STATE OF CALIFORNIA

STATE BOARD OF EQUALIZATION
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March 24, 2017

To Interested Parties:

TITLE 18. BOARD OF EQUALIZATION

The State Board of Equalization Proposes to Adopt Amendments to California Code of Regulations, Title 18, Section 1591, *Medicines and Medical Devices*

NOTICE IS HEREBY GIVEN that the State Board of Equalization (Board), pursuant to the authority vested in it by Revenue and Taxation Code (RTC) section 7051, proposes to adopt amendments to California Code of Regulations, title 18, section (Regulation or Reg.) 1591, *Medicines and Medical Devices*. The proposed amendments to Regulation 1591, subdivision (b)(2), clarify that articles permanently implanted in the human body to "monitor" a medical condition qualify as medicines and that tax does not apply to the sale or use of articles permanently implanted in the human body to "monitor" 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 Regulation 1591, subdivision (d)(1) through (d)(6).

PUBLIC HEARING

The Board will conduct a meeting in Room 121 at 450 N Street, Sacramento, California on May 23-25, 2017. 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* at least 10 days in advance of the meeting.

A public hearing regarding the proposed regulatory action will be held at 9:00 a.m. or as soon thereafter as the matter may be heard on May 23, 24, or 25, 2017. 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 and 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).) 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; Reg. 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. (RTC, 6201, 6401.) The use tax is imposed on the person actually storing, using, or otherwise consuming the property. (RTC, § 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. (RTC, § 6203; Reg. 1684.)

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 Regulation 1591, *Medicines and Medical Devices*, to implement, interpret, and make specific the exemption provided by 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 United States 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 currently 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 currently includes several categories of articles and devices (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. And, prior to the 2015 amendments (discussed below), Regulation 1591, subdivision (b)(2), provided that:

> (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.

Also, as relevant here, the Board's Legal Department had previously determined, as early as 1965, that diagnostic "opaques and dyes" are medicines as defined in RTC section 6369. This determination is found in Sales and Use Tax Annotation 425.0580, which provides as follows:

> **Opaques and Dyes.** Opaques and dyes used by hospitals and doctors in examination of patients are given internally to the patients and facilitate the taking of diagnostic x-ray photographs. Since such opaques and dyes are intended for use by internal application to the human body in diagnosis of disease they qualify as medicines under section 6369 of the Revenue and Taxation Code. 9/1/65.

(Annotations are summaries of conclusions reached in selected legal rulings of Board counsel, as applied to specific factual situations, and do not have the force and effect of law (Reg. 5700).) A breast tissue marker (BTM) is a sterile disposable medical device that is 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. A doctor places a BTM in soft breast tissue during a surgical or percutaneous (i.e., performed through the skin) biopsy for the purpose of marking the site so that the site 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 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 locate and diagnosis breast cancer, and BTMs perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. Therefore, the Board determined that the BTMs at issue were "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that there was an issue (or problem) with

Regulation 1591 because it did not specifically address items that are fully implanted in the human body to mark the location of a medical condition, such as BTMs, and, to address the issue, the Board Members unanimously voted to direct staff to draft amendments to Regulation 1591 to clarify the treatment of such "fully" implanted items.

Subsequently, during the Board's April 2015 meeting, the Board Members unanimously voted to adopt amendments adding the following quoted language to the first paragraph in Regulation 1591, subdivision (b)(2), that was recommended by Board staff, and the amendments became effective on October 1, 2015:

- "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"; and
- 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).

The Board determined that the 2015 amendments were reasonably necessary for the specific purpose of clarifying the application of tax to articles, such as BTMs, that are permanently implanted in the human body to mark the location of a medical condition.

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

However, during the April 2015 meeting, the Board expressed concerns that the new language being added to Regulation 1591 by the 2015 amendments may be too narrow to clarify the treatment of all fully implanted items that are similar to BTMs, and that there may still be an issue (or problem within the meaning of Gov. Code, § 11346.2, subd. (b)(1)) with Regulation 1591 if it still excludes some articles that are permanently (and fully) implanted in the human body and perform similar functions to BTMs from the definition of "medicines." Therefore, Board staff examined the concern further and subsequently determined that the 2015 amendments were too narrow because they did in fact exclude some articles that are permanently (and fully) implanted in the human body and perform similar functions to BTMs from the definition of medicines.

