

Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Notice to Consumers

Section Affected: California Code of Regulations (CCR), Title 16, Division 17, Article 2, Amend Section 1707.6

Hearing Date: None unless requested, see Notice of Proposed Action

Background

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, pharmacy interns, and pharmacy technicians. The board’s mandate and its mission are to protect the public (Business and Professions Code (BPC) section 4001.1).

Problems Addressed

Existing pharmacy law specifies in general terms that a licentiate cannot obstruct a patient from obtaining a prescription drug (BPC 733). Further, this section provides that a notice to consumers shall include a statement that describes the rights established. Additionally, existing law requires every pharmacy to prominently post in a conspicuous place and readable by prescription drug consumers a notice that is produced and provided by the board (BPC 4122). The section also provides that a written receipt containing the same information may be provided in lieu of the posting of the notice. The board currently produces and distributes a “Notice to Consumers” (Notice) poster and a “Point to your language” poster (Language) – the contents of which are specified in 16 CCR section 1707.6. The two posters are produced and printed by the board and are distributed to pharmacies at no cost. Additionally, the two posters are also available on the board’s website in a portable document format (PDF) for utilization. The two posters provide education to consumers of their rights and encourage an open dialogue with their pharmacist.

This proposal will revise the Notice and Language posters as part of the board’s consumer awareness initiative. The proposal will require the Notice to include a QR code that links consumers to a translation of the Notice in the top 16 languages spoken by Californians with limited English proficiency, as determined by the U.S. Department of Health and Human Services and the California Department of Health Care Services. Additionally, it will require pharmacies to place the Notice poster (or to display the Notice on a video screen) in places that are conspicuous and physically accessible so consumers can scan a QR code to obtain a language translation of the Notice when needed. Further, the proposal will require the Language notice to be printed in the top 16 languages as determined by the U.S. Department of Health and Human Services and the California Department of Health Care Services. The proposal will require pharmacies to either post or provide on the patient’s written receipt a statement describing patients’ rights per BPC 733 and BPC 4122.

The proposal will also replace gendered terms with gender-neutral language in order to bring the regulatory text into compliance with Assembly Concurrent Resolution No. 260 of 2018 (ACR 260), in which the Legislature resolved that “state agencies should ... use gender-neutral pronouns and avoid the use of gendered pronouns when drafting policies, regulations, and other guidance.”

Anticipated Benefits of the Proposed Regulations

The board’s mission statement is to “protect and promote the health and safety of Californians by pursuing the highest quality of pharmacist’s care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement.” The board seeks to educate consumers about the practice of pharmacy through a consumer education campaign of consumer-facing materials to improve consumer awareness of their rights and how to take their medications. This awareness will improve the health and welfare of California residents by encouraging consumers to discuss medications with their pharmacists, providing education on the importance of complying with prescription treatment regimens, and ensuring that consumers are better informed about their drug therapy and overall health.

Specific Purpose of Proposed Changes and Rationale

Subsection (a) is amended to require pharmacies to place the notice to consumers in places that are conspicuous and physically accessible so consumers can scan a QR code to obtain a translation of the Notice. The board determined that, as technology has advanced, including a scannable QR code on the Notice would allow consumers with limited English proficiency to obtain the Notice in a different language. Additionally, the subsection is amended to require that the Notices must be posted at all locations where a consumer receives medication. As more pharmacies are establishing drive-thru pickup windows, the board determined that the Notice should be posted at all locations where a consumer receives medication because not all consumers physically enter the pharmacy. Finally, subsection (a) is amended to add a requirement for those pharmacies that utilize video screens as an alternative to printed Notices. The screens must utilize QR code technology with sufficient display time for consumers to access the QR translation technology. While this regulation does not mandate the use of video screens, the board is aware that many pharmacies choose to use video screens for a variety of reasons. This option is designed to meet the goal of providing consumer information with a pharmacy’s chosen delivery method.

