



STATE BOARD OF EQUALIZATION

450 N STREET, SACRAMENTO, CALIFORNIA
PO BOX 942879, SACRAMENTO, CALIFORNIA 94279-0092
1-916-324-1825 • FAX 1-916-322-4530
www.boe.ca.gov

SEN. GEORGE RUNNER (Ret.)
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State Controller

DAVID J. GAU
Executive Director

August 19, 2016

Dear Interested Party:

Enclosed are the Agenda, Issue Paper, and Revenue Estimate for proposed amendments to Regulation 1591, *Medicines and Medical Devices*, which will be presented at the Board's August 30 - 31, 2016 Business Taxes Committee meeting. The proposed amendments clarify that permanently implanted articles that "otherwise monitor" a medical condition qualify as "medicines" under subdivision (b)(2), *Permanently Implanted Articles*.

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

Thank you for your input on these issues and I look forward to seeing you at the Business Taxes Committee meeting on **August 30 - 31, 2016** in Room 121 at the address shown above. If you wish to attend the meeting or watch the webcast, see the Public Agenda Notice found under "Upcoming Meetings" at <http://www.boe.ca.gov/meetings/boardcomm.htm>.

Sincerely,

Chief, Tax Policy Division
Business Tax and Fee Department

JP:map

Enclosures

cc: (all with enclosures, via email and/or hardcopy as requested)
Honorable Fiona Ma, CPA, Chairwoman
Honorable Diane L. Harkey, Vice Chair
Honorable George Runner, First District
Honorable Jerome E. Horton, Third District
Honorable Betty T. Yee, State Controller, c/o Ms. Yvette Stowers (MIC 73)
Ms. Genevieve Jopanda, Board Member's Office, Second District

Ms. Kathryn Asprey, Board Member's Office, Second District
Mr. John Vigna, Board Member's Office, Second District
Mr. Tim Morland, Board Member's Office, Second District
Ms. Natasha Ralston Ratcliff, Board Member's Office, Second District
Mr. Russell Lowery, Board Member's Office, Fourth District
Mr. Ted Matthies, Board Member's Office, Fourth District
Ms. Lisa Renati, Board Member's Office, Fourth District
Mr. Clifford Oakes, Board Member's Office, Fourth District
Mr. Sean Wallentine, Board Member's Office, First District
Mr. Lee Williams, Board Member's Office, First District
Mr. Brian Wiggins, Board Member's Office, First District
Mr. Cary Huxsoll, Board Member's Office, First District
Mr. Alfred Buck, Board Member's Office, First District
Ms. Kari Hammond, Board Member's Office, Third District
Ms. Linda Cheng, Board Member's Office, Third District
Mr. Chris Armenta, Board Member's Office, Third District
Mr. David Gau (MIC 73)
Ms. Amy Kelly (MIC 83)
Ms. Susanne Buehler (MIC 43)
Ms. Debra Kalfsbeek (MIC 62)
Mr. Todd Gilman (MIC 70)
Mr. Wayne Mashihara (MIC 47)
Mr. Kevin Hanks (MIC 49)
Mr. Mark Durham (MIC 67)
Mr. Robert Tucker (MIC 82)
Mr. Jeff Vest (MIC 85)
Mr. Jeff Angeja (MIC 85)
Mr. David Levine (MIC 85)
Ms. Dana Brown (MIC 85)
Ms. Casey Tichy (MIC 85)
Ms. Nikki Mozdyniewicz (MIC 85)
Mr. Rick Zellmer (MIC 85)
Mr. Bradley Heller (MIC 82)
Mr. Lawrence Mendel (MIC 82)
Mr. John Thiella (MIC 73)
Mr. Scott Claremon (MIC 82)
Ms. Kirsten Stark (MIC 50)
Ms. Lynn Whitaker (MIC 50)
Mr. Marc Alviso (MIC 73)
Mr. Chris Lee (MIC 73)
Ms. Lauren Simpson (MIC 70)
Ms. Karina Magana (MIC 47)
Mr. Bradley Miller (MIC 92)
Mr. Joe Fitz (MIC 67)
Mr. Robert Wilke (MIC 50)
Mr. Michael Patno (MIC 50)

Agenda – August 30 – 31, 2016 Business Taxes Committee Meeting
Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*

