



California State Board of Pharmacy
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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 V. Discussion and Possible Action Related to Proposed Regulations, Title 16, California Code of Regulations Section 1707.6 Relating to Notice to Consumers, Including Review of Comments Received During the 15-Day Comment Period on 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).

At the December 13, 2023 Board meeting, the Board reviewed the edits requested by OAL, including the identification of the top 16 languages spoken by limited-English-proficient individuals in California, the reinstatement of previously stricken language at the end of the Notice as it is required on the Notice to Consumers pursuant to BPC section 733(f), and an amendment to subdivision (d) for improved clarity at the request of the OAL attorney. Finally, the statement "You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font," was removed as it is required by CCR 1707.5 and no longer meaningful information for patients.

At this Meeting:

The Board will have the opportunity to discuss the regulation, the comments received, and consider whether to adoption the regulation, as noticed, is appropriate. Attached following this memo are the following are the proposed text released for the 15-day public comment period, staff prepared summarized comments with recommendations, and the comments received during the 15-day comment period.

Possible Adoption Language:

Accept the Board staff recommended comment responses and adopt the regulation text as noticed on December 13, 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
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.



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

Summarized 15-day Comments Regarding Notice to Consumers with Board Staff Recommendations:

Written Comments from Mark Johnston, CVS Health

Comment 1: 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 1: Board staff does not recommend 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 733 would violate BPC 4122(a). Furthermore, Board staff notes that this language is existing text on the current Notice to Consumer poster and the language is required by the Office of Administrative Law.

Written Comments from Stanley Hill, Pharm.D.

Comment 2: 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 2: Board staff does not recommend any changes to the text based upon the comment. Board staff note 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. Board staff 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.

Written Comments from Jennifer Koh, Santa Clara Valley Healthcare.

Comment 3: 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 3: Board staff does not recommend any changes to the text based upon the comment. Board staff notes that this comment is outside the scope of the comment period. Additionally, Board staff note that the poster is providing information to patients about what information to check prior to leaving the pharmacy. Board staff do 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 4: 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 4: Board staff does not recommend 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 733 would violate BPC 4122(a). Furthermore, Board staff notes that this language is existing text on the current Notice to Consumer poster and the language is required by the Office of Administrative Law.

COMMENTS RECEIVED OUTSIDE COMMENT PERIOD

Written Comments from Ashley Thomas, Valley Children's Healthcare

Comment 5: 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 5: Board staff does not recommend any changes to the text based upon the comment. BPC section 4122 explicitly states every pharmacy is required to post the Notice as specified. Board staff 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.

Comment 6: Commenter states that 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 § 70263(c)(2).

Response to Comment 6: Board staff does not recommend any changes to the text based upon the comment. Board staff 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.

12/28/23

Lori Martinez

Address: 2720 Gateway Oaks Drive, Ste. 100

Sacramento, CA 95833

PharmacyRulemaking@dca.ca.gov

Dear Ms. Martinez,

I am writing to you in my capacity as Executive Director of Pharmacy Regulatory Affairs for CVS Health ("CVS") and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of California through our integrated offerings across the spectrum of pharmacy care that includes over 1,000 pharmacies located within California. We appreciate the opportunity to submit comments on the Board's proposed amendments to Section 1707.6 to Title 16 of the California Code of Regulations. The proposed changes to the required sign include language from Business and Professions Code 733 that indicates a pharmacy *must provide any medicine or device legally prescribed* for a patient absent a few exceptions.

"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."

We believe this language will be taken out of context by patients who read this sign at their pharmacy leading to unintended consequences. As stated at the 12/13/23 meeting of the Board, by both Board members and members of the public, the original intent of this code was extremely narrow and related to pharmacists' religious beliefs; as proposed however, this sign can be interpreted to apply to all prescriptions. While the consequences of such an interpretation can be endless, here are a few important examples of interpreting the current written language more broadly than originally intended:

- Controlled substances would be included, such as promethazine with codeine, which CVS Health and other pharmacies do not stock due to the drug's high abuse potential and the associated public safety risk of armed robbery;
- Medications facing shortages would be included, and the sign could be interpreted to mean that a pharmacy must locate drugs that are unavailable from the manufacturer and thus nearly impossible to locate;
- Specialty pharmacies or pharmacies that specialize in specific therapies or disease states, such as an HIV clinic, could be required to carry or locate all drugs that are prescribed via prescriptions that are presented at the pharmacy; and

- Such a reading could be interpreted to prohibit a pharmacy from making sound decisions as to how to stock their pharmacies and care for their patients, such as not carrying an expensive drug, not accepting third party reimbursement below cost, or focusing their inventory to meet the needs of their routine patient base.

Therefore, CVS Health is opposed to this proposed amendment and requests that the Board remove any reference to Business and Professions Code 733 altogether. Feel free to contact me directly to discuss.

Sincerely,



Mark Johnston, R.Ph

CVS Health,

Executive Director,

Board of Pharmacy Regulatory Affairs

From: Stanley E Hill III <SHill@memorialcare.org>

Sent: Wednesday, December 13, 2023 5:19 PM

To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>

Cc: Stanley E Hill III <SHill@memorialcare.org>

Subject: Feedback on proposed modifications to Title 16 CCR § 1707.6, related to the Notice to Consumers

Ms. Martinez

I am writing in regards to the Board of Pharmacy's proposed modifications to Title 16 CCR § 1707.6, related to the Notice to Consumers. In 1707.6(a), it states that "every pharmacy shall post a notice containing the text in subsection (b)..." My concern is that there is no differentiation between types of pharmacies. An obvious example will be the inherent difference between a hospital pharmacy and a community pharmacy. I agree that this text is applicable for patient facing pharmacies but do not believe they apply in the proposed text to other pharmacy types such as hospital pharmacies. I request the Board of Pharmacy indicate in the regulation text the specific pharmacy types included or excluded or that in hospital this notice to consumers can be located in a central area such as patient waiting area or admitting area.

