

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 December 27, 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 December 13, 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, 4075, and 4114, Business and Professions Code; section 11127, Health and Safety Code and to implement, interpret or make specific sections 144, 163.5, 851, 4005, 4019, 4021, 4022, 4027, 4029, 4030, 4037, 4038, 4040, 4043, 4050, 4051, 4052, 4070, 4075, 4081, 4101, 4105, 4110, 4112, 4113, 4114, 4115, 4116, 4117, 4119, 4120, 4127.1, 4160, 4180, 4190, 4196, 4200, 4200.1, 4200.2, 4201, 4202, 4203, 4204, 4205, 4231, 4232, 4234, 4301, 4305, 4330, 4332, 4333, 4342, 4400, 4401, 4403, Business and Professions Code; sections, 11055, 11153, 11154, 11166, 11200, and 11165 Health and Safety Code of the Business and Professions 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 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 4019 of the Business and Professions Code defines “order.”

Section 4021 of the Business and Professions Code defines “controlled substance.”

Section 4022 of the Business and Professions Code defines “dangerous drug or dangerous device.”

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 4030 of the Business and Professions Code defines “intern pharmacist.”

Section 4037 of the Business and Professions Code defines “pharmacy.”

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

Section 4040 of the Business and Professions Code defines “prescription.”

Section 4043 of the Business and Professions Code defines “wholesaler.”

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 4070 of the Business and Professions Code establishes requirements for handling electronic prescriptions.

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

Section 4081 of the Business and Professions Code establishes record keeping and inventory requirements for board licensees.

Section 4101 of the Business and Professions Code requires notification of the board when a pharmacist-in-charge or exemptee-in-charge terminates employment.

Section 4105 of the Business and Professions Code establishes requirements for board licensees related to the handling and storage of required documentation.

Section 4110 of the Business and Professions Code prohibits the operation of a pharmacy without a license from the Board of Pharmacy.

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

Section 4113 of the Business and Professions Code requires each pharmacy to designate a pharmacist-in-charge and specifies that the pharmacist-in-charge is responsible for the lawful operation of the 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 4119 of the Business and Professions Code permits pharmacies to furnish dangerous drugs or dangerous devices to licensed health facilities emergency medical service providers under specified circumstances.

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 4127.1 of the Business and Professions Code requires pharmacies compounding sterile injectable drug products to be licensed by the Board of Pharmacy.

Section 4160 of the Business and Professions Code requires drug wholesalers to be licensed by the Board of Pharmacy.

Section 4161 of the Business and Professions Code requires out-of-state distributors to be licensed by the Board of Pharmacy.

Section 4180 of the Business and Professions Code permits specified clinics to obtain a license to purchase drugs from the Board of Pharmacy.

Section 4190 of the Business and Professions Code permits surgical clinics to obtain a license to purchase drugs from the Board of Pharmacy.

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 4200.1 of the Business and Professions Code requires that pharmacist candidates who fail the licensure examination four times must satisfy additional education requirements.

Section 4200.2 of the Business and Professions Code specifies the content of the Multi-State Pharmacy Jurisprudence Examination.

Section 4201 of the Business and Professions Code specifies the information required of an applicant for a site license from the Board of Pharmacy.

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

Section 4203 of the Business and Professions Code specifies the requirements of an application for a clinic license issued pursuant to Section 4180.

Section 4204 of the Business and Professions Code specifies the requirements of an application for a clinic license issued pursuant to Section 4190.

Section 4205 of the Business and Professions Code specifies the requirements for a hypodermic license issued pursuant to Section 4141.

Section 4231 of the Business and Professions Code requires pharmacists to complete continuing education as a condition of renewing their license.

Section 4232 of the Business and Professions Code specifies the content of continuing education courses.

Section 4234 of the Business and Professions Code permits the Board of Pharmacy to make exceptions to the continuing education requirement in emergency or hardship cases.

Section 4301 of the Business and Professions Code requires the Board of Pharmacy to take action against any licensee who is guilty of unprofessional conduct and defines unprofessional conduct.

Section 4305 of the Business and Professions Code specifies that the failure to notify the Board of Pharmacy of the termination of the pharmacist-in-charge of a pharmacy is grounds for disciplinary action.

Section 4330 of the Business and Professions Code specifies that failing to put a pharmacist in charge of a pharmacy or interference with the pharmacist-in-charge operating the pharmacy in a lawful manner is a misdemeanor.

Section 4332 of the Business and Professions Code specifies that violation of the record keeping requirements of Section 4081 is a misdemeanor.

Section 4333 of the Business and Professions Code requires that records required by section 4081 must be kept on the premises for three years and further specifies that violation of that requirement is a misdemeanor.

Section 4342 of the Business and Professions Code permits the Board of Pharmacy to take actions to prevent the distribution of unsafe drugs and devices.

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 issuing or renewing a pharmacist license without the required fees.

Section 11055 of the Health and Safety Code specifies those chemical entities classified as Schedule II controlled substances.

Section 11153 of the Health and Safety Code specifies that a pharmacist has a responsibility to ensure that a controlled substance is issued for a legitimate medical purpose.

Section 11154 of the Health and Safety Code prohibits the dispensing or furnishing of a controlled substance in violation of the California Uniform Controlled Substances Act.

