



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
PUBLIC EDUCATION AND COMMUNICATION COMMITTEE
MINUTES**

DATE: January 6, 2014

LOCATION: DCA Headquarters
1625 N Market Blvd – Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Ryan Brooks, Chair
Lavanza Butler, PharmD
Ramon Castellblanch, PhD
Shirley Wheat
Albert Wong, PharmD

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Michael Santiago, DCA Staff Counsel
Carolyn Klein, Manager II
Joyia Emard, Public Information Officer
Laura Hendricks, Administrative Analyst

The meeting was called to order at 9:38 a.m. Ryan Brooks, chair, welcomed those in attendance. Roll call was taken and a quorum was established. Chair Brooks said that he would be taking agenda items out of order.

6. Update on *The Script*

Mr. Brooks stated that work has begun on the next issue of *The Script*, which will focus on new laws that became effective in 2014. He said the board anticipates issuing the newsletter in February and the board has updated the website with summaries of new laws that became effective on January 1.

8. Public Outreach Activities Conducted by the Board

Executive Officer Virginia Herold provided an update on public outreach activities conducted by board staff in the past quarter, and referenced a handout that listed the activities. Ms. Herold stated e-Pedigree California was preempted by federal legislation on November 27, 2013. Ms. Herold said she has conducted or participated in several webinars on this topic during the past quarter. Ms. Herold stated that public outreach related to compounding is increasing and she reminded the committee that

on January 10 the Enforcement and Compounding Committee will meet. Chair Brooks commented on the upcoming continuing education training opportunities that will be provided by the board and the Drug Enforcement Administration, which will feature a component on a pharmacist's corresponding responsibility. He said that the January 22 session will be held in Brea and the January 31 session will be held in Sacramento. Chair Brooks encouraged all committee members to attend one of the sessions. Ms. Herold added that the continuing education is free, but pre-registration is required.

Dr. Castellblanch arrived at the meeting at 9:43 a.m.

5. Update on the Committee's Goals for 2012-2017 to Fulfill the Board's Strategic Plan

Chair Brooks commented on the committee's goals for the 2012-2017 Strategic Plan and development. Ms. Herold suggested that the committee make a strong commitment to complete *The Script* at least two times a year. She introduced the board's new public information officer, Joyia Emard, who is the new editor of the board's newsletter. Ms. Herold recommended that the activities of the new Prescription Drug Abuse Subcommittee be incorporated into the board's strategic plan.

1. Discussion and Action on Requests from California Pharmacies for Exemption from Title 16 California Code of Regulations Section 1707.6

a. "Notice of Interpreter Availability" Poster (16 Cal.Code Reg § 1707.6(e)) Walmart Request To Use an Alternate Format in all Walmart and Sam's Club Pharmacies

Background

Chair Brooks reminded the committee that the board delegated to the Public Education and Communication Committee the authority to take action on all requests for an alternate format or display methodology of the "Notice of Interpreter Availability" and "Notice to Consumers" posters.

Discussion and Comment

Chair Brooks opened the discussion to address Walmart's request to use an alternate format of the "Notice of Interpreter Availability" poster. He added that in October 2013, the committee denied Walmart's request because specific language that is required by regulation was not on the notices. At that time, the committee requested that any request to use an alternate format of the poster also include a notation that the notice is required by the Board of Pharmacy to be posted. Mr. Brooks referred to the copies of the Walmart and Sam's Club notices of interpreter availability that were provided in the meeting materials. The notices contained the required regulatory language, as well as the verbiage in the 12 specific languages referenced in the board's regulation. In addition, each notice contained a footer that the notice was required to be posted by the California State Board of Pharmacy. Mr. Brooks noted that Walmart is requesting approval to use the alternate format poster in all Walmart and Sam's Club pharmacies currently licensed by the board, as well as in those that may be licensed by the board in the future.

Dr. Castellblanch sought staff's comment on the enforcement of the poster. Ms. Herold stated that when inspectors conduct inspections, they look to see if the posters are displayed according to the regulation.

