

**Board of Pharmacy**  
**Initial Statement of Reasons**

Subject Matter of Proposed Regulation: Community Pharmacy Staffing

Section Affected: Add Section 1714.3 of Article 2 of Division 17 of Title 16, California Code Regulations

**Problems Addressed**

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).

Prior to January 2019, pharmacists were frequently left alone in the pharmacy for extended periods of time. This resulted in the pharmacist having to perform non-pharmacist related functions, including staffing the cash register and assisting customers with non-pharmacy purchases. Performing these duties takes time away from the pharmacist's professional responsibilities and could impact public health as the pharmacist has insufficient time to safely and lawfully exercise their professional judgement while reviewing and filling prescriptions. Additionally, it impacts the pharmacist's ability to provide appropriate patient centered care.

Senate Bill (SB) 1442 (Wiener, Statutes of 2018, Chapter 569) established that licensed pharmacists are health care professionals, who play 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 or 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 criteria that the pharmacy must meet to comply with the statute, including identifying the name of the assigned person who shall be available to assist the pharmacist, ensure that the assigned person is able to perform the duties identified in 16 CCR section 1793.3, ensure that the assigned person qualifies to have access to controlled substances (i.e. a background check has been completed), and ensure that the person assigned is available to assist within 5 minutes of 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 address 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.

## **Benefits**

The board has determined that this regulatory proposal benefits the health and welfare of California residents, and promotes worker safety. The proposed regulation will ensure that the pharmacist is aware of the designated person or people assigned to assist them and that the assigned person or people have completed the necessary background check(s), 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 who 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.

## **Specific Purpose of Proposed Changes and Rationale**

The board's proposal makes the following addition:

### **Add Section 1714.3 of Article 2 of Division 17 of Title 16 of the CCR**

The board is proposing to add section 1714.3 to Article 2 of Division 17 of Title 16 within the CCR. The title of the section will read "Community Pharmacy Staffing." This title will provide clarity to the regulated public with respect to whom the section applies to and allow for easy reference. It also specifies that the section only applies to those community pharmacies that are required to comply with B&P section 4113.5. This ensures that those pharmacies exempted by statute are aware that this section would not apply to their pharmacy.

Subdivision (a) lists the requirements that the pharmacy must meet to make another person available to assist the pharmacist when the pharmacy is open, and the pharmacist is working without another pharmacy employee currently working. These specifics implement the requirements of B&P section 4113.5. For clarity and completeness, there is minor duplication of the statutory requirement for the pharmacy to make another person available to assist the pharmacist, because without it, the context regarding the pharmacy's responsibility for designating names is less clear.

Subdivision (a)(1) is added to require the pharmacy to specifically identify the name or names of one or more people who will be available to assist the pharmacist if needed. This requirement is added to ensure that the pharmacist knows who to contact when he or she needs assistance, and the pharmacy can ensure that a specifically designated person is available when the pharmacist is not working with another pharmacy employee. Clearly identifying staff will help to ensure that assistance is available and reduce confusion when assistance is needed.

Subdivision (a)(2) is added to ensure that the person or persons designated to assist the pharmacist are able to perform the minimum duties as specified with section 1793.3 of the board's regulations. Section 1793.3 identifies specific tasks a non-licensed person may perform while working within a pharmacy. As the designated person is there to help the pharmacist, they must be able to perform the duties specified in law. Simply having a body present does not

provide enough assistance to the pharmacist if the pharmacist still must perform the tasks or duties a non-qualified person usually performs.

Subdivision (a)(3) is added to require that the pharmacy ensure that the designated person or persons qualify to work in the pharmacy as they will have access to controlled substances. Title 21 of the Code of Federal Regulations states that a DEA registered pharmacy cannot employ or allow access to controlled substances any person who has been convicted for a felony offense related to controlled substances or who has had a DEA registration denied, revoked, or surrendered for cause. The section ensures that the pharmacy is aware that any designated person must meet the federal requirements for access to controlled substances in order to assist the pharmacist in the pharmacy, and requires that a background check be conducted in order to obtain the required information that the pharmacy must have to allow access of any designated person to controlled substances.