This is because articles, such as BTMs, are permanently implanted in the human body to mark the locations of medical conditions so that doctors can "monitor" and if necessary treat the medical conditions, themselves. There are other articles that are permanently implanted in the human body so that doctors can "monitor" and if necessary treat medical conditions, but that do not mark the locations of medical conditions, and these additional articles should also qualify as medicines because they are permanently implanted in the human body and perform similar functions to BTMs in regard to the diagnosis and treatment of medical condition. However, these similar articles were unintentionally excluded from the clarifications made by the 2015 amendments to the definition of medicines precisely because they do not mark the locations of

medical conditions. Therefore, to address this issue (or problem) Board staff drafted and proposed two minor amendments to Regulation 1591, subdivision (b)(2), to clarify that articles permanently implanted in the human body to mark the location of "or otherwise monitor" a medical condition qualify as medicines and that tax does not apply to the sale or use of articles permanently implanted in the human body to mark the location of "or otherwise monitor" 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 Regulation 1591, subdivision (d)(1) through (d)(6).

On May 27, 2016, Board staff provided its proposed amendments to Regulation 1591, subdivision (b)(2), to the interested parties, along with a discussion paper explaining the amendments. Staff conducted an interested parties meeting regarding the proposed amendments on June 8, 2016. Staff also received a letter dated June 23, 2016, from Mr. Wade Downey and Mr. Roderick Calub of Downey, Smith, & Fier regarding staff's proposed amendments. The letter explained that Downy, Smith & Fier represented the taxpayer in the appeal involving BTMs (discussed above) and stated that "Downey, Smith, & Fier, and its clients, strongly support the proposed clarification to Regulation 1591 and believe the changes will assist medical vendors, hospitals, and other healthcare providers . . . ."

Subsequently, Board staff prepared Formal Issue Paper 16-007 and distributed it to the Board Members for consideration at the Board's August 30, 2016, Business Taxes Committee (BTC) meeting. Formal Issue Paper 16-007 recommended that the Board propose to adopt staff's draft amendments to clarify Regulation 1591, subdivision (b)(2), to address the issue (or problem) described above by ensuring that all articles that are permanently implanted in the human body and perform similar functions to BTMs are included in the definition of medicines, as the Board originally intended. At the conclusion of the discussion of the issue paper on August 30, 2016, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary to have the effect and accomplish the objective of addressing the issue (or problem) with Regulation 1591, discussed above, by clarifying that articles permanently implanted in the human body to mark the location of "or otherwise monitor" a medical condition qualify as medicines and that tax does not apply to the sale or use of articles permanently implanted in the human body to mark the location of "or otherwise monitor" 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 Regulation 1591, subdivision (d)(1) through (d)(6).

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by clarifying the application of tax to articles permanently implanted in the human body to monitor a medical condition.

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.

ONE-TIME COST TO THE BOARD, BUT NO OTHER COST OR SAVINGS TO ANY STATE AGENCY, LOCAL AGENCY, OR SCHOOL DISTRICT

The Board determined that the proposed amendments to Regulation 1524 will result in an absorbable $396 one-time cost for the Board to update its website after the amendments are completed. The Board has determined that the adoption of the proposed amendments to Regulation 1591 will result in no other 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 assessed the economic impact of the proposed amendments to Regulation 1591 on California businesses and individuals and 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 prepared the economic impact assessment (EIA) required by Government Code section 11346.3, subdivision (b)(1), for the proposed amendments and included it in the initial statement of reasons. In the EIA, the Board determined that the adoption of the proposed amendments to Regulation 1591 will neither create nor eliminate jobs in the State of California nor create new businesses or eliminate existing businesses within the state nor expand businesses currently doing business in the state. Furthermore, the Board 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, 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, or by mail at State Board of Equalization, Attn: Rick Bennion, MIC:80, 450 N Street, P.O. Box 942879, Sacramento, CA 94279-0080. Mr. Bennion is the designated backup contact person to Mr. Heller.

