

## Board of Pharmacy

### Initial Statement of Reasons

Hearing Date: January 20, 2010

Subject Matter of Proposed Regulation: Patient-Centered Prescription Labels

Sections Affected: Add 16 Cal.Code Reg. §1707.5

#### Specific Purpose of the Proposed Changes:

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

### Factual Basis/Rationale

Business and Professions Code section 4005 generally authorizes the board to amend rules and regulations necessary for the protection of the public pertaining to the practice of pharmacy and the administration of Chapter 9 of Division 2 of the Business and Professions Code.

Business and Professions Code section 4076 specifies information that is required to be placed on a prescription drug container label dispensed to a patient in California.

Business and Professions Code section 4076.5 requires the board to promulgate regulations on or before January 1, 2011, that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. It also specifies what factors the Board of Pharmacy must consider in establishing such a label. Those factors include:

- Medical literacy research
- Improved directions for use
- Improved font types and sizes
- Placement of information that is patient-centered
- Needs of patients with limited English proficiency
- Needs of seniors
- Technology requirements for implementation

### Background

In 2005, Senator Jackie Speier authored Senate Concurrent Resolution 49 (SCR 49), Chapter 123 Statutes of 2005, to create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. As required, that panel prepared and submitted to specific legislative committees a final report (referenced as the SCR 49 Report) containing its conclusions and recommendations to recommend improvements, additions or changes which would result in errors associated with the delivery of prescription and over-the-counter medications to consumers.

Additionally, Senator Ellen Corbett authored SB 472, resulting in the enactment of the California Patient Medication Safety Act (Chapter 470, Statutes of 2007). Therein, the Legislature stated the importance of reducing medication-related errors and increasing health care literacy regarding prescription drugs and prescription container labeling—which can increase consumer protection and improve the health, safety and well-being of consumers. Additionally, the Legislature affirmed the importance of identifying deficiencies in, and opportunities for improving, patient medication safety systems in order to identify and encourage the adoption of structural safeguards related to prescription drug container labels. To further these objectives, the Legislature authorized the Board per SB 472 (now Business and Professions Code section 4076.5) to adopt regulations to implement standardized, “patient-centered” prescription drug container labels in California.

To facilitate development of this regulation proposal, the President of the Board appointed a SB 472 Label Subcommittee to conduct public forums and to develop recommendations to implement the provisions of SB 472 to establish a patient-centered prescription drug label. Public forums, separate from regularly-scheduled board meetings, were held throughout the state. At these public forums, at other outreach events, through its Web site, and at other board and committee meetings, the board sought public input and feedback on what elements of a prescription drug container label were important to them and how that label could be improved. The board developed and made available to the public a prescription label survey in May 2008. The questions were open-ended, allowing participants to provide as little or as much information as desired. Board staff used the survey to interview consumers at public outreach events including health/community fairs in Sacramento, Elk Grove, Los Angeles, Riverside, San Diego, Merced, and San Francisco. Printed surveys and self-addressed return envelopes were provided to attendees who chose to return responses by mail. The survey was provided in English and Spanish. The board also provided fact sheets entitled, "Do you understand the directions on your Rx medicine label?" and samples of faux prescription labels serving as visual aids. The survey was posted on the Board's public Web site and to interested parties and organizations including the Gray Panthers and the Latino Coalition for a Healthy California. Board members also interviewed consumers, and returned the responses by mail. Survey results were provided to the board at SB 472 Subcommittee public forums and at public board meetings.

At public forums and at board and committee meetings, the board considered testimony and information provided on medical literacy research, improved directions for use, improved font types and sizes, the placement of information that is patient-centered, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standards developed. The minutes of these meetings, as well as the documents listed in the "Underlying Data" section, reflect the information received and considered. Based upon the foregoing information received and considered by the Board, the Board developed this proposed language to implement the requirements of Business and Professions Code section 4076.5.

In exercising its authority over the practice of pharmacy in the state of California, the board believes that this proposed regulation is necessary to implement Section 4076.5. By providing a uniform, standardized format for prescription drug container labels and requiring pharmacies to provide oral language translations to patients with limited English proficiency, the Board believes that this proposed regulation will aid in the reduction of medication errors associated with the delivery of prescription drugs dispensed to patients in California. (Subsections (a), (d) of proposed Section 1707.5.)