Subsection (b) is amended to require the Notice include a QR code that informs and assists consumers in obtaining a translation of the notice in the top 16 languages spoken by Californians with limited English proficiency, as determined by the U.S. Department of Health and Human Services, Office for Civil Rights, and the California Department of Health Care Services. This amendment is reasonably necessary to align the regulation with current Medi-Cal requirements (All Plan Letter 21-004 issued by the Department of Health Care Services). Section 1557 of the Affordable Care Act (ACA) requires taglines to be posted in at least the top 15 languages (plus English) for

individuals with limited English proficiency of the relevant state. Within California, the Department of Health Care Services has identified those languages as Arabic, Armenian, Cambodian, Chinese, Farsi, Hindi, Hmong, Japanese, Korean, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese for 2022.

Additionally, the specific text on the actual Notice to Consumer were amended, stricken, or added as follows:

- The title of the notice was changed from “Notice to Consumers” to “Know Your Rights” to provide more information to consumers about the purpose of the notice. Based on feedback from consumers, the title “Notice to Consumers” does not identify the purpose of the notice. The board determined that changing the name to “Know Your Rights” may encourage more consumers to read the information on the notice.
- The first paragraph under “Know Your Rights” was amended to add “upon your request” following the language “California law requires a pharmacist to speak with you,” to provide clarity to the consumer that they may request a patient consultation should they have questions. The following additional language was added at the end of the first sentence: “and every time you get a new prescription dosage form, strength, or written directions.” This language is reasonably necessary to clarify to consumers that they should be receiving a consultation, if requested, not only when they receive a new prescription, but also when there is a change in dosage form, strength, or written directions of any prescription.
- The board also determined that adding “Talk to the Expert – Speak with your Pharmacist” in capitalized letters will provide education to consumers that the pharmacist is an expert as it relates to their prescription medication. This education informs consumers that they can talk to their pharmacist about their medications, and they do not need to wait to speak with their physician. The pharmacist is readily available to provide patient care and, often, is more readily accessible than a physician as pharmacies are open to public, do not require an appointment, and are available outside standard working hours.
- The first paragraph under “Talk to the Expert – Speak with your Pharmacist” in capitalized letters was reorganized and written as a bulleted list instead of a long paragraph. This formatting is reasonably necessary to make the notice easier to read; it will help consumers quickly identify what elements they should check before leaving the pharmacy. Previously, the paragraph read that the consumer should “know” the listed items prior to taking the medication. The revision recommends that consumers “check” the items before they leave the pharmacy so the consumer is still at the pharmacy should there be an issue or should the consumer have a question. The bulleted list is as follows:
 - “The patient name on the label is correct.” This is to ensure that the consumer received the medication prescribed to them.
 - “The medication matches the description on the label.” This is to ensure

that the consumer received the correct medication from the pharmacy. (A description of the medication – such as the color or shape of a pill - is printed on the label, so the consumer can confirm the description matches what is in the container.)

- “The name of the medicine and what it does.” This is an existing requirement and is reasonably necessary for the consumer to validate that the name and the reason for the medication matches what was discussed with their prescriber.
 - “How and when to take the medication, for how long, and what to do if you miss a dose.” This is an existing requirement and ensures that the consumer understands how to take the medication. The board believes this understanding will help ensure medication compliance.
 - “Possible side effects and what you should do if they occur.” This is an existing requirement and ensures that the consumer understands any side effects and what action they should take if they experience such effects. The board believes this understanding will help ensure medication compliance and patient safety.
 - “Whether the medication will work safely with other medicines or supplements.” This is an existing requirement and ensures that the consumer is aware of what medications or supplements should not be taken in conjunction with the prescribed medication. The board believes this understanding will help ensure medication compliance and avoid preventable negative side effects or consequences, promoting patient safety.
 - “What foods, drinks, or activities should be avoided while taking the medicine.” This is an existing requirement and ensures that the consumer understands what foods, drinks, or activities to avoid. The board believes this understanding will help ensure medication compliance and avoid preventable negative side effects or consequences, thereby promoting public safety.
- Finally, the board’s contact information (address, phone number, and website) is added to advise consumers that they may contact the board to file a complaint about the pharmacy. This is a convenience to a potential complainant, and may also assist in directing notifications to the board of any violations, which promotes public safety.
 - The next paragraph was stricken. This paragraph stated that the pharmacy is required to provide the medication unless it is not covered by insurance and the consumer cannot pay for it or if the pharmacist determines it would be against the law or harmful. This paragraph was stricken as a pharmacist can refuse to dispense a medication pursuant to BPC 733. Additionally, the board removed the sentence about drug pricing and generic drugs. The board determined that with the implementation of BPC section 4079, which requires a pharmacy to inform a customer when the retail cost of a prescription is lower than the co-payment cost unless that pharmacy automatically charges the lowest price, this

advisory was not as necessary as it had been previously and is therefore being removed due to space limitations.