WRITTEN COMMENT PERIOD

The written comment period ends at 9:00 a.m. on May 23, 2017, or as soon thereafter as the Board begins the public hearing regarding the adoption of the proposed amendments to Regulation 1591 during the May 23-25, 2017, Board meeting. Written comments received by Mr. Rick Bennion at the postal address, email address, or fax number provided above, prior to the close of the written comment period, will be presented to the Board and the Board will consider the statements, arguments, and/or contentions contained in those written comments before the Board decides whether to adopt the proposed amendments to Regulation 1591. The Board will only consider written comments received by that time.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an underscored and strikeout version of the text of Regulation 1591 illustrating the express terms of the proposed amendments. The Board has also prepared an initial statement of reasons for the adoption of the proposed amendments to Regulation 1591, which includes the economic impact assessment required by Government Code section 11346.3, subdivision (b)(1). These documents and all the information on which the proposed amendments are based are available to the public upon request. The rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed amendments and the initial statement of reasons are also available on the Board's Website at *www.boe.ca.gov*.

SUBSTANTIALLY RELATED CHANGES PURSUANT TO GOVERNMENT CODE SECTION 11346.8

The Board may adopt the proposed amendments to Regulation 1591 with changes that are nonsubstantial or solely grammatical in nature, or sufficiently related to the original proposed text that the public was adequately placed on notice that the changes could result from the originally proposed regulatory action. If a sufficiently related change is made, the Board will make the full text of the proposed regulation, with the change clearly indicated, available to the public for at least 15 days before adoption. The text of the resulting regulation will be mailed to those interested parties who commented on the original proposed regulation orally or in writing or who asked to be informed of such changes. The text of the resulting regulation will also be available to the public from Mr. Bennion. The Board will consider written comments on the resulting regulation that are received prior to adoption.

AVAILABILITY OF FINAL STATEMENT OF REASONS

If the Board adopts the proposed amendments to Regulation 1591, the Board will prepare a final statement of reasons, which will be made available for inspection at 450 N Street, Sacramento, California, and available on the Board's Website at *www.boe.ca.gov*.

Sincerely,

Joann Richmond

Joann Richmond, Chief
Board Proceedings Division

JR:reb

STATE BOARD OF EQUALIZATION

BOARD APPROVED

At the May 23, 2017 Board Meeting

Joann Richmond

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, PROBLEM 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 or Reg.) 1591, *Medicines and Medical Devices*, to implement, interpret, and make specific the exemption provided by 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 United States 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 currently 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 currently includes several categories of articles and devices (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. And, prior to the 2015 amendments (discussed below), Regulation 1591, subdivision (b)(2), provided that:

> (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.

Also, as relevant here, the Board's Legal Department had 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[1] 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.

A breast tissue marker (BTM) is a sterile disposable medical device that is 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. A doctor places a BTM in soft breast tissue during a surgical or percutaneous (i.e., performed through the skin) biopsy for the purpose of marking the site so that the site 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 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 locate and diagnosis breast cancer, and BTMs perform an almost identical function to diagnostic opaques and dyes that are injected into the body for the purpose of appearing on imaging technologies. Therefore, the Board determined that the BTMs at issue were "medicines" for purposes of the exemption provided by RTC section 6369. The Board also recognized that there was an issue (or problem) with

[1] Annotations, which are published in the Board's Business Taxes Law Guide**,** are summaries of conclusions reached in selected legal rulings of Board 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 Reg. 5700.)

Regulation 1591 because it did not specifically address items that are fully implanted in the human body to mark the location of a medical condition, such as BTMs, and, to address the issue, the Board Members unanimously voted to direct staff to draft amendments to Regulation 1591 to clarify the treatment of such "fully" implanted items.

Subsequently, during the Board's April 2015 meeting, the Board Members unanimously voted to adopt amendments adding the following quoted language to the first paragraph in Regulation 1591, subdivision (b)(2), that was recommended by Board staff, and the amendments became effective on October 1, 2015:

- "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"; and
- 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).

