

DEPARTMENT OF CONSUMER AFFAIRS
TITLE 16. BOARD OF PHARMACY

**NOTICE OF PROPOSED REGULATORY ACTION CONCERNING:
DISCIPLINARY GUIDELINES**

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (Board) proposes taking the rulemaking action described below under the heading Informative Digest/Policy Statement Overview. 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 at its office by April 8, 2024.

PUBLIC HEARING

The Board has not scheduled a public hearing on this proposed action. The Board will, however, hold a hearing if it receives a written request for a public hearing from any interested person, or that person’s authorized representative, no later than 15 days prior to the close of the written comment period. A hearing may be requested by making such request in writing, addressed to the individuals listed under “Contact Person” in this notice.

Authority and Reference: Sections 315, 315.2, 315.4, and 4005 of the Business and Professions Code (BPC) and section 11400.20 of the Government Code (GC) authorize the Board to adopt this regulation. The proposed regulation implements, interprets, and makes specific BPC sections 4300 and 4301 and GC sections 11420.20 and 11425.50(e). The Board is considering amending section 1760 of title 16 of the California Code of Regulations (CCR).

Informative Digest/Policy Statement Overview

The Board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The Board’s mandate and mission are to protect the public (BPC section 4001.1).

Existing law authorizes the Board (in conjunction with other healing arts boards, as part of a Substance Abuse Coordination Committee) to develop specific standards in dealing with substance-abusing licensees (BPC section 315). Existing law also 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 (BPC section 315.2), if the licensee commits major violations (BPC section 315.4), or when the Board orders a licensee to undergo a clinical diagnostic evaluation (*id.*).

Additionally, existing law authorizes the Board to amend rules and regulations pertaining to the practice of pharmacy (BPC section 4005), and to discipline a licensee (BPC section 4300), refuse to issue a license to an applicant (*id.*), and take action

against a licensee “who is guilty of unprofessional conduct” (as defined in BPC section 4301).

Further, existing law authorizes the Board to adopt “regulations to govern an adjudicative proceeding” (GC section 11400.20), and prohibits a penalty from being based upon a guideline unless the guideline has been adopted as a regulation (GC section 11425.50(e)).

An existing regulation, at Title 16 CCR section 1760, requires the Board to consider the disciplinary guidelines, incorporated by reference, when “reaching a decision on a disciplinary action”. Board staff, Deputy Attorney Generals, Administrative Law Judges, licensees, and attorneys use these guidelines to assist in determining penalties in disciplinary cases against Board licensees. The Board proposes updating the “Disciplinary Guidelines”, incorporated by reference, to include the requirement to disclose respondent’s email address, use gender inclusive language, and use updated terms for consistency throughout the document (including Pharmacy Law Language). Clarification of relevant terms, changes to categories of violations, additional optional terms, language regarding reinstatement of a license, and timeframes for when specific actions must be taken are also proposed. In addition, the proposed update addresses probation, for new licenses issued, under specified conditions. The current document incorporated by reference was previously amended in February of 2017, and the revised version is dated January 2022.

Anticipated Benefits of the Proposed Regulations

The Board has determined that this regulatory proposal will have the following benefits to the health and welfare of California residents and worker safety,

This proposal would ensure that the disciplinary guidelines reflect changes in current law, use gender inclusive language, and provide clarification of certain terminology.

Updating and clarifying the disciplinary guidelines (Rev. 1/2022) strengthens the Board’s ability to monitor licensees on probation and will benefit the health, safety, and welfare of California residents, and worker safety. By updating and clarifying 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.

This regulatory proposal does not affect the state’s environment.

Evaluation of Consistency and Compatibility with Existing State Regulations

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

Incorporation By Reference

Documents incorporated by reference:

1. Disciplinary Guidelines (Rev. 1/2022)

DISCLOSURES REGARDING THIS PROPOSED ACTION

Fiscal Impact and Related Estimates

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

This proposal provides a more accurate overview of the Board's process in formal disciplinary actions, which will provide greater clarity to licensees, consumers, the Board, the Office of Attorney General, and the Office of Administrative Hearings by outlining relevant and transparent standards directly related to violations outlined in current law.

