

TITLE 16. BOARD OF PHARMACY

NOTICE OF PROPOSED REGULATORY ACTION CONCERNING: COMPOUNDING LIMITATIONS AND REQUIREMENTS: SELF-ASSESSMENT

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 August 15, 2022.

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.

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 the 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 (BPC) authorize the board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4005, 4029, 4037, 4051, 4052, 4126.8 and 4127 of the Business and Professions Code.

Informative Digest/Policy Statement Overview

The board is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, hospital pharmacies, clinics, wholesalers, third-party logistics providers, and outsourcing facilities. The board's mandate and its mission is to protect the public (BPC § 4001.1).

Existing regulation at 16 CCR section 1735.2, specifies the limitations and requirements for compounded drug preparations. Subdivision (k) of section 1735.2 requires the pharmacist-in-charge (PIC) to complete a self-assessment form prior to allowing any drug product preparation, before July 1 of every odd-numbered year; and within 30 days whenever: (1) a new pharmacy permit has been issued; (2) there is a change in the PIC, and they become the new PIC of a pharmacy; or (3) there is a change in the

licensed location of a pharmacy to a new address. The self-assessment form assists the pharmacy to evaluate and improve its compliance with federal and state requirements, makes the pharmacy inspection process more meaningful and provides relevant information to PICs. This self-assessment form was last updated in February 2012.

On January 1, 2017, the board updated its compounding regulations due to changes to the federal United States Pharmacopeia (USP), which is the national practice standard for compounding. This proposal will repeal and replace the self-assessment form that is incorporated by reference to: (1) update citations/references since the last revisions (2/12); (2) correct previously misstated references and typographical errors; (3) make formatting changes; and (4) incorporate references to new regulatory or statutory requirements. These changes would assure the PIC that the information and references contained therein reflect current statutory and regulatory requirements. Due to the extensive changes that occurred to the compounding regulations (16 CCR §§ 1735 and 1751 et seq.) effective January 1, 2017, as well as statutory changes in 2020 and 2021; for clarity the board has repealed the existing compounding self-assessment form dated 2/12 and has replaced the compounding self-assessment form with a completely new document dated 1/22.

Anticipated Benefits of the Proposed Regulations

This regulatory proposal benefits the health and welfare of California residents and benefits employee safety. The proposed regulation will update the self-assessment form with current law and regulations. The self-assessment form aids licensees in assessing their compliance with federal requirements and state law and regulations. The proposal updates the form to include the laws and regulations adopted since 2012 and to exclude the laws and regulations that have been superseded or repealed since 2012.

As the PIC must complete the self-assessment form, biennially, they will identify any areas where the compounding facility may be out of compliance. This awareness can increase self-correction and make the facility site inspection process more meaningful by providing useful information to the PIC about controlling statutes and regulations. This periodic review and accountability will result in increased consumer safety, specific to compounded medication, and will improve facility operations with respect to employee safety and the state's environment.

As the PIC is the person responsible to complete the self-assessment form, this requirement helps educate the PIC and ensure that the PIC has knowledge of all applicable laws and regulations, which will in turn, help ensure that the compounding pharmacies are follow practice standard, thus protecting the safety and quality of compounded drug preparations. This regulatory proposal benefits workers' safety because having pharmacies follow all applicable laws and regulations makes the pharmacies a safer place to work. The self-assessment form is being updated to add and/or remove law and regulations. The self-assessment form does not impose the new laws. PICs are already obligated to comply with the laws and regulations, and the self-assessment form is simply a tool provided by the board to aid them in doing so. The

proposed changes work to reassure PICs that the information and references contained in the form is current as of the new revision date.

Incorporation by Reference

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment 17M-39 (Rev. 1/22).

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.

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. The proposed regulations do not result in a fiscal impact to the state.

The Board currently requires PICs to complete and submit self-assessments, as specified. The regulations do not increase the number of self-assessments to be submitted or require additional Board workload or costs from the current process.

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 determined 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. This determination is based on the fact that the proposed regulation does not establish new law. PICs are already obligated to comply with the new laws and regulations, and the self-assessment form is simply a tool provided by the Board to aid them in doing so.

Cost Impact on Representative Private Person or Business:

The board is not aware of any negative cost impacts that a representative private person or business would necessarily incur in reasonable compliance with proposed action. Any pharmacy licensed by the board that compounds drug preparations must comply with Articles 4.5 and 7 of Division 17 of Title 16 of the California Code of Regulations and is already required to complete the self-assessment form, when applicable.

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 this proposal would not affect small businesses. The board already requires pharmacists to complete a self-assessment form, so the board finds that correcting and updating the form used to conduct the self-assessment will have no impact on small businesses.

Business Reporting Requirements

This regulatory proposal does require pharmacists or pharmacies to fulfill reporting requirements because the compounding self-assessment form is to be completed by the PIC and maintained at the pharmacy. The Board reviews the self-assessment form during site inspections to ensure completion and identify if areas of non-compliance identified during completion have been remedied by the PIC. It is necessary for health, safety, or welfare of the people of the state that the regulation apply to businesses.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board concludes that since the regulatory change is to update the self-assessment form that is already required to be completed by pharmacists:

- (1) this proposal will not create jobs within California;
- (2) this proposal will not eliminate jobs within California;
- (3) this proposal will not create new businesses within California;
- (4) this proposal will not eliminate existing businesses within California;
- (5) this proposal will not expand businesses currently doing business in the State of California.

Benefits of Regulation:

This regulatory proposal benefits the health and welfare of California residents because having pharmacies follow all applicable laws and regulations helps ensure the safety and quality of compounded drug preparations. This regulatory proposal benefits workers’ safety because having pharmacies follow all applicable laws and regulations makes the pharmacies a safer place to work. This regulatory proposal does not affect the state’s environment as it simply brings up-to-date forms incorporated by reference in regulation that PICs already must complete biennially.

Consideration of Alternatives

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 either be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposal described in this Notice, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person during the written comment period.

Initial Statement of Reasons and Information

The Board has prepared an Initial Statement of 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 any document incorporated by reference, and of 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>.

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:

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The backup contact person is:

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Website Access

Materials regarding this proposal can be found at the Board of Pharmacy's website:
https://www.pharmacy.ca.gov/laws_regs/pending_regs.shtml.