

TITLE 16: BOARD OF PHARMACY FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Notice to Consumers

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

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (Board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on February 24, 2023 and ended on April 10, 2023. The Board's notice indicated that the Board did not intend to hold a hearing on the matter, unless requested. No request for a hearing was received by the Board during the 45-day comment period.

During the 45-day comment period one comment was received. At its April 19-20, 2023 Board meeting, the Board adopted the regulation text as noticed on February 24, 2023 and delegated to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

On September 26, 2023, the final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review. Following review, edits were necessary to ensure compliance with the Administrative Procedure Act (APA) and Business and Professions Code (BPC) sections 733 and 4122.

Specifically, the Board must clearly identify the top 16 languages spoken by limited-English-proficient individuals in California. As adopted by the Board, the regulatory text identified the top 16 languages as determined and published by the U.S. Department of Health and Human Services, Office for Civil Rights, and the California Department of Health Care Services (DHCS). This conflicts with the APA, as the languages are not codified in statute or regulation and can change without going through a public comment period. The Board amended the regulation text to list the top 16 languages, as identified by the agencies above, as Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese. These languages were selected as these are the top 16 languages identified by DHCS as of 2022 in California. This amendment was made to subdivisions (b) and (c).

Additionally, the Board added back in the stricken language at the end of the Notice. Specifically, "This pharmacy must provide any medicine or device legally prescribed for you, unless you are unable to pay the cost of the drug or device; or the pharmacist determines doing so would be against the law or potentially harmful to the patient's

health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner. You may ask this pharmacy for information on drug pricing and use of generic drugs.” A statement that describes patients’ rights relative to BPC section 733 is required on the Notice to Consumers pursuant to BPC section 733(f).

Further, during the review of the regulation text, to improve clarity, subdivision (d) was amended. The Board amended the regulation text to mirror the language of BPC section 4122 for consistency within the regulation. The new language reads “As an alternative to posting the notice from subdivision (b) in a conspicuous place, pharmacies may instead provide the notice on a patients’ written receipt.” Finally, the Board removed the statement “You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font” from the poster. Pursuant to CCR section 1707.5, prescription labels shall be in 12-point font, as such, patients no longer need to ask, so including the statement on the poster does not provide meaningful information to patients.

The Board voted to initiate a 15-day public comment period, which commenced on December 13, 2023 and concluded on December 28, 2023. Several comments were received during the comment period. At its February 8, 2024, Board meeting, the Board adopted the regulation text as noticed on December 13, 2023 and delegated to the executive officer the authority to make technical or nonsubstantive changes as may be required by the Control agencies to complete the rulemaking file.

Specific Technologies or Equipment

The Board is requiring the use of QR technology for so that consumers can quickly access the Notice to Consumer in additional languages. QR codes are intuitive to use with modern smartphones and mobile applications. Their advantages include increased customer engagement, more accessible access to information, and digital utility in areas like digital signage. According to Pew Research Center, 97% of Americans own a cellphone and of that, 9 out of every 10 phones is a smartphone. This makes QR technology readily available and easy to use to provide information to consumers.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the Board does not have nor does it maintain data to determine if any of its licensees (pharmacies and clinics) are a “small business,” as defined in Government Code section 11342.610, the Board has made a determination that the proposed regulatory action will not have a significant adverse economic impact on small businesses. Although the proposed regulation will directly affect businesses statewide, which may include small businesses, the Board does not anticipate any adverse economic impact as the Board prints and provides the posters to licensees at no cost to the business.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Board considered not including the QR code on the Notice to Consumer poster; however, having the Board determined that having the poster available in alternative languages was a benefit to consumer health.

Objections or Recommendations/Responses to Comments

During the public comment period from February 24, 2023 to April 10, 2023, the Board received one comment. The comment was provided in the meeting materials for the April 19-20, 2023 Board meeting, and the Board reviewed and considered it.

Summarized 45-day Comments Regarding Notice to Consumers:

Written Comments from Stanley Hill, Pharm.D.

Comment 1: The commenter indicated that the language is ambiguous with respect to acute care facilities. The language requires the sign to be posted at all locations where a consumer receives medication. Because nurses administer medications to patients in these facilities, as opposed to how it is dispensed typically in a pharmacy setting, it is ambiguous. The commenter requested an exemption for acute care, skilled nursing, and other similar facilities. Additionally, commenter requested that the notice to consumer posters be placed in a common patient area, such as the entrance or lobby of the facility.

Response to Comment 1: The Board reviewed the comment and did not make any changes to the text based upon the comment. Business and Professions Code section 4122 explicitly states every pharmacy is required to post the Notice as specified. The Board notes that the language included in subdivision (a) of the regulation text “Every Pharmacy” shall post the notice to consumer “where a consumer receives medication” is consistent with the statute. Exceptions are needed for facilities that are not licensed as a pharmacy, as such a skilled nursing facility.

