



California State Board of Pharmacy

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STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

DATE: January 19, 2012

LOCATION: Department of Consumer Affairs
Building Two
1747 North Market Boulevard, Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Ryan Brooks, Chair
Roselyn Hackworth, Public Member
Deborah Veale, RPh
Shirley Wheat, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Ramón Castellblanch, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kim Brown, Public Information Officer
Tessa Miller, Staff Analyst

Call to Order

Committee Chair Ryan Brooks called the meeting to order at 10:24 a.m.

Executive Officer Virginia Herold conducted a roll call. Board Members Brooks, Hackworth, Veale, and Wheat were present. Board President Stan Weisser was in attendance in the audience.

1. **Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels and Review of Labels in Use**

Report

Ms. Herold discussed a recent consumer complaint regarding a prescription label that was difficult to read. She indicated that this is one of the first complaints that the board has received regarding the new patient-centered prescription labels.

Ms. Herold provided that the board has a requirement to provide a report to the Legislature by January 1, 2013 on implementation of the patient-centered labels. She discussed that in preparation for this report, board inspectors have been directed to pick up sample prescription container labels from every pharmacy they enter. Ms. Herold stated that the goal is to secure copies of actual labels in use and compare these with the board's regulation requirements to see if additional changes in the requirements may be needed and to identify the best labels and promote them on the board's website.

Ms. Herold provided that the labels collected by the board will be reviewed at a future meeting.

Discussion

Mr. Brooks sought clarification regarding the board's authority to make changes to the regulation.

Ms. Herold discussed that the board will be reviewing the regulation in preparation for the January 2013 report to the Legislature and during a self-directed reevaluation period in December 2013. She stated that the board will have the opportunity to review and make modifications during these reviews or as needed.

Public Comment

Steve Gray, speaking as an individual, encouraged the board to seek consumer feedback during its review. He also encouraged the board to collect prescription labels from non-resident pharmacies.

Dr. Gray discussed that the requirement to cluster required elements into a 50 percent area of the label is impacting readability as described in the consumer complaint.

Dr. Gray provided comment regarding including the purpose of a medication on the label and discussed the implementation of ICD-10 diagnosis codes. He recommended that the board address this issue and cautioned against waiting until 2013 for this review.

Committee Member Deborah Veale encouraged Dr. Gray to submit his comments in writing to the board.

Ms. Herold discussed that the board is inspecting for compliance with the regulation. She stated that enforcement statistics in this area will be reported to the board.

2. Discussion Surrounding the Developed Translations of Directions for Use for Patient Medication as Specified in 16 California Code of Regulations Section 1707.5

Report

Chair Brooks provided that translations of the standardized directions for use listed in the labeling requirements were developed by nationally known researchers who vetted them in field studies through a grant to the researchers funded by the California Endowment. He indicated that translations have been developed in Spanish, Russian, Chinese, Vietnamese, and Korean.

Chair Brooks provided that since the October 2011 Board Meeting, these translations underwent a second review by Carmazzi Global Solutions, a translation service contracted by DCA. He stated that there were minor issues with the Chinese translation, which have been resolved with the researchers.

Chair Brooks indicated that the board is now ready to post these translations on its webpage.

Discussion

Ms. Herold indicated that the translations will be posted soon.

Committee Member Shirley Wheat referenced the following Disclaimer for Translations, developed by Staff Counsel Kristy Shellans to be posted on the board's website with the translations:

The California Endowment, in an effort to support quality labels for those who do not read English, funded a project with national patient literacy researchers to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. While every effort was made to ensure accuracy and reliability of these translations, the Board cannot ensure that a particular translation is appropriate for a particular patient. The Board recommends that each pharmacy and pharmacist confirm the validity and the medical appropriateness of any given translation for a particular patient before using it for the patient's drug label.

Ms. Herold discussed translations that are currently offered within the industry and discussed that New York City includes English on translated labels. She discussed that the board will need to determine if it will also require English on translated labels for prescriptions dispensed in California.

Ms. Wheat expressed concern regarding translated labels and discussed that also including the information in English will aid the patient's doctors and caregivers.

Chair Brooks discussed that it is the standard of practice for pharmacies to provide services based on the community demographics and the language of their customer base.