The Board determined that the 2015 amendments were reasonably necessary for the specific purpose of clarifying the application of tax to articles, such as BTMs, that are permanently implanted in the human body to mark the location of a medical condition.

Proposed Amendments

However, during the April 2015 meeting, the Board expressed concerns that the new language being added to Regulation 1591 by the 2015 amendments may be too narrow to clarify the treatment of all fully implanted items that are similar to BTMs, and that there may still be an issue (or problem within the meaning of Gov. Code, § 11346.2, subd. (b)(1)) with Regulation 1591 if it still excludes some articles that are permanently (and fully) implanted in the human body and perform similar functions to BTMs from the definition of "medicines." Therefore, Board staff examined the concern further and subsequently determined that the 2015 amendments were too narrow because they did in fact exclude some articles that are permanently (and fully) implanted in the human body and perform similar functions to BTMs from the definition of medicines.

This is because articles, such as BTMs, are permanently implanted in the human body to mark the locations of medical conditions so that doctors can "monitor" and if necessary treat the medical conditions, themselves. There are other articles that are permanently implanted in the human body so that doctors can "monitor" and if necessary treat medical conditions, but that do not mark the locations of medical conditions, and these additional articles should also qualify as medicines because they are permanently implanted in the human body and perform similar functions to BTMs in regard to the diagnosis and treatment of medical condition. However, these similar articles were unintentionally excluded from the clarifications made by the 2015 amendments to the definition of medicines precisely because they do not mark the locations of medical conditions. Therefore, to address this issue (or problem) Board staff drafted and proposed two minor amendments to Regulation 1591, subdivision (b)(2), to clarify that articles

permanently implanted in the human body to mark the location of "or otherwise monitor" a medical condition qualify as medicines and that tax does not apply to the sale or use of articles permanently implanted in the human body to mark the location of "or otherwise monitor" 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 Regulation 1591, subdivision (d)(1) through (d)(6).

On May 27, 2016, Board staff provided its proposed amendments to Regulation 1591, subdivision (b)(2), to the interested parties, along with a discussion paper explaining the amendments. Staff conducted an interested parties meeting regarding the proposed amendments on June 8, 2016. Staff also received a letter dated June 23, 2016, from Mr. Wade Downey and Mr. Roderick Calub of Downey, Smith, & Fier regarding staff's proposed amendments. The letter explained that Downy, Smith & Fier represented the taxpayer in the appeal involving BTMs (discussed above) and stated that "Downey, Smith, & Fier, and its clients, strongly support the proposed clarification to Regulation 1591 and believe the changes will assist medical vendors, hospitals, and other healthcare providers . . . ."

Subsequently, Board staff prepared Formal Issue Paper 16-007 and distributed it to the Board Members for consideration at the Board's August 30, 2016, Business Taxes Committee (BTC) meeting. Formal Issue Paper 16-07 recommended that the Board propose to adopt staff's draft amendments to clarify Regulation 1591, subdivision (b)(2), to address the issue (or problem) described above by ensuring that all articles that are permanently implanted in the human body and perform similar functions to BTMs are included in the definition of medicines, as the Board originally intended. At the conclusion of the discussion of the issue paper on August 30, 2016, the Board Members unanimously voted to propose the amendments to Regulation 1591 recommended by staff.

The Board determined that the proposed amendments to Regulation 1591 are reasonably necessary for the specific purpose of addressing the issue (or problem) with Regulation 1591, discussed above, by clarifying that articles permanently implanted in the human body to mark the location of "or otherwise monitor" a medical condition qualify as medicines and that tax does not apply to the sale or use of articles permanently implanted in the human body to mark the location of "or otherwise monitor" 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 Regulation 1591, subdivision (d)(1) through (d)(6).

The Board anticipates that the proposed amendments to Regulation 1591 will promote fairness and benefit taxpayers, Board staff, and the Board by clarifying the application of tax to articles permanently implanted in the human body to monitor a medical condition.

