

## 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 November 28, 2011.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held at: Embassy Suites San Francisco Airport –Waterfront, 150 Anza Blvd. Burlingame, CA 94010 at 1:30 p.m. on January 31, 2012.

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 section 4005 of the Business and Professions Code and section 11420.20 of the Government Code and to implement, interpret, and make specific sections 315, 315.2, 315.4, 4300 and 4301 of the Business and Professions Code, and sections 11420.20 and 11425.50(e) of the Government 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

The California State Board of Pharmacy (Board) protects consumers by licensing and regulating all aspects of the practice of pharmacy in California, including the pharmacist, the pharmacy, and prescription drugs and devices. The Board also regulates drug wholesalers, veterinary food-animal drug retailers (VFADR), designated representatives (manager responsible for ensuring compliance of wholesaler or VFADR), and other practitioners such as pharmacist interns and technicians. The Board licenses thousands of individuals and firms, and administers and enforces 12 regulatory programs. The Board fulfills its public protection mandate by imposing discipline on licensees who violate the Pharmacy Law.

Business and Professions Code section 4005 generally authorizes the board to adopt and 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.

Business and Professions Code section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs (Department) and required the SACC to formulate uniform and specific standards for use by healing arts boards in dealing with substance abusing licensees.

Business and Professions Code Section 315.2, specifies that a healing arts board within the Department is required to order a licensee to cease practice 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, authorizes healing arts boards within the Department to order a licensee on probation or in a diversion program to cease practice for major violations and when the board orders a licensee to undergo a clinical diagnostic evaluation pursuant to the uniform and specific standards adopted and authorized under Section 315.

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.

Title 16, California Code of Regulations Section 1760 currently incorporates by reference the Board's 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 amend Section 1760 of Division 17 of Title 16 of the California Code of Regulations. The purpose for amending the regulation is to update the Disciplinary Guidelines that are incorporated by reference in section 1760, and revised in September 2011. The board is proposing to update the "Disciplinary Guidelines" to conform with changes to the Pharmacy Law (Business and Professions Code sections 4000 et seq.), 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.

Further, in April 2011, the SACC finalized a document named *Uniform Standards Regarding Substance-Abusing Healing Arts Licensees*, which contained the sixteen uniform standards as required by Section 315. The Board is proposing to use the SACC's standards, where applicable, throughout its guidelines as a way to facilitate implementation of the uniform standards.

Provided below is information on the general changes proposed for the Board's Disciplinary Guidelines.

1. Proposed changes resulting from reorganization of the Guidelines:
  - Consolidation of all the lists of standard terms and conditions of probation into one list for all individual license types (Pharmacist, Intern Pharmacist, Pharmacy Technician and Designated Representative).
  - Removal of all legal citations under each separate category of violations. These can be made available via an attachment for those who want such a reference.
  - Revised definitions for the various categories of violations and inclusion of sample violations within each category of violation.
2. Proposed changes to Disciplinary Orders and Terms of Probation for Individual Licensees:

New Model Disciplinary Order Language for a:

- License Reinstatement Order with Conditions Prior to Issuing License
- General License Reinstatement

Changes to Model Language for the following types of Disciplinary Orders:

- Revocation
- Suspension
- Issuance of Probationary License
- Surrender

New term of probation

- Suspension

Changes to the following existing terms of probation:

- Cooperate with Board Staff: This term would be revised to clarify what activities require cooperation within the term as well as specify that such cooperation must occur timely.
- Restrictions on Supervision and Oversight of Licensed Facilities: This term would be renamed to better reflect the requirements of the term and to specify that it is appropriate only for pharmacist and designated representative licensees. Further this term would provide for the consolidation of other existing terms - - No Supervision of Ancillary Personnel and Consultant for Owner or Pharmacist-in-Charge. This term would also be changed to facilitate consolidation of the individual license types.
- Reimbursement of Board Costs: This term would be renumbered. Also, a new option would be created that would allow a respondent to submit payments to the board pursuant to an approved plan, and would specify that payment in full must be completed at least one year prior to the end of probation. Further, the proposed change would remove the language stating that the filing of bankruptcy does not relieve the respondent of the requirement to pay the board.
- Certification Prior to Resuming Work (Pharmacy Technician Only): For purposes of consolidation, this term would be moved to a new consolidated section. Further, the term would reflect that it is appropriate only for pharmacy technician licensees.
- Notification of Departure: For purposes of consolidation, this term would be moved to apply to all individual licensees, not just pharmacy technicians and designated representatives as currently authorized.
- License Practice Requirements – Tolling: This term would be renamed to better reflect the provisions contained therein. Proposed changes are necessary to facilitate consolidation of the individual license types. Additionally, the optional language would be changed to allow the board greater flexibility in meeting the

employment needs of a respondent while balancing the board's probation monitoring needs to ensure that necessary rehabilitation occurs. A new option would also be created specific for intern pharmacists to reflect the experiential requirements of pharmacy education.