Public Comment

Ellen Wu, representing the California Pan-Ethnic Health Network (CPEHN), discussed that patients should have access to translation services in all communities. She asked if there is a way to determine the number of times the translations are accessed or downloaded from the board's website. Ms. Wu also asked whether the translations are to be used in a particular format.

Ms. Sodergren discussed that the board can track the number of visits to its website; but, is unable to track the number of times the translations are accessed.

Ms. Herold provided that formatting will be determined by each individual pharmacy as there is no specific format for use of the translations. She indicated that the board may be interested in collaborating with CPEHN in this area.

3. Discussion Regarding the Future Design of New Notice to Consumers Posters (Pending 16 California Code of Regulations Section 1707.6)

Report

Chair Brooks provided that the board has begun work on new posters to display the revised new Notice to Consumers, reflecting the new text.

Chair Brooks provided that the rulemaking to create the new Notice to Consumers requirements is currently under review at the Office of Administrative Law.

Chair Brooks provided that once the new design has been selected, it will be published and mailed to all pharmacies. He shared that meanwhile, the staff will secure translations of the posters and have them printed in the same design and make these available to pharmacies that wish to display the posters in additional languages.

Chair Brooks provided that the total cost of printing and mailing these posters in the past has been about \$40,000.

Discussion

Public Information Officer Kim Brown presented sample poster designs to the committee. She explained that as initial samples produced by the Department of Consumer Affairs did not meet the board's needs, additional samples were produced by the Office of State Printing and by the board's part-time graphics designer.

Ms. Brown reviewed challenges in designing an effective poster including the pharmacy environment, consumer behavior, and ensuring all required information is included on the poster. She discussed that consumers typically only look at a poster or advertisement for 4 seconds before moving on and typically look at the top portion of the poster first. Ms. Brown also indicated that consumers prefer advertisements that offer tips or an action that will benefit them.

Ms. Brown stated that the samples were designed with these considerations and include an emphasized message (i.e. "Talk to your pharmacist") as well as specific questions for consumers to ask the pharmacist (i.e. "Any side effects?;" "What if I miss a dose?").

Ms. Brown discussed that the samples are designed to be the same size as the current notice. She also discussed that the board can choose two posters rather than one as proposed.

Discussion

Ms. Veale provided comment in support of requiring only one poster as pharmacies have limited wall space to post the notice.

Ms. Hackworth also provided comment in support of one poster. She also recommended that the size of the graphics on the samples be decreased to allow for more space for the notice text.

Ms. Wheat spoke in support of one poster and encouraged the board to move to expedite the design and approval process of the notice. She suggested that bullet points be used to display the notice text and also suggested that a larger text size be used.

Ms. Wheat sought clarification regarding where the notice is required to be posted in the pharmacy.

Ms. Herold reviewed the following requirement pursuant to § 1707.6(a):

(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).

Mr. Brooks also spoke in support of one poster. He discussed the challenges in balancing the required text with the graphics and stated that visuals help to draw consumers in.

Ms. Herold discussed that the notice is an opportunity to increase name recognition for the board and to ensure credibility by including the board's logo or the state seal. She cautioned that a poster that looks like a drug advertisement may not catch the attention of consumers.

Chair Brooks recommended that a watermark be added to serve this purpose.

The committee discussed that it should evaluate its top priorities/elements to be emphasized on the poster. Several items were evaluated including the phrase “talk to your pharmacist,” questions to ask a pharmacist, label font size, and interpreter services.

Chair Brooks directed the committee members to individually evaluate their top priorities for the poster and report back to Ms. Herold within two weeks.

Ms. Brown indicated that she will review the committee’s submissions to modify the samples and bring them for review by the committee at a future meeting.

Ms. Wheat requested that the current Notice to Consumers poster be brought to the next meeting to compare with the samples.

Public Comment

Ellen Wu, representing the California Pan-Ethnic Health Network (CPEHN), provided comment in support of establishing the availability of interpreter services as a priority on the poster.

Ms. Veale provided that the pending regulation also requires a separate notice regarding interpreter services in which consumers can point to their language.