<p>Action 1 – Agreed Upon Items</p> <p>Agenda, pages 2-3.</p>	<p>Alternative 1</p> <p>Approve and authorize publication of proposed amendments to Regulation 1591 to clarify that permanently implanted articles that mark the location of "<u>or otherwise monitor</u>" a medical condition qualify as "medicines" under subdivision (b)(2), <i>Permanently Implanted Articles</i>.</p> <p style="text-align: center;">OR</p> <p>Alternative 2</p> <p>Do not approve proposed amendments to Regulation 1591.</p>
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**Agenda – August 30 – 31, 2016 Business Taxes Committee Meeting
Proposed Amendments to Regulation 1591, Medicines and Medical Devices**

Action Item	Staff and Industry's Proposed Regulatory Language
<p>Action 1 – Staff Recommendation</p>	<p>REGULATION 1591, MEDICINES AND MEDICAL DEVICES.</p> <p><i>Reference:</i> Sections 6006 and 6369, Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250, Health and Safety Code.</p> <p><i>Only the relevant subdivision of the regulation being amended is included in this exhibit.</i></p> <p>(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:</p> <p>[¶] . . . [¶]</p> <p>(2) PERMANENTLY IMPLANTED ARTICLES. Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines. 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).</p> <p>Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their</p>

Agenda – August 30 – 31, 2016 Business Taxes Committee Meeting
Proposed Amendments to Regulation 1591, *Medicines and Medical Devices*

Action Item	Staff and Industry's Proposed Regulatory Language
	<p>implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants, including the ear implant's interdependent internal and external components. Sutures are also included whether or not they are permanently implanted. A non-returnable, nonreusable needle fused or prethreaded to a suture is regarded as part of the suture.</p> <p>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.</p>

Issue Paper Number 16-07



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

Regulation 1591, *Medicines and Medical Devices*

I. Issue

Whether the Board should amend Regulation 1591, *Medicines and Medical Devices*, to clarify that permanently implanted articles that mark the location of "or otherwise monitor" a medical condition qualify as "medicines" under subdivision (b)(2), *Permanently Implanted Articles*.

II. Alternative 1 - Staff Recommendation

Staff recommends the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2. The proposed amendments clarify that in addition to implanted articles that mark the location of a medical condition, articles that otherwise monitor a medical condition also qualify as "medicines" under subdivision (b)(2), *Permanently Implanted Articles*.

This recommendation is supported by Mr. Wade Downey and Mr. Roderick Calub on behalf of Downey, Smith, & Fier.

III. Other Alternative(s) Considered

Do not approve the proposed amendments to Regulation 1591.

IV. Background

Revenue and Taxation Code (RTC) section 6369 provides an exemption from the application of sales and use tax 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 "specified circumstances"). Section 6369, subdivision (b), defines "medicines" as "any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and commonly recognized as a substance or preparation intended for that use." Section 6369, subdivision (b), further provides that certain items are excluded from the definition of medicines, including "(2) Articles that are in the nature of splints, bandages, pads, compresses, supports, dressings, instruments, apparatus, contrivances, appliances, devices or other mechanical, electronic, optical or physical equipment or article or the component parts and accessories thereof." However, section 6369, subdivision (c), includes additional specific items that are, notwithstanding subdivision (b), considered to be medicines, including, "[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." (RTC §6369, sub.(c)(2).)

Regulation 1591 implements, interprets, and makes specific RTC section 6369. Regulation 1591, subdivision (a)(9) defines medicines as follows:

- (A) Except where taxable for all uses as provided in subdivision (c), any product fully implanted or injected in the human body, or any drug or any biologic, when such are approved by the U.S. Food and Drug Administration to diagnose, cure, mitigate, treat or prevent any disease, illness or medical condition regardless of ultimate use, or
- (B) Any substance or preparation intended for use by external or internal application to the human body in the diagnosis, cure, mitigation, treatment, or prevention of disease and which is commonly recognized as a substance or preparation intended for that use. The term medicines also 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, electronic, optical or physical equipment or article or the component parts and accessories thereof. . . ." Notwithstanding subdivision (c), subdivision (b) sets forth several categories of articles, devices and appliances, which are included in the definition of medicines, either generally or for specific uses, and also identifies specific items that are included in or excluded from those categories. Specifically, subdivision (b)(2) states, "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."

V. Discussion

During the February 2014 Board of Equalization (BOE) 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 specified circumstances. BTMs are sterile disposable medical devices that are comprised of an introducer needle and applicator as well as a radiographic (i.e., readable by x-ray or other imaging technologies), implantable titanium or metal alloy marker. A doctor inserts the BTM in soft breast tissue during surgical or percutaneous (i.e., performed through the skin) biopsies for the purpose of marking the site so that it can be accurately identified by

ultrasound, MRI or other imaging methods at a future date. The Board determined that the BTMs at issue were medicines for purposes of the exemption provided by RTC section 6369, and directed staff to initiate the rulemaking process to clarify the application of Regulation 1591 to these types of implanted items.

