



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
COMMUNICATION AND PUBLIC EDUCATION COMMITTEE
MINUTES**

DATE: July 15, 2009

LOCATION: Radisson Hotel at Los Angeles Airport
6225 West Century Boulevard
Los Angeles, CA 90045

**COMMITTEE MEMBERS
PRESENT:**

Stanley C. Weisser, RPh, Treasurer
Robert Swart, PharmD
Shirley Wheat, Public Member

**COMMITTEE MEMBERS
NOT PRESENT:**

Ryan Brooks, Public Member, Chair

**STAFF
PRESENT:**

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Schieldge, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager

Call to Order

Robert Swart called the meeting to order at 3:30 p.m.

General Announcements

Dr. Swart announced that he would be acting as Chair in the absence of Ryan Brooks.

- 1. Presentation of Consumer Education Videos Produced by California Pharmacy Students, Shown During the Pharmacy Foundation of California's Film Festival in February**

Executive Officer Virginia Herold provided that at the California Pharmacists Association Outlook annual meeting in February 2009, the Pharmacy Foundation of California hosted a “film festival” of u-tube like videos dealing with such topics as don’t share your medicine. She explained that the videos were produced by pharmacy students in California schools of pharmacy.

Several of the award winning videos were presented to the committee.

Recognition of Former Board Member Tim Dazé

President Ken Schell recognized former board member Tim Daze for his years of service on the Board of Pharmacy. He presented Mr. Dazé with a clock of appreciation.

Mr. Daze thanked the board for its recognition. He encouraged the board to continue with its efforts.

2. Update on Implementation of SB 472, Patient-Centered Medication Container Labels

Dr. Swart provided that Senate Bill 472 (Chapter 470, Statutes of 2007) added Section 4076.5 to the Business and Professions Code, relating to development of patient-centered prescription drug labels. He stated that the statute requires the board to promulgate regulation for standardized, patient-centered, prescription drug labels on all prescription medication dispensed to patients in California by January 1, 2011.

Dr. Swart provided that the timeline envisioned for this process was:

- 2008: conduct public hearings statewide – six meetings were envisioned
- 2009: develop regulations and adopt the requirements by the end of the year
- 2010: pharmacies implement requirements to be ready for 1/1/11 implementation
- 2011: requirements become effective and labels on prescription medicine are compliant

Dr. Swart provided that the first special public forum was held at a community center in Fremont on April 12, 2008. He stated that approximately 40 people attended, though most attendees were from the pharmaceutical industry.

Dr. Swart provided that the board has also convened special meeting of the subcommittee on November 20, 2008 at the Professionals Achieving Consumer Trust Summit in Los Angeles, on January 27, 2009 in San Diego, and in the evening in March 12 in Sacramento.

Dr. Swart provided that three attendees at the initial forum were “public” participants. He stated that the vast majority of attendees at the next three meetings have not been consumers per se, but representatives of consumer groups or pharmacy stakeholders. Dr. Swart advised that early on, it became apparent that the board would need to find alternative venues to increase participation from consumers.

a. Consumer Surveys Conducted by the Board of Pharmacy

Dr. Swart provided that in May 2008, board staff developed a prescription label survey for distribution at public outreach events. He stated that the survey is available in English and Spanish.

Dr. Swart provided that since late May, board staff has been using the survey to interview attendees at public events. He stated that consumers have been invited to complete surveys on-site during the events, or mail them to the board using the self-addressed envelopes provided. Dr. Swart explained that this method of soliciting information has proved less intimidating to consumers than individually speaking at public hearings. He indicated that board staff attending the community events has also reported positive feedback when discussing this initiative with the public. Dr. Swart provided that in October 2008, pharmacist and pharmacy associations agreed to share the surveys with their members to aid the board in data collection.

Dr. Swart provided that this survey can be completed and submitted electronically on the board's Web site. He stated that is also available on the board's Web site in Spanish. Dr. Swart indicated that AARP has invited consumers to “Put in Your Two Cents on Prescription Labeling” in the AARP September 2008 newsletter.