A member of the public encouraged the board to implement a smaller notice that can be placed on the counter at the point of sale or pickup to increase the likelihood that the consumer will actually see and read it.

4. Discussion of Video Display Template for Notice to Consumers

Report

Chair Brooks provided that staff has also begun work on the video format option of the new Notice to Consumers. He referenced the following requirements for this format:

§ 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). 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) 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.

Chair Brooks provided that staff has identified a text and graphics format that will convey the video notice in an easily readable format. He stated that staff is also exploring in-house resources to produce something similar to the health education videos produced by the Patient Education Institute for the National Institutes of Health (NIH).

Chair Brooks provided that a sample video from the NIH can be viewed at the following link. Note: the Board's video messaging will not include audio, only text/graphics on screen.

http://www.nlm.nih.gov/medlineplus/tutorials/takingacetaminophensafely/htm/_yes_50_no_0.htm

Discussion

Ms. Brown discussed that the video produced by NIH utilizes a very simple format that would be conducive to displaying the notice on a video screen.

The committee discussed the NIH format and recommended that this format be replicated for the board's video format option.

Public Comment

Ellen Wu, representing the California Pan-Ethnic Health Network (CPEHN), asked whether it is possible to also translate the video notice.

Ms. Herold indicated that this is an option.

Steve Gray, representing Kaiser Permanente, asked whether audio can be used in the video notice.

Ms. Herold indicated that there is no prohibition for use of audio in the video notice within the regulation.

5. Format for Notice of Interpreter Availability

Report

Chair Brooks provided that the board also has begun work on the notice about availability of a free interpreter in the pharmacy. He reviewed the following relevant section of the new notice to consumers regulation:

1707.6 (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 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 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.

Chair Brooks provided that the board is contracting with a translation firm to translate this text into the specified languages. He stated that the cost for this translation is estimated to be \$735.

Chair Brooks provided that the goal is to have this notice printed in colors that provide good contrast.

Chair Brooks provided that the committee will have a chance to discuss types of format for this notice.

Discussion

Ms. Herold discussed that there are currently several similar handouts being used within the industry and referenced an example provided in the meeting materials.

Public Comment

Dr. Gray provided comment on the availability of a similar document provided by the Department of Managed Health Care.

Ellen Wu, representing the California Pan-Ethnic Health Network (CPEHN), expressed concern regarding the listing of the required languages for the notice in the regulation. She suggested that threshold languages be specified to allow for demographic changes.

Ms. Herold provided that the board was advised that the specific languages needed to be specified in the regulation. She discussed that changes can be made to the listed languages as needed and welcomed CPEHN to advise the board of any significant changes in demographics.

Chair Brooks discussed that the 12 languages listed in the regulation are the minimum. He stated that pharmacies can notify consumers of any additional languages that they serve.

6. Fortieth Annual Report of the Research Advisory Panel of California

Report

Ms. Herold provided that the California Health and Safety Code establishes the Research Advisory Panel to oversee research involving use of controlled

Ms. Herold provided that the board has received the panel's 2010 report. She stated that the Board of Pharmacy has one representative on this panel – Dr. Peter Koo of UCSF.

Ms. Herold provided that a representative of this panel will attend the Board Meeting on January 31, 2012 to provide information about the work of the committee. She indicated that Mr. Ed O'Brien will attend on behalf of the Research Advisory Panel.

There was no committee discussion or public comment.

7. Update on an Assessment of the Board's Public Education Materials

Report

Chair Brooks provided that an assessment of the board's public educational materials will be initiated in the next few months by new Public Information Officer Kim Brown.

Chair Brooks provided that in the interim, Ms. Brown has developed a consumer brochure on how to buy prescription medications safely from online pharmacies. He stated that this brochure is in the final stage of completion. Chair Brooks advised that the board is waiting for written approval from the NABP for use of their VIPPS seal (Verified Internet Pharmacy Practice Sites) in the brochure.

Discussion

Ms. Brown presented a sample of the brochure to the committee. She discussed that the small brochure was designed to easily fit in a pocket or purse to encourage consumers to take the brochure home.

Chair Brooks requested that board staff research counterfeit of the VIPPS seal and asked whether the board's website provides any information regarding the importance of the VIPPS seal.

