

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 31, 2007.

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 14, 2007.

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, and to implement, interpret or make specific sections 4051, 4052, 4059, 4076, 4081, 4127, and 4127.7 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.

Current pharmacy regulations addressing compounding only govern the physical circumstances, procedures and recordkeeping requirements for general compounding and do not address quality, strength and purity.

The proposed regulations provide a balance of consumer protection with the need for pharmacies to compound medication for patients, either pursuant to a prescription or based upon the need for future furnishing. Records, labeling and quality assurance are needed for any product a pharmacy compounds, even if the pharmacy does it only rarely. The level of record keeping and quality assurance required as specified in these regulations does depend on the frequency and volume of medicine compounded. The pharmacy that rarely compounds medicine or does so to a limited extent may provide most of the record keeping on the prescription document itself. When larger volumes of medicine are compounded, the board expects more record keeping and higher quality assurance. This proposal distinguishes between the two levels.

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 determination is based on the absence of testimony provided in a number of public meetings.

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.

This determination is based on the absence of testimony provided in a number of public meetings.

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 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).

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:

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| Name: | Anne Sodergren |
| Address: | 1625 N. Market Blvd. N219 Sacramento, CA 95834 |
| Telephone No.: | (916) 574-7913 |
| Fax No.: | (916) 574-8618 |
| E-Mail Address: | anne_sodergren@dca.ca.gov |

The backup contact person is:

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| 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 |

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