



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: March 27, 2012

LOCATION: Department of Consumer Affairs
Headquarters Building II
1747 N. Market Boulevard, Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Ryan Brooks, Public Member, Chair
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

COMMITTEE MEMBERS

NOT PRESENT: Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Carolyn Klein, Legislation and Regulation Manager
Kim Brown, Public Information Officer
Tessa Miller, Staff Analyst

Call to Order

Chair Ryan Brooks called the meeting to order at 10:06 a.m.

Chair Brooks conducted a roll call. Board Members Rosalyn Hackworth and Deborah Veale were present. Board President Stan Weisser was in attendance in the audience.

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

Report

Chair Brooks 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. He reviewed the following requirement:

4076.5(f)(2): On or before January 1, 2013, the board shall report to the Legislature the status of implementation of the prescription drug label requirements adopted pursuant to this section.

Chair Brooks provided that since January 1, 2012, board inspectors have been directed to pick up sample prescription container labels from every pharmacy they enter to conduct a comparison of actual labels in use with the board's regulation requirements to see if additional changes in the requirements may be needed.

Discussion

The committee reviewed and discussed the sample labels collected by board inspectors.

Chair Brooks expressed concern that some of the directions for use are not clear and suggested that the board release a subscriber alert or include information in the Script to advertise the availability of sample labels and translations of pill directions on the board's Web site.

Ms. Veale provided that it appears industry initially focused on compliance with the font size requirement and now needs to shift its focus to ensure compliance and clarity for directions for use.

Board Member Ramón Castellblanch arrived to the meeting at 10:12 a.m.

Executive Officer Virginia Herold distributed a handout depicting preliminary results of compliance with the patient-centered labeling conducted during inspections through March 17, 2012. A copy of this handout is attached, following this meeting summary. She advised that the data will be revised to accurately reflect updated information and will be shared with the board at a future meeting.

Discussion continued. The committee stressed the need to educate licensees and promote use of clear directions for use.

Dr. Castellblanch recommended that the board focus on outreach. He suggested that the board convene a meeting with statewide representatives for the major chains as well as outreach events for independent pharmacies.

Mr. Brooks suggested that the board develop a guideline template to promote standardized directions for use.

Public Comment

Steve Gray, representing Kaiser Permanente, indicated that several of the example labels do not include a description of the pill as required. He indicated that patients rely on the description of the pill and commented on the CVS label that displays this information appropriately. Dr. Gray also underscored the importance of the patient-consultation and discussed some unintended consequences in this area. Dr. Gray suggested that the board discuss the compliance findings with the California Pharmacy Counsel to heighten the awareness of schools or pharmacy and pharmacy students on these provisions.

Chair Brooks stated that additional outreach may be premature at this time given where the board is in its process. He requested that the revised data include more information about the practice setting (e.g. chain vs. independent) and specify what percentage of each group is not in compliance.

2. Discussion and Possible Action to Finalize the Design of New Notice to Consumers Posters (as Required by 16 California Code of Regulations Section 1707.6)

Discussion

Kim Brown, Public Information Officer, presented a revised design for the new Notice to Consumers poster which incorporates modifications requested by the committee at the January 2012 Committee Meeting.

The committee discussed the revised design and requested the following modifications:

- Orange text to be replaced with red text.
- Text at bottom of poster to be in a larger font size.
- Text regarding interpreter services to be emphasized/bolded.
- Emphasis and relocation of the board's seal to be consistent with all other board publications.
- Emphasis on the following text:
 "California law requires a pharmacist to speak with you every time you get a new prescription."

Dr. Castellblanch expressed concern that there is no emphasis on the availability of interpreter services.

The committee discussed that a separate notice is now required to inform consumers of the availability of interpreter services.

Public Comment

Steve Gray, representing Kaiser Permanente, provided comment in support of emphasizing the language regarding the patient consultation requirement. He cautioned that use of graphics may detract from the text in the poster. Dr. Gray recommended emphasis and inclusion of the following language:

“California law requires a pharmacist to speak with you every time you get a new prescription and to have interpreter services.”

Michael Negrete, representing the California Pharmacists Association, provided comment on the two phrases included in the draft regarding the consultation requirement and encouraging consumers to speak to a pharmacist if they have any questions. He stated that both phrases are important information and should be included on the poster. Dr. Negrete suggested that the state seal or board logo be emphasized to differentiate the notice from drug advertisements posted in pharmacies.

The committee requested that the draft be revised and brought back to the committee for evaluation.

3. Discussion and Possible Action to Finalize the Video Display Format Option for Notice to Consumers (as Required by 16 California Code of Regulations Section 1707.6)

Discussion

Ms. Brown presented a sampled video display of the video display format option for the notice to consumers.

