



STATE OF CALIFORNIA

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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 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 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 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**

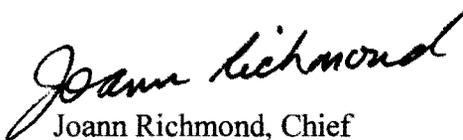
The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory 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.

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

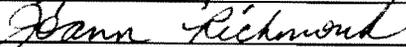
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**STATE BOARD OF EQUALIZATION**



BOARD APPROVED

At the April 28, 2015 Board Meeting

  
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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 sSection 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.

## 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