Carrie Sanders, from the California Pan-Ethnic Health Network, spoke in support of the request, in that the posters submitted by Walmart contain all the languages required by regulation. She spoke in support of pharmacies that may also provide additional languages for consumers. Ms. Sanders encouraged the board to be vigilant in its enforcement of the requirement to display the notices as required.

Motion: Approve Walmart’s request to use the alternate format of the “Notice of Interpreter Availability” in all Walmart and Sam’s Club pharmacies, as presented at the meeting, so long as these notices are printed on 8 ½ x 11” paper.

M/S: Brooks/Wheat

Support: 5 Oppose: 0 Abstain: 0

**b. “Notice to Consumers” Poster (16 Cal.Code Reg § 1707.6(a))
Safeway Request for Approval To Use an Alternate Display Methodology**

Background and Discussion

Chair Brooks reminded the committee that the board delegated to the Public Education and Communication Committee the authority to take action on all requests for an alternate format or display methodology of the “Notice of Interpreter Availability” and “Notice to Consumers” posters.

Mr. Brooks provided an overview of the Safeway request to use an alternate display methodology of the board’s “Notice to Consumers” poster, and referenced the request and information provide in the committee materials. Mr. Brooks recognized Dr. James McCabe from Safeway.

Dr. McCabe provided an overview of how Safeway intends to display the poster on a vertically-mounted video display screen and referenced the images contained in the meeting materials. Dr. McCabe clarified that as required by the regulation, the poster will be displayed for no less than 60 seconds at a time, and that no more than five minutes will elapse before the poster is again displayed. He added that Safeway may rotate in other non-English versions of the poster (those available on the board’s website). Dr. McCabe said displaying non-English versions of the board’s “Notice to Consumers” poster is a solution that reaches out to communities and allows them to read the poster in their language – providing them with an opportunity they may have not had before. Dr. McCabe said that Safeway may also use the video screen to display the board’s “Notice of Interpreter Availability” poster, but that paper copies of this notice would be available to consumers at the pharmacy counter at all times. He assured the committee that the video screens will not be used for advertisements, but will be used for pharmacy-related and public health information.

Ms. Wheat sought clarification of the request, and asked if the video screen meets the requirements of the regulation: 24” measured diagonally; that the notice will remain on the screen for a minimum of 60 seconds: and that no more than five minutes will elapse from the time the notice is displayed to the time it re-displays (if rotated off the screen).

Mr. McCabe confirmed this is the case. She spoke in support of Safeway’s stated intent to also rotate on the screen the Spanish or other non-English versions of the poster (based on Safeway’s demographics).

Dr. Wong stated it would be nice if the pharmacy could display the video as well as post the hard copy of the poster. Chair Brooks noted that the regulation allows for alternatives.

Ms. Sodergren noted that Safeway has represented in the request that the video mount will be at the pharmacy counter.

Dr. Castellblanch said he would still like to know what the font size on the screen.

Chair Brooks and Ms. Wheat spoke in support of the request, indicating it is consistent with the intent of the board's regulation.

Dr. Castellblanch expressed concern as to the size the poster would be on the video display, adding that the font size on the poster would be so small and may be difficult for people to read.

Dr. Butler expressed her agreement with Dr. Castellblanch's comments. She also expressed concern that while the "Notice to Consumers" poster is rotated off the screen, consumers would not have access to the information. She asked if Safeway intends to also have the paper version of the poster mounted in the pharmacy.

Dr. McCabe stated that Safeway wishes to use the video display screen to display the required poster, but Safeway, Von's and Pavillions pharmacies would always have the Notice to Consumers posters available to the public.

Chair Brooks and Ms. Wheat spoke in support of the request in that the board's actual poster will be displayed

Dr. McCabe addressed the committee and explained that the video screen will be mounted vertically at the pharmacy drop-off window. He said it will be mounted in a manner that a consumer can touch it. He said that the English version of the poster will rotate in five minute intervals, and that any other language version would be rotated within that five minutes. Dr. McCabe said the pharmacy may use the video screen to also display a video version of the "Point To Your Language" poster and other pharmacy-related information, but in all cases the English poster would re-start at every five minutes.

