

## Title 16. California Board of Pharmacy

**NOTICE IS HEREBY GIVEN** that the California State 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 January 15, 2001.

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 December 29, 2000.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposal substantially as described below or may modify the proposal if the 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 the contact person. The notice also 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: The Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations pursuant to the authority vested by sections 4005 of the Business and Professions Code and to interpret or make specific Business and Professions Code sections 4021, 4022, 4029, 4030, 4037, 4038, 4040, 4050, 4052, 4070, 4081, 4101, 4105, 4113, 4115, 4119, 4133, 4305, 4330, 4332 and 4333. These changes are discussed below.

### INFORMATIVE DIGEST/PLAIN ENGLISH POLICY STATEMENT OVERVIEW

#### **Amend section 1715, Self-Assessment of a Pharmacy by the Pharmacist-in-Charge**

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations pertaining to the practice of pharmacy.

Sections 4021 and 4022 define dangerous drugs and controlled substances.

Section 4029 defines "hospital pharmacy."

Section 4030 defines "intern pharmacist."

Section 4037 defines "pharmacy."

Section 4038 Defines “pharmacy technician.”

Section 4040 defines "prescription" and who may prescribe.

Sections 4050 and 4052 establish the parameters of the practice of pharmacy.

Section 4105 establishes the criteria for making and retaining pharmacy records.

Section 4070 defines “electronic transmission of prescriptions.”

Section 4081 establishes the criteria for the availability of pharmacy records.

Section 4101 establishes the notification procedures in the event a "pharmacist-in-charge" (PIC) terminates employment.

Section 4105 establishes the criteria for making and retaining pharmacy records.

Section 4113 establishes the requirement that each pharmacy be in the charge of a registered pharmacist who has been designated a PIC.

Section 4115 sets forth the duties of a pharmacy technician.

Section 4119 establishes the criteria for furnishing drugs to a specified licensed facility.

Section 4305 establishes the requirements regarding the reporting to the board the termination of services for a pharmacist who was the PIC of a pharmacy.

Section 4330 defines the crime of failure to appoint a PIC when the pharmacy owner is a non-pharmacist.

Section 4332 defines the crime of failure to maintain or produce pharmacy records.

Section 4333 establishes the board’s authority to grant a waiver for off-site storage of records.

The objective of this proposal to assist pharmacies in increasing their compliance with legal requirements and therefore increase public safety as a result of this compliance. The proposal would provide PICs and pharmacy staff with forms that are more user-friendly and that reflect current laws that affect the practice of pharmacy. In addition, it would move the compliance date to July 1 of each odd-numbered year consistent with beginning of the state’s fiscal year to assist the board in tracking compliance and gathering data related to updating the forms.

The board is proposing to amend section 1715 to: 1) add references to its web site on the letterhead that appears on the instructions and the first page of each form, 2) add text to the top of each form that encourages PICs to share the forms with appropriate pharmacy staff, 3) rename the “COMMENTS” section “CORRECTIVE ACTION OR ACTION PLAN” to reflect a more specific

use of the space. All the statements contained in the forms are simplified summaries of existing law. Each pharmacy is required to comply with all the laws referenced. By changing the heading for this area of the forms, the board is designating how the space for the PIC can be used when filling out the assessment of the pharmacy. He or she can note what changes must be made to achieve compliance and the plan to accomplish this task, 4) update existing entries to reflect current law and add entries that reflect newly adopted or amended existing laws that have become relevant since the time of the original adoption and amend and 5) move the compliance date to July 1 of each odd-numbered year consistent with beginning of the state's fiscal year to assist the board in tracking compliance and gathering data related to updating the forms.

Due to the nature of the forms, it is not possible to present the proposed changes in the customary strikeout and underline format. Therefore, the board has provided copies of each form in the current version as well as the proposed amended version. In order to facilitate comparison of the two versions, the board has included a narrative that outlines each change and its appearance on the proposed amended version.

#### FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

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 determined that the proposed regulatory action would have no significant adverse impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

The following relevant information was relied upon in making the above determination. While no formal studies were conducted, the board is confident that the proposal does not have a significant adverse economic impact on business because this action would provide a PIC with an updated version of the specific compliance information that the board seeks when conducting a pharmacy audit. The requirements for conducting a pharmacy outlined in the self-assessment are not new requirements and pharmacies are already required to comply with them.

The board intends that a PIC would have the most current and user-friendly version of the mandated forms that allow a PIC to determine the extent to which the

pharmacy is or is not in compliance with pharmacy law, make adjustments to bring the pharmacy into compliance and thereby improve the pharmacy's performance in meeting state and federal requirements. This would benefit public safety. Moreover, an updated assessment form would provide pharmacies and the PIC with the knowledge they need to comply with California and federal requirements for the practice of pharmacy.

Impact on Jobs/New Businesses: None

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.

The Board of Pharmacy has determined that this regulatory proposal should increase pharmacists' ability to comply with legal requirements for operating a pharmacy.

Statement of Potential Cost Impact on Private Persons or Businesses Directly Affected: Minimal.

This proposal would amend the existing self-assessment form that is used by a PIC once every odd-numbered year and in the event there was a change in the PIC. A PIC is responsible for the conduct of a pharmacy. Moreover, this assessment is part of the process a new PIC undertakes to familiarizing him or herself with the pharmacy. It is essential that PICs, who are responsible for assuring the pharmacy is in compliance with state and federal requirements daily, have an up-to-date form. Currently PICs and pharmacists rely on the existing self-assessment forms to comply with applicable components of pharmacy law.

Effect on Housing Costs: None

#### PLAIN ENGLISH REQUIREMENT

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

The express terms of the proposed action are available from the agency contact person named in this notice.

#### CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no alternative which it considered would either be more effective in carrying out purpose for which the action is proposed or would be as effective as and less burdensome on affected private persons than the proposal described in this Notice.

## STATEMENT OF REASONS AND INFORMATION

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

## TEXT OF PROPOSAL

Copies of the exact language of the proposed regulation and of the statement of reasons and other information, if any, may be obtained upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814.

## 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 mentioned above.

## CONTACT PERSON

Inquiries concerning the proposed administrative action may be addressed to Patricia Harris at the above address or at (916) 445-5014.

(11/30/00)