPS, the California Society of Dermatology and Dermatologic Surgery, the California Academy of Ophthalmology, and the California Medical Association to amend Regulation 1591, it was pointed out that in the FDA approved product insert for Botox and Botox Cosmetic it specifically stated that

“(BOTOX) is currently licensed for the treatment of cervical dystonia in adults to decrease the severity of abnormal head position and neck pain associated with cervical dystonia”. It also stated “Under this approval, Botulinum Toxin Type A (Botox Cosmetic) may be used for the temporary improvement in the appearance of moderate to severe glabellar lines”. Furthermore, an associated document published by the FDA describes glabellar lines as “a medical condition that is not serious”. Establishing that Botox and Botox Cosmetic are both approved by the FDA to be used to treat medical conditions, regardless of whether the procedure was considered, allows them to be exempt from sales taxes under the proposed amendments to Regulation 1591.

Breast implants, which are approved by the FDA, are commonly used to treat multiple medical conditions including but not limited to breast reconstruction, breast asymmetry, Poland’s syndrome, and congenital underdevelopment of the breasts. Although CSPS has not verified the FDA approved product language for breast implants, it is our belief that the FDA approved language will specify the use of breast implants to treat medical conditions. We are continuing to research the FDA approved product documentation associated with various breast implants to verify our assumptions. Upon verification that breast implants are approved by the FDA to be used to treat medical conditions, CSPS believes that breast implants will also have met the “bright line” test to be exempt from sales taxes.

Approving the amended regulatory change above will create the “bright line” test that will relieve the audit staff of trying to determine what is a cosmetic procedure.

CSPS appreciates the opportunity to submit comments on this important matter.

Regards,



Malcolm Paul, M.D.  
President, California Society of Plastic Surgeons (CSPS)

cc: Jeffrey L. McGuire  
Chief, Tax Policy Division  
Sales and Use Tax Department