

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. 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 January 4, 2010.

Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held 1625 N. Market Blvd., Hearing Room, Sacramento, California, at 9:30 a.m. on January 20, 2010.

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 4076 and 4076.5, of said Code, the Board of Pharmacy is considering changes to Division 17 of Title 16 of the California Code of Regulations as follows:

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

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). However, existing law does not describe with specificity what elements are necessary to make the label "patient-centered," as required by Business and Professions Code section 4076.5. Proposed regulation at Section 1707.5 specifies *how* prescription drug information is to be placed on the prescription drug container label, and clarifies what interpretive services are required to be provided by pharmacies in compliance with Section 4076.5 of the Business and Professions Code.

As mandated by Business and Professions Code section 4076.5 (The California Patient Medication Safety Act enacted by SB 472, Stats. 2007, ch. 470) and to make specific the prescription drug container label requirements found in Business and Professions Code section 4076, the Board of Pharmacy has proposed to add Section 1707.5 to Title 16 of the California Code of Regulations. This proposal would establish the requirements for a standardized, patient-centered prescription drug container label. This regulation would, among other things, mandate the format of all prescription drug container labels for prescription drugs dispensed in California, including: font type, font size, placement, wording, and grouping of information. It would require pharmacists, when applicable, to use standardized words and phrases, as specified, to describe directions for use of the drug on the drug container label.

This regulation would also require the California State Board of Pharmacy (Board) to publish on its Web site by October 2011 translations of certain directions for use, as specified, into at least five (5) languages other than English to facilitate the use of these translations by pharmacies. The Board would also be required, beginning in October 2010, to collect and publish on its Web site examples of labels conforming to the requirements of this proposed regulation.

In addition, this regulation would require a pharmacy, upon request by a patient with limited English proficiency, to provide oral translation of the prescription drug container label's information.

Under this proposal, the Board would be required to re-evaluate the requirements of this regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5

FISCAL IMPACT ESTIMATES

Fiscal Impact on Public Agencies Including Costs or Savings to State Agencies or Costs/Savings in Federal Funding to the State: None

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 not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. This regulatory proposal applies to pharmacies that dispense prescription drug medications to patients in California – licensed pharmacy sites within California, as well as those nonresident sites outside of California.

Additionally, the proposed regulation requires that a pharmacy that dispenses prescription drug medication to patients in California, and upon request by the patient, to provide an oral language translation of specified information on the label. To address the needs of patients with limited English proficiency and who require oral language interpretation of prescription drug label information, subdivision (d) of the proposed regulation contains language requiring a pharmacy, upon request of the patient, to provide an oral language interpretation of the prescription drug label information specified in subdivision (a)(1). The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to patients with limited English proficiency and that a regulation requiring a pharmacy to provide this service would not impose any further economic impact. Additionally, and as required in subdivision (b) of the proposed regulation, the board will post on its Web site the translation of the standard

directions for use phrases (subdivision (a)(4)) in five non-English languages. The board will work with health care advocates to develop these translations.

For more than two years prior to this notice, the Board has publicly engaged in discussions at hearings and at public meetings to seek input and determine how the board can best implement its mandate to promulgate regulations by January 1, 2011, to develop a patient-centered prescription drug label. The board has received input and information from industry representatives, affected businesses, and others and has determined that the proposed regulation will provide patients with a prescription drug container label that they can better understand, as well as one that will aid the patient to take their prescription drug medications as instructed by their physician. Ultimately, this will improve patient adherence to a prescription drug therapy and aid in better health by reducing medication errors.

Impact on Jobs/New Businesses: The Board of Pharmacy has determined that the proposed regulatory action would have no significant statewide adverse economic impact affecting business, including the ability of California businesses to compete with businesses in other states.

The following studies/relevant data were relied upon in making the above determination:

Senate Concurrent Resolution No. 49—Relative to Medication Errors. Resolution Chapter 123, Filed with Secretary of State September 2005.

SCR 49 Final Report on Medication Errors

SCR 49, Senate Health Committee Analysis (for bill version 6/15/05, hearing date 6/22/05)

Senate Bill 470 (Corbett)—Chapter 472, Statutes of 2007

Meeting Materials and Minutes from the following:

Information, comments and/or testimony received at Senate Bill 472 Medication Label Subcommittee Public Forums held on the following dates: April 12, 2008, November 20, 2008, January 27, 2009 and March 12, 2009

Information, comments and/or testimony received at Communication and Public Education Committee meetings held on the following dates: June 27, 2007, January 8, 2008, April 12, 2008, July 23, 2008, and October 2, 2008.