Section 11166 of the Health and Safety Code prohibits the dispensing of a controlled substance prescription after six months from the date of issuance.

Section 11200 of the Health and Safety Code specifies the circumstances under which a controlled substance prescription may be dispensed or refilled.

Section 11165 of the Health and Safety Code generally establishes the Controlled Substance Utilization and Review Evaluation System and requires pharmacies to periodically report the dispensing of Schedule II and Schedule III prescriptions to the Department of Justice.

1. Section 1706.2

This change consolidates provisions related to the abandonment of applications.

2. Section 1712

Senate Bill 1913 (Chapter 695, Statutes of 2004) amended Business and Professions Code section 4115 to allow the use of systems approved by board regulations and this regulation implements that provision.

3. Section 1715

Existing versions of the pharmacy self assessment forms require updating to reflect numerous recent changes to pharmacy law.

4. Section 1715.5

This section is repealed because Senate Bill 151 (Chapter 406, Statutes of 2003) amended section 11165 of the Health and Safety Code to specify how pharmacies must report the dispensing of controlled substances.

5. Section 1717

This section is amended to make technical corrections.

6. Section 1719

This change will allow the board to issue intern pharmacist licenses to students in pharmacy schools with candidate status and for the board to allow graduates of pharmacy schools with candidate status to sit for the licensing examinations. Schools with candidate status are at the penultimate step of accreditation, but final accreditation can occur after students have been enrolled and need to obtain internship hours or to be qualified to take the licensure examinations.

7. Section 1720

These changes are made to conform to the examination structure specified in Senate Bill 361 (Chapter 539, Statutes of 2003) and to delete provisions related to application abandonment that are relocated to section 1706.2.

8. Section 1720.1

Senate Bill 1913 (Chapter 695, Statutes of 2004) requires graduates of foreign pharmacy schools to become certified by the FPGEC. FPGEC has the same degree and education requirements specified in section 4200 which makes board evaluation of those standards redundant.

9. Section 1725

These are technical changes and conforms to the proposed language in section 1720 regarding recognized schools of pharmacy.

10. Section 1726

Interns are no longer required to be supervised by preceptors. Accordingly, references to preceptors are eliminated.

11. Section 1727

Senate Bill 1913 (Chapter 695, Statutes of 2004) establishes the standards for issuing intern pharmacist licenses in Section 4208 of the Business and Professions Code and are inconsistent with existing provisions of this section.

12. Section 1728

The proposed regulation will streamline the board's application process by requiring pharmacist candidates to have completed all other requirements for licensure prior to applying to take the

licensure examinations. The intern hour requirements have been amended to eliminate the first year maximum and preceptor supervision requirements to reflect changes to the pharmacy curriculum in ACPE accredited pharmacy schools.

13. Section 1732

The proposed regulation would eliminate unnecessary definitions.

14. Section 1732.05

The changes update and clarify existing requirements for continuing education accreditation agencies.

15. Section 1732.1

The changes update and clarify existing requirements for continuing education providers.

16. Section 1732.2

The changes update and clarify existing requirements for Board of Pharmacy accredited continuing education providers.

17. Section 1732.3

The changes update and clarify existing requirements for continuing education courses.

18. Section 1732.4

The proposed changes make minor technical changes.

19. Section 1732.5

The proposed changes make minor technical changes.

20. Section 1732.6

The proposed changes make minor technical changes.

21. Section 1732.7

The proposed changes make minor technical changes.

22. Section 1745

Changes made by Senate Bill 151 (Chapter 406, Statutes of 2003) allow the period for partial filling to be extended to 60 days and expands the authority to perform partial fills when a pharmacy does not have an adequate supply to fill the entire prescription in conformance with 21CFR section 1306.13. These changes will provide patients and pharmacists with greater flexibility when

handling Schedule II prescriptions.

23. Section 1749

The proposed regulation includes minor technical changes and the following substantive changes:

1. Subdivision (l) eliminates language relating to the extension of an intern pharmacist license in conformance with Business and Professions Code section 4208 which prohibits the extension or renewal of an intern pharmacist license.
2. Subdivision (m) is eliminated because this fee is specified in statute (Business and Professions Code section 4400) and existing language duplicates that provision.
3. Subdivision (n) is eliminated to conform with changes to continuing education regulations proposed in this rulemaking.
4. Subdivision (p) is eliminated to conform with changes regarding foreign graduates proposed in this rulemaking.
5. Subdivision (r) is eliminated because the board no longer regulates medical device retailers.

24. Section 1750

This section is repealed to conform with the repeal of its authorizing statute (section 11127 of the Health and Safety Code).

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 written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address.

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 upon request from the Board of Pharmacy at 400 R Street, Suite 4070, Sacramento, California 95814, 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 website listed below.

CONTACT PERSON

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

Name: Virginia Herold
Address: 400 R Street, Suite 4070
Sacramento, CA 95814
Telephone No.: (916) 445-5014 x 4005
Fax No.: (916) 327-6308
E-Mail Address: Virginia_Herold@dca.ca.gov

The backup contact person is:

Name: Patricia Harris
Address: 400 R Street, Suite 4070
Sacramento, CA 95814
Telephone No.: (916) 445-5014 x4004
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E-Mail Address: Patricia_Harris@dca.ca.gov

Website Access: Materials regarding this proposal can be found at www.pharmacy.ca.gov.