

California State Board of Pharmacy 2720 Gateway Oaks Drive, Ste 100 Sacramento, CA 95833

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www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item IX. Discussion, Consideration and Possible Action Related to Proposed Regulations to Amend Title 16, California Code of Regulations Section 1707.6, Including Any Comments Received During the 45-Day Comment Period

Background:

At the January 28, 2022, Board meeting, the Board approved proposed regulation text to amend Section 1707.6 related to the Notice to Consumers. This proposal updates the Notice of Consumer requirements.

As required by the Administrative Procedure Act, Board staff released the proposed text for the 45-day comment period on February 24, 2023, which ended on April 10, 2023. One comment was received during the comment period.

Attached following this memo are the following:

- 1. The proposed text released for the 45-day public comment period.
- 2. Board staff prepared summarized comment with recommendation.
- 3. Comment received during the 15-day comment period.

At this Meeting:

The Board will have the opportunity to discuss the regulation and determine what course of action it wishes to pursue. Among its options:

- 1. Adopt the regulation text as noticed on February 24, 2023.
- 2. Amend the regulation to address concerns expressed by stakeholders and notice the modified text for a 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment response and adopt the regulation text as noticed on February 24, 2023. Additionally, delegate to the executive officer the authority to make technical or non-substantive changes as may be required by the Control agencies to complete the rulemaking file.

Title 16. Board of Pharmacy Proposed Text

<u>Underline</u> is text that will be added. Strikethrough is text that will be deleted.

Amend Section 1707.6 to Title 16 of the California Code of Regulations, to read as follows:

§ 1707.6. Notice to Consumers.

- (a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Every pharmacy shall post a notice containing the text in subsection (b) and shall place the notice in a conspicuous place, physically accessible to a prescription drug consumer (consumer) so that the consumer can easily read the notice, and use the QR code displayed on the notice to obtain language translation of the notice. Such notice shall be posted at all locations where a consumer receives medication. Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) The video screen utilizes QR code technology for the consumer to access translation of the notice, with sufficient display time for consumers to access the QR code; and (5) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.
- (b) The notice must also include a QR code that assists limited-English-proficient individuals and informs consumers that the QR code may be used to obtain a translation of the notice. Consumers must be able to use the QR code to obtain translation of the notice in the top 16 languages 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. It shall contain the following text:

NOTICE TO CONSUMERS KNOW YOUR RIGHTS

California law requires a pharmacist to speak with you <u>upon your request</u>, every time you get a new prescription, and every time you get a new prescription dosage form, <u>strength</u>, or <u>written directions</u>.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

TALK TO THE EXPERT – SPEAK WITH YOUR PHARMACIST

Before <u>you leave the pharmacy</u>, <u>CHECK</u>: taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a does; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

- The patient name on the label is correct;
- The medication matches the description on the label;
- The name of the medicine and what it does;
- How and when to take the medication, for how long, and what to do if you miss a dose:
- Possible side effects and what you should do if they occur;
- Whether the medication will work safely with other medicines or supplements; and
- What foods, drinks, or activities should be avoided while taking the medicine.

The address and contact information for consumers to send any complaints about the pharmacy:

California State Board of Pharmacy 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833 (916) 518-3100 www.pharmacy.ca.gov.

This pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to 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 of generic drugs.

(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in the top 16 languages 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 text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests they request assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.

(d) Every pharmacy shall either post or provide on the patient's written receipt a statement describing patients' rights per Business and Professions Code sections 733 and 4122.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.



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Proposed Regulation to Amend Title 16 CCR Section 1707.6, Notice to Consumers

<u>Summarized 45-day Comments Regarding Notice to Consumers with Board Staff</u> Recommendations:

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: Board staff does not recommend any changes to the text based upon the comment. Business and Professions Code section 4122 expressly states every pharmacy is required to post the Notice as specified. Board staff notes that the proposed language in subdivision (a) of the noticed text is that "Every pharmacy" shall post the notice to consumer "where a consumer receives medication" is consistent with the statute. Exceptions are not needed for facilities that are not licensed as a pharmacy, such as a skilled nursing facility.

From: Stanley E Hill III

PharmacyRulemaking@DCA To:

Subject: Comments for proposed text on 1707.6 Tuesday, February 28, 2023 4:07:36 PM Date:

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image003.png

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Board of Pharmacy

In regards to the proposed text for 1707.6, the use of "every pharmacy" and "posted at all locations where a consumer receives medication" are ambiguous for acute care facilities. This due to a nurse typically administering in the medication versus it being dispensed in a typical pharmacy fashion. In addition, the nurses provide education at the time of administration.

I would request that exceptions for acute care, skilled nursing, and other similar facilities be made to reflect the nature medication dispensing. I would also request that these signs be posted in a common patient area such as facility entrance or lobby.

Stanley Hill, PharmD

Executive Director of Pharmacy Services shill@memorialcare.org

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