This proposal does not change the fines amounts for violations and is not anticipated to increase the number of citations and fines issued. As a result, no additional workload costs or revenues are anticipated.

Nondiscretionary Costs/Savings to Local Agencies: None

Mandate Imposed on Local Agencies or School Districts: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact Estimates:

The Board has made an initial determination that the proposed regulatory action will 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.

This initial determination is based on the absence of testimony to that effect during the public discussion and development of the proposed amendments to the regulation. Additionally, the proposal does not establish new requirements and simply updates the guidelines to strengthen the Board's ability to monitor licensees on probation by improving clarity of the terms of probation.

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 in reasonable compliance with the proposed action. Combining the requirements of multiple existing statutes and regulations into one regulation (through the document incorporated by reference) would ease

some of the administrative burden on pharmacists, which will increase the availability of the pharmacists to provide patient-centered care, which may result in a minor cost savings to licensees.

Effect on Housing Costs: None

Effect on Small Business:

While the Board does not have, nor does it maintain, data to determine if any of its licensees (pharmacies and clinics) are a “small business,” as defined in Government Code section 11342.610, the Board has made an initial determination that the proposed regulatory action will not affect small businesses. Although the proposed regulation will directly affect businesses statewide that are licensed by the Board and placed on probation, which may include small businesses, the Board does not anticipate any adverse economic impact. Licensees on probation are required to comply with numerous terms and conditions of probation.

RESULTS OF ECONOMIC IMPACT ASSESSMENT/ANALYSIS:

Impact on Jobs/New Businesses:

The Board concludes that this proposal will not:

- (1) create jobs within California;
- (2) eliminate jobs within California;
- (3) create new businesses within California;
- (4) eliminate existing businesses within California; and,
- (5) expand businesses currently doing business in the State of California.

The Board has determined that this regulatory proposal will not have a significant impact on the creation or elimination of jobs or new businesses, or the expansion of businesses, in the State of California. This initial determination was made because the proposed regulation only affects licensees that have been disciplined by the Board. Additionally, licensees on probation are currently subject to these disciplinary guidelines.

Benefits of Regulation:

The Board has determined that this regulatory proposal benefits the health and welfare of California residents and worker safety by strengthening the Board’s ability to monitor licensees who are on probation for violation of pharmacy law.

Additionally, the Board determined that this regulatory amendment will not impact the state’s environment, as these changes do not involve the environment.

Business Reporting Requirements

This regulatory action does not require businesses to file a report with the Board.

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code section 11346.5(a)(13), the Board must determine that no reasonable alternative that it considered to the regulation, or that has otherwise been identified and brought to its attention, would be more effective in carrying out the purpose for which the action is proposed, as effective and less burdensome to affected private persons than the proposal described in this notice, or more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

During the written comment period, any interested person may submit to the Board statements or arguments, in writing, relevant to the above determinations at the address listed below for the Contact Person.

AVAILABILITY OF STATEMENT OF REASONS AND RULEMAKING FILE

The Board has compiled a record for this regulatory action, which includes the Initial Statement of Reasons (ISOR), proposed regulatory text, and all the information upon which this proposal is based. This material is contained in the rulemaking file and is available for public inspection upon request to the contact persons named in this notice.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations, any document incorporated by reference, and 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 2720 Gateway Oaks Drive, Ste. 100, Sacramento, California 95833, or from the Board of Pharmacy's website at http://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments, the Board, upon its own motion or at the request 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, with the modifications clearly indicated, will be available for review and written comment for 15 days prior to its adoption from the person designated in this notice as the Contact Person and will be mailed to those persons who submit written comments or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

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: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

The backup contact person is:

Name: Julie Ansel
Address: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3100
Fax No.: (916) 574-8618
E-Mail Address: PharmacyRulemaking@dca.ca.gov

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Copies of the Notice of Proposed Action, the Initial Statement of Reasons, and the text of the regulations with modifications noted, as well as the Final Statement of Reasons when completed, and modified text ,if any, can be accessed through the Board of Pharmacy’s website at: https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.