

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

Subject Matter of Proposed Regulation:     Duty to Consult

Section Affected:     Amend Section 1707.2 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 (BPC) section 4000, et seq.) The board’s mandate and its mission is to protect the public. (BPC section 4001.1.) Additionally, existing law establishes that the board is authorized to issue a pharmacy license (BPC sections 4037 and 4110) and a nonresident pharmacy license (BPC section 4112).

The board is required under the provisions of BPC section 4112(h) to adopt regulations that apply the same standards for oral consultation to a nonresident pharmacy as are required of a resident pharmacy in BPC section 4037. This section, specifically BPC section 4112(f), also establishes the minimum hours of operation a nonresident pharmacy must maintain during which a patient can contact a pharmacist via a toll-free telephone number.

Data shows that 25 percent of all prescriptions are dispensed to patients through mail order pharmacies, yet current “Duty to Consult” regulations do not provide for a direct means for patients to access a pharmacist to receive vital prescription drug information.

The board’s current “Duty to Consult” regulations regarding prescriptions received via mail lack specificity regarding the minimum threshold for pharmacist availability to consumers for purposes of providing pharmacist consultation. From a policy perspective, a patient should have ready access to a pharmacist for purposes of consultation even when drugs are shipped to the consumer. It is for that purpose that the board is promulgating this regulation.

This proposal would amend the current “Duty to Consult” regulations to:

- Specify the minimum requirements a pharmacist must be available for patients to speak to, and the maximum time a consumer must wait before speaking to a pharmacist.
- Updates the authority and reference sections to comply with legal requirements and ensure readers’ understanding of the underlying sections of pharmacy law that support the regulation.
- Expand the current requirements for when a pharmacist shall provide oral consultation and expand the requirements to all settings.

## **Benefits**

The regulation will ensure patients have efficient access to a pharmacist to provide oral consultation irrespective of the location of the patient and the pharmacy. This will enable patients to have ready access to vital prescription information, resulting in improved patient outcomes, better medication adherence and reduced risks that can result from improper administration, drug interactions and a lack of understanding of drug warnings and side effects.

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

The board's proposal makes the following change:

### **Amend Section 1707.2 of Article 2 of Division 17 of Title 16 of the CCR**

Subsection (a) is amended to remove the word "care" immediately preceding "settings". This change is made to clarify that the duty to consult applies in all pharmacy settings, including where drugs are dispensed outside of a traditional "care" setting. This is necessary to eliminate any possible confusion that there may be pharmacy settings where oral consultation is not required. Such patient consultation is required in all such settings, and the use of the word "care" is unnecessary and a source of confusion. There is also no legitimate basis to treat pharmacists in traditional care settings differently from pharmacists in other settings. The proposed amendment corrects this possible incongruity.

Subsection (a)(1) is amended to remove the word "or" because former Subsections (b)(1)(A) and (B) were incorporated into the list of when a pharmacist shall provide oral consultation. A semi-colon was added to Subsection (a)(2) for this reason as well, to ensure grammatical consistency in the regulation.

Subsection (b)(1) was deleted because the regulation is being updated to include all pharmacy settings. The duty to consult should not be different when the patient or patient's agent is present or not present. Deleting this distinction and requiring that all pharmacists in any setting consult when one of the four situations listed occurs is necessary to protect the public. Patients should have an oral consultation when the prescription drug has not previously been dispensed or when the drug has not previously been dispensed in the same dosage form, strength, or with the same written instructions regardless of whether the patient or patient's agent is present. Patients in all settings should be educated about a new prescription drug so that they may understand and manage their medication. Patients in all settings should also be consulted when their medication or regiment has been altered so that they are aware of the changes and how that might affect them. Finally, this change makes the regulations consistent with the requirements set forth in Business and Professions Code Section 4112(h), which requires identical standards for in-state and out-of-state pharmacies.

Former Subsection (b)(1)(A) and (B) are moved up and renumbered (a)(3) and (a)(4) respectively to make the numbering consistent with the changes to the regulation. Placing all the requirements for the instances where a consult by a pharmacist is required is necessary for reasons already discussed in connection with subsection (a) and (b)(1).

Subsection (b) paragraph (1) is renumbered and revised to add “patient” before the word “agent” for consistency throughout the regulation, commas to make the sentence grammatically correct, and “or delivery” to make it clear that the subsection also includes pharmacies that may offer a delivery service of medication to patients. The phrase, “the patient receives written notice”, was moved and included in both subparagraphs (A) and (B) of this Subsection to clarify the expectations of the written notice. None of these changes are substantive changes.

Subsection (b) paragraph (1) subparagraph (A), previously included in section (b)(2), now includes “the patient receives written notice” to clarify that when the patient or patient’s agent is not present, written notice must be provided. “And” has been moved because an additional requirement has been added and therefore is no longer needed in this place. These changes are not substantive changes.

Subsection (b) paragraph (1) subparagraph (B), formerly (b)(2), is renumbered and revised to provide clarity to the regulated public that the pharmacy shall provide, in writing, the hours that the consultation is available. Absent this amendment, it may be unclear to pharmacies how it should provide this information. This amendment also ensures that the patient is aware of the times that the consultation can be given so that he or she can call the telephone number at a time when a pharmacist will be able to consult, and requires the pharmacy to be transparent and accountable for certain times that the consult can take place.

