

TITLE 16. BOARD OF PHARMACY

NOTICE IS HEREBY GIVEN that the Board of Pharmacy is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments relevant to the action proposed in writing. Written comments, including those sent by mail, facsimile, or e-mail to the addresses listed under Contact Person in this Notice, must be received by the Board of Pharmacy at its office not later than 5:00 p.m. on July 11, 2011

The board will conduct a hearing on this matter at 1625 N. Market Blvd., First Floor Hearing Room, Sacramento, 95864, at 10:00 a.m. on July 27, 2011. At that time, any person interested may present statements or arguments orally or in writing relevant to the action proposed.

The Board of Pharmacy, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for 15 days prior to its adoption from the person designated in this Notice as contact person and will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

Authority and Reference. Pursuant to the authority vested by Section 4005 of the Business and Professions Code, and to implement, interpret or make specific Sections 733, 4005, 4076, 4075.4, 4122 of the Business and Professions Code, and Section 1707.5 of Title 16 of the California Code of Regulations, the Board of Pharmacy is proposing to add section 1707.6 and to amend 1707.2 of Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

The Board of Pharmacy (“board”) proposes to amend Section 1707.2 and add Section 1707.6 to Article 2 of Division 17 of Title 16 of the California Code of Regulations (“CCR”) for the purpose of revising and recasting the “Notices to Consumers” that are required to be available in all California pharmacies. Existing law at Business and Professions Code Section 4122 requires every pharmacy to prominently post in a conspicuous place and readable by prescription drug consumers a notice that is produced and provided by the board. That section describes the general content areas of the notice and requires the board to adopt the wording of the notice by regulation. The board currently produces and distributes two “Notices to Consumers” – the contents of which are specified in 16 CCR Section 1707.2(f) and (g). The notices are produced and printed by the Board of Pharmacy and are distributed to pharmacies at no cost to the pharmacy. The notices are also available on the Board of Pharmacy’s Web site in a portable document format (PDF).

Proposed amendments to Sections 1707.2(f) and (g) would consolidate existing consumer notices and move all requirements for consumer notices into one new proposed Section at 1707.6. Specifically, the existing regulations provide notice to consumers about the availability of prescription price information, the possibility of generic drug product selection, and talking to a pharmacist so that the patient can thoroughly understand how to take their medication(s)

appropriately. This proposed regulation would revise or re-phrase this information and would place those notices in a new section at 1707.6(b).

Existing regulations at 16 CCR Section 1707.2(g) specify the content of a second “Notice to Consumers,” which includes notice of a patient’s rights concerning medicine and devices that are prescribed to them and the right to have their prescription(s) returned to them or transferred to another pharmacy if the pharmacy is unable to fill the prescription. This proposed regulation would revise or re-phrase this information and would place this notice in a new section at 1707.6.(b).

Existing law sets forth the requirements for a prescription drug container label for any drug dispensed to a patient in California (Business and Professions Code section 4076). On January 1, 2011, the board’s regulation at Title 16, California Code of Regulations (CCR) Section 1707.5 became effective. This regulation established requirements for a patient-centered prescription drug container label, to include minimum font size for some items on a prescription drug container label, the format of the prescription drug container label, a patient’s right to receive oral language interpretive services, and other requirements. The regulation also specifies that a patient can request that the pharmacy provide them with a prescription drug container label that has larger (12-point) font on the label (as an alternative to the minimum 10-point font) for specific “patient-centered” items on the label. However, current law does not require pharmacies to post notices to consumers informing consumers of their rights under this newly adopted regulation. This proposal would implement such a requirement.

Existing regulations from subdivisions (a) through (e) at Section 1707.2 of Title 16 of Division 17 of the California Code of Regulations specify a pharmacist’s duty to consult a patient or the patient’s agent. This proposal does not modify existing requirements regarding a pharmacist’s duty to consult.

Specifically, this proposed regulation would add Section 1707.6 to Article 2 of Title 16 of Division 17 of the California Code of Regulations. Subdivision (a) of the proposed regulation would specify that every pharmacy shall prominently post in a place conspicuous to and readable by a prescription drug consumer a notice, as specified, unless the pharmacy receives approval from the Board of Pharmacy to display the content in another format or display methodology. This subdivision would delegate the board’s authority to approve such formats or methodologies to the Executive Officer or to a committee of the board. Further, and as an alternative to displaying a printed version of the notice provided by the board, the proposed regulation authorizes a pharmacy to display the notice on a video screen, so long as the video screen is in a place that is conspicuous to and readable by prescription drug consumers. This proposed regulation specifies the minimum size of the video screen; requires that the video image of the board’s notice be displayed; the length of time that the notice shall be displayed on a video screen, and the maximum amount of time that may lapse between the final screen of the notice, and the time that the notice re-displays.

