

Title 16. Board of Pharmacy

Proposed Language

To Amend §1707.2 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.2. ~~Notice to Consumers and~~ Duty to Consult.

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy.

(2) When the patient or agent is not present (including but not limited to a prescription drug that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:

(A) of his or her right to request consultation; and

(B) a telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(3) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

(c) When oral consultation is provided, it shall include at least the following:

- (1) directions for use and storage and the importance of compliance with directions; and
- (2) precautions and relevant warnings, including common severe side or adverse effects or interactions that may be encountered.

(d) Whenever a pharmacist deems it warranted in the exercise of his or her professional judgment, oral consultation shall also include:

- (1) the name and description of the medication;
- (2) the route of administration, dosage form, dosage, and duration of drug therapy;
- (3) any special directions for use and storage;
- (4) precautions for preparation and administration by the patient, including techniques for self-monitoring drug therapy;
- (5) prescription refill information;
- (6) therapeutic contraindications, avoidance of common severe side or adverse effects or known interactions, including serious potential interactions with known nonprescription medications and therapeutic contraindications and the action required if such side or adverse effects or interactions or therapeutic contraindications are present or occur;

(7) action to be taken in the event of a missed dose.

(e) Notwithstanding the requirements set forth in subsection (a) and (b), a pharmacist is not required to provide oral consultation when a patient or the patient's agent refuses such consultation.

~~(f) In every pharmacy subject to the provisions of Business and Professions Code Section 4122, there shall be prominently posted in a place conspicuous to and readable by prescription drug consumers the following notice:~~

"NOTICE TO CONSUMERS"

~~At your request, this pharmacy will provide its current retail price of any prescription without obligation. You may request price information in person or by telephone.~~

~~Ask your pharmacist if a lower cost generic drug is available to fill your prescription.~~

~~Prescription prices for the same drug vary from pharmacy to pharmacy. One reason for differences in price is differences in services provided.~~

~~Before taking any prescription medicine, talk to your pharmacist; be sure you know:~~

~~What is the name of the medicine and what does it do?~~

~~How and when do I take it and for how long? What if I miss a dose?~~

~~What are the possible side effects and what should I do if they occur?~~

~~Will the new medicine work safely with other medicines and herbal supplements I am taking?~~

~~What foods, drinks or activities should I avoid while taking this medicine?~~

~~Ask your pharmacist if you have additional questions.~~

~~(g) In addition to the "NOTICE TO CONSUMERS" referred to in subdivision (f), every pharmacy subject to the provisions of Business and Professions Code §4122 shall prominently post in a place conspicuous to and readable by prescription drug consumers the following notice:~~

~~Know your rights under California law concerning medicine and devices prescribed to you.~~

~~You have the right to receive medicine and devices legally prescribed to you, unless:~~

~~1. The medicine or device is not in stock in the pharmacy;~~

~~2. The pharmacist, based upon his or her professional judgment determines providing the item:~~

~~• is against the law;~~

~~• could cause harmful drug interaction, or~~

~~• could have a harmful effect on your health~~

~~This pharmacist may decline to fill your prescription for ethical, moral or religious reasons, but the pharmacy is required to help you get the prescription filled at this or another nearby pharmacy timely.~~

COMMENT: Mr. Peter Scalet stated that he noticed the religious exemption for filling a prescription on the Notice to Consumers has been removed. He requests that the religious exemption, a First Amendment right, be placed back on the Notice to Consumers poster to help prevent misunderstanding.

~~The pharmacy may decline to provide the medicine or device if it is not covered by your insurance or if you are unable to pay for the item or any copayment you owe.~~

~~If the pharmacy is unable to fill your prescription, you are entitled to have the prescription returned to you or transferred to another nearby pharmacy. Ask about our procedure to help you get an item that we don't have in stock.~~

~~Any questions? Ask the pharmacist!~~

Note: Authority cited: Sections 4005, 4076 and 4122, Business and Professions Code. Reference: Sections ~~733~~, 4005, 4076 and 4122, Business and Professions Code and Section 1707.5 of Division 17 Title 16 of the California Code of Regulations.

(Continued on next page.)

To Add § 1707.6. to Article 2 of Division 17 of 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). 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) 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.

COMMENT: Richard Sakai, Pharm.D. comments on the dispensing of prescription drugs in a hospital setting and asks "where does the posting of the notice need to be or can a hospital pharmacy that provides a 'limited' retail prescription service request an exemption from this regulation?"

Possible Response: Business and Professions Code section 4122(a) requires every pharmacy to prominently post in a place conspicuous to, and readable by, prescription drug consumers, a notice provided by the board. That section further specifies the information to be contained in the notice. The board does not possess the statutory authority to grant exemptions to this requirement.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

COMMENT: Dr. Michael Negrete believes the notice should include a statement clearly notifying consumers that pharmacists are required to provide them with a consultation on all new prescriptions. He suggests that the first statement on the poster should be "California law requires a pharmacist to speak with you every time you get a new prescription." For additional background, Dr. Negrete provided an (attached) report from a meeting held with a multi-stakeholder group.

You have the right to ask for and receive from any pharmacy prescription drug labels in

COMMENTS: The board received the following comment, or similar wording, from three individuals: Senator Ellen Corbett; Caroline B. Sanders Director of Policy Analysis for the California Pan Ethnic Health Network; and Luis Miguel, PhD:

Comments thanking the board for requiring pharmacies to provide translated notices about the rights of patients to have larger, 12-point font size for prescription drug labels.