Subsection (b)(1)(C) is added to the regulations to outline the parameters for pharmacist availability for consultation. Consistent with the provisions of BPC 4112, a pharmacist must be available to speak to a patient no less than 6 days a week, and for a minimum of 40 hours per week. Further, the addition establishes the requirement that a pharmacist is available to speak with the patient or patient’s agent during regular hours of operation, within ten minutes of the call, on average, or schedule a return call. The board chose to include “during its regular hours of operation” to be clear that a pharmacy does not have to answer a phone call within ten minutes if they are not open, and to be consistent with the statute that governs the nonresident pharmacies. “Within an average of ten minutes or less” is used because of a documented problem of patients waiting long wait times to receive their consultation. Such a requirement is necessary to ensure patients have ready access to a pharmacist and that callers are not stuck in a phone tree or other phone system that impedes such access. A review of pending consumer complaints indicates that patients get frustrated when they are unable to quickly reach a pharmacist and as a result some give up, never receiving the information or care that they need from the pharmacist. Indeed, the board conducted a review of investigations alleging violations by mail order pharmacies. Specifically, the board reviewed 27 pending consumer complaints. A survey was conducted by board staff to receive information from consumers about their ability to easily reach a pharmacist to receive patient consultation.

Review of the survey results revealed that patients had to make numerous contacts to the mail order pharmacy to follow up on information or have questions answered on prescriptions they had already received. For example, in one case the consumer contacted the pharmacy at least 5 times. Further, when queried most consumers indicated that they spoke with a customer service representative, not a pharmacist, even though pharmacists are obligated to consult with the patients. In addition, the wait times a caller experienced to speak with a pharmacist ranged, with one individual noting that after 15-20 minutes the caller just gave up. This problem must be addressed as patients risk harm when they do not have appropriate drug therapy information. Since the law requires that nonresident pharmacies be available by phone during their business hours to facilitate such patient consultation over the telephone, it is not unreasonable for a pharmacist to speak to the patient in ten minutes or less. Ten minutes allows enough time for someone to assess whether the patient needs a consultation or whether they have an issue that does not warrant speaking to a pharmacist (e.g. an inquiry about when their medication will be delivered). An average time of 10 minutes is necessary to provide some flexibility in the standard. In most cases, the board anticipates that a pharmacist will be available in less than 10 minutes, but in some cases, it may take slightly longer than 10 minutes. Accordingly, a running average of 10 minutes will provide a level of flexibility to account for these variations.

In addition, the board recognizes that it is not always possible for a pharmacist to speak to a patient within an average of ten minutes or less. Therefore, “unless a return call is scheduled to occur within one business hour” was also added. This allows a pharmacist some additional flexibility to assess their current workload when a call comes in to schedule a return call to the patient within one business hour. If a pharmacist was consulting another patient, they would not have to stop their current consultation to meet the ten-minute average requirement. This also gives the patient the knowledge that a return call will be coming, and they do not have to wait on hold for an excessive amount of time or until they give up. “Business hour” was necessary to ensure that if a call came in right as the pharmacy was closing, the pharmacist could schedule the return call the next business day.

Former Subsection (b)(3) is renumbered (b)(2) for clarity and to follow the renumbering above.

The authority and reference citations were updated to ensure that the correct statutory references were included in the regulation.

### **Underlying Data**

1. Presentation on Mail Order Pharmacies Consumer Surveys
2. Relevant Meeting Materials from Board of Pharmacy Licensing Committee Meeting held April 19, 2018 (Meeting Materials Pages 1-2 and Attachment 1.)
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held May 2-3, 2018 (Meeting Materials Pages 1-4 and Attachment 1, Minutes Pages 5-10)

## **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 including the ability of California businesses to compete with businesses in other states. This determination is based on the absence of testimony to that effect during the development of the proposed regulation, which occurred over a few months. In addition, public comment from mail order pharmacy representatives at the board's May 2018 meeting were supportive of the proposal.

## **Economic Impact Assessment**

The board concludes that this regulatory proposal will have the following effects:

- (1) It is unlikely that the proposal will create or eliminate any jobs within California;
- (2) It is unlikely that the proposal will create new, or eliminate existing, businesses in California; and,
- (3) It is unlikely that the proposal will expand businesses currently doing businesses within the state.

The board concludes that the economic impact of this proposal will not be significant. This proposal will impact California pharmacies as well as businesses acting as a mail order pharmacy within California. However, the proposed regulation will not create new, eliminate existing, or expand business in California. The requirement to provide consultation was already specified within California regulation; however, this proposal ensures patients receive timely consultation. California licensed pharmacies and pharmacies that provide mail orders to California patients may hire an additional pharmacist or other staff to meet the 10-minute average requirement; however, the board does not anticipate this to be a standard practice and believes most pharmacies will meet the requirement without additional staff. As the board concludes that impacted pharmacies will be able to meet the mandate without additional staff, the board concludes it will not create or eliminate jobs or businesses in California.

This regulatory proposal benefits the health and welfare of California residents because it ensures, irrespective of the location of a pharmacy, patients will have ready access to a pharmacist.

This regulatory proposal does not affect worker safety or the state's environment.

## **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 alternative:

The board considered not promulgating the regulation change. However, this would be contrary to the board's statutory mandate and fail to address the problem some consumers currently experience when obtaining prescription medications from mail order pharmacies.