As described above, this proposed regulation would add Section 1707.6 subdivision (b) to specify the content of the Notice to Consumers that shall be developed by the board and made available to pharmacies. This subdivision incorporates the requirements of Business and

Professions Code Section 4122(a).

This proposed regulation would add Section 1707.6 subdivision (c) to require that a pharmacy post or provide to a prescription drug consumer a notice regarding the consumer's right to interpreter services upon request, at no cost to the consumer. This proposed regulation specifies that the text of the notice be repeated in at least 12 languages (Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese) and positioned in a manner so that a consumer can easily point to and touch the statement identifying the language in which he or she is requesting assistance. The proposed regulation would require a pharmacy to use a standardized notice that is made available by the Board of Pharmacy, unless the pharmacy has received the board's approval to display the notice in another format or display methodology. The proposed regulation would delegate the board's authority to approve such formats or methodologies to the Executive Officer or to a committee of the board. As proposed, if the pharmacy wishes to use a flyer or handout notice, the regulation would specify the minimum size of the flyer or handout to be at least 8 ½ inches by 11 inches, and that it shall be clearly visible to and kept within easy reach of each pharmacy counter where dangerous drugs are dispensed or furnished. The proposed regulation also mandates that the notice be available at all hours that the pharmacy is open.

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: The board estimates a one-time cost of approximately \$20,000 in FY 2011/12.

Nondiscretionary Costs/Savings to Local Agencies: None

Local Mandate: None

Cost to Any Local Agency or School District for Which Government Code Sections 17500 – 17630 Require Reimbursement: None

Business Impact: The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that the proposed regulation does not impose a new requirement on a pharmacy licensed with the Board of Pharmacy; rather, it proposes to modify the existing Notices to Consumers that is produced by the Board of Pharmacy and distributed to licensed pharmacies at no cost to a pharmacy. As an alternative to posting the notice provided by the board, the proposal would allow a business to utilize alternative means to display a required notice in an alternative format, display methodology or via video screen, as specified.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that this regulatory proposal will not have a significant impact on the creation of new or

elimination of existing jobs businesses or the expansion of businesses in the State of California.

Cost Impact on Representative Private Person or Business: The agency is not aware of any cost impacts that a representative business would necessarily incur in reasonable compliance with the proposed action. This determination is based on the fact that a pharmacy licensed by the board is required to post Notices to Consumers that are produced and distributed by the board at no cost to the licensee.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This initial determination is based on the fact that a pharmacy licensed by the board is required to post Notices to Consumers that are produced and distributed by the board at no cost to the pharmacy.

CONSIDERATION OF ALTERNATIVES

The board estimates this proposal could result in a fiscal impact to the Board of Pharmacy of approximately \$20,000 to publish and distribute the revised “Notice to Consumer” posters to pharmacies. This is an important consumer education tool and the board will absorb these costs within its existing resources.

The only alternative would be to not pursue this regulation. This alternative is not reasonable because the board believes that patients have a right to know that they can ask for larger print on their prescription drug container labels, and also that they have the right to interpretive services at no cost to the patient. In addition, the proposed regulation would allow a pharmacy to provide the Notices either by posting the notices provided by the board (at no cost) or – if the pharmacy desires – to utilize a different format or display methodology.

No reasonable alternative to adopting or amending the regulations would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons than the proposed regulations.

Any interested person may present statements or arguments in writing relevant to the above determinations at the address listed for the Contact Person.

INITIAL STATEMENT OF REASONS AND INFORMATION

The Board of Pharmacy has prepared an initial statement of the reasons for the proposed action and has available all the information upon which the proposal is based.

TEXT OF PROPOSAL

Copies of the exact language of the proposed regulations and of the initial statement of reasons, and all of the information upon which the proposal is based, may be obtained upon request from the Board of Pharmacy at 1625 N. Market Blvd., N219, Sacramento, California 95834, or from the Board of Pharmacy's Web site <http://www.pharmacy.ca.gov>.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE

All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named below.

You may obtain a copy of the final statement of reasons once it has been prepared, by making a written request to the contact person named below or by accessing the Board of Pharmacy's Web site (www.pharmacy.ca.gov).

CONTACT PERSON

Inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name:	Carolyn Klein
Address:	1625 N. Market Blvd., N219 Sacramento, CA 95834
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E-Mail Address:	Carolyn.Klein@dca.ca.gov

The backup contact person is:

Name:	Anne Sodergren
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Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.