The committee evaluated the video and offered suggested revisions.

Ms. Herold advised that the video is a working draft and still needs to be edited to ensure compliance with the requirements in the regulation.

Mr. Brooks suggested that the board’s logo be incorporated at the bottom of the screen display.

Dr. Castellblanch expressed concern regarding the duration of the video.

Dr. Castellblanch requested that future drafts be displayed to the committee on a video screen that is at least 24 inches, as required by the regulation. He expressed concern regarding the amount of language required to be on the video and suggested that this be reconsidered at a future meeting.

Ms. Herold advised that the board can address the language as part of the report to the legislature on the implementation of the regulation in January 2013.

Public Comment

Michael Negrete, representing the California Pharmacists Association, suggested that each pharmacy can include a sample of its label within the video.

Steve Gray, representing Kaiser Permanente, discussed that the video can also incorporate audio to add interest and to better attract and engage patients while they wait for their prescription.

4. Discussion and Possible Action to Finalize the Format for Notice of Interpreter Availability (as Required by 16 California Code of Regulations Section 1707.6)

Report

Chair Brooks provided that the board has developed the notice of availability of a free interpreter in the pharmacy in both printed and video formats. He reviewed the following section:

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.

Discussion

The committee reviewed a sample draft notice. A copy of the draft is attached, following this meeting summary.

Ms. Veale requested that the text be enlarged to at least a 12-point font.

Dr. Castellblanch suggested that the notice include language indicating that consumers “have the right to interpreter services at no cost.”

The committee requested that the board’s logo and contact information be included in the notice.

Ms. Herold suggested removal of the finger graphic and the name of the language in each specific language and to only include the language name in English as a vertical title in each box to save space and reduce the amount of text.

The committee requested that a revised notice be brought to the committee at a future meeting for consideration.

No public comment was provided.

5. Discussion on Pharmacy Compliance with Interpreter Availability and Patient-Centered Labeling Requirements

Ms. Herold provided that since January 1, 2012, board inspectors have been asking how every pharmacy they inspect complies with the interpreter requirements. She provided an overview of the survey results and indicated that full compliance with the interpreter requirements has not yet been achieved.

There was no committee discussion or public comment.

6. Discussion on Securing Consumer Comments on the Board’s Regulation Requirements for Patient-Centered Labels and Translations for Limited English Speaking Individuals

Report

Chair Brooks provided that consumer comments will be an important part of the board’s review of the patient-centered labeling and interpreter requirements. He stated that the committee will be holding meetings on the following dates to secure public participation:

- May 10, 2012
- August 29, 2012
- November 7, 2012

Discussion

The committee discussed possible meeting location for these dates.

Chair Brooks offered to secure a location in the San Francisco area.

Meetings will also be held in Orange County and San Diego. Confirmed meeting locations and dates will be posted on the board's Web site.

The committee discussed the survey and encouraged that it be designed to solicit feedback on the new label rather than conduct a comparison of previous labels.

Legislation and Regulation Manager Carolyn Klein suggested that the board survey people in a sample of chain and independent pharmacies to solicit feedback as consumers pickup their prescriptions.

The committee spoke in support of the suggestion to survey in pharmacies.

Ms. Herold also indicated that the board staff will survey nonresident pharmacies for compliance in this area.

Public Comment

Michael Negrete, representing the California Pharmacists Association, suggested that the board solicit help from other pharmacy organizations and pharmacy students to assist with the survey.

Steve Gray, representing Kaiser, recommended that the board conduct the survey at county fairs and ask surveyors if they have noticed that their label has changed.

Dr. Negrete indicated that he has received feedback from consumers indicating that they have noticed a change in their labels.

Chair Brooks spoke in support of the in person surveys and stressed that the instructions provided to the surveyors must be very specific.

Ms. Herold provided that staff will try some pilot tests before the May 2012 Board Meeting.

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

Report

Chair Brooks advised that the assessment of the board's public education materials is still in development.

No public comment was provided.

8. Update on The Script

Report

Chair Brooks provided that the March 2012 issue of The Script has been released and is available on the board's Web site.

Chair Brooks provided that work on the next issue has begun and will focus on application of board laws and activities.

Chair Brooks requested that the next issue include additional examples of patient-centered prescription labels.

There was no committee discussion or public comment.