Ms. Herold provided that an informational video for consumers regarding purchasing drugs from the internet is available on the board's website. She indicated that this video does focus on the VIPPS seal.

Ms. Veale recommended that the VIPPS seal be added to the front cover of the brochure.

Ms. Herold provided that a brochure on buying pet medications from online sites is in the planning stage.

No public comment was provided.

8. Discussion of New Webpage Design for the Board of Pharmacy

Report

Chair Brooks provided that for approximately one year, the board has been waiting for the go ahead from the department to institute a new webpage that conforms to a new, more user friendly, state format for websites. He stated that there is no timeline for this to occur, but the estimate from the department was about four months.

Discussion

Ms. Sodergren provided that the new format will have set parameters for the board to follow and will be similar to the Governor's current website format.

Ms. Brooks asked whether the department has secured wifi internet access in department meeting rooms.

Ms. Sodergren provided that the department is currently in the testing phase for wifi access.

No public comment was provided.

9. Update to the Board's Webpage about Implementation of SB 41 (Yee, Chapter 738, Statutes of 2011) regarding Needle Exchange

Report

Chair Brooks provided that SB 41 (Yee, Chapter 738, Statutes of 2011) requires the board to post or maintain a link to information developed by the California Department of Public Health Office of AIDS on accessing sterile syringes and other health information on HIV and viral hepatitis drug testing and treatment.

Ms. Brown provided that the Board now has two links to the Access to Sterile Syringes website that is maintained by the California Department of Public Health Office of AIDS. She stated that the links are contained in the "Information for Consumers" and "What's New" sections, under the title Access to Sterile Syringes.

There was no board discussion or public comment.

10. Update on The Script

Report

Chair Brooks provided that the next issue of The Script has been written and completed legal review. He stated that it should be released about the time of the board meeting.

Chair Brooks indicated that work on the next issue has begun.

Discussion

Ms. Herold provided that the next issue will focus on implementation of new pharmacy laws and will also provide information regarding patient-centered prescription labels and medication errors.

Ms. Herold discussed that the board receives positive feedback from licenses regarding the content of The Script.

Chair Brooks suggested that the board solicit feedback for future topics. He also suggested that the board consider an opportunity for licensees to submit an article to be included in The Script

Ms. Veale asked whether comments can be submitted on the board's website.

Ms. Herold provided that the board's website does allow for submission of comments. She stated that the board can also issue a subscriber alert to solicit comments and suggestions.

Public Comment

Steve Gray, representing Kaiser Permanente, encouraged the board to utilize The Script to educate and reinforce its top priorities to licensees. Specifically, he recommended focus on patient consultation, drug abuse, and improvement to the board's enforcement timeframe.

11. Public Outreach Activities Conducted by the Board

Report

Chair Brooks provided that since late spring, state government has been subject to a travel freeze that restricts all but the most essential travel.

Chair Brooks referenced to the following public and licensee outreach activities performed during the second quarter of fiscal year 2011/12:

- October 24: Supervising Inspector Hunt represented the board at a public fair for seniors convened by Assembly Member Hayashi in San Leandro.
- November 4 and 5: Executive Officer Herold and Supervising Inspector Coyne staffed a board information booth at CSHP's annual meeting Seminar in Orange County.
- November 5: Executive Officer Herold provided a major presented on 2012 Pharmacy Law changes to attendees of CSHP Seminar.
- December 7: President Weisser, Executive Officer Herold and Assistant Executive Officer Sodergren represented the board at a meeting to discuss standardized directions for use and translations of directions for use on prescription container labels, a follow up to the California Endowment's funding of the translated labels.
- December 8: Executive Officer Herold provides a presentation at the Sacramento Valley Society of Health Systems Pharmacists meeting on 2012 changes to California pharmacy law and major current initiatives before the board.

There was no board discussion or public comment.

12. Public Comment for Items Not on the Agenda

No public comment was provided.

Chair Brooks recognized Board President Stan Weisser for his contributions to the board and congratulated him on his recent reappointment to the board.

Chair Brooks commended board staff board staff for their efforts. He also recognized the public and thanked them for their participation.

The meeting was adjourned at 12:05 p.m.