

## 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 April 13, 2020.

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 (B&P) authorizes the board to adopt this regulation. The proposed regulation implements, interprets, and makes specific sections 4110 and 4113.5 of the Business and Professions Code.

### **Informative Digest/Policy Statement Overview**

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Professions Code (B&P) section 4000, et seq.). The board's mandate and its mission is to protect the public (B&P section 4001.1).

Senate Bill (SB) 1442 (Wiener, Statutes of 2018, Chapter 569) established that licensed pharmacists are health care professionals, who pay a vital role in protecting public health. SB 1442 added Section 4113.5 to the B&P, which prohibits a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy while the pharmacy is open to the public unless another employee of the pharmacy is present and working in the pharmacy, or an employee of the establishment is always made available to assist the pharmacist. This statute also specifies that the prohibition shall not apply to pharmacies that meet specific criteria, including, but not limited to, a hospital pharmacy (as defined by B&P section 4029 or 4056), a hospital outpatient pharmacy, or a government owned pharmacy.

This proposal will add section 1714.3 to Title 16 of the California Code of Regulations (CCR) to identify the requirements that the pharmacy must meet to comply with the statute, including identifying the name of the assigned person/people who shall be available to assist the pharmacist, ensure that the assigned person/people is/are able to perform the duties identified in 16 CCR section 1793.3, ensure that the assigned person/people qualifies/qualify to have access to controlled substances (i.e. a background check has been completed), and ensure that the person/people assigned is/are available to assist within a required amount of time following the request for assistance by the pharmacist. Additionally, sections 1714.3(b) and (c) identify the requirement for the pharmacy to develop and maintain policies and procedures that addresses the training of the assistant(s), the process for the pharmacist to request assistance, ensure that all impacted staff read and sign a copy of the policies and procedures, and maintain the policies and procedures within the pharmacy in a readily retrievable format.

### **Anticipated Benefits of the Proposed Regulations**

Protection of the public is the board's highest priority in exercising its licensing, regulatory and disciplinary functions. This regulatory proposal benefits the health and welfare of California residents, as well as, benefiting employee safety. The proposed regulation will ensure that the pharmacist is aware of the designated person assigned to assist them, should help be needed. This will ensure the pharmacist can provide more complete patient centered care, which will benefit the health and welfare of California residents. Additionally, this will improve employee safety by ensuring that the staff that are responsible for aiding the pharmacist are aware of the requirements and receive appropriate training for working within the pharmacy.

### **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: The CA Department of Justice could see an increase in fingerprinting revenue should additional background checks be necessary. The board believes this possible increase in revenue to be minor.

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 business, including the ability of California businesses to compete with businesses in other states. This proposal does reinforce the requirement that the person designated to aid the pharmacist must qualify to have access to controlled substances (i.e. a background check has been completed). This requirement is established by Federal regulation (21 CFR 1301.76 and 1301.90 *et seq.*) and is current law. It is not establishing a new requirement. The pharmacy may need to have the person designated to aid the pharmacist complete a fingerprint background check, if one was not completed as part of the hiring process to work in the retail store. The current processing fees associated with Live Scan fingerprinting are \$32.00 for DOJ and \$17.00 for FBI, with some Live Scan agencies charging additional fees for “rolling” fingerprints and/or administrative processing. The board believes these costs to be minor. Additionally, the proposal establishes the requirement for policies and procedures that address specific criteria. Pharmacies are already required to have policies and procedures in place with respect to other areas of pharmacy practice. The additional policies and procedures can be incorporated into the pharmacies existing policies and procedures. These requirements will not have a significant statewide adverse economic impact on business, including the ability of California businesses to compete with businesses in other states.

**Cost Impact on Representative Private Person or Business:**

The board estimates that there may be a minimal expense to the pharmacy for supply costs to develop the policies and procedures (i.e. paper) and the time it will take to write the policies and procedures and obtain staff signatures. The board estimates that the process should not take more than a few hours. Additionally, the pharmacy may need to have the person designated to aid the pharmacist complete a fingerprint background check, if one was not completed as part of the hiring process to work in the retail store. The current processing fees associated with Live Scan fingerprinting are \$32.00 for DOJ and \$17.00 for FBI, with some Live Scan agencies charging additional fees for “rolling” fingerprints and/or administrative processing. The board believes these costs to be minor. The board anticipates no costs to an individual.

**Effect on Housing Costs:** None

**Effect on Small Business:**

The board does not have nor does it maintain data to define if any of its licensees are a “small business” as defined in Government Code § 11342.610. However, the board has determined that the proposed regulation will not affect small businesses. While some community pharmacies may be considered a small business, B&P section 4113.5(b)(4) exempts a pharmacy

owned by a person or persons who own fewer than four pharmacies in California, which would likely exempt a community pharmacy that is considered a small business.

Additionally, there are approximately 750 vendors statewide who provide fingerprinting services. There should be no initial or ongoing cost impact upon the vendors because they are already equipped to provide the service and any necessary fingerprinting will be minor and completed randomly.

### **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 benefits the health and welfare of California residents and worker safety. This regulatory proposal benefits the health and welfare of California residents, as well as, benefiting employee safety. The proposed regulation will ensure that the pharmacist is aware of the designated person assigned to assist them, should help be needed. This will ensure the pharmacist can provide more complete patient centered care, which will benefit the health and welfare of California residents. Additionally, this will improve employee safety by ensuring that the staff that are responsible for aiding the pharmacist are aware of the requirements and receive appropriate training for working within the pharmacy. 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 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 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
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
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**Website Access**

Materials regarding this proposal can be found at the Board of Pharmacy’s website: [www.pharmacy.ca.gov](http://www.pharmacy.ca.gov).