Stanley Hill, PharmD

Executive Director of Pharmacy Services

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From: Koh, Jennifer <jennifer.koh@hhs.sccgov.org>
Sent: Wednesday, December 27, 2023 8:58 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Cc: Singh, Narinder <Narinder.Singh@hhs.sccgov.org>
Subject: Notice to Consumers Comment – Santa Clara Valley Healthcare

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WARNING: This email originated from outside of the organization! Do not click links, open attachments, or reply, unless you recognize the sender's email.

Report Suspicious

Hello,

My name is Jennifer Koh from Santa Clara Valley Healthcare. For the “Notice to Consumers – Modified Text,” we would like to propose a modification introducing the statement “as appropriate (in red).” This addresses pertinent/most relevant considerations such as the most common side effects, potential drug interactions, and considerations related to the food/drinks/activities instead of the complete list of considerations.

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;
- 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 **as appropriate**
- Whether the medication will work safely with other medicines or supplements **as appropriate**; and
- What foods, drinks, or activities should be avoided while taking the medicine **as appropriate**.

Thank you,
Jennifer

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Lorri Walmsley, RPh., FAzPA
Director, Pharmacy Affairs
Walgreen Co.
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p: 602-214-6618
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December 22nd, 2023
California State Board of Pharmacy
Attention: Anne Sodergren, Executive Director
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Via Email: PharmacyRulemaking@dca.ca.gov

RE: § 1707.6 Notice to Consumers

Dear Executive Director Sodergren and members of the California Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. licensed in the State of California, we thank the Board for the opportunity to comment on the proposed rules. We ask the board to review our comments, concerns, and suggested edits to the proposed text of the amended sections of §1707.6 to Title 16, Division 17, Article 2 of the California Code of Regulations.

Walgreens supports and promotes the board's mission to ensure equitable access to healthcare services and supports patients' rights to translations services when needed. Walgreens also supports the board's requirement for signage to ensure all patients are aware of available translation services and rights established for pharmacy services. Additionally, we support the Board's discussion from the December 13th, 2023 Board meeting regarding OAL's proposed changes to comply with CA Bus & Prof Code § 733 (BPC 733), which states, "A licentiate cannot obstruct a patient from obtaining a prescription drug or device". However, we feel this should not be interpreted to mean that a pharmacist "must provide any medicine or device legally prescribed" in every circumstance. BPC 733 has allowances for a licensee to refuse to dispense a medication which also includes refusal on ethical, moral, or religious grounds. There are many situations where a pharmacist can and should refuse to dispense a medication in compliance with BPC 733 and the proposed text may be interpreted incorrectly by the public. The current proposed text for the signage will cause confusion, misunderstandings, and frustration for many patients if a pharmacist makes the professional determination to refuse to fill a prescription in accordance with the allowances in BPC 733. Additionally, when a medication is not immediately available or not in stock, the proposed text again misinterprets BPC 733, which provides various options for handling these situations, which include transferring the prescription or returning the prescription to the patient. Walgreens requests the board to strike the language below as it does not provide additional valuable information for patients and unintentionally misleads the public regarding the rights established for patients.

~~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.~~

Walgreens thanks the Board for the opportunity to comment on these proposed amended text. If the Board would like additional information, please feel free to contact me.

Sincerely,

Lorri Walmsley, RPh, FAzPA

Late Comment:

Received After the
Closure of the
Comment Period

From: Ashley Thomas <AClark2@valleychildrens.org>
Sent: Friday, December 29, 2023 11:57 AM
To: PharmacyRulemaking@DCA <PharmacyRulemaking@dca.ca.gov>
Subject: Notice to Consumers Comment

Good morning,
Please see the attached comments for the proposed changes to Notice to Consumers.
Thank you for your consideration.

Best,
Ashley
We bring our best, knowing children are counting on us.

Ashley Thomas, PharmD, BCPPS
Medication Safety & Regulatory Compliance
Vice Chair, Medication Safety Joint Subcommittee



9300 Valley Children's Place | Madera, CA 93636
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Institution:	Valley Children’s Hospital 9300 Valley Children’s Place Madera, CA 93636	
State Board Section	Proposed/Modified Text	Comments/Recommendations
16 CCR 1707.6	<p>(a) 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.</p> <p>(c) 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.</p>	<p>Comments: Request to add an exemption to pharmacies that are not patient facing (e.g., inpatient hospital pharmacy, home care pharmacy, etc.). Additionally, General Acute Care Hospitals and Home Care facilities also dispense medications based on an approved formulary as required per Title 22 § 70263 (C)(2). Section 1707.6 appears to require all pharmacies to work with the patient to obtain a potentially non-formulary medication.</p> <p>Recommendations to the modified language: (a) Every pharmacy that directly dispenses drugs and devices to patients in a retail location 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.</p> <p>(c) Each pharmacy that directly dispenses drugs and devices to patients in a retail location 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.</p>