

TITLE 16. BOARD OF PHARMACY

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 by November 01, 2021.

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 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: Section 4005 of the Business and Professions Code (BPC) authorizes the Board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4081, 4104, and 4332 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, clinics, and pharmacists. The Board's mandate and its mission is to protect the public (BPC section 4001.1).

On April 1, 2018, the Board's regulation, 16 Title, California Code of Regulations (CCR) section 1715.65, establishing the requirement for pharmacies and clinics to perform inventory reconciliation activities to detect and prevent the loss of controlled substances became effective. In July 2019, the Board began a post-implementation review of the regulation to determine if any changes should be considered. During discussions with stakeholders at several Board meetings, the Board determined that the regulatory language should be amended.

This proposed regulation will clarify what an inventory reconciliation is and define "inventory activities," it will identify four non-Schedule II controlled substances

(Alprazolam, 1 milligram/unit, Alprazolam, 2 milligrams/unit, Tramadol, 50 milligrams/unit, and Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product) that will require an inventory at least once every twelve months, and specify that all other controlled substances must have an inventory completed within 3 months of a discovered loss and at least once every two years, when no loss is found.

Additionally, the proposal will require that all individuals involved in completing the inventory or preparing the report be identified, and that the individual who performs the inventory to sign and date it.

Furthermore, this proposal will allow for the use of a digital, electronic, or biometric identifier in lieu of a physical signature if a printed signed statement confirming the accuracy of the report is retained according to existing retention requirements.

Finally, the proposal will clarify the inventory requirements for an inpatient hospital pharmacy where drugs are stored within a drug storage area under the pharmacy's control and for the inventory of an automated drug delivery system (ADDS) within the inpatient hospital.

Anticipated Benefits of the Proposed Regulations

This proposal will require pharmacies and clinics to perform a physical count inventory at least once every twelve months for four non-Schedule II controlled substances. According to the National Council on Alcoholism and Drug Dependence, Inc., the availability of opioids is partly the cause of the epidemic misuse of prescription medication.

By requiring the inventory of the four non-Schedule II controlled substances yearly and of other non-Schedule II controlled substances biennially, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. This will reduce the supply of controlled substances available for misuse and abuse without denying pain relief for those that need it. Additionally, the proposal will improve clarity among the regulated public and ensure that complete and accurate inventories are being completed.

Consistency and Compatibility with Existing State Regulations

During the process of 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 Board will ensure facilities comply with the regulations through routine inspections and no additional workload or costs are anticipated.

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 businesses and/or employees. This initial determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over several months.

Additionally, pharmacies and clinics are currently required to perform an inventory reconciliation on all Schedule II controlled substances. While this proposal does add an additional four controlled substances that must be inventoried, the Board does not anticipate an impact on businesses from this additional requirement. The Board notes that the proposed regulation does not require the use of specific computer software. The inventory counts are to be completed by hand and can be recorded using pen and paper or basic computer spreadsheet software that the pharmacy currently utilizes.

Cost Impact on Representative Private Person or Business:

The Board is not aware of any cost impacts that representative private persons or businesses would necessarily incur in reasonable compliance with proposed action. The Board indicates approximately 8,800 licensees would be subject to the proposed requirements, of which approximately 453 (or 5 percent) do not use PIS and will need to hand count. These locations may need to schedule additional staffing hours for these purposes, which could result in minor additional costs.

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 the proposed regulatory action would not have a significant adverse economic impact directly affecting small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the Board concludes that

the adverse economic impact, including the ability of California businesses to compete with businesses in other states, will not be significant.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board concludes that:

- (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:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents and worker safety because the proposed regulation will require better inventory and control of controlled substances. By reducing the amount of controlled substances diverted, it will reduce the number of drugs being misused and abused. This will result in improved health for Californians. Additionally, the job accidents may decrease if fewer employees and/or co-workers are working under the influence of a misused or abused controlled substance. The proposed regulation will not impact the state's environment.

Consideration of Alternatives

The Board must determine that no reasonable alternative 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 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 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:

Name: Lori Martinez
Address: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
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The backup contact person is:

Name: Debbie Damoth
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Website Access

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