Subsection (c) is amended to strike the sentence listing specific languages and require that the notice about the availability of interpreter services – “Point to your language. Interpreter services will be provided to you upon request at no cost.” -- be printed in the top 16 languages as spoken by limited-English-proficient individuals in California, as determined by the U.S. Department of Health and Human Services, Office for Civil Rights, and the California Department of Health Care Services. This amendment aligns the regulation with current Medi-Cal requirements as specified in Section 1557 of the ACA and All Plan Letter 21-004 issued by the Department of Health Care Services. The ACA requires taglines to be posted in at least the top 15 languages (plus English) for individuals with limited English proficiency of the relevant state. Within California, the Department of Health Care Services has identified those languages as Arabic, Armenian, Cambodian, Chinese, Farsi, Hindi, Hmong, Japanese, Korean, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese for 2022. By referring to the conferred authority, instead of listing the specific languages, the regulation will remain current should the top 16 languages change over time in California.

Subsection (c) is further amended to strike “he or she requests” and replace it with “they request” in order to remove gendered language and use gender-neutral language, consistent with ACR 260.

Subsection (d) is added and requires pharmacies to either post or provide on the patient’s written receipt a statement describing patients’ rights as required by BPC 733 and BPC 4122. This requirement is duplicated from statute and is reasonably necessary to promote clarity and to ensure the notification requirements for patients’ rights are included in one regulatory section.

Underlying Data

1. Relevant Public Board Meeting Materials and Minutes from Board Meeting held October 27-28, 2021
2. Relevant Public Board Meeting Materials and Minutes from Board Meeting held July 28-29, 2021
3. Relevant Public Committee Meeting Materials from the Communication and Public Education Committee Meeting held July 14, 2021
4. All Plan Letter 21-004 issued by the Department of Health Care Services
<https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2021/APL21-004.pdf>

Business Impact

The board has made the initial determination that the proposed regulations will not have a significant statewide adverse economic impact directly affecting businesses including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose

new requirements on licensees; rather, the proposal modifies the existing Notice and Language posters that are produced by the board and distributed to licensed pharmacies at no cost to a pharmacy. Under existing law, as an alternative to posting the posters provided by the board, pharmacies may utilize alternative means to display the required posters in an alternative format, display methodology or via video screen, as specified; however, this alternative format is not mandated. The proposal does require that pharmacies utilizing the alternative means to display the required poster must include a QR code so that consumers can utilize the QR translation technology. The inclusion of the QR code will not have a significant impact as the QR graphic will be printed on the posters by the board and can be embedded into the electronic file.

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 cause any of the foregoing because it does not impose new requirements on licensees; rather, the proposal modifies the existing Notice and Language posters that are produced by the board and distributed to licensed pharmacies at no cost to a pharmacy. The proposal does impose a requirement for a pharmacy that utilizes an alternative means to display the required poster to include a QR code. The QR code will be printed on the posters and can be utilized by pharmacies free of charge. Additionally, the board determined that this regulatory proposal will not impact worker safety or the state's environment as these changes do not involve worker safety or the environment.

The board determined that this regulatory proposal benefits the health and welfare of California residents by educating consumers about their rights and fostering a quality dialogue between pharmacists and patients (or the patient's agent).

Fiscal Impact Assessment:

The board estimates this proposal could result in a one-time fiscal impact to the board of approximately \$15,000 - \$20,000 to publish and distribute the revised Notice and Language posters to pharmacies. The board will absorb these costs within its existing resources and estimates this one-time cost would occur in the 2023/2024 Fiscal Year.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment; however, the regulation provides an option for pharmacies to use video display technology in lieu of paper posters. If pharmacies elect to use this technology, they

must include a QR code. The QR code will be provided by the board on the printed Notice and may be utilized at no cost by pharmacies.

Consideration of Alternatives

The board has initially determined that 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. However, the board welcomes public comments.