

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 on March 23, 2020.

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 request 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 (B&P) to implement, interpret, and make specific Sections 4081, 4105, and 4333 of the Business and Professions Code, the Board is proposing to amend Section 1707 of Article 2 of Division 17 of Title 16 of the California Code of Regulations as follows:

Informative Digest/Policy Statement Overview

The Board proposes to amend Section 1707 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR) for the purpose of amending the Board's regulation specific to waiver requirements for the off-site storage of records.

Existing pharmacy law specifies that protection of the public is the highest priority for the Board in exercising its licensing, regulatory, and disciplinary functions and generally authorizes the Board to adopt and amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy. Additionally, existing law authorizes the Board to issue a license to a pharmacy.

Existing law specifies the record keeping requirements for the manufacture, sale, acquisition, receipt, shipment, and disposition of dangerous drugs or dangerous devices (B&P section 4081). Additionally, current law requires that records of acquisition and disposition of dangerous drugs or dangerous devices be stored in a readily retrievable form (B&P section 4105). Lastly, existing statute requires that pharmacies keep a record of any prescriptions filled on the licensed premises of the pharmacy and allows for the Board to grant a waiver of that requirement (B&P section 4333 (a) and (c)(1)).

Some pharmacies struggle to find space to store these paper records and still maintain a safe working environment for their employees. This proposal will allow the Board more discretion

when approving a waiver and clarify that a waiver will allow storage of these records outside of the licensed area of the pharmacy.

Anticipated Benefits of Proposal

This proposal will benefit a pharmacy that lacks sufficient space to store records within the licensed area of the pharmacy by allowing the records to be stored outside the licensed premises while maintaining public protection. Smaller pharmacies as well as high-volume pharmacies do not have the physical space on the licensed premises to store the amount of records required by licensing regulations. This proposal will help to create a safer work environment by allowing the Board discretion to grant a waiver of the storage requirement so that a pharmacy can avoid the fire hazard as well as the health and safety hazard of storing boxes of files in a pharmacy with inadequate space.

Consistency and Compatibility with Existing State Regulations

During the process of developing these regulations and amendments, the Board 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 an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees. This includes the ability of California businesses to compete with businesses in other states.

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.

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 because this regulation is related to the storage of records and not jobs.

Benefits of Regulation:

The Board has determined that this regulatory proposal will benefit worker safety because the proposed regulation will allow pharmacies to minimize health and safety hazards within the pharmacy by allowing the storage of records outside of the licensed area of the pharmacy.

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 regulation, 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 <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
Phone No.: (916) 518-3078
Fax No.: (916) 574-8618
E-Mail Address: Lori.Martinez@dca.ca.gov

The backup contact person is:

Name: Debbie Damoth
Address: 2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone No.: (916) 518-3090
Fax No.: (916) 574-8618
E-Mail Address: Debbie.Damoth@dca.ca.gov

Website Access

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