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 16-07, the exhibits to the issue paper, and the comments made during the Board's discussion of the issue paper during its August 30, 2016, 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, 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 to Regulation 1591, subdivision (b)(2), clarify that articles permanently implanted in the human body to "monitor" a medical condition qualify as medicines and that tax does not apply to the sale or use of articles permanently implanted in the human body to "monitor" 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 Regulation 1591, subdivision (d)(1) through (d)(6). The Research and Statistics Section of the Board's Legislative and Research Division determined that the proposed amendments will result in an annual loss of approximately $243,517 in sales and use tax revenue that is currently collected on the sale and use of permanently implanted monitoring devices, and an absorbable $396 one-time cost for the Board to update its website after the amendments are completed (assuming that average hourly compensation costs are $49.48 per hour and that it will take approximately eight hours). The Research and Statistics Section determined that businesses and individuals will not incur any costs to comply with the proposed amendments. The Research and Statistics Section also determined that if the Board had alternatively decided to take no action and not amend Regulation 1591 at this time, then there would be no new benefits to businesses and individuals and no new costs imposed on business and individuals as a result of that alternative.

There was no direct source of information available to Research and Statistics Section staff regarding the sales and use tax revenue that is currently collected on the sale and use of

permanently implanted monitoring devices. However, there was data available from the United States Food and Drug Administration (FDA) and United States Census Bureau (Census Bureau) that Research and Statistics Section staff determined that they could use to estimate the amount of sales of permanently implanted monitoring devices in California, and the sales and use tax revenue currently collected on the sale and use of such devices.

First, Research and Statistics Section staff downloaded the FDA's "List of Medical Devices, by Product Code, that FDA classifies as Implantable, Life-Saving, and Life-Sustaining Devices for purposes of Section 614 of FDASIA amending Section 519(f) of the FDC Act" (as updated by the FDA in March 2015). Staff examined the data in the list and determined that it consisted of 480 devices. Staff visually determined that four of these devices appeared to be classified as permanently implanted monitoring devices that would be exempt from sales and use tax under the proposed amendments to Regulation 1591, but not exempt under the current provisions of the regulation. Staff also determined that these four devices constituted approximately one percent of the 480 devices on the FDA list.

Second, Research and Statistics Section staff examined the United States Census Bureau's published 2012 United States values of shipments for detailed (10-digit) products and services codes found in the *Economic Census of the United States: Manufacturing: Industry Series: Product or Service Statistics for the U.S.: 2012*. Staff found that the Census Bureau's detailed products and services codes descriptions did not specifically distinguish implanted monitoring devices from non-implanted devices. Staff found that there were many products and services codes for specific types of monitoring devices, such as temperature and blood pressure monitoring units, but the products and services codes descriptions for these types of monitoring devices seemed to imply that none of these devices were implanted. Therefore, staff concluded that permanently implanted monitoring devices must be included in the category called "All Other Patient Monitoring Equipment," after reviewing all of the potentially applicable products and services codes descriptions for monitoring devices, and staff found that the Census Bureau data showed that in 2012 the product shipments value of All Other Patient Monitoring Equipment was $1,205,051,000.

Then, Research and Statistics Section staff made its revenue estimate by using an average statewide sales and use tax rate of 8.42 percent[2] and making the following two assumptions due to a lack of further data:

1. Staff assumed that two percent of the Census Bureau's 2012 value of $1,205,051,000 for All Other Patient Monitoring Equipment was for permanently implanted monitoring devices that would be exempt from sales and use tax under the proposed amendments to Regulation 1591, but not exempt under the current provisions of the regulation. This is because staff determined that such permanently implanted monitoring devices constituted approximately one percent of the "Implantable, Life-Saving, and Life-Sustaining

[2] 4.1875 percent (or approximately 4.19%) of the 8.42 percent average statewide sales and use tax rate is attributable to taxes that provide revenue for the state's general fund and the state's Education Protection Account. The remaining 4.2325 percent (or approximately 4.23%) of the 8.42 percent average statewide sales and use tax rate is attributable to taxes that provide revenue for local government.

Devices" on the FDA list (discussed above) and staff determined that it would be reasonable to double that percentage to account for growth in sales since 2012 and to allow for the possibility that staff may have missed some devices in the FDA list that may be exempt from sales and use tax under the proposed amendments to Regulation 1591, but not exempt under the current provisions of the regulation.

