

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 October 19, 2015.

The board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the written comment period.

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 315, 315.2, 315.4, and 4005 of the Business and Professions Code and section 11420 et seq of the Government Code and to implement, interpret, and make specific sections 4300 and 4301 of the Business and Professions Code, and section 11420.20 and 11425.50(e) of the Government Code, the Board of Pharmacy is proposing to amend Section 1760 of Article 8 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST

A. Informative Digest/Policy Statement Overview

The Board of Pharmacy proposes to amend Section 1760 of Article 8 of Division 17 of Title 16 of the California Code of Regulations and to update Authority and Reference citations.

Existing regulation at Section 1760 requires the board to consider the disciplinary guidelines document when reaching a decision on a disciplinary case. The document, "Disciplinary Guidelines" (Rev. 10/2007) is incorporated by reference; the proposed regulation amends this document and incorporates by reference an updated "Disciplinary Guidelines" with a revision date of July 2015.

Business and Professions Code section 315 generally authorizes the board to develop specific standard in dealing with substance-abusing licensee.

Business and Professions Code section 315.2 generally authorizes the board to suspend a licensee on probation from the practice of pharmacy if the licensee tests positive for any substance that is prohibited under the terms of the licensee's probation or diversion program.

Business and Professions Code section 315.4 generally authorizes the board to suspend a licensee on probation from the practice of pharmacy for major violations or when the board orders a licensee to undergo a clinical diagnostic evaluation.

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

Business and Professions Code section 4300 authorizes the board to discipline a licensee as well as refuse to issue a license to an applicant.

Business and Professions Code section 4301 authorizes the board to take action against a licensee for unprofessional conduct as defined.

Government Code section 11420.20 authorizes the board to adopt regulations to govern an adjudicative proceeding.

Government Code section 11425.50(e) prohibits a penalty from being based upon a guideline unless the guideline has been adopted as a regulation.

16 California Code of Regulations Section 1760 incorporates by reference the Disciplinary Guidelines. Board staff, Deputy Attorneys General, Administrative Law Judges, licensees, and attorneys use these guidelines to assist in determining penalties in the disciplinary case against board licensees. The board is proposing to update the "Disciplinary Guidelines" to conform with changes to the pharmacy law, to clarify some existing terms and conditions of probation that appear ambiguous, establish new terms and conditions necessary to ensure rehabilitation of licensees and remove terms no longer utilized or necessary in the interest of public protection.

B. Anticipated Benefits of Proposal

This proposal would ensure that the disciplinary guidelines reflect changes in current law. The updated guidelines, (Rev. 7/2015), incorporated by reference in this proposal would include uniform standardization to conform to legal requirements and incorporate changes made to facilitate implementation of SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008). Standardizing and updating the disciplinary guidelines to strengthen the board's ability to monitor licensees on probation will benefit the health, safety, and welfare of California residents, workers, and the state's environment. By standardizing the disciplinary guidelines, the board will be better equipped to ensure licensees whose licenses are restricted pursuant to administrative action complete appropriate rehabilitation and prevent further harm to the public consistent with the Board's consumer protection mandate.

C. Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board of Pharmacy has conducted a search of any similar regulations on this topic and has concluded that these regulations are neither inconsistent nor incompatible with existing state regulations.

INCORPORATION BY REFERENCE

Documents incorporated by reference:

1. Disciplinary Guidelines (Rev. 7/2015)

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs/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 Sections 17500 – 17630 Require 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 businesses, including the ability of California businesses to compete with businesses in other states as it only affects licensees that have been disciplined by the board.

Cost Impact on Representative Private Person or Business:

The board is not aware of any cost impacts that a representative private person or business would necessarily incur unless that individual is licensed by the board and subject to disciplinary action by the board.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS:

The Board of Pharmacy has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small business as it will only effect businesses licensed by the board that are subject to disciplinary action.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The board 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. This initial determination is based on the fact that the proposed regulation only affects licensees that have been disciplined by the board. Additionally, licensees are currently subject to these disciplinary guidelines.

Benefits of Regulation:

The Board of Pharmacy has determined that this regulatory proposal will have a significant impact on health and welfare of California residents, worker safety, and state's environment. This proposal specifies the disciplinary guidelines to be followed in board disciplinary actions related to violations of the practice of pharmacy. Disciplining those that violate pharmacy law will ensure that the health and welfare of California residents, workers, and the environment are protected.

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, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

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 any document incorporated by reference, 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 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <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

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

Name: Lori Martinez
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Phone No.: (916) 574-7917
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E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren
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Website Access: Materials regarding this proposal can be found at the Board of Pharmacy's website: www.pharmacy.ca.gov.