

**STATE OF CALIFORNIA  
OFFICE OF ADMINISTRATIVE LAW**

AGENCY: BOARD OF ) EQUALIZATION ) )	DECISION OF DISAPPROVAL OF REGULATORY ACTION (Gov. Code section 11349.3)
ACTION: Amendment of section 1591 of ) title 18 of the California Code of Regulations) ) _____)	OAL File No. 03-0317-01 S

**DECISION SUMMARY**

This regulatory action would have amended what constitutes "medicine" under Revenue and Taxation Code section 6369, and therefore, is not taxable. On April 29, 2003, the Office of Administrative Law (OAL) notified the Board of Equalization (Board) that OAL disapproved the regulatory action because it failed to comply with the Necessity and Clarity standards contained in Government Code section 11349.1.

**DISCUSSION**

Regulations adopted by the Board of Equalization must be adopted pursuant to the Administrative Procedure Act (APA; Gov. Code sec. 11340 et seq.). (See generally, Revenue and Taxation Code section 7051.) Any regulatory action a state agency adopts through the exercise of quasi-legislative power delegated to the agency by statute is subject to the requirements of the APA unless a statute expressly exempts or excludes the act from compliance with the APA. (Gov. Code section 11346.) No exemption or exclusion applied to the regulatory action here under review. Thus, before the instant regulatory action could become effective, OAL reviewed it for compliance with both the procedural requirements of the APA and certain substantive standards.

**NECESSITY**

Government Code section 11349.1, subdivision (a)(1), requires OAL to review all regulations for compliance with the Necessity standard. Government Code section 11349, subdivision (a) defines "Necessity" to mean

“ . . . the record of the rulemaking proceeding demonstrates by substantial evidence the need for a regulation to effectuate the purpose of the statute, court decision, or other provision of law that the regulation implements, interprets, or

makes specific, taking into account the totality of the record. For purposes of this standard, evidence includes, but is not limited to, facts, studies, and expert opinion.”

Section 10, subdivision (b), of title 1 of the CCR provides that in order to meet the “necessity standard” the rulemaking record must include:

“(1) A statement of the specific purpose of each adoption, amendment, or repeal; and

(2) information explaining why each provision of the adopted regulation is required to carry out the described purpose of the provision. Such information shall include, but is not limited to, facts, studies, or expert opinion. When the explanation is based upon policies, conclusions, speculation, or conjecture, the rulemaking record must include, in addition, supporting facts, studies, expert opinion, or other information. An ‘expert’ within the meaning of this section is a person who possesses special skill knowledge by reason of study or experience which is relevant to the regulation in question. [Emphasis added.]”

Complying with the Necessity standard requires more than a general discussion of the need for a regulatory action as a whole or simply a description of the regulatory action. It requires substantial evidence supporting an explanation of why each provision of each proposed regulation is required to carry out its described purpose.

The rulemaking record does not contain substantial evidence supporting or demonstrating the need for the addition of the following proposed language or requirements:

1. Revenue and Taxation Code section 6369 exempts from taxes the gross receipts from the sale in California of, and the storage, use, or other consumption in California of, medicines. Section 1591 of title 18 of the CCR implements and interprets section 6369 of the Revenue and Taxation Code. The Board proposes to add the language "breast tissue expanders and tissue expanders (both operative January 1, 2003)" to section 1591 under three different categories: permanently implanted articles (section 1591(b)(2)), orthotic devices (section 1591(b)(4)), and prosthetic devices (section 1591(b)(5)). The rulemaking record contains one sentence regarding the addition of this language: "The Board also concluded that operative January 1, 2003, breast and tissue expanders should be considered as permanent implants, orthotic devices and prosthetic devices. [Emphasis added.]" (Initial Statement of Reasons, p. 3.) The rulemaking record does not contain facts, studies, expert opinion, or other information to support this conclusion made by the Board.

2. Revenue and Taxation Code section 6369 provides that, in order to be included as “medicines,” and therefore, qualify for exemption from sales tax, orthotic and prosthetic devices shall be “designed to be worn on the person.” The Board added the following language, "(1) have sustained physical contact with the body and (2) the purpose is the treatment of the body structure," to further interpret the statutory phrase "worn on the person." The rulemaking record contains substantial evidence supporting or demonstrating the need for the first part of this interpretation, “(1) have sustained physical contact with the body.” However, the rulemaking record does not contain substantial evidence supporting or demonstrating the need for the second part, "and (2) the purpose is the treatment of the body structure," which apparently is the second prong of the test a device must meet in order to be considered "worn on the person." There is no explanation or information as to why this second prong of the test is needed when the statute provides that the device be worn on the person "as a brace, support or correction for the body structure" (if the device is an orthotic device), or "to replace or assist the functioning of a natural part of the human body" (if the device is a prosthetic device).

### **CLARITY**

In adopting the APA, the Legislature found that the language of many regulations was unclear and confusing to the persons who must comply with the regulations. (Gov. Code, sec. 11340(b).)