Dr. McCabe expressed concern with the board's current regulation that already allows the pharmacy to display an alternate format of the Notice to Consumers poster (without further board approval), in that the PowerPoint slide deck available for this purpose contains ten slides. He said it is not possible to display each slide for a minimum of 60 seconds, and also ensure the PowerPoint slides re-start (at the beginning) every five minutes.

Dr. Wong spoke in support of the request, where the notice would be available on the video screen and also in hard copy.

Ms. Sanders from CPEHN spoke in support of the innovation to display the Notice to Consumers poster on the video screen, and sought clarification regarding a consumer's access to the "Notice of Interpreter Availability" poster.

Chair Brooks directed the committee to the regulation at Section 1707.5(c) that allows a pharmacy to post the Notice of Interpreter Availability on a video screen so long as a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance.

Ms. Herold noted that the video screen is not interactive.

Mr. McCabe assured the committee that hard copies of the “Notice of Interpreter Availability” would be available in the pharmacy at all times.

Motion: Approve Safeway’s request to use the alternate display methodology of the board’s “Notice to Consumers” poster as presented at the meeting, so long as a hard copy of the language poster is maintained on the premises and made available to consumers.

Support: 4 Oppose: 1 (*Castellblanch*) Abstain: 0

2. Update on the Status of the Update Emergency Contraception Fact Sheet, as Required by 16 California Code of Regulations Section 1746

Ms. Herold advised the committee that the board utilized the interpreter services used by the Department of Consumer Affairs to have the board’s Emergency Contraception Fact Sheet translated into six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. Ms. Klein said the translations have been finalized and the fact sheets are now available on the board’s website.

3. Review and Discussion of a Research Project on Prescription Container Labels

Dr. Anandi V. Law, professor and chair of Pharmacy Practice and Administration of the College of Pharmacy, Western University of Health Sciences, presented the committee with findings of her research published in March 2011 related to the design of patient-centered prescription labels. A copy of the PowerPoint presentation is appended to these minutes.

Dr. Anandi answered questions related to the scope of the study and numbers of participants. Dr. Wong asked if more than one language was used in the study. Dr. Anandi stated that only English was used in the study.

Ms. Wheat commented that from a pharmacy perspective, if the label were printed in a translated language, the pharmacist is liable for the information on the label, whether or not they can read the non-English language, so that is a concern of hers. She added that she does like the format of the patient-centered labels that were used in the study.

Chair Brooks stated he liked how the warning labels were displayed.

Dr. Castellblanch asked if she had an opinion on the translations developed by Dr. Wolf. Dr. Anandi said that they used translations used in the market. Ms. Herold indicated that the translations developed by Dr. Wolf, which were vetted, are available on the board’s website.

Dr. Castellblanch commented on Spanish translations of easy directions. He complimented Dr. Anandi on the study related to the impact of people not being able to read their labels, and also with respect to a 50 percent increase in comprehension where the control groups also received educational intervention. Dr. Anandi said they are looking at cost impacts of these translations. She said while badly designed labels result in negative outcomes, they still do not have positive evidence that good labels produce good outcomes.

Dr. Wong commented on the use of numerals on the study group labels, in that replacing a word “two” with a number “2” may save space on the label.

Dr. Butler said she liked the format of the labels used in the study. She said it was very thorough and easy to identify the times when the patient should take his or her medicine.

4. Assessment of California’s Patient-Centered Labeling Requirements as Required by 16 California Code of Regulations Section 1707.5(e)

Background and Discussion

Chair Brooks summarized prior actions taken as part of the review of patient-centered labels.

Ms. Herold provided a re-cap in that the board voted on two proposed amendments to the patient-centered label requirements that were vetted by the committee previously. She said the board reviewed the requirements of Section 1707.5 subdivision by subdivision, and that the following proposed amendments were approved by the board, as follows:

Board Approved Change 1:

1707.5. (a)(1) Each of the following items, **and only these four items**, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 10-point sans serif typeface or, if requested by the consumer, at least a 12-point typeface, and listed in the following order:

- A. Name of the patient
- B. Name of the drug and strength of the drug. For the purposes of this section, name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.
- C. The directions for use
- D. The condition or purpose, if it is indicated on the prescription.