Dr. Swart provided that the board has also provided consumers with one-page fact sheets entitled, "Do you understand the directions on your Rx medicine label?" He stated that the fact sheet provides background information related to SB 472, and printed samples of faux prescription labels as a visual aid.

Dr. Swart provided that a total of 695 consumers completed board surveys as of July 7, 2009. He stated that every consumer provided an answer to each question, while others provided multiple answers to individual questions. Dr. Swart advised that many consumers gave the same response (i.e., larger font) to more than one question.

Dr. Swart provided that trends have been identified in the answers provided thus far. He stated that many responses suggest that the purpose of the drug be printed on the prescription label, and that a larger or bolder type font be used.

Dr. Swart provided the following survey results:

When asked what would make prescription labels easier to read, the top two responses were:

- Larger or bolder print (347 of 578 responses = 60.0%)
- Highlighting directions for use and other information in colors other than black (65 of 578 responses = 11.3%)

When asked what to change on the prescription label, the top three responses were:

- Print should be larger or darker (194 of 616 responses = 31.5%)
- No changes should be made to label – references were made to Target, Raley's, CVS and Kaiser labels (148 of 616 responses = 24.0%)
- Include purpose of the drug – state what condition the medication is intended to treat (71 of 616 responses = 11.5%)

When asked what information on the label was most important, the top three responses were:

- Directions for use (257 of 1,361 responses = 18.9%)
- Name of drug; if generic, brand name and generic (253 of 1,361 responses = 18.6%)
- Dosage prescribed (242 of 1,361 responses = 17.8%)

When asked for other suggestions, the top two responses were:

- Easy-open lids should be used; no child-proof caps for seniors (30 of 158 responses = 19.0%)
- Include purpose of the drug – state what condition the medication is intended to treat (22 of 158 responses = 13.9%)

Committee Discussion

Stan Weisser referenced to the question regarding changes to the label. He discussed that the labels mentioned do not share in many commonalities.

Shirley Wheat asked what the board should do at this time to ensure that it is fulfilling its obligation to SB 472.

Ms. Herold referenced to the surveys that have been conducted and provided that the board has fulfilled the obligation under SB 472 to survey the public. She stated that the board will need to further discuss several issues before it can move to a regulation hearing.

Dr. Swart provided that consumers may not always be satisfied with new changes to a label, even if these changes were what they have requested. For example, he explained that a compromise is often necessary as a larger vial may be used to accommodate requests for a larger font.

Ms. Herold provided that the developed regulation will need to be a compromise between many competing interests.

Ms. Wheat sought clarification regarding how SB 470 would impact SB 472.

Ms. Herold provided that it is intended that the changes to the label will also include the purpose of the medication.

The board discussed the requirements of SB 470. It was clarified that purpose of the medication will be added to the label if requested at the point of prescribing.

There was no additional board discussion. No public comment was provided.

3. Informational Hearing of Draft Proposed Regulation Requirements to Mandate Patient-Centered Medication Container Labels Pursuant to SB 472 (Corbett, Chapter 470, Statutes of 2007).

Dr. Swart provided that the board is directed by SB 472 to develop patient-centered prescription labels.

Dr. Swart provided that at the January 27, 2009 committee meeting, the committee reviewed each prescription label requirement specified in California Business and Professions Code section 4076 and selected those with the greatest importance to consumers.

Dr. Swart provided that the committee generated a basic list that identified three key items of most importance to a patient using a medication and the container's label:

- trade name/ generic name,
- directions
- strength

Dr. Swart provided that additionally, the board's executive officer has participated as a member of a National Association of Boards of Pharmacy (NABP) task force in developing model guidelines for patient-centered labels for all states. He stated that the results of this task force were shared at the NABP Annual Meeting in May 2009. Dr. Swart indicated that the key recommendations of the task force report with respect to patient-centered labels are that: (page 49):

The task force agreed that the following information is critical and must appear on the label with emphasis (either highlighting or bolding) in a sans-serif font, with a minimum point size of 12, and which must never be truncated:

- patient name
- directions for use and, if included on the prescription drug order, the purpose/indication

- drug name and strength
- date by which the medication should be used

Dr. Swart provided that in developing California's regulation, the board will need to consider the general format of prescription container labels to maximize value to patients, and yet consider the diversity of containers in use by pharmacies. He stated that the NABP task force report on pages 4 and 5 show two sample labels that highlight essential consumer information and minimize other information. Dr. Swart advised that the board's staff also developed sample labels based on the elements identified as most important for consumers at the January meeting. He indicated that these labels were shared at the March subcommittee meeting.