2. Staff assumed that 12 percent of the Census Bureau's 2012 value of $1,205,051,000 for All Other Patient Monitoring Equipment was for California sales based upon the state's 12 percent share of the United States' population. The 12 percent share was determined using the California Department of Finance Demographic Research Unit's population estimates for California and the Census Bureau's population estimates for the United State population for 2015.

As a result, Research and Statistics Section staff estimated that the proposed amendments would result in a $243,517 ($1,205,051,000*.02*.12*.0842) loss of sales and use tax revenue and that approximately 49.7625 percent or $121,180 of the loss was state revenue and approximately 50.2375 percent or $122,337 of the loss was local revenue.

In addition, Research and Statistics Section staff determined that permanently implanted monitoring devices are generally sold or furnished by large general medical and surgical hospitals, and it is unlikely that any of the hospitals selling or furnishing such devices are small businesses as defined in Government Code section 11342.610. There are approximately 430 large general medical and surgical hospitals operating in California that may benefit from the tax savings resulting from the proposed amendments to Regulation 1591 and that patients, insurers, and state government agencies could also benefit from reduced costs if the tax savings from the proposed amendments is passed on to consumers. Also, large general medical and surgical hospitals may perform a few more procedures to permanently implant monitoring devices as a result of the proposed amendments, but that the tax savings from the proposed amendments is too small to increase or decrease the number of large general medical and surgical hospitals operating in California or measurably increase or decrease jobs in large general medical and surgical hospitals.

Furthermore, once the Board's amendments to Regulation 1591 are effective they will apply retroactively (RTC, § 7051), and the Board will be authorized to refund the sales and use tax paid on the prior sale or use of medical devices that are retroactively exempt if a timely claim for refund is filed with the Board by the proper person. In general, a claim for refund is timely if it is filed within the later of: (1) three years from the due date of the return for the reporting period for which the tax was paid; (2) six months after the sales or use tax was paid to the Board; or (3) six months after a determination issued by the Board became final with respect to payments on the determination. (RTC, §§ 6901, 6902.) Also, a consumer is the proper person to file a claim for refund with the Board for use tax imposed on the consumer with regard to the purchase of a non-taxable medical device. (Reg. 1684.) A retailer is the proper person to file a claim for refund for sales tax imposed on the retailer with regard to the sale of a non-taxable medical device, regardless of whether the retailer collected sales tax reimbursement on the sale, but any refund of sales tax reimbursement collected from a customer must be returned to that customer. (RTC, § 6901.5; Reg. 1700.) And, a customer is not the proper person to file a claim for refund of sales tax imposed on a retailer, even if the customer paid reimbursement to the retailer for

such tax, because the collection of sales tax reimbursement depends solely upon the terms of the agreements of sale. (Civ. Code, § 1656.1; Reg. 1700.) In addition, the Board is not aware of any claims for refund that have already been filed for sales or use tax paid on the prior sale or use of medical devices that will be retroactively exempt once the proposed amendments are effective. Moreover, it is reasonable to assume that insurance paid a substantial portion of the sales tax reimbursement or use tax collected by retailers on the sale or use of medical devices that will be retroactively exempt once the proposed amendments to Regulation 1591 are effective, and the companies that paid such taxes will need to be reimbursed from any refunds. As a result, there is a lot of uncertainty as to whether a timely claim for refund will be filed by the proper person for the specific sales or use tax previously paid to the Board on the sale or use of each medical device that will be retroactively exempt. Consequently, refunds could vary from zero dollars to a maximum of up to three times the estimated annual revenue loss from the proposed amendments of $243,517 (3 x $243,517 = $730,551) based upon the three-year statute of limitations discussed above. However, the California Supreme Court has held that the RTC "provides the exclusive means by which [a] dispute over the taxability of a retail sale may be resolved" and that consumer protection statutes, such as Business and Professions Code section 17200 et seq., "cannot be employed to avoid the limitations and procedures set out by the [RTC]." (*Loeffler v. Target Corp.* (2014) 58 Cal.4th 1081, 1092.) So, the Board does not currently anticipate that consumers will file lawsuits, including consumer class action lawsuit, to obtain refunds.