- **Restricted Practice:** This term would be renumbered for purposes of consolidation and language would be added to authorize a designee to perform board functions. In addition, this term would be revised to include a requirement for submission of written proof of compliance. It would also add an option to include requirements for "satisfactory proof" of compliance to the Board that may include written acknowledgment of compliance with the restriction on practice from a licensee's direct supervisor, pharmacist in charge, and owner or owner representative.
- **Pharmacist Exam (Pharmacists Only):** This term would be renumbered and a notation that this term shall be used only for pharmacists would be provided with this change. The phrase "he or she" would be replaced with [he/she] to allow the drafter to select the gender of the respondent. The suspension language contained within this term would also be modified to clarify the prohibited functions during any such suspension. Further, if the respondent is required to complete 16 semester units of remedial education, the board would clarify with this change that proof of completion of such coursework must be provided.
- **Psychotherapy:** This term would be renumbered and updated to clarify the conditions when inclusion of this term is appropriate. The suspension language would be modified to clarify those activities that are prohibited during any such suspension.
- **Medical Evaluation:** This term would be renumbered and modified to facilitate consolidation of each of the individual license types. The suspension language would be modified to clarify those activities that are prohibited during any such suspension. The same types of changes are being made to the two options provided in this term.
- **Pharmacists Recovery Program (Pharmacists and Pharmacist Interns Only):** The term would be updated to clarify the conditions when inclusion of this term is appropriate. This term would also be modified to clarify what actions a respondent must take to comply with the term as well as the timeline for completion. The term would also clarify that the respondent must comply with the treatment contracts established by the PRP and that failure to comply will result in the automatic suspension of practice by the respondent. The suspension language would be modified to clarify those activities that are prohibited during any such suspension. The option language would be modified to clarify the intent of the option, which is to allow the PRP the ability to monitor a respondent under specified conditions prior to the respondent successfully completing the PRP.
- **Abstain from Drugs and Alcohol:** This term would be renumbered and portions rewritten to clarify exceptions to the prohibition.
- **Prescription Coordination and Monitoring of Prescription Use:** This term would be updated to clarify the conditions when inclusion of this term is appropriate. This term would also be modified to allow for consolidation of each of the individual license types and to clarify that the board may identify a designee to

perform board functions. The suspension language would also be changed to clarify those activities that are prohibited during any such suspension.

- Community Service Program: This term is being renumbered and modified to facilitate consolidation of each of the individual license types. In addition, the term would specify that proof of completion must be provided and clarifies that the board may allow a designee to perform board functions.
- Supervised Practice: This term would be renumbered and a notation would be added to indicate this term only applies to pharmacists, pharmacist interns and designated representatives. This term would be recast to better describe the requirements of the term and to provide better guidance to the respondent on the board's expectations. This term would define what constitutes a violation of probation and the suspension language would be changed to clarify those activities that are prohibited during any such suspension.
- Surrender of DEA Permit (Pharmacists and Pharmacist Interns Only): This term would be renumbered and a notation would be added to clarify that this term should only be used for pharmacists and pharmacist interns. This term would be modified to replace the phrase "his or her" with [his/her] to allow for the respondent's gender to be accurately reflected in the decision. In addition, this term would clarify what acts are prohibited under this term and the two optional terms are being numbered.
- Ethics Course: This term would be renumbered and a notation would be made to clarify that this term should only be used for pharmacists and pharmacist interns. In addition, this term would be modified to accurately reflect the course requirements as detailed in Title 16, California Code of Regulations Section 1773.5 and specify that proof of enrollment and completion must be provided to the board. The term would also specify that failure to provide such proof will be considered a violation of probation.

