

## TITLE 16 . California Board of Pharmacy

**NOTICE IS HEREBY GIVEN** that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments only in writing relevant to the action proposed.

Written comments must be received by the Board of Pharmacy at its office not later than 5 p.m. on Monday, October 29, 2001. Comments may be submitted by facsimile at (916) 327-6308. Comments may be submitted by email to Paul\_Riches@dca.ca.gov. Comments may be submitted by mail to:

Board of Pharmacy  
Attn: Paul Riches  
400 R Street, Suite 4070  
Sacramento, CA 95814

The board does not intend to hold a hearing in this matter. If any interested party wishes that a hearing be held, he or she must make the request in writing to the board. The request must be received in the board office no later than 5 p.m. on October 15, 2001.

The Board of Pharmacy upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference: Pursuant to the authority vested by Sections 4005 of the Business and Professions Code, and to implement, interpret or make specific Section 4067 of the Business and Professions Code and Section 56.36 of the Civil Code, the California Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

### INFORMATIVE DIGEST/ POLICY STATEMENT OVERVIEW

**Add Sections:** 1777, 1777.1, 1777.2, 1777.3, 1777.4, 1777.5, 1778, 1778.1, 1778.2, 1778.3

### **Confidentiality of Medical Information**

Section 4005 of the Business and Professions Code permits the Board of Pharmacy to adopt regulations to protect the public. Section 56.10 of the Civil Code requires that all healthcare providers or contractors obtain the consent of a patient prior to disclosing medical information regarding that patient except in specified circumstances. Section 56.36 of the Civil Code establishes penalties for violations of section 56.10 and other provisions of the Confidentiality of Medical Information Act (Act). Among the penalties provided for in Section 56.36 are administrative fines.

Section 1777, subdivision (a) specifies the authority of a committee of the board to issue

citations and fines for violations of the Act. The subdivision also requires the issuance of an order of abatement requiring disgorgement of proceeds obtained for any willful violation.

Section 1777, subdivision (b) specifies the elements and requirements for a citation.

Section 1777, subdivision (c) specifies the procedural requirements for a respondent to request a hearing to dispute a finding of a violation.

Section 1777, subdivision (d) defines the procedure for a committee of the board considering alleged violations and issuing citations and fines. The procedures permit the board to issue a citation and fine in the absence of a respondent after two failures to appear before the committee. This authority is required to prevent alleged violators from delaying action by refusing to appear.

Section 1777.1, subdivision (a) specifies the penalties for a pharmacist who negligently discloses medical information in violation of the Act.

Section 1777.1, subdivision (b) specifies the penalties for a pharmacist who willfully discloses medical information in violation of the Act.

Section 1777.1, subdivision (c) specifies the penalties for a pharmacist who willfully discloses medical information for financial gain in violation of the Act.

Section 1777.1, subdivision (d) specifies that the board may not impose a fine on the same individual under section 1777.1 and 1777.2 for the same violation.

Section 1777.2, subdivision (a) specifies the penalties for a persons licensed by the board, than a pharmacist, who negligently disclose medical information in violation of the Act.

Section 1777.2, subdivision (b) specifies the penalties for persons licensed by the board, other than a pharmacist, who willfully disclose medical information in violation of the Act.

Section 1777.2, subdivision (c) specifies the penalties for persons licensed by the board, other than a pharmacist, who willfully disclose medical information for financial gain in violation of the Act.

Section 1777.2, subdivision (d) specifies that the board may not impose a fine on the same individual under section 1777.2 and 1777.1 for the same violation.

Section 1777.3 specifies the factors for a committee of the board to consider when imposing a fine.

Section 1777.4, subdivision (a) provides for the extension of an order of abatement in specified circumstances.

Section 1777.4, subdivision (b) specifies the manner of delivery for an order of abatement and the consequences for failure to comply with an order of abatement.

Section 1777.4, subdivision (c) specifies the consequences for the failure to pay a fine imposed by the board.

Section 1777.5 specifies the procedure for contesting a citation.

## **Internet Violations**

Section 4005 of the Business and Professions Code permits the Board of Pharmacy to adopt regulations for public protection and to govern the practice of pharmacy. Section 4067 of the Business and Professions Code permits the board to issue citations and fines for dispensing or furnishing dangerous drugs or dangerous devices on the internet without a valid prescription.

Section 1778, subdivision (a) specifies the authority of a committee of the board to issue citations and fines for violations of section 4067. The subdivision also requires the issuance of an order of abatement requiring disgorgement of proceeds obtained for any willful violation.

Section 1778, subdivision (b) specifies the elements and requirements for a citation.

Section 1778, subdivision (c) specifies the procedural requirements for a respondent to request a hearing to dispute a finding of a violation.

Section 1778, subdivision (d) defines the procedure for a committee of the board considering alleged violations and issuing citations and fines. The procedures permit the board to issue a citation and fine in the absence of a respondent after two failures to appear before the committee. This authority is required to prevent alleged violators from delaying action by refusing to appear.

Section 1778.1 specifies the maximum fine and the factors for a committee of the board to consider when imposing a fine.

Section 1778.2, subdivision (a) provides for the extension of an order of abatement in specified circumstances.

Section 1778.2, subdivision (b) specifies the manner of delivery for an order of abatement and the consequences for failure to comply with an order of abatement.

Section 1778.2, subdivision (c) specifies the consequences for the failure to pay a fine imposed by the board.

Section 1778.3 specifies the procedure for contesting a citation.

## FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: \$79,000 (\$77,400 ongoing) in added costs for the Board of Pharmacy.

Nondiscretionary Costs/Savings to Local Agencies: None.

Local Mandate: None.

Cost to Any Local Agency or School District for Which Government Code Section 17561 Requires Reimbursement: None.

Significant Adverse Economic Impact on Business: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California businesses, including the ability of California businesses to compete with businesses in other states.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have any impact on the creation of jobs or businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California.

Cost Impacts on Representative Private Persons or Businesses: The Board of Pharmacy is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse impact on housing costs.

#### EEFFECT ON SMALL BUSINESSES

The Board of Pharmacy has determined that the proposed regulations would affect small businesses.

#### CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative which it considered or that has otherwise been identified and brought to the attention of the board would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

#### INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared the initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

#### TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons and other information, if any, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814 and at the Board of Pharmacy's website <http://www.pharmacy.ca.gov>.

## FINAL STATEMENT OF REASONS

The Board of Pharmacy will prepare a final statement of the reasons for the proposed action and a copy of this will be available upon request from the board or from the board's website <http://www.pharmacy.ca.gov>.

## AVAILABILITY AND LOCATION OF THE RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the Board of Pharmacy at the address mentioned above.

## CONTACT PERSON

Inquiries regarding the substance of the proposed action may be addressed to Paul Riches at the above address or at (916) 445-5014 ext. 4016 (Paul\_Riches@dca.ca.gov). Inquiries regarding notices for this or other rulemaking proposals may be addressed to Candy Place at the above address or at (916) 445-5014 ext. 4006. Inquiries regarding notices for this or other rulemaking proposals may be addressed to Paul Riches at the above address or at (916) 445-5014 ext. 4016.