Subdivision (a)(4) is added to require that the pharmacy ensure that a designated person is available within 5 minutes of the request for assistance. The statute provides that the designated person be available to assist at all times, which the board interprets as always physically able to respond. Then, the board determined that a 5-minute response time from the request was appropriate to allow the designated person to complete or reach a stopping point on the task they are performing, or to get to the pharmacy from another part of the store.

Subdivision (b) is added to require that the pharmacy maintain policies and procedures that address specified requirements. Each pharmacy will determine the implementation, how a pharmacist will identify the person(s) designated as available to assist them, how the pharmacist will seek assistance, and how the designated people are trained. Maintaining the policies and procedures will ensure that all pharmacy employees are educated on the process. When policies and procedures are in place, it reduces confusion within the pharmacy and helps ensure that operating procedures are followed. Finally, the board reviews policies and procedures while performing site inspections and will be able to confirm if the policies and procedures implemented by the pharmacy meet the regulatory requirements.

Subdivision (b)(1) is added to require that the policies and procedures include the required criteria and training for the designated person or persons, which shall be consistent with the requirements of subdivision (a). It is necessary for this information to be included in the policies and procedures to ensure that the criteria and training procedures being used are in compliance with existing law.

Subdivision (b)(2) is added to require that the policies and procedures include the process by which a pharmacist shall request assistance and that the pharmacist shall document the response time of the designated person. It is necessary for this information to be included in the policies and procedures to ensure that consistent procedures are being followed and that the pharmacy, pharmacist, the pharmacy employees, and designated people understand the process and the expectations. Documenting the response time will allow the pharmacy, the pharmacist, and the board to ensure that the pharmacy is complying with the response time identified in subdivision (a)(4). Upon review of the response time, if it is determined that the

designated person is not timely responding, corrective measures can be taken by the pharmacy to address the issue without board intervention.

Subdivision (c) is added to require that all impacted pharmacy employees and designated people read the policies and procedures and that they sign indicating that they read the document. "Impacted pharmacy employees" is defined to capture the pharmacists and other employees who need to prepare for or who bear any responsibility for implementing or executing the policy and procedures. This is to ensure that all staff who need to be are aware of the process and the expectations. This also ensures consistent communication with staff. The board reviews policies and procedures while performing site inspections and will be able to confirm if all staff have reviewed the policies and procedures. All these requirements help ensure that the law is complied with and the public is protected.

Subdivision (d) is added to require that the pharmacy maintain the policies and procedures within the pharmacy in a readily retrievable format. Board inspections are unannounced and because the board reviews policies and procedures while performing site inspections to ensure regulatory compliance, it is necessary to have the policies and procedures readily available.

### **Underlying Data**

1. United Food and Commercial Workers Union Petition (UFCW) dated March 25, 2019.
2. Board of Pharmacy's response to the UFCW Petition dated July 2, 2019.
3. Senate Bill (SB) 1442 (Wiener, Statutes of 2018, Chapter 569).
4. Title 21 Code of Federal Regulations (CFR) 1301.76 and 1301.90 *et seq.*  
(<https://www.ecfr.gov/cgi-bin/ECFR?page=browse>)
5. Relevant Meeting Materials and draft Meeting Minutes from Board of Pharmacy Enforcement Committee Meeting held March 14, 2019 (Meeting Materials (Pages 1, 3, and Attachment 3), Minutes Pages (1, 4-6)).
6. Relevant Meeting Materials and Excerpt of Meeting Minutes from Board of Pharmacy Meeting held May 7-8, 2019 (Meeting Materials (Enforcement Committee Pages 1-3, and Attachment 2)).
7. Relevant Meeting Materials from Board of Pharmacy Legislation and Regulation Meeting held July 24, 2019 (Meeting Materials (Pages 1-2, and Attachment 1)).
8. Relevant Meeting Materials and Excerpt of Meeting Minutes from Board of Pharmacy Meeting held July 24-25, 2019 (Meeting Materials (Legislation and Regulation Committee Pages 1, 10-12 and Attachment 6 and meeting handout)).