Information, comments and/or testimony received at Legislation and Regulations Committee meetings held on the following dates: April 3, 2007, July 5, 2007, July 10, 2008, and October 29, 2008.

Information, comments and/or testimony received at Board of Pharmacy Board Meetings held on the following dates: August 19, 2009, and October 21-22, 2009.

Hernandez, Lyla M., Rapporteur. Roundtable on Health Literacy. "Standardizing Medication Labels: Confusing Patients Less, Workshop Summary." ISBN: 0-309-11530-2

Testimony from Doreena Wong, National Health Law Program, November 20, 2008; and Issue Brief: Language Services in Pharmacies: What is Required?

Board of Pharmacy Prescription Container Label Survey; survey responses; and Fact sheet: Do you understand the directions on your Rx medicine label?

Improving Prescription Drug Container Labeling the United States, A Health Literacy and Medication Safety Initiative. A White Paper commissioned by the American College of Physicians Foundation, October 12, 2007.

Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review, *The Annals of Pharmacotherapy*, 2007 May, Volume 41

Shrank, William H., MSHS, MD; Agnew-Blais, Jessica, BA; Choudhry, Niteesh K., MD PhD; Wolf, Michael S., PhD, MPH; Kesselheim, Aaron S., MD, JD; Avorn, Jerry, MD; Shekelle, Paul, MD PhD. *The Variability and Quality of Medication Container Labels*. ARCH INTERN MED/VOL 167 (No. 16), September 10, 2007.

2009-2010 Chain Industry Pharmacy Profile, National Association of Chain Drug Stores

Cost Impact on Representative Private Person or Business: The Board of Pharmacy is not aware of any cost impacts that a representative private person would incur in reasonable compliance with the proposed action. This regulation proposal applies to pharmacy sites licensed by the board, not individual licensees.

For a pharmacy licensed by the board that distributes prescription drug medications to patients in California, that business may incur one-time costs associated with the configuration or re-configuration of how their prescription drug labels are printed. The board received testimony in October 2009 from one industry member who indicated that his pharmacy may incur a \$1,000 one-time cost to re-configure the printing of that pharmacy's prescription labels to ensure compliance with the proposed regulation.

The board heard testimony in October 2009 from the California Retailers Association and pharmacy chain representatives who indicated that the interpretive language services they currently provide to patients with limited English proficiency as a result of their compliance with regulations established by the Department of Managed Health Care and the Department of Insurance (SB 853, Chapter 713 Statutes of 2003) will be extended to all pharmacy patients. Thus, the board is not aware of a significant cost impact to industry for providing oral language interpretive services of specified prescription label content.

Effect on Housing Costs: None

EFFECT ON SMALL BUSINESS

To determine the number of small businesses that may be affected by this proposed regulation, the board utilized data from the National Association of Chain Drug Stores (NACDS) 2009-2010 Chain Pharmacy Industry Profile (2008 data), which reports that in 2008 California had 4,828 chain drug, supermarket, mass merchant and independent drug store locations. Of that number, NACDS considers 1,670 (or approximately 35%) to be independent pharmacies. The board also utilized its own licensee data that shows that as of December 2008 the board issued licenses to 6,149 pharmacies. (This number does not include those licenses issued to correctional facilities, hospitals or licensed clinics – these are pharmacies that rarely dispense prescription drug medications to outpatients.) Utilizing the NACDS profile data, if 35% of California's pharmacies are considered independent pharmacies, this would represent that – using actual licensee data – California would have approximately 2,150 independent pharmacies.

CONSIDERATION OF ALTERNATIVES

The Board of Pharmacy must determine that no reasonable alternative it considered to the regulation or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposal described in this Notice.

Any interested person may present statements or arguments in writing relevant to the above determinations by e-mailing, mailing, or transmitting by facsimile to the Contact Person on or before January 4, 2010. Interested persons may also present to the board statements or arguments orally or in writing relevant to the above determinations at the regulation hearing scheduled for January 20, 2010.

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 (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
Address: 1625 N. Market Blvd., N219
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Website Access. Materials regarding this proposal can be found at www.pharmacy.ca.gov.