This regulation is also necessary to assist pharmacies with implementation of the new patient-centered drug container label standards contained in the proposed regulations. Proposed subsections (b) and (c) would require the 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. 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. The board intends to address this in two ways. First, the board is working with health care advocates to

translate the standard directions for use phrases identified in subparagraph (a)(4) and have those available on the board's Web site by October 2011. Second, subdivision (d) 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) for non-English speaking patients. The board received testimony from chain and retail pharmacy industry representatives that this service is already provided to their non-English speaking patients and that providing this service would not impose any further economic impact.

To ensure continuing consideration and analysis of the effectiveness of this proposal in light of the factors contained in Section 4076.5 (e.g., new developments in technology), this regulation is necessary to mandate that the board will re-evaluate the requirements of the regulation by December 2013.

#### Underlying Data

1. Senate Concurrent Resolution No. 49—Relative to Medication Errors. Resolution Chapter 123, Filed with Secretary of State September 2005.
2. SCR 49 Final Report on Medication Errors
3. SCR 49, Senate Health Committee Analysis (for bill version 6/15/05, hearing date 6/22/05)
4. Senate Bill 470 (Corbett)—Chapter 472, Statutes of 2007
5. Meeting Materials and Minutes from
  - a. Senate Bill 472 Medication Label Subcommittee Public Forums  
April 12, 2008                      January 27, 2009  
November 20, 2008                March 12, 2009
  - b. Communication and Public Education Committee Meetings  
June 27, 2007                      January 8, 2008                      July 23, 2008  
   April 12, 2008                      October 2, 2008
  - c. Legislation and Regulations Committee Meetings  
April 2007                              July 10, 2008  
July 5, 2007                            October 29, 2008
  - d. Board of Pharmacy Meetings  
August 19, 2009  
October 21-22, 2009
6. Hernandez, Lyla M., Rapporteur. Roundtable on Health Literacy. "Standardizing Medication Labels: Confusing Patients Less, Workshop Summary." ISBN: 0-309-11530-2

7. Testimony from Doreena Wong, National Health Law Program, November 20, 2008; and Issue Brief: Language Services in Pharmacies: What is Required?
8. Board of Pharmacy Prescription Container Label Survey; survey responses; and Fact sheet: Do you understand the directions on your Rx medicine label?
9. 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.
10. *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
11. 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.
12. 2009-2010 Chain Industry Pharmacy Profile, National Association of Chain Drug Stores

#### 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 following facts or evidence/documents/testimony and also applies to pharmacies outside of California that provide prescription drug products to California patients.

Consistent with the requirements of Senate Bill 853 (Escutia, Chapter 713 Statutes of 2003), the Department of Managed Health Care and the Department of Insurance have established regulations that require oral language interpretation services for their patients with limited English proficiency at all points of care. To facilitate clients with these requirements, many pharmacies already provide such interpretive services to California patients. The board heard testimony in October 2009 from the California Retailers Association as well as pharmacy chain representatives who indicated that the interpretive language services provided to patients with limited English proficiency are already provided to their pharmacy patients.

One industry member testified at the October 2009 board meeting that they may incur one-time costs to configure the labeling of that pharmacy's prescription drug label – resulting in a one-time approximate cost of \$1,000.

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.

Additionally, as of December 2008, California issued licenses to 359 non-resident pharmacies – those located outside the state that ship, mail, or deliver, in any manner, controlled substances, dangerous drugs, or dangerous devices into California. The board does not maintain separate statistics to show if these licensees are independent, community, or chain drug stores; however, the board does not believe these licensees are small businesses.

Likewise, the board included in the proposed regulation, the board's requirement to re-evaluate the requirements of the regulation by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

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 at no cost to the agency.

#### Specific Technologies or Equipment

While this regulation does not mandate the use of specific technologies or equipment, pharmacies may need to modify how their prescription container labels are printed so as to be in compliance with the font type, font size and placement of information on a prescription drug container label for prescription drugs dispensed to a patient in California.

#### Consideration of Alternatives

The Board of Pharmacy is mandated to promulgate regulations to specify a standardized, patient-centered prescription drug container label by January 1, 2011. Therefore, failing to adopt regulations is not a legally viable alternative.

The board considered information and testimony received over a period of approximately 18 months and believes that no alternative it considered would be either more effective than or as effective as and less burdensome on affected private persons than this proposed regulation.



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No reasonable alternative to amending the regulation 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 regulation.