Proposed changes to the terms and conditions of probation of the Guidelines to use the Uniform Standards for Substance Abusing Licensees as set forth by the SACC in its April 2011 document:

- Amend "Notice to Employers" and rename as "Reporting of Employment and Notice to Employers" term
- Add "Clinical Diagnostic Evaluation" and delete "Mental Health Examination" term
- Amend "Random Drug Screening" and rename as "Drug and Alcohol Testing" term
- Add "Facilitated Group Recovery and/or Support Meetings" term
- Add "Work Site Monitor" term
- Add "Attend Substance Abuse Recovery Relapse Prevention and Support Groups" term

### 3. Proposed changes to Premises Licensees:

Changes to the Model Disciplinary Orders Language for the following types of discipline:

- Revocation
- Suspension
- Issuance of a Probationary License
- Surrender

- Public Reprimand

#### Add new terms of probation

- Definition: Respondent
- Sale or Discontinuance of Business: This term would specify that the board, in its sole discretion, will determine if it retains jurisdiction over a licensed location that has either changed location or ownership (full or partial) irrespective if a new license number is issued. If the board makes such a determination, the jurisdiction would be carried over to the new location or license number and the terms and conditions of probation would carry over for the remainder of the probation period. The substance of this proposed change is currently contained in a different term (License Surrender While on Probation).
- Premises Open for Business: This term would require a business to remain open for a specified period of time. The language allows flexibility to the board in determining the minimum number of hours per calendar month the business must be open and sets forth the reporting requirements for this term.
- Suspension: This term would be added as separate, optional term of probation.

#### Proposed changes to existing terms of probation

- Cooperate with Board Staff: This term would be renumbered and modified to clarify what activities are required in cooperation with the board.
- Reimbursement of Board Costs: This term would be renumbered and would be modified to remove the word “owner” as a definition of respondent is being added in a separate term to provide clarity. Also, a new option would be created that will allow a respondent to submit payments to the board pursuant to an approved plan, and would specify that payment in full must be completed at least one year prior to the end of probation.
- Status of License: This term would be renumbered and would be modified to remove the word “owner” as a definition of respondent is being added in a separate term to provide clarity. Further a provision that currently specifies that the board would retain jurisdiction would be removed.
- Posted Notice of Probation: This term would be renumbered and would be modified to remove the word “owner” as a definition of respondent is being added in a separate term to provide clarity. In addition, this term would provide for the timeframe for compliance with the posting requirements.
- Report of Controlled Substances: This term would be modified to allow the board greater flexibility in determining the frequency of reports and the number that should be submitted. This term would also clarify that the board allows the use of a designee to complete functions on its behalf. In addition this term would be renumbered and would be modified to remove the word “owner” as a definition of respondent is being added in a separate term to provide clarity.
- Posted Notice of Suspension: This term would be renumbered and the word “owner” would be removed. In addition, the board would specify the timeframe for posting the notice to provide the respondent with clear direction on the board’s expectation for compliance with this term. This term would additionally specify that failure to comply with this requirement will be considered a violation of probation.

## 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 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 business, 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.

Impact on Jobs/New Businesses: The board has made an initial determination that the proposed regulatory action would have no significant impact on the creation of jobs or new businesses or the elimination of jobs or existing businesses or the expansion of business in the State of California.

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. Further, an individual subject to random drug screening as a term and condition of probation could incur an additional \$78 to \$88 per urine screen, if the frequency of tests was increased to the specified requirements. The Board does not maintain data relating to the number or percentage of licensees who own a business; therefore the number or percentage of businesses that may be impacted cannot be predicted. Accordingly, the initial or ongoing costs for a small business owned by a licensee who is the subject of disciplinary action cannot be projected. Businesses operated by licensees who are in compliance with the law will not incur any fiscal impact.

Effect on Housing Costs: None.

## EFFECT ON SMALL BUSINESS

The board 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..

## CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered 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 or would be as effective as and less burdensome to affected private persons than the proposed action.

Any interested person may present written statements relevant to the above determinations to the Board of Pharmacy at the above-mentioned address or may present statements orally 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 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 Web site ([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 regulation is 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:	Anne Sodergren
Address:	1625 N. Market Blvd. N219 Sacramento, CA 95834
Telephone No.:	(916) 574-7910
Fax No.:	(916) 574-8618
E-Mail Address:	<a href="mailto:anne.sodergren@dca.ca.gov">anne.sodergren@dca.ca.gov</a>

The backup contact person is:

Name: Carolyn Klein  
Address: 1625 N. Market Blvd. N219  
Sacramento, CA 95834  
Telephone No.: (916) 574-7913  
Fax No.: (916) 574-8618  
E-Mail Address: carolyn.klein@dca.ca.gov

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