Staff's proposed amendments to Regulation 1591 were presented at the April 2015 Business Taxes Committee meeting. The Board Members unanimously approved the revisions to Regulation 1591, which had an effective date of October 1, 2015. However, the Members did express concerns that the amendments may still too narrowly construe the definition of medicines, and exclude items that perform similar functions to BTMs and that share many of the characteristics that cause BTMs to meet that definition of medicines: items that, for instance, are permanently (and fully) implanted, are related to the functioning of a particular organ and result from advancements in medical technology.

To address these concerns, staff recommends adding the phrase "or otherwise monitor" in subdivision (b)(2) where the previous additions were made so that the definition of medicines includes "articles permanently implanted in the human body to mark the location of or otherwise monitor a medical condition" Staff believes that this language will clearly indicate that any item that is permanently implanted to assist the functioning of a natural organ, artery, vein, or limb by monitoring it in any way, not just by marking the location of medical conditions that affect it, are included in the definition of medicine. Staff believes that this addition is consistent with the Board's intent in directing staff to amend Regulation 1591 during the February 2014 meeting, and addresses the concerns raised by the Board Members at the April 2015 meeting.

Staff received a submission on June 23, 2016, from Mr. Wade Downey and Mr. Roderick Calub of Downey, Smith, & Fier (Exhibit 3) regarding the proposed amendments. They strongly support staff's recommendation and believe the changes will assist medical vendors, hospitals, and other healthcare providers in determining whether sales or use tax applies to a particular transaction.

VI. Alternative 1 - Staff Recommendation

A. Description of Alternative 1

Staff recommends the Board approve and authorize publication of the proposed amendments to Regulation 1591, as set forth in Exhibit 2. The proposed amendments clarify that implanted articles that mark the location of "or otherwise monitor" a medical condition qualify as "medicines" under subdivision (b)(2), *Permanently Implanted Articles*.

B. Pros of Alternative 1

The amendment will further clarify for taxpayers the application of tax to permanently implanted medical devices. Interested parties strongly support the proposed amendments.

C. Cons of Alternative 1

None.

D. Statutory or Regulatory Change for Alternative 1

No statutory change is required; however, staff's recommendation does require regulatory change.

E. Operational Impact of Alternative 1

Staff will publish the proposed amendments to Regulation 1591 and begin the formal rulemaking process.

F. Administrative Impact of Alternative 1

1. Cost Impact

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

2. Revenue Impact

See Revenue Estimate (Exhibit 1).

G. Taxpayer/Customer Impact of Alternative 1

Amendments to Regulation 1591 will provide clarity to taxpayers on the application of tax to permanently implanted medical devices that monitor medical conditions. Staff will update the BOE publications and manuals that provide information regarding Regulation 1591 to taxpayers.

H. Critical Time Frames of Alternative 1

None.

VII. Other Alternatives

A. Description of Alternative 2

Do not amend Regulation 1591.

B. Pros of Alternative 2

The BOE will not incur the workload associated with revising the regulation.

C. Cons of Alternative 2

Taxpayers may still have uncertainty with regard to the application of tax to permanently implanted articles that monitor a medical condition.

D. Statutory or Regulatory Change for Alternative 2

None.

E. Operational Impact of Alternative 2

None.

F. Administrative Impact of Alternative 2

1. Cost Impact

None.

2. Revenue Impact

None. See Revenue Estimate (Exhibit 1).

FORMAL ISSUE PAPER #16-07

G. Taxpayer/Customer Impact of Alternative 2

None.

H. Critical Time Frames of Alternative 2

None.

Preparer/Reviewer Information

Prepared by: Tax Policy Division, Business Tax and Fee Department

Current as of: August 8, 2016

REVENUE ESTIMATE

STATE OF CALIFORNIA
BOARD OF EQUALIZATION



Proposed Regulation 1591, *Medicines and Medical Devices*

I. Issue

Whether the Board should amend Regulation 1591, *Medicines and Medical Devices*, to clarify that permanently implanted articles that mark the location of “or otherwise monitor” a medical condition qualify as "medicines" under subdivision (b)(2), *Permanently Implanted Articles*. The three words “or otherwise monitor” are added to the regulatory language. This is the only change to the regulation.

II. Alternative 1 - Staff Recommendation

Staff recommends approval and authorization to publish the proposed amendments to Regulation 1591, as set forth in Exhibit 2.

III. Alternative 2

Do not approve the proposed amendments to Regulation 1591.