Board Approved Change 2:

1707.5.(a)(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in ~~at least a 10-point sans serif typeface or, if requested by the consumer,~~ at least a 12-point **sans serif** typeface, and listed in the following order:

- A. Name of the patient

- B. Name of the drug and strength of the drug. For the purposes of this section, name of the drug” means either the manufacturer’s trade name of the drug, or the generic name and the name of the manufacturer.
- C. The directions for use
- D. The condition or purpose, if it is indicated on the prescription.

a. Should 1707.5(a)(B) be modified?

Ms. Herold said the board sent the remainder of the discussion back to the committee to have a more deliberative discussion on the remainder of the requirements.

Dr. Castellblanch agreed with Ms. Herold.

Ms. Wheat expressed concern that the committee was trying to revisit items that are not a problem.

Ms. Herold said the board did not come to a consensus on the issue of requiring the name of the manufacturer within the required patient-centered elements. The other issue was that of requiring the use of the phrase “generic for...” when a generic is being dispensed for a trade name drug.

Chair Brooks directed the committee to discuss a prior committee recommendation to modify Section 1707.5(a)(1)(B) to remove the requirement that the manufacturer’s name be listed in the patient-centered clustered area of the label when a generic is dispensed.

Brian Warren, with the California Pharmacists Association, sought clarification if, based on the foregoing, the patient-centered items would all be in 12-point font, and that only the four items listed in Section 1707.5(a)(1) could be in the patient-centered portion of a prescription label.

Ms. Herold and Dr. Castellblanch confirmed Mr. Warren’s understanding. Mr. Warren expressed concern over having a lot of information that is required to be in the patient-centered portion of the label, all in 12 point font.

A member of the public asked about the use of a generic that has been on the market for a very long time and where no one may even remember the trade name.

Dr. Wong spoke in support of a requirement that where a trade name is prescribed, the words “generic for” be on the label.

Dr. Butler said when the physician writes for the generic, the name of the manufacturer of the generic will still be on the label somewhere.

Dr. Anandi asked what are you going to do when the name brand is no longer available?

Chair Brooks suggested he would like the full board to have a discussion on this.

Dr. Castellblanch said that the full board just kicked it back to the committee. Dr. Castellblanch asked if staff could advise how other states handle this and what the policy considerations may be.

b. Should Purpose or Condition be in the patient-centered clustered items? Should it be a requirement for labels generally?

Ms. Herold said that the Medical Board of California has been supportive of having the purpose or condition on the prescription label.

Dr. Wong stated the problem is that the prescribers are not required to put the condition or purpose on the prescription document.

Dr. Butler reiterated that it is within a pharmacist's scope of practice to put the purpose or condition on the label if needed.

Dr. Wong said he runs into problems when a drug can be used for multiple purposes and you aren't sure for which purpose they are using the drug.

Dr. Anandi said that her research shows that patients want the condition or purpose on the label, but that patients are concerned about privacy – that they do not want a diagnosis on a prescription label. She suggested an approach where the condition or purpose is on the label unless specifically omitted by the physician. She spoke in support of more generic descriptions of why medications are used.

Ms. Herold suggested that to require a physician to put the condition or purpose on the prescription label may require a statutory change.

Jonathan Nelson, from the California Society of Health-System Pharmacists (CSHP), said that CSHP has long supported the right of a pharmacist to include the condition or purpose on a prescription label based on his or her professional judgment.

Mr. Brooks questioned how a pharmacist might know, with all certainty, the condition or purpose for which the drug was being dispensed.

Mr. Nelson stated that the pharmacist could contact the prescriber if need be.

DCA Counsel Michael Santiago indicated that a statutory change would then be a requirement to have it on the label across the board.

Mr. Brooks questioned the board's ability to make this a requirement, and he also expressed concern over privacy concerns.

Dr. Castellblanch said that he would like to hear from the Medical Board of California before moving forward on this.

