



California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Agenda Item IV. Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations, section 1707.6, Related to Notice to Consumers, Including Changes Requested by the Office of Administrative Law

Background:

At the April 2023 Board meeting, following a 45-day public comment period, the Board adopted the regulation text to amend Section 1707.6 related to Notice to Consumers. This proposal updates the Notice of Consumer requirements.

On September 26, 2023, the final rulemaking package was submitted to the Office of Administrative Law (OAL) for formal review. Following their review, OAL has requested three amendments to the regulatory text to ensure compliance with the Administrative Procedure Act (APA).

Specifically, OAL has requested the Board clearly identify the top 16 languages spoken by limited-English-proficient individuals in California. As adopted by the Board, the regulatory text identifies the top 16 languages as determined by the U.S. Department of Health and Human Services, Office for Civil Rights, and the California Department of Health Care Services. OAL has indicated that 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. Board staff recommend that the reference to the top 16 languages be replaced with Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese, as these are the language identified by DHCS. This amendment would be made to subdivision (b) and (c).

Additionally, OAL has requested that the Board add 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 with OAL, the OAL attorney requested that the text be amended to improve clarity with respect to subdivision (d). Board staff recommend that the text be amended to mirror 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, Board staff also recommend the statement "You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font," be removed from the poster. Pursuant to CCR 1707.5, prescription labels shall be in 12-point font, as such, patients no longer need to ask and the statement on the poster does not provide meaningful information to patients.

At this Meeting:

The Board will have the opportunity to discuss the changes requested by OAL and initiate a 15-day comment period as requested by OAL. Attached following this memo is the amended regulation text as recommended by Board staff and OAL and revision to the draft Notice to Consumers poster.

Possible Motion:

Approve the amended regulation text and initiate a 15-day comment period. Additionally, if no adverse comments are received during the 15-day comment period, authorize the Executive Officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at Section 1707.6 as noticed. Further, 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
Modified Text**

Proposed Text: Underline is text that will be added. ~~Strikethrough~~ is text that will be deleted.

Modified Text: Double Underline is text that will be added. ~~Double 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 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. Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese.~~ It shall contain the following text:

NOTICE TO CONSUMERS
KNOW YOUR RIGHTS

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

~~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 you leave the pharmacy, CHECK: 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 dose; 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 the drug or device a copayment; 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.

(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 Arabic, Armenian, Chinese, English, Farsi, Hindi, Hmong, Japanese, Korean, Khmer / Cambodian, Punjabi, Russian, Spanish, Tagalog, Thai, and Vietnamese. 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) 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. 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.

Talk to the Expert

Speak with Your Pharmacist

Before you leave the pharmacy CHECK:

- 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;

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- 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.

Know Your Rights

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

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.

Interpreter services are available to you upon request at no cost. You may ask this pharmacy for information on drug pricing and use of generic drugs.

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BE AWARE AND TAKE CARE:
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY



Translation
Traducción
翻译
ଅନୁବାଦ



www.pharmacy.ca.gov/publications/ntc.shtml