Committee Discussion

Ms. Herold reviewed a draft of the proposed labeling regulation. She stated that a patient-centered prescription label emphasizes the information of most importance to patients.

Ms. Herold discussed the components considered in development of the regulation including medical literacy research, improved directions for use, improved font types and sizes, the placement of patient-centered information, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standard.

Ms. Herold provided that the legislative report is due January 1, 2010. She indicated that an implementation report will be due January 1, 2013.

Ms. Herold explained the purpose of a label with regards to the consumer, pharmacy, and the regulator.

Ms. Herold reviewed the National Association of Boards of Pharmacy (NABP) policy on patient-centered labels. She explained that it is the goal of NABP to create a single standard across state lines. Ms. Herold provided that the board is the first to start this effort.

Ms. Herold discussed the logistics involved with standardizing a label when considering the diversity of containers currently being used.

Ms. Herold recommended that, while maintaining its focus on patient-centered information, the board should retain as much as flexibility in the size of the label to allow a pharmacy to choose the appropriate size of the label for their container.

Ms. Herold reviewed elements that promote legibility and readability including using a sans serif font, a minimum of a 12 point font, highlighting and/or bolding

to emphasize important information, and “chunking” or clustering important information in one area of the label.

Ms. Herold recommended that the board standardize directions for use on labels. She explained that this help to alleviate confusion for patients. Ms. Herold provided a list of standardized directions that have been developed by researcher Michael Wolf, PhD. She indicated that Dr. Wolf states that about 90 percent of all directions for use will fit into one of these statements.

Ms. Herold provided that standardizing the directions for use will be important for securing translations of the directions into key languages used in California.

The committee discussed the elements of a patient-centered label. It was suggested, that instead of specific size font, that the board recommend a specified ratio of included information to better accommodate different sized vials. It was also suggested that minimum standards be established.

Ms. Herold prompted the committee with a series of questions.

1. Should the board specify the minimum cluster size for the patient centered elements?

Ms. Wheat discussed the order or placement in which information is provided on a label. She suggested that a standardized order or placement of information would promote consistency for consumers who have prescriptions filled at different pharmacies.

Dr. Swart provided that like a check, the elements of a prescription label could have a standardized placement. This concept was referred to as the “check book” model.

Ms. Herold provided that the board will need to determine the costs associated with this regulation.

Dr. Swart expressed concern that standardizing these requirements may negatively impact innovations such as Target’s new prescription label and container.

Kristy Schieldge, DCA Legal Counsel, clarified that the elements that have been presented are a result of consumer and patient surveys. She provided that a “prescriptive” regulation would allow the board to specifically define how the label will look. Ms. Schieldge explained that the current regulation would be a “performance standard” that will provide guidelines for what the board would like to see on the label.

Ms. Herold provided that standardizing directions for use may help to alleviate issues with regards to health literacy.

Mr. Weisser provided that the label should be designed to best accommodate people with limited literacy.

Ms. Herold provided that existing research should be used to ensure that labels are designed to allow people to easily read and understand them.

The committee discussed the potential costs associated with new regulation compliance. The committee also evaluated the possible implementation of the “checkbook” model. It was the consensus of the committee to support this model.

Ms. Sodergren provided that the results of focus groups conducted by Western may provide the committee with some guidance regarding the placement of information on the label.

2. Should the board develop translations in the top 5 languages for directions for use?

Ms. Wheat responded no. She expressed concern regarding the regulation and accuracy of translations.

Ms. Herold provided that under SB 853, the patient has to be provided with written literature in his or her own language.

Ms. Schieldge expressed concern that the board would be liable for developing translations to be used by pharmacies. She clarified that under the proposal, the board would be responsible for translating the directions for use and placing it in the top 5 languages on the board’s Web site.

