

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy (Board) 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 at its office not later than 5:00 p.m. on November 30, 2015.

The Board does not intend to conduct a Regulation Hearing on the matter, unless requested. Any interested person may submit a written request for a public hearing no later than 15 days prior to the close of the written comment period.

The Board, 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 to implement, interpret, and make specific sections 4081, 4104 and 4332 of the Business and Professions Code, the Board is proposing to add and adopt Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations as follows:

Informative Digest/Policy Statement Overview

The Board of Pharmacy (Board) proposes to add and adopt Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of adding to the Board's regulations specific requires for reconciliation and inventory reporting of controlled substances as part of the Board's efforts to combat drug loss and diversion from within pharmacies and prescription drug abuse within California.

Business and Professions Code (B&P) section 4001.1 specifies that protection of the public shall be the highest priority for the California State Board of Pharmacy 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 amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy.

B&P section 4081 generally specifies the record requirements for the manufacture, sale, acquisition, receipt, shipment, and disposition of dangerous drugs or dangerous devices. Additionally, this section generally specifies that a current inventory to be kept by all licensees who maintain a stock of dangerous drugs or dangerous devices.

B&P section 4104 generally specifies the requirements for reporting theft or diversion of a licensed employee.

B&P section 4105 generally specifies the record requirements for the acquisition and disposition of dangerous drugs or dangerous devices in a readily retrievable form.

B&P section 4332 specifies that any person who fails to maintain or produce a drug or device record is guilty of a misdemeanor.

CCR Section 1714 specifies that the pharmacy and pharmacist are responsible for the security of the prescription department while on duty, including effective control against theft and diversion of drugs, devices, and records.

CCR Section 1715.6 specifies that the pharmacy shall report the loss of any controlled substance within 30 days of discovery. The loss shall include the amount of the loss and the strengths.

CCR Section 1718 defines “current inventory” as used in B&P sections 4081 and 4332 to be complete accountability for all dangerous drugs handled by every licensee enumerated in B&P sections 4081 and 4332.

This proposal will require pharmacies and clinics to perform a physical count inventory at least every three months of all Schedule II controlled substances and at least one additional controlled substance as identified by the board based on drug loss reports. By conducting a physical count inventory, pharmacist, pharmacies, and clinics will have more accountability and control over controlled substances.

Anticipated Benefits of Proposal

This proposal will require pharmacies and clinics to perform a physical count inventory at least every three months of all Schedule II controlled substances and at least one additional controlled substance as identified by the Board based on drug loss reports. 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 at least a quarterly inventory of all Schedule II controlled substances, 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.

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 Estimates

Fiscal Impact on Public Agencies Including Costs/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 Sections 17500 – 17630 Require Reimbursement: None

Business Impact:

The Board has made a 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, 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 a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Effect on Housing Costs: None

Effect on Small Business:

While the Board does not have nor does it 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. 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.

Results of Economic Impact Assessment/Analysis:

Impact on Jobs/New Businesses:

The Board 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. This initial determination is based on the fact that under CCR Section 1714, a pharmacist is currently responsible for the security of the pharmacy or clinic, including the effective control against theft and diversion of controlled substances. This regulation establishes a needed method of control against theft and diversion.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit the health and welfare of California residents, worker safety, and state's environment 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 amount of drugs being misused and abused. This will result in improved health for Californians. If fewer people are misusing and abusing controlled substances, there may be a corresponding reduction in petty crimes seeking prescription medications. Additionally, reducing the amount of controlled substances diverted will reduce the amount of drugs being misused and abused. On the job accidents will decrease if fewer employees and/or co-workers are working under the influence of a controlled substance. Finally, by reducing the amount of controlled substances diverted, it will reduce the amount of drugs flushed down the toilet or thrown out in the trash, contaminating lakes, rivers, streams, and soil.

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.

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 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 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's website <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: 1625 N. Market Blvd., N219
Sacramento, CA 95834
Phone No.: (916) 574-7917
Fax No.: (916) 574-8618
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Anne Sodergren
Address: 1625 N. Market Blvd., N219
Sacramento, CA 95834
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Website Access

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