

## 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 10, 2006.

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 September 24, 2006.

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 to implement, interpret or make specific sections 4022.5, 4201, and 4160 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

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

The objective of this proposal is to provide designated representatives in charge (DRC) and the wholesaler premises with information regarding pharmacy law and the board's expectations for the practice of pharmacy within legal requirements. These are the elements reviewed by the board during unannounced inspections. A completed self-assessment form would serve as a reference for the DRC to use when managing wholesaler operations. Use of the self-assessment form in wholesalers could potentially reduce the need for DRC's to call the board with questions regarding pharmacy law.

The board is proposing to adopt section 1784 to require that the DRC of each wholesaler complete a self-assessment form according to specific criteria.

Additionally, section 1784 would detail the components of the self-assessment form for evaluating compliance with state and federal pharmacy laws regarding the condition of a wholesaler facility, DRC and owner responsibilities, drug stock, sale or transfer of drugs, delivery of drugs, policies and procedures and record keeping requirements. Specific sections referenced in the self assessment document include citations of the Business and

Professions Code (B & P), California Code of Regulations (CCR), Health and Safety Code (H & S) and Code of Federal Regulations (CFR).

The proposed regulation also specifies under what circumstances this self-assessment must be completed and the retention schedule for the form.

### 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 determined that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

This action would provide the DRC with the specific compliance information that the board seeks when conducting a wholesaler inspection. The requirements for conducting a wholesaler outlined in the self-assessment are not new requirements. Wholesalers are currently required to comply with these laws.

The board intends that the DRC would actually determine the extent to which the wholesaler is or is not in compliance with Pharmacy Law, make necessary adjustments to bring the wholesaler into compliance and thereby improve the wholesaler's performance in meeting state and federal requirements. This would benefit public safety. Moreover, the assessment form provides wholesalers and the DRC with the knowledge they need to comply with state and federal requirements for licensed wholesalers.

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.

The proposal would necessitate a self-assessment by the DRC of the wholesaler premises every odd-numbered year or in the event of a change of location of the

licensed premises or change in the DRC. This self-assessment form would be a tool to aid the DRC and the wholesaler in general in this regard.

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.

### CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative which it considered either would be more effective than or as effective as and less burdensome on affected private persons than the proposal described.

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 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 website listed below.

### CONTACT PERSON

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

Name: Virginia Herold  
Address: 1625 N. Market Blvd. N219  
Sacramento, CA 95834  
Telephone No.: (916) 574-7911  
Fax No.: (916) 574-8618  
E-Mail Address: virginia\_herold@dca.ca.gov

The backup contact person is:

Name: Christine Sanchez  
Address: 1625 N. Market Blvd. N219  
Sacramento, CA 95834  
Telephone No.: (916) 574-7932  
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Website Access: Materials regarding this proposal can be found at [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).