

TITLE 16. 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 relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on April 10, 2006.

The board will hold a public hearing starting at 1:30 p.m. on April 26, 2006 at the Red Lion Hotel, 1401 Arden Way, Sacramento, CA 95815, telephone (916) 922-8040. At the hearing any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The board requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

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, 4075 and 4114 of the Business and Professions Code, and to implement, interpret or make specific Sections 4005, 4052, 4116 and 4117 of said Code, the 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

Section 4005 of the Business and Professions Code grants the Board of Pharmacy authority to adopt regulations relating to the practice of pharmacy.

Section 4022 of the Business and Professions Code defines the phrase "dangerous drug."

Section 4037 of the Business and Professions Code defines the word "pharmacy" in Pharmacy Law.

Section 4052 of the Business and Professions Code describes the range of activities in which a pharmacist may engage.

Section 4116 and 4117 of the Business and Professions Code limits the access of controlled substances and other dangerous drugs in a pharmacy to specified individuals including pharmacists and pharmacy interns. It authorizes the board to establish security standards for pharmacies.

Section 4125 of the Business and Professions Code describes a pharmacy assurance program as a program that will document medication errors attributable, in whole or in part, to the pharmacy or its personnel. The purpose of the quality assurance program is to assess errors that occur in the pharmacy in dispensing or furnishing prescription medications so that the pharmacy may take appropriate action to prevent a recurrence.

Division 17, Title 16 of the California Code of Regulations, section 1717 describes the practice of pharmacy with regard to receiving and filling prescriptions and the dispensing of medications.

This proposed regulation will permit the use of prescription drop-off boxes and automated, self-services delivery devices. The regulation authorizes a patient to deposit a prescription in a secure container that is at the same address as the licensed premises. The pharmacy is responsible for the security and confidentiality of prescription documents deposited into the container.

The regulation will also allow a patient to access his or her filled prescription medication from a self-services automated delivery device in a pharmacy under the following specified conditions:

- The automated delivery device is used to deliver refill prescription medication only.
- It is the patient's choice to use the automated delivery device.
- The device has a means to identify each patient and only release that patient's prescription medications.
- The pharmacy provides a means for each patient to obtain an immediate telephone or in-person consultation with a pharmacist if requested by the patient.
- The automated delivery device is located adjacent to the licensed pharmacy counter.
- The device is secure from access and removal by unauthorized individuals.
- The pharmacy must review every incident involving the device where a complaint, delivery error, or omission has occurred as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.
- The pharmacy is responsible for the prescription medication stored in the automated delivery device.
- A pharmacist is not to use the automated delivery device to dispense refilled prescription medication if the pharmacist determines the patient requires counseling pursuant to Title 16 of the California Code of Regulations section 1707.2(a)(2).

1. Add Section 1713

This section establishes requirements for the placement and use of secure prescription drop boxes and secure automated delivery devices. This section also contains some provisions currently contained in section 1717(e), which is otherwise being repealed.

2. Repeal Section 1717(e)

This provision is being repealed and certain of its contents dealing with the delivery of medication to patients at specific locations has been incorporated into section 1713.

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. The proposed regulation does not mandate the use of drop-off boxes or automated delivery devices; it permits the use of the devices for pharmacies that choose to use the technology.

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.

Business Impact: The Board of Pharmacy has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting business, including the ability of California businesses to compete with businesses in other states. The proposed regulation does not mandate the use of drop-off boxes or automated delivery devices; it permits the use of the devices for pharmacies that choose to use the technology. For pharmacies that choose to use a drop-off box or an automated delivery device, there will be initial short-term costs to purchase the equipment, install the equipment, and comply with the board's regulations. These costs may be offset by increases in pharmacy sales from customers who like the convenience of the machines. However, there may be no benefit to the pharmacy to use the devices if the patients do not "opt-in" to use them.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of businesses in the State of California. Pharmacists typically do not consult patients on refill medication unless a patient ask questions or a pharmacist believes that the patient needs to be consulted about the refill medication. In the former case, patients are given a means to an immediate consultation with a pharmacist in person or via telephone. In the later case, the medication would not be placed in the delivery machine because the pharmacist wants to talk to the patient.

Cost Impact on Representative Private Person or Business: 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: None

EFFECT ON SMALL BUSINESS

The proposed regulation does not mandate the use of automated delivery devices or drop off boxes; it permits the use of the equipment for pharmacies that choose to use the technology. Consequently, there will be no effect on small business.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either 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 written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address or during the hearing.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an 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 all of the information upon which the proposal is based, may be obtained at the hearing or prior to the hearing upon request from the Board of Pharmacy at 1625 North Market Blvd, Suite N 219, Sacramento, CA 95834, or from the Board of Pharmacy Web site (www.pharmacy.ca.gov).

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND 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 person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Web site listed below.

CONTACT PERSON

Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Jan E. Perez
Address: 1625 North Market Blvd, Suite N 219
Sacramento, CA 95834
Telephone No.: (916) 574-7919
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E-Mail Address: jan_perez@dca.ca.gov

The backup contact person is:

Name: Virginia Herold
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Web site Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.