Therefore, 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 create new businesses or eliminate existing businesses within the state nor expand businesses currently doing business in the state.

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, but it is unlikely because hospitals selling or furnishing permanently implanted monitoring devices are not likely to be small businesses as defined in Government Code section 11342.610.

Final Text of Proposed Amendments to

California Code of Regulations, Title 18, Section 1591

1591. Medicines and Medical Devices.

(a) Definitions.

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

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

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

(4) Health Facility. "Health Facility" as used herein has the meaning ascribed to the term in section 1250 of the Health and Safety Code, and also includes "clinic" as defined in sections 1200 and 1200.1 of the Health and Safety Code.

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

(B) Section 1200 of the Health and Safety Code provides that "clinic" means an organized outpatient health facility which provides direct medical, surgical, dental, optometric, or podiatric advice, services, or treatment to patients who remain less than 24 hours, and which may also provide diagnostic or therapeutic services to patients in the home as an incident to care provided at the clinic facility. A place, establishment, or institution which solely provides advice, counseling, information, or referrals on the maintenance of health or on the means and measures to prevent or avoid sickness, disease, or injury, where such advice, counseling, information, or referrals does not constitute the practice of medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this subdivision.

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

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

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

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

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

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

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

(C) The date of issue.

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

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

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

(8) Physicians, Dentists, Optometrists, and Podiatrists. "Physicians," "dentists," "optometrists," and "podiatrists" are persons authorized by a currently valid and unrevoked license to practice their respective professions in this state. "Physician" means and includes any person holding a valid and unrevoked physician's and surgeon's certificate or certificate to practice medicine and surgery, issued by the Medical Board of California or the

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

(9) Medicines. "Medicines" means:

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

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

(4) Orthotic Devices. Orthotic devices and their replacement parts, designed to be worn on the person of the user as a brace, support or correction for the body structure are medicines as provided under Revenue and Taxation Code section 6369(c)(3). The sale or use of orthotic devices and their replacement parts is not subject to tax when sold or furnished under one of

the conditions provided in subdivision (d)(1) through (d)(6). Orthotic devices and their replacement parts do not need to be furnished by a pharmacist, within the meaning of subdivision (d)(1), to be considered dispensed on prescription provided the devices are furnished pursuant to a written order of a physician or podiatrist. For the purposes of this regulation, orthotic devices furnished pursuant to a written order of a physician or podiatrist by, but not limited to, medical device retailers, clinics, physical therapists, device suppliers, intermediate care facilities, or other such persons, are deemed to be dispensed on prescription within the meaning of subdivision (d)(1).

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

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

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

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

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

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

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

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

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

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

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

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

(1) Orthodontic, prosthetic (except as described in subdivision (b)(5)), auditory, ophthalmic or ocular devices or appliances.

(2) Articles which are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof. "Medicines" does not include arch supports, cervical pillows, exercise weights (boots or belts), hospital beds, orthopedic shoes and supportive devices (unless an integral part of a leg brace or artificial leg), plastazote inserts, plastazote shoes, plastic shoes (custom or ready-made), sacro-ease seats, shoe modifications, spenco inserts, traction units (other than those fully worn on the patient), thermophore pads, nor foot orthoses.

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

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

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

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

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

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

(5) sold to this state or any political subdivision or municipal corporation thereof, for use in the treatment of a human being; or furnished for the treatment of a human being by a medical facility or clinic maintained by this state or any political subdivision or municipal corporation thereof, or

(6) effective January 1, 1995, furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being, or to an institution of higher education for instruction or research. Such medicine must be of a type that can be dispensed only: (a) for the treatment of a human being, and (b) pursuant to prescriptions issued by persons authorized to prescribe medicines. The exemption provided by this subdivision applies to the constituent elements and ingredients used to produce the medicines and to the tangible personal property used to package such medicines.

(e) Specific Tax Applications.