Background, Methodology, and Assumptions

Alternative 1 – Staff Recommendation

Subdivision (b)(2) of Regulation 1591 states, "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."

This alternative proposes inserting the words “or otherwise monitor” in the last sentence, such that it reads:

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.

Staff has no information regarding the value of implanted devices that may otherwise monitor medical conditions. The U.S. Food and Drug Administration (FDA) has a “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.” The list staff downloaded was updated by the FDA on March 2015. This list consists of 480 devices. Board staff visually determined four of these devices appeared to be classified under the proposed new wording (“or otherwise monitor”) without having been included under the current wording of the regulation. These four devices constitute about one percent of the 480 devices on the FDA list.

Another federal agency, the U.S. Census Bureau, published 2012 U.S. values of shipments for detailed (10-digit) products and services codes. The data are found in *Economic Census of the United States: Manufacturing: Industry Series: Product or Service Statistics for the U.S.: 2012*. The Census Bureau products and services code descriptions did not specifically distinguish implanted devices from non-implanted devices. While there are many monitoring devices, such as temperature and blood pressure monitoring units, the products and services code descriptions seemed to imply that none of these devices were implanted. Staff was led to conclude that implanted devices must be included in the category called “All Other Patient Monitoring Equipment.” Census Bureau data show that in 2012 product shipments value of All Other Patient Monitoring Equipment was \$1,205,051,000.

Staff made a revenue estimate for devices sold under the proposed wording of Regulation 1591 using the following assumptions.

1. Two percent of the value of All Other Patient Monitoring Equipment are implanted. Staff doubled the one percent of the number of devices visually observed in the FDA list of devices discussed above to account for growth in sales since 2012 and to allow for the possibility that staff may have missed some devices that may fall under the proposed wording. While staff acknowledges that devices numbers percentages may not necessarily correspond with percentages of device value, staff has no more accurate information available.
2. California sales of such devices are estimated by the state’s 12 percent share of U.S. population.
3. Sales tax revenues are estimated using an average statewide sales and use tax rate of 8.42 percent.

Multiplying these figures results in revenues of \$243,517 ($\$1,205,051,000 \cdot .02 \cdot .12 \cdot .0842$)

Revenue Summary

Alternative 1 – The staff recommendation will result in a revenue loss of \$243,517.

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

Preparation

Mr. Joe Fitz, Research and Statistics Section, Legislative and Research Division, prepared this revenue estimate. This estimate has been reviewed by Mr. Mark Durham, Manager, Research and Statistics Section, Legislative and Research Division. For additional information, please contact Mr. Fitz at (916) 323-3802.

Current as of August 8, 2016.

REGULATION 1591, MEDICINES AND MEDICAL DEVICES.

Reference: Sections 6006 and 6369, Revenue and Taxation Code, and sections 1200, 1200.1, 1204.1, and 1250, Health and Safety Code.

Only the relevant subdivision of the regulation being amended is included in this exhibit.

(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:

[¶] . . . [¶]

(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.



DOWNEY·SMITH·FIER
STATE & LOCAL TAX

June 23, 2016

Lynn Whitaker
Sales and Use Tax Department
State Board of Equalization
450 M. Street
Sacramento, CA 94279-0092

Re: BTC Comments - Proposed Revisions to Regulation 1591, *Medicines and Medical Devices*

On behalf of our hospital and medical supply clients, Downey, Smith & Fier appreciates the opportunity to participate in the Interested Parties process and to provide input as the Board clarifies Regulation 1591, Medicines and Medical Devices.

Downey, Smith & Fier works very closely with the State Board of Equalization, including the audit group, refund section and policy group on behalf of our clients. DSF also represented the taxpayer in its appeal involving breast tissue markers (BTMs) and participated in the resulting rulemaking process following that decision. The administration of sales and use tax in this area and the taxability of medical products present many unique challenges based on ever changing healthcare technology, advances in patient treatments and new products that are saving lives.

As we communicated during the June 8, 2016 discussion, Downey, Smith & Fier, and its clients, strongly support the proposed clarification to Regulation 1591 and believe that the changes will assist medical vendors, hospitals and other healthcare providers to make better sales and use tax decisions. The clarification will go a long way to address a category of products that has caused significant confusion over the years.

If we can be of any further assistance, please feel free to reach out to us at (562) 249-6000.

Sincerely,

Wade M. Downey
Partner
Downey, Smith & Fier

Roderick Calub
Healthcare, Senior Manager
Downey, Smith & Fier

Cc: Michael A. Patno, Program Policy Specialist, BTC