Summarized 15-day Comments Regarding Notice to Consumers:

Written Comments from Mark Johnston, CVS Health

Comment 2: The commenter indicates that they believe patients will take the requirement that a pharmacy must provide any medicine or device legally prescribed for a patient, absent a few exceptions, out of context and they recommend that the language be amended to remove any reference to Business and Professions Code

(BPC) section 733.

Response to Comment 2: The Board reviewed the comment and did not make any changes to the text based upon the comment. BPC section 4122(a) explicitly states that the Notice shall contain “a statement describing patients’ rights relative to the requirements imposed on pharmacists pursuant to section 733.” Additionally, BPC section 733(f) explicitly states that the notice to consumers required by section 4122 shall include “a statement that describes patients’ rights relative to the requirements of this section.” Removing reference to BPC section 733 would violate BPC section 4122(a). Furthermore, the Board notes that this language is existing text on the current Notice to Consumer poster and the language is necessary to ensure compliance with the APA and Business and Professions Code (BPC) sections 733 and 4122.

Written Comments from Stanley Hill, Pharm.D.

Comment 3: The commenter indicated that the language is ambiguous with respect to acute care facilities. The language requires the sign to be posted at all locations where a consumer receives medication. The commenter thinks that language is ambiguous given that nurses administer medications to patients in these facilities, as opposed to how it is dispensed typically in a pharmacy setting. The commenter requested an exemption for acute care, skilled nursing, and other similar facilities. Additionally, commenter requested that the notice to consumer posters be placed in a common patient area, such as the entrance or lobby of the facility.

Response to Comment 3: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board notes that this comment was also submitted during the 45-day comment period. BPC section 4122 explicitly states every pharmacy is required to post the Notice as specified, and the Board notes that the language included in subdivision (a) of the regulation text “Every Pharmacy” shall post the notice to consumer “where a consumer receives medication” is consistent with the Statute. Making this change would violate pharmacy law. The poster would not be required where a consumer is not receiving medication.

Written Comments from Jennifer Koh, Santa Clara Valley Healthcare.

Comment 4: The commenter requested that the proposed text on the poster be amended to include the statement “as appropriate” after the bullet points for possible side effects, potential drug interactions, and considerations related to the food/drinks/activities instead of the complete list of considerations.

Response to Comment 4: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board notes that this comment is outside the scope of the comment period. Additionally, the Board notes that the poster is providing information to patients about what information to check prior to leaving the pharmacy and does not believe the addition of “as appropriate” is necessary, as patients will not know whether the information is appropriate.

Written Comments from Lorri Walmsley, Walgreens

Comment 5: The commenter indicates that they believe patients will be confused by the requirement that a pharmacy must provide any medicine or device legally prescribed for a patient absent a few exceptions and that the language will lead to misunderstandings. Commenter recommends that this language be stricken from the notice.

Response to Comment 5: The Board reviewed the comment and did not make any changes to the text based upon the comment. BPC section 4122(a) explicitly states that the Notice shall contain “a statement describing patients’ rights relative to the requirements imposed on pharmacists pursuant to section 733.” Additionally, BPC section 733(f) explicitly states that the notice to consumers required by section 4122 shall include “a statement that describes patients’ rights relative to the requirements of this section.” Removing reference to BPC section 733 would violate BPC section 4122(a). Furthermore, the Board notes that this language is existing text on the current Notice to Consumer poster and the language is necessary to ensure compliance with the APA.

COMMENTS RECEIVED OUTSIDE COMMENT PERIOD

Written Comments from Ashley Thomas, Valley Children’s Healthcare

Comment 6: Commenter requests the addition of an exemption for pharmacies that are not patient facing (e.g., inpatient hospital pharmacy, home care pharmacy, etc.).

Response to Comment 6: The Board reviewed the comment and did not make any changes to the text based upon the comment. BPC section 4122 explicitly states every pharmacy is required to post the Notice as specified, and the Board notes that the language included in subdivision (a) of the regulation text “Every Pharmacy” shall post the notice to consumer “where a consumer receives medication” is consistent with the Statute. Making this change would violate pharmacy law. The poster would not be required where a consumer is not receiving medication.

Comment 7: Commenter states that 16 CCR section 1707.6 appears to require all pharmacies to work with the patient to obtain a potentially non-formulary medication. General Acute Care Hospitals and Home Care facilities dispense medications based on an approved formulary as required per 22 CCR section 70263(c)(2).

Response to Comment 7: The Board reviewed the comment and did not make any changes to the text based upon the comment. The Board thanks commenter for the information. No changes are being requested that are appropriate based on current pharmacy law or the subject of the comment period.