(1) Prescriptions. No person other than a licensed physician, dentist, optometrist or podiatrist is authorized to prescribe or write a prescription for the treatment of a human being. Tax does not apply to the sale or use of medicines prescribed by a licensed physician, dentist, optometrist, or podiatrist for the treatment of a human being and dispensed on prescription filled by a pharmacist.

(2) Licensed Physician, Dentist or Podiatrist. Tax does not apply to a specific charge made by a licensed physician, dentist or podiatrist to his or her own patient for medicines furnished for the treatment of the patient. Tax also does not apply to sales of medicines to licensed physicians, dentists or podiatrists for the treatment of a human being regardless of whether the licensed physician, dentist or podiatrist makes a specific charge to his or her patient for the medicines furnished.

(3) Health Facility. Tax does not apply to sales of medicines by a health facility (as defined in subdivision (a)(4)) for the treatment of any person pursuant to the order of a licensed physician, dentist or podiatrist. Tax does not apply to sales of medicines to a health facility for the treatment of a human being regardless of whether or not a specific charge is made for the medicines.

(4) Pharmaceutical Manufacturer or Distributor. Tax does not apply to the storage, use or consumption of medicines furnished by a pharmaceutical manufacturer or distributor without charge to a licensed physician, surgeon, dentist, podiatrist, or health facility for the treatment of a human being or furnished without charge to an institution of higher education for instruction or research provided the medicines furnished are of a type that can be dispensed only (1) on prescription by persons authorized to prescribe and (2) for the treatment of a human being. The exemption from tax includes the costs of the materials used to package the "sample" medicines, such as bottles, boxes, blister packs, patches impregnated with medicines, or pre-filled syringes, and the elements and ingredients used to produce the "samples" whether or not such items are purchased under a resale certificate in this state or outside this state. When a pre-filled syringe or other such delivery device is used to package and contain a sample medicine (i.e., pre-filled with the medicine) as well as to inject or otherwise administer the medicine to the patient, the exemption from tax will not be lost due to the fact that the device is used for a dual purpose. However, the use of empty syringes or other such delivery devices, furnished to the licensed physician separately or included in the packages with the medicines, is subject to tax.

This exemption applies in the same manner to the use of clinical trial medicines during the United States Food and Drug Administration's drug development and approval process. "Clinical trial medicines" are substances or preparations approved as "Investigational New Drugs" by the United States Food and Drug Administration intended for treatment of, and application to, the human body, which are furnished by a pharmaceutical developer, manufacturer, or distributor to a licensed physician and subsequently dispensed, furnished, or administered pursuant to the order of the licensed physician. "Clinical trial medicines" do not

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

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

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

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

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

Except as provided in Regulation 1591.1(b)(4), tax applies to the sale or use of test kits and equipment used to analyze, monitor, or test samples of cells, tissues, organs and blood, saliva, or other bodily fluids. Such items do not qualify as medicines regardless of whether they are prescribed for an individual by a person authorized to prescribe and dispensed pursuant to a prescription.

(f) Insurance Payments.

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

(2) Medicare.

(A) Medicare Part A. Tax does not apply to the sale of items to a person insured pursuant to Part A of the Medicare Act as such sales are considered exempt sales to the United States Government. Under Part A, the healthcare provider has a contract with the United States Government to provide certain services. Therefore, sales of medicines, devices, appliances, and supplies in which payment is made under Part A qualify as exempt sales to the United States Government.

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

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

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

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

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

Name of purchaser

Name of doctor

Date of sale

Item sold

The sale price

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

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

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

Regulation History

Type of Regulation: Sales and Use Tax

Regulation: 1591

Title: *Medicines and Medical Devices*

Preparation: Bradley Heller
Legal Contact: Bradley Heller

The State Board of Equalization proposes to adopt amendments to Sales and Use Tax Regulation 1591, *Medicines and Medical Devices*, to clarify that articles permanently implanted in the human body to "monitor" a medical condition qualify as medicines.

History of Proposed Regulation:

March 24, 2017	OAL publication date; 45-day public comment period begins; Interested Parties mailing
March 14, 2017	Notice to OAL
August 30, 2016	Business Tax Committee, Board Authorized Publication (Vote 5-0)

Sponsor:	NA
Support:	NA
Oppose:	NA