9. Public Outreach Activities Conducted by the Board

Report

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

- January 18 – presentation on the board's enforcement program's components and new pharmacy laws for 2012 to 80 pharmacists at the Sacramento Valley Pharmacists Association Meeting.
- February 3 and 4 – board staffs an information booth about the board's program at the annual California Pharmacists Association Meeting in Sacramento.
- February 3 – Assistant Executive Officer Sodergren provides a presentation about the board at a consumer focus meeting at the California Pharmacists Association Meeting in Sacramento.
- February 4 – Board President Weisser and EO Herold provide a presentation on the board's enforcement program at the California Pharmacists Association Meeting in Sacramento; this presentation had the largest attendance of any at the conference (179).
- February 6 – SI Nurse does a presentation at Loma Linda University on the requirements of being a PIC and how to prevent drug diversion to students and faculty.
- February 9 – EO Herold attends the NDPDP Technology Meeting in San Diego, the standards setting group for electronic data transmissions in pharmacy to describe the requirements of California's e-pedigree requirements.
- February 10 – EO Herold and AEO Sodergren provide a presentation to 15 members of a Chinese delegation visiting the US on California pharmacy law.
- March 13 – EO Herold provides a presentation to 200 pharmacy students at Touro University on the board's enforcement program and accessing board services.
- March 21 – Inspector Toevs provides a presentation to Western University School of Pharmacy students on duties of a PIC, pharmacy law and the functions of the board.

There was no committee discussion or public comment.

10. Public Comment for Items Not on the Agenda

Dr. Castellblanch requested that the report to the legislature regarding the implementation of the regulation for patient-centered prescription labels be added as an agenda item for a future meeting.

Michael Negrete, representing the California Pharmacists Association, requested that the board consider a few issues on patient-consultation surrounding the use of nonresident pharmacies and the role of pharmacists in medication monitoring.

Steve Gray, representing Kaiser Permanente, requested that the board discuss the obligations of pharmacies to share medication information when a patient is receiving care in a hospital.

The meeting was adjourned at 12:09 p.m.

Patient-Centered Labeling Inspections through March 17, 2012

Number of Inspections	266
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Patient-Centered Label (B&P 4076[a] & CCR 1707.5[a][1][A] - [D])

# in Compliance	226
# NOT in Compliance	27
# 10-point font only	23
# 12-point font only	122
# 10-point & 12-point	41
# of corrections issued	25

Interpretive Services (CCR 1707.5[d])

# in Compliance	176
# NOT in Compliance	74
<i>If in compliance:</i>	0
# prov. by staff	34
# prov. by telephone	56
# prov. by staff & teleph	120
# prov. by other means	3
# corrections issued	65

Point to your language

Interpreter services will be provided at no cost

<p>ARABIC العربية </p> <p>اختر لغتك.</p> <p>يتم تقديم خدمات الترجمة الفورية لك عند الطلب دون أي تكلفة.</p>	<p>ARMENIAN հայերեն </p> <p>Նշեք ձեր լեզուն:</p> <p>Թարգմանչի ծառայություններն անվճար կտրամադրվեն ձեզ ըստ պահանջի:</p>
<p>CAMBODIAN</p>	<p>CANTONESE 廣東話 </p> <p>指向您的語言</p> <p>將根據您的要求免費為您提供翻譯服務。</p>
<p>FARSI</p> <p>زبان خود را مشخص کنید.</p> <p>خدمات ترجمه شفاهی بر حسب درخواست شما به صورت رایگان فراهم خواهد شد.</p>	<p>HMONG HMOOB </p> <p>Taw rau koj yam lus</p> <p>Kev pab cuam neeg txhais lus yuav muaj pub rau koj raws li kev thov yam tsis yuav nqi</p>
<p>KOREAN 한국어 </p> <p>언어를 지정해 주십시오.</p> <p>요청 시 통역 서비스를 무료로 제공해 드립니다.</p>	<p>MANDARIN 普通话 </p> <p>指向您的語言。</p> <p>將根據您的要求免費為您提供翻譯服務。</p>
<p>RUSSIAN Русский </p> <p>Указать на ваш язык.</p> <p>Услуги переводчика будут бесплатно предоставлены Вам по требованию.</p>	<p>SPANISH ESPAÑOL </p> <p>Indique su idioma.</p> <p>Se le proporcionaran servicios de interprete sin costo si lo solicita.</p>
<p>TAGALOG TAGALOG </p> <p>Ituro ang iyong wika.</p> <p>Ang serbisyo ng interpreter ay ibibigay sa iyo kapag hihilingin nang walang bayad.</p>	<p>VIETNAMESE tiếng Việt </p> <p>Xin hãy chỉ vào ngôn ngữ của quý vị.</p> <p>Dịch vụ thông dịch sẽ được cung cấp cho quý vị miễn phí theo yêu cầu</p>