

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the California State Board of Pharmacy (board) is proposing to take 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 not later than 5:00 p.m. on September 17, 2018.

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 his or her authorized representative, no later than 15 days prior to the close of the written comment period.

The board may, after considering all timely and relevant comments, adopt the proposed regulations substantially as described in this notice, or may modify the proposed regulations 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: Sections 4005 and 4127 of the Business and Professions Code authorize the board to adopt these regulations. The proposed regulations implement, interpret, and make specific sections 4005, 4029, 4036, 4037, 4051, 4052, and 4127 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The board proposes to clarify and make specific the standards for pharmacies and pharmacists compounding drug preparations.

Business and Professions Code (B&P) section 4001.1 specifies that protection of the public is the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions. This section further states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

B&P section 4005 generally authorizes the board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. It also specifically authorizes it to adopt regulations: relating to the sanitation

of persons and facilities licensed by the board; pertaining to licensed facilities wherein any drug is compounded, prepared, furnished or dispensed; pertaining to minimum equipment for licensed facilities; and for the proper and effective enforcement and administration of Pharmacy Law.

B&P section 4127 generally authorizes the board to adopt and amend regulations establishing standards for compounding sterile drug products in a pharmacy.

B&P section 4029 established the definitions of a hospital pharmacy and a hospital satellite compounding pharmacy.

B&P section 4036 establishes the definition of a pharmacist.

B&P section 4037 establishes the definition of a pharmacy.

B&P section 4051 generally specifies those functions and duties relating to dangerous drugs or dangerous devices, including compounding, which must be performed by a pharmacist.

B&P section 4052 further specifies general functions a pharmacist may perform, including how a pharmacist may furnish drugs to a prescriber and those functions a pharmacist may perform in a health care facility, clinic or in other health care settings.

California Code of Regulations, title 16, division 17, articles 4.5 and 7 specify the conditions under which pharmacies and pharmacists may compound drug preparations.

The regulations proposed in this rulemaking would modify the requirements for a pharmacy and pharmacist compounding drug preparations, including how pharmacists may establish beyond use dates (BUD) for compounded drug preparations. The proposed amendments would also clarify definitions of compounding terms used, clarify standards relating to equipment used in compounding (including biological safety cabinets), and clarify standards for facilities performing sterile compounding (including smoke studies).

The regulations regarding BUDs for compounded drug preparation were also the subject of an emergency regulation that took effect on December 19, 2017.

Anticipated Benefits of the Proposed Regulations

The broad objective of this proposal is to ensure that compounding is performed in a manner and under conditions that ensure the compounded drug preparations dispensed to the public by a pharmacy and pharmacist are safe and effective. The specific benefits anticipated by the proposed amendments are to protect the public from risks of unsafe and or ineffective compounding of drug preparations. Unsafe compounded drug preparations pose risks to patients, including a risk of death. Ineffective compounded drug preparations can pose a risk to patients if the patient does not receive the

prescribed dose of a medicine. A pharmacist's expanded ability to extend the BUD for non-sterile compounded drug preparations makes such preparations more accessible, and therefore makes patients healthier by increasing the compliance with a doctor's directions. It also includes benefits such as the protection of public health and safety, worker safety, the environment, and the increase in openness and transparency in business and government.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the board 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.

Fiscal Impact and Related Estimates

The board has made the following initial fiscal impact determinations:

Local Mandate: None

Fiscal Impact on Public Agencies:

- Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None
- Costs/Savings to State Agencies: Minimal cost savings
- Nondiscretionary Costs/Savings to Local Agencies: None
- Costs/Savings in Federal Funding to the State: None

Significant Statewide Adverse Economic Impact Directly Affecting Businesses (If Any):

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.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The board concludes that it is:

- (1) Unlikely that the proposal will create or eliminate any jobs within California;
- (2) Unlikely that the proposal will create new, or eliminate existing, businesses in California;

- (3) Unlikely that the proposal will expand businesses currently doing businesses within the state;
- (4) The benefits to the public are for consumer protection and increased assurance that any compounding services will be provided safely and effectively with minimal risk, that patients will have better access to nonsterile compounded medications, that workers and environments will be protected during the compounding of drugs and that the board will be better able to monitor compliance.

Benefits of the Proposal:

The board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and the state's environment. Unsafe or inadequately prepared or handled compounded medications pose risks to consumers' health; drugs compounded in an unsafe manner pose risks to employees and the environment. By regulating the circumstances under which a pharmacy and pharmacist may compound drug preparations and provide them to consumers, the board makes it more likely compounded drugs are safe and effective for consumers and makes it more likely that the employees and the environment are protected. The proposed amendments modify how pharmacists and pharmacies can compound drug preparations, which will increase patient access to these products, will ensure they are safely prepared, will ensure that workers and the environment are protected, and that the board can appropriately monitor for compliance.

Cost Impact on Representative Private Person or Business:

The board anticipates that the regulatory proposal could result in patients receiving a larger supply of medication at one time and could result in fewer visits to the doctor and/or pharmacy and therefore lower patient costs. Pharmacies may also experience cost savings due to decreased testing requirements to extend the duration of a drug preparation's usefulness. It anticipates minimal, if any, additional costs in pharmacy recordkeeping and storage when a pharmacy documents its extension of a beyond use date.

Business Reporting Requirement

The proposal requires pharmacies and pharmacists extending the BUD for nonsterile compounded drug preparations to create a record of their analysis and to keep it in the pharmacy's files. For the health, safety, or welfare of the people of the state, the board finds that it is necessary that proposed section 1735.2(i)(1)(G) apply to businesses.

Effect on Small Business:

The board believes this regulation will impact small businesses. Although the board does not have nor maintain data to define if any of its licensees (pharmacies) are a “small business” as defined in Government Code section 11342.610, the board has made an initial determination that the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. This is based on the determination that the regulatory proposal could result in existing pharmacies, some of which are likely small businesses, offering more nonsterile compounding services, lower costs for those services, patients receiving a larger supply of medication at one time, and fewer patient visits to the doctor and/or pharmacy. Pharmacies that are small businesses may experience cost savings due to decreased testing requirements to extend the duration of a drug preparation’s usefulness; it is also possible that they may experience a very minor increase in costs related to record keeping in so doing.

Consideration of Alternatives

The board must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention (1) would be more effective in carrying out the purpose for which the action is proposed, (2) would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or (3) would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The board invites interested persons to present statements or arguments with respect to the alternatives to the proposed regulations during the public comment period.

Availability of Initial Statement of Reasons, Text of Proposed Regulations and Rulemaking File

The board will have the entire rulemaking file available for inspection and copying throughout the rulemaking process at its office at the address above. As of the date this notice is published in the Notice Register, the rulemaking file consists of this notice, the proposed text of the regulations, the initial statement of reasons, and all of the documents upon which the proposal is based.

Availability of the Final Statement of Reasons

Upon its completion, you may obtain a copy of the final statement of reasons by accessing the website listed below or by contacting the person named 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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The backup contact person is:

Name: Anne Sodergren
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Website Access

Copies of this notice, the initial statement of reasons, and the text of the proposed regulations in underline and strikeout can be found at the California State Board of Pharmacy's website: www.pharmacy.ca.gov.