### **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.

### **Economic Impact Assessment:**

The Board has determined 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.

The board determined that this proposal will not create or eliminate jobs or businesses. The proposal identifies the criteria that the pharmacy must meet to comply with B&P section 4113.5, including identifying the name of the assigned person who shall be available to assist the pharmacist, ensuring that the assigned person is able to perform the duties identified in 16 CCR section 1793.3, ensuring that the assigned person qualifies to have access to controlled substances (i.e. a background check has been completed), and ensuring that the person assigned is available to assist within 5 minutes of the request for assistance by the pharmacist. While the proposal does impact community pharmacies, it will not create or eliminate jobs or businesses or expand businesses doing business in California.

The Board indicates there are approximately 3,737 community pharmacies impacted by the proposed regulations in the state. The Board anticipates each community pharmacy will be required to train two existing staff positions to ensure compliance. Because the existing staff are already working at the community pharmacy and being compensated, no additional salary costs are anticipated.

The initial economic impact is estimated to be \$5 million as follows:

**Initial Economic Impact to Community Pharmacies**

<b>Workload Activity</b>	<b>Time (hours)</b>	<b>Cost per hour</b>	<b>Total Costs</b>
Scheduling of Two Staff	26	\$30	\$780
Basic Training	16	\$15	\$240
Background Checks	N/A	\$65	\$130
Information Technology Tracking	1	\$30	\$30
Update Policies and Procedures	1	\$30	\$30
Policies and Procedures Training	1	\$124	\$124
		Subtotal:	\$1,334
Number of Community Pharmacies:		3,727	\$4,985,158

The ongoing economic impact is estimated to be \$2.9 million per year as follows:

**Ongoing Economic Impact to Community Pharmacies**

<b>Workload Activity</b>	<b>Time (hours)</b>	<b>Cost per hour</b>	<b>Total Costs</b>
Scheduling of Two Staff	26	\$30	\$780
		Subtotal:	\$780
Number of Community Pharmacies:		3,727	\$2,914,860

The total economic impact over the next ten years is estimated to be \$31.2 million as follows:

**Ten Year Economic Impact**

Initial Costs	<b>\$4,985,158</b>
Nine Years of Ongoing costs:	<b>\$26,233,740</b>
<b>Total Costs:</b>	<b>\$31,218,898</b>

This regulatory proposal benefits the health and welfare of California residents. The proposed regulation will ensure that the pharmacist is aware of the designated person assigned to assist them and that the assigned person has completed the necessary background check, 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.

This regulatory proposal benefits worker safety because it will ensure that the staff responsible for aiding the pharmacist are aware of the requirements and receive appropriate training for working within the pharmacy.

The regulatory proposal does not affect the state’s environment. The proposal impacts community pharmacies and designated staff working within a community pharmacy, which will not impact the state’s environment.

### **Fiscal Impact Assessment:**

The Board will be required to ensure Community Pharmacies comply with the staffing requirements as proposed in the regulations through routine inspections. Any workload and costs to ensure compliance is anticipated to be minor and absorbable within existing resources.

### **Specific Technologies or Equipment**

This regulation does not mandate the use of specific technologies or equipment.

### **Consideration of Alternatives**

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The board considered the following alternatives:

- (1) The board considered not establishing the specific time requirement of 5 minutes and indicate a reasonable time. The board rejected this as the term “reasonable” is vague and will vary from person to person.
- (2) The board considered not requiring the documentation of the request time and the response time for each occurrence and only require documentation of exceptions to the 5-minute response time. The board rejected this alternative as the pharmacist may not recall the time of the request if the initial request was not documented when it was made.
- (3) The board considered requiring minimal pharmacy training and not the more in-depth training required by CCR 1793.3. The board rejected this alternative as the designated person should be able to assist with specific pharmacy operations while the pharmacist is handling a patient center care issue. If the designated person is not assisting with pharmacy operations (i.e. typing labels), that work will still need to be completed by the pharmacist and no help will have been provided to the pharmacist.

The costs of each alternative is estimated to be consistent with the proposed regulations.