For this reason, Government Code section 11349.1 requires in subdivision (a)(3) that OAL review all regulations for compliance with the Clarity standard. Government Code section 11349, subdivision (c), defines “Clarity” as meaning “. . . written or displayed so that the meaning of regulations will be easily understood by those persons directly affected by them.”

In addition, section 16 of title 1 of the CCR states:

“In examining a regulation for compliance with the 'clarity' requirement of Government Code section 11349.1, OAL shall apply the following standards and presumptions:

“(a) A regulation shall be presumed not to comply with the 'clarity' standard if any of the following conditions exists:

- (1) the regulation can, on its face, be reasonably and logically interpreted to have more than one meaning; or
- (2) the language of the regulation conflicts with the agency's description of the effect of the regulation; . . .

(3) the regulation uses terms which do not have meanings generally familiar to those 'directly affected' by the regulations, and those terms are defined neither in the regulation nor in the governing statute; or

(4) the regulation uses language incorrectly. This includes, but is not limited to, incorrect spelling, grammar or punctuation; . . .”

1. In title 18, CCR, section 1591, the meaning of “health facility” is amended to include any "clinic" as defined in Health and Safety Code section 1200, to reflect the same amendment that was made to Revenue and Taxation Code section 6369, subdivision (d). There is an incorrect transition from the sentence in (a)(4) to the paragraphs of (a)(4)(A)-(C) that renders the proposed addition unclear.
2. The language "breast tissue expanders and tissue expanders (both operative January 1, 2003)" is added as exempt “medicines” under three different categories: permanently implanted articles (section 1591(b)(2)), orthotic devices (section 1591(b)(4)), and prosthetic devices (section 1591(b)(5)). Adding this language in three different device categories is unclear, especially since Revenue and Taxation Code section 6369, subdivision (g), deals with "mammary prostheses."
3. The regulation text appears to further interpret the statutory language "worn on the person" by adding the following definition: "(1) have sustained physical contact with the body and (2) the purpose is the treatment of the body structure." This definition is included under "Orthotic devices" (section 1591(b)(4)) as well as under "Prosthetic Devices" (section 1591(b)(5)). The language "treatment of the body structure" is confusing because it is used to further describe orthotic as well as prosthetic devices. However, Revenue and Taxation Code section 6369 defines orthotic devices as devices "designed . . . as a brace, support, or correction for the body structure." Section 6369 further defines prosthetic devices as "designed . . . to replace or assist the functioning of a natural part of the human body." The meaning of "treatment of the body structure" is unclear because it is used to define both orthotic and prosthetic devices which the statute defines as devices with two different designs or purposes.
4. The Legislature amended section 6369, subdivision (d), of the Revenue and Taxation Code as follows:

"(d) 'Health facility' as used in this section has the meaning ascribed to it in Section 1250 of the Health and Safety Code, and also includes any 'clinic' as defined in Section 1200 of the Health and Safety Code. [Underlined language added by Stats. 2001, c. 706 (A.B. 646), sec. 1, eff. Oct. 11, 2001, operative April

1, 2002.]

In title 18, CCR, section 1591, the meaning of “health facility” was amended to include any "clinic" as defined in Health and Safety Code section 1200, in response to the statutory change of Revenue and Taxation Code section 6369, subdivision (d).

The Final Statement of Reasons in the rulemaking record contains the following statement:

"[The Board] also decided that the exemption previously available only to hospitals should be available to surgery clinics on the same basis and that this amendment [e.g., the addition of "clinic," as defined in Health and Safety Code section 1200, as being included within the meaning of "health facility"] should be fully retroactive beyond the operative date of the statute. [Emphasis added.]" (Final Statement of Reasons, p. 1.)

A reading of the proposed amendment to section 1591 adding “clinic” provides no indication that this addition of “clinic” is to be applied retroactively before the operative date of the statute. Furthermore, the rulemaking record provides that the “purpose of the proposed amendments is to interpret, implement, and make specific Revenue and Taxation Code section 6369,” and then refers specifically to A.B. 646, chapter 706 (2001), which amended Revenue and Taxation Code section 6369, subdivision (d). (See Initial Statement of Reasons, p. 1.) Though the Legislature specified that this statutory change would not become operative until April 1, 2002, the Board's description of the effect of the addition of "clinic" to section 1591 of title 18, CCR, is to be applied "fully retroactive beyond the operative date of the statute."

A person directly affected by this regulation could not easily determine the actual operative date of this regulatory change from reading the regulation. The inconsistency between the April 1, 2002, operative date of the amendment to Revenue and Taxation Code section 6369, subdivision (d), that is being implemented and the Board’s description of the operative effect of the regulatory change creates an ambiguity that the regulation does not resolve.

## CONCLUSION

For the reasons discussed above, OAL has disapproved the amendment of section 1591 referenced above. If you have any questions, please do not hesitate to contact me at (916) 323-6831.

Decision of Disapproval  
of Regulatory Action

Board of Equalization

DATE: May 6, 2003

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