12-point font.

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

Before 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.

COMMENT: Michael Negrete, PharmD, asks if additional time could be built into the [regulatory] process to allow for some consumer testing of the proposed language to explore issues including health literacy, relative importance of various messages (to help determine the order and size of each statement), etc. Dr. Negrete expressed particular interest in studying the preceding paragraph (beginning with “Before taking your medicine,”). He expresses concern that the information may not be presented in a manner that helps ensure consumers will see it, read/understand it and its importance, and act upon it.

He states that if the Board is willing to extend the revision process for a few months, a member of the Pharmacy Foundation of California’s Board of Directors and he would be interested in securing grant funding to perform an evaluation of the language, as proposed, and provide the board with suggestions for improving the language

Comment regarding time: Once the Notice is published in the California Regulatory Notice Register, the APA rulemaking process is officially started and the agency has one year within which to complete the rulemaking file to the Office of Administrative Law. Limited provisions allow the Director of the DCA to extend that period, based on the receipt of a final rulemaking record for review.

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 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 [see comment] text:

COMMENT: Mike Podgurski suggests adding the words "or similar" in subdivision (c) adding that the brochure utilized by his pharmacy "is not EXACTLY the same."

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

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

(Continued on next page [comments].)

COMMENTS: The board received the following comment, or similar wording, from three individuals: Senator Ellen Corbett; Caroline B. Sanders Director of Policy Analysis for the California Pan Ethnic Health Network; and Luis Miguel, PhD:

Comments thanking the board for requiring pharmacies to provide translated notices about the rights of patients to have interpreter services. Offering notices in 12 language is a good first step to implementing SB 472's goal of providing consumer information to limited English-proficient patients. Dr. Miguel adds that proper notification of the rights to interpreter services is essential for all patients to understand how to take their medication safely and effectively. Ms. Sanders adds that proper notification will positively impact the health and safety of consumers, including the 40% of Californians who speak a language other than English at home.

Each commenter urges the board to add language that establishes "an objective threshold" for when a pharmacy must provide notices in additional languages that includes all languages spoken by at least 20,000 or more limited-English-proficient health consumers in order to reach the broadest number of patients and more accurately reflect California's changing demographics..

Senator Corbett states the regulation should say that a pharmacy must provide a notice translated into any language the Board determines, based upon the most recent United States census data, is spoken by at least 20,000 residents of California. Senator Corbett states this additional language is necessary to ensure limited English-proficient patients have access to crucial information, and more accurately reflect California's changing demographics.

Ms. Sanders urges the board to amend subdivision (c) to require that notices "be translated into languages spoken by at least 20,000 or more limited-English-Proficient Californians." Ms. Sanders states that CPEHN's data reflects that this amendment would add just five more languages to the list of translated notices: French, Portuguese, Hindi, Japanese and Thai

COMMENT: Richard Sakai, Pharm.D. comments that English is not listed as one of the languages for which interpretation must be provided, and states his assumption that the language used on the poster would be English and not any other language. He states that if you need interpretation in another language, how can one read the notice in English to understand what services are offered in other languages?

COMMENT: Amy Brotzman states that a pharmacy should provide notice to patients that they may have an interpreter for all 12 languages. She states "It should not be based on a threshold as many who need services may not be those who speak and understand languages of the larger group of individuals. The smaller groups of individuals who speak non prevalent languages may be in need of this type of information at a greater level."

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 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.

Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code, and Section 1707.5 of Division 17 of Title 16 of the California Code of Regulations.

ADDITIONAL COMMENTS:

The board received the following general comments regarding the board's proposal.

COMMENT: Michael Negrete, PharmD, asks if additional time could be built into the [regulatory] process to allow for some consumer testing of the proposed language in 1707.6 (b) to explore issues including health literacy, relative importance of various messages (to help determine the order and size of each statement), etc.

Comment regarding time: Once the Notice is published in the California Regulatory Notice Register, the APA rulemaking process is officially started and the agency has one year within which to complete the rulemaking and submit the rulemaking file to OAL. Limited provisions allow the Director of the DCA to extend that period, based on the receipt of a final rulemaking for department review.

COMMENT: Paul Huntzinger, R.Ph. commented on "interpreter services at pharmacies," referencing 1707.6(c). He states that while well intentioned, the law "will likely increase the likelihood of dispensed medications as well as increase the incidence of consumer misinformation." He states that medication errors may occur because over-burdened pharmacists must manage "one more task" and that the "no fee" caveat guarantees there will not be technical assistance to make up the cost. Regarding consumer misinformation, he states there are not enough translators available that are appropriately trained in pharmaceutical terminology. Mr. Huntzinger adds that the solution is immersion in the predominant language.

Possible Response: The board's proposed language at 16 CCR §1707.6(c) does not propose any new requirement on a pharmacy or pharmacist. The board promulgated regulations at 16 CCR § 1707.5, effective January 1, 2011, regarding Patient-Centered Labels for Prescription Drug Containers; Requirements – as required by Business and Professions Code Section 4076.5. Subdivision (d) of § 1707.5 requires a pharmacy to have in place policies and procedures to help patients with limited or no English proficiency understand the information on a prescription label. That section also specifies that the pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

COMMENT: Richard Sakai, Pharm.D. asks if physician offices that dispense medications are required to post the Notice to Consumers.

Possible Response: The board's proposed regulations would apply to pharmacies licensed by the board.