

## 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 March 29, 2004.

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 not later than 5 p.m. on March 15, 2004.

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 163.5, 851, 4005, 4007, 4038, 4075, 4114, 4115, and 4202 of the Business and Professions Code and to implement, interpret or make specific Sections 4005, 4007, 4019, 4027, 4029, 4038, 4040, 4050, 4051, 4052, 4071, 4072, 4075, 4112, 4114, 4115, 4116, 4117, 4120, 4125, 4196, 4200, 4202, 4400, 4401, and 4403 of the Business and Professions Code, Section 11150 et seq. of the Health and Safety Code, and Sections 56.10 and 56.11 of the Civil 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 163.5 of the Business and Professions Code authorizes specifies that delinquency fees for licenses issued by an agency within the Department of Consumer Affairs shall be fifty percent of the renewal fee.

Section 851 of the Business and Professions Code permits licensing boards within the Department of Consumer Affairs to require applicants to meet the standards of a private voluntary society or association.

Section 4005 of the Business and Professions Code authorizes the board to adopt rules and regulations for the protection of the public including the following:

- For the proper and more effective enforcement and administration of the Pharmacy Law
- Pertaining to the practice of pharmacy
- Pertaining to establishments wherein any drug or device is compounded, prepared, furnished, or dispensed
- Providing for standards of minimum equipment for establishments licensed under this chapter

Section 4007 prohibits the board from adopting a regulation requiring a pharmacist from performing any duty that does not require a pharmacist's training.

Section 4019 of the Business and Professions Code defines "order" and specifies the care settings in which orders may be used to dispense or administer dangerous drugs or dangerous devices.

Section 4027 of the Business and Professions Code defines "licensed health care facility."

Section 4029 of the Business and Professions Code defines "hospital pharmacy."

Section 4038 of the Business and Professions Code defines "pharmacy technician."

Section 4040 of the Business and Professions Code defines "prescription."

Section 4050 of the Business and Professions Code declares the practice of pharmacy to be a profession.

Section 4051 of the Business and Professions Code prohibits the practice of pharmacy without a license.

Section 4052 of the Business and Professions Code specifies those professional services that a pharmacist may provide.

Section 4071 of the Business and Professions Code permits prescribers to authorize their agents to transmit prescriptions.

Section 4072 of the Business and Professions Code permits specified healing arts licentiates to transmit prescriptions authorized by a prescriber in specified care settings.

Section 4075 of the Business and Professions Code permits the board to adopt regulations designed to prevent the unauthorized furnishing of drugs.

Section 4112 of the Business and Professions Code requires non-resident pharmacies to register with the Board of Pharmacy.

Section 4114 of the Business and Professions Code permits the board to adopt regulations governing the activities of pharmacy interns.

Section 4115 of the Business and Professions Code specifies the activities that may be performed by a pharmacy technician.

Section 4116 of the Business and Professions Code specifies who may enter a pharmacy and grants the board authority to adopt regulations requiring security measures in pharmacies.

Section 4117 of the Business and Professions Code restricts access to a hospital pharmacy to certain personnel.

Section 4120 of the Business and Professions Code requires drug wholesalers to obtain a license from the Board of Pharmacy and makes declarations regarding non-resident pharmacies.

Section 4125 of the Business and Professions Code requires pharmacies to develop and implement quality assurance programs to reduce medication errors.

Section 4196 of the Business and Professions Code requires veterinary food-animal drug retailers to be licensed by the board.

Section 4200 of the Business and Professions Code specifies the requirements to become licensed as a pharmacist.

Section 4202 of the Business and Professions Code specifies the requirements to become licensed as a pharmacy technician.

Section 4400 of the Business and Professions Code specifies the fees for various licenses issued by the Board of Pharmacy.

Section 4401 of the Business and Professions Code requires pharmacists to renew their licenses every two years.

Section 4403 of the Business and Professions Code prohibits the board from specifies the requirements to become licensed as a pharmacist.

Section 11150 et seq. of the Health and Safety Code regulates the use and distribution of controlled substances.

Section 56.10 of the Civil Code requires patient consent prior to the disclosure of confidential medical information and establishes specific exceptions to that consent requirement.

Section 56.11 of the Civil Code establishes minimum standards for valid consent to disclose confidential medical information.

#### 1. Amend Section 1710

This proposal would permit hospital pharmacies to contract with other pharmacies to perform the centralized filling of drug orders dispensed in individual patient cassettes.

#### 2. Amend Section 1711

This proposal would require a pharmacist must notify the patient or prescriber of a medication only when the patient took the drug or the error results in a clinically significant delay in therapy.

#### 3. Amend Section 1717.1

This proposal would require pharmacies employing a common electronic file for prescription information to adopt policies and procedures to ensure that confidential medical information is only disclosed as permitted by the Confidentiality of Medical Information Act (Civil Code Section 56 et

seq.).

4. Amend Section 1717.4

This proposal would require that any person who transmits, maintains or receives a prescription ensure the prescription's authenticity.

5. Amend Section 1720

This proposal shortens the time a pharmacist applicant has to pay the required fee for licensure and specifies that applicants are responsible for compliance with requirements established by the administrators of the pharmacist licensure examination. This proposal also requires applicants for the pharmacist licensure examination to take the examination within one year of being determined to be eligible.

6. Amend Section 1721

This proposal increases the penalties for cheating on the pharmacist licensure examination.

7. Amend Section 1723.1

This proposal eliminates reference to the exemptee examination which is no longer required for an exemptee license.

8. Amend Section 1724

This proposal revises the passing score on the pharmacist licensure exam to reflect changes made by Senate Bill 361 (Chapter 539, Statutes of 2003).

9. Amend Section 1749

This proposal would incorporate fee provisions for pharmacy technicians that are deleted from Section 1793.5 in this proposed rulemaking, conform the pharmacist application fee to changes in Senate Bill 361 (Chapter 539, Statutes of 2003), deletes an obsolete reference to medical device retailers, and makes a number of technical and clarifying changes.

10. Amend Section 1793

This proposal makes technical and clarifying changes to this section.

11. Amend Section 1793.1

This proposal eliminates language incorporated in Section 1793.7 by this proposal, deletes a provision that is unnecessary, and makes technical and clarifying changes.

12. Amend Section 1793.2

This proposal eliminates language that is duplicative of existing statute.

13. Repeal Section 1793.4

This proposal repeals this section as it is preempted by the passage of Senate Bill 361 (Chapter 539, Statutes of 2003) which specifies the qualifications for a pharmacy technician license in statute.

14. Amend Section 1793.5

This proposal amends the application requirements for a pharmacy technician to conform with changes made by Senate Bill 361 (Chapter 539, Statutes of 2003).

15. Amend Section 1793.6

This proposal amends pharmacy technician training program requirements to conform with changes made by Senate Bill 361 (Chapter 539, Statutes of 2003).

16. Amend Section 1793.7

This proposal eliminates provisions of the regulation that are duplicative of statutory provisions and incorporates a provision removed from Section 1793.1.

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

Business Impact:

The board 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.

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.

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 Board of Pharmacy has determined that the proposed regulations would not adversely affect small businesses. The proposed regulations provide greater flexibility to pharmacies and streamline application processes for certain license classifications.

#### 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 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 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 400 R Street, Suite 4070, Sacramento, California 95814, or from the Board of Pharmacy website ([www.pharmacy.ca.gov](http://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 website listed below.

#### CONTACT PERSON

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

Name: Paul Riches  
Address: 400 R Street, Suite 4070  
Sacramento, CA 95814  
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The backup contact person is:

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Website Access: Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).