Ms. Herold stated that the board may need to hire a translator to confirm compliance. She discussed a pilot that would test the accuracy of translations. Ms. Herold provided that the top 5 languages in California will need to be determined. She indicated that the board’s Notice to Consumers poster is currently provided in 6 languages.

Public Comment

Dorena Wong provided that the needs of the limited English speaking population need to be addressed. She encouraged the board to establish and meet these needs. Ms. Wong discussed various models that can be used to determine the languages that should be translated. She stated that major pharmacies in New York have agreed to translate instructions and provide interpreters in their pharmacies. Ms. Wong suggested that this New York program may provide useful guidance for the board.

Ms. Wheat sought clarification regarding implementation issues and requirements with providing translations.

Ms. Herold highlighted the benefits of the board providing translations.

Stan Weisser discussed the population that would be covered by the top 5 languages. He provided that it may be possible for businesses or local pharmacies to address their community and specific language if it is not included in the top 5.

Ms. Wheat provided that this business model will allow for specificity.

Dr. Swart discussed what content would be translated.

Ms. Herold discussed possible research areas and funding for this area.

Ms. Schiedge reviewed the legal risks involved with the board providing translations.

The committee discussed legal liabilities and the option of pharmacies obtaining translations through a contracted service instead of from the board. The committee did not reach a consensus on this issue.

3. How should the board deal with the labels for the remaining 10% of the directions for use?

Ms. Herold discussed the California requirement that a description of the pill appear on the container. She asked if the board should require that this description be translated or suggested that a picture could be provided.

The committee discussed the use of pictures on medication labels. Concern was expressed regarding the quality of the picture.

4. If the board translates the directions for use, how do you deal with translating the other patient centered items on the label?

The committee did not discuss this question.

5. The National Association of Boards of Pharmacy (NABP) also identified expiration date as patient centered and the board did not. Does the committee wish to reclassify this component?

The committee reached a consensus that the expiration date should not be classified as a patient centered element.

6. How should the board deal with auxiliary labels?

Ms. Herold provided that auxiliary labels are not standardized or translated. She stated that they are often confusing to patients because they can receive two different labels providing the same warning.

The committee chose to discuss this question at a later date.

Ms. Herold provided that the regulation requirements will need to be reevaluated after the first four years and then periodically thereafter. She discussed the establishment of measurement standards with regards to compliance for the implementation report due in 2013.

There was no additional board or public comment.

4. Update on *The Script*

Ms. Schieldge provided that *The Script* is currently undergoing review by the director's office.

No board or public comment was provided.

5. Update on Public Outreach Activities

Dr. Swart referenced to the list of public and licensee outreach activities performed during the fourth quarter of Fiscal Year 08/09 contained within the board packet.

No board or public comment was provided.

6. Strategic Plan Update for the Communication and Public Education Committee for 200/10

Dr. Swart confirmed that no changes to the strategic plan are necessary.

No board or public comment was provided.

7. Fourth Quarterly Report on Committee Goals for 2008/09

Dr. Swart referenced to the fourth quarterly report on the Communication and Public Education Committee's goals contained within the board packet.

No board or public comment was provided.

8. Update and Discussion on Consumer Fact Sheets

Assistant Executive Officer Anne Sodergren provided that several fact sheets are currently undergoing executive review and will be provided to the committee at a future committee meeting.

No board or public comment was provided.

9. Update and Discussion on Consumer Fact Sheet Series with California School of Pharmacy Interns

Ms. Sodergren provided that board staff has reached out to schools of pharmacy to integrate pharmacy students into public outreach activities. She stated that staff is finalizing a template to provide to each school that participates as well as a list of potential subjects.

Ms. Sodergren provided that the committee may wish to consider the development of a recognition program and an award on an annual basis for the intern that develops the best fact sheet.

No board or public comment was provided.

10. Translated Notice to Consumers Posters Available

Ms. Sodergren provided that the Notice to Consumers poster has been translated into 6 different languages and is available on the board's Web site.

No board or public comment was provided.

11. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 5:21 p.m.