Ms. Herold said she understands that the California Senior Legislature may be pursuing this type of legislation again this year because they want the condition or purpose on the label. Ms. Herold said that the NABP, USP and others support having the purpose or condition on the label.

Dr. Butler stated pharmacists know what different types of medication are used for, such as "for infection."

Chair Brooks recommended and there was committee consensus to table this discussion for the next committee meeting.

c. Should the existing requirements for “added emphasis” in the patient-centered area of the prescription label be modified?

There was no committee or public discussion on this item.

d. Translations on Labels -- Translated directions for use are available on the board’s website. Should the board require use of them to aid patients with limited or no English proficiency understand the information on the prescription label? Should there be additional requirements?

Ms. Herold asked the committee to consider various questions related to the use of translated directions for use on prescription labels. Ms. Herold said that most pharmacies are using translated labels, but staff does not believe certified translators are being used.

Ms. Herold said she believes few are using the posted “directions for use” that are available on the board’s web site, and asked if the committee felt these should be required to be used.

Ms. Wheat spoke in support of having English be the main and most prominent language on the label.

Chair Brooks sought legal counsel’s direction as to whether the board has the authority to require that translations be used and Mr. Santiago confirmed that the board does have this authority.

Ms. Herold said the board needs to consider if a translated label is in the patient’s best interest and securable in the pharmacy. She noted that the board did not take a position on Senate Bill 204 (Corbett), which would require translations of the directions for use on a prescription label.

Dr. Castellblanch spoke in support of the board’s efforts to ensure that translations are used on prescription labels. He believes the directions for use should be in a language that the individual can understand and thinks the board should advocate such a statutory change.

Chair Brooks would like staff to gather information on what types of translations are provided in pharmacies. He would like to see the board seek input from pharmacies, software manufacturers, first responders and others to gather information and to even determine if this is an issue.

Ms. Wheat stated she would like to know how the current translations are working before changing the requirements.

Public Comment

Carrie Sanders, CPHEN, thanked the committee for its work. She said asking the board if they support translated labels has been asked and answered. She said the landscape of patients are changing and that with the passage of health care legislation, many more will now be able to get health coverage. Ms. Sanders said that the USP recommends the use of translations for medical purposes only. She referenced the board’s survey results and urged the committee and the board to ensure that translations are quality translations. She advocated that the translated directions for use on the board’s website were

professionally vetted. She encouraged the board to conduct follow-up surveys and partner with researchers to identify best practices to frame requirements for pharmacies. Ms. Sanders offered to provide the committee with information. She said physicians have indicated to CPHEN that even when they request a pharmacy give a patient a translated label, that the requests are not always honored. Ms. Sanders said USP states that the name of the drug shall be in English.

Ms. Anandi recommended that the board determine to what extent the translations on the board's website are being used. She expressed concern that when translated directions are used, they need to be quality translations. She asked if the board has considered the use of pictograms and other visual indicators.

Dr. Castellblanch referenced research (Shrank) used in the promulgation of the regulation and said the research indicated that pictograms were not significantly helpful.

A member of the public said the board should take steps to ensure the best needs of communities and patients are met. He said the committee has to have the discussion, take action and move forward.

Chair Brooks said this item will be more be fully discussed at the next meeting.

h. Should the board consider technology standards to enhance the patient-centered requirements?

Ms. Herold commented that many pharmacies have pictures of the pill on the prescription label. She asked the committee if they were interested in discussing any technology standards or requiring items like a picture of the pill on the label.

Mr. Brooks said he would like to see empirical data on this topic.

Dr. Castellblanch agreed with Chair Books and wanted to ensure that the technology is available for all pharmacies before making additional requirements in this area.

Mr. Brooks asked staff to provide the committee with information on visual cues and technology considerations for a future discussion.

9. Public Comment for Items Not on the Agenda

There was no public comment.

Mr. Brooks said he would like to receive information on the percentage of patients for which interpretive services are requested.

Ms. Herold said this information may be available from some of the associations.

Chair Brooks adjourned the meeting at 12:21 p.m.