



Communication and Public Education Committee Minutes

Date: Monday, October 7, 2013
Location: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

Committee Members Present:

Stan Weisser, Professional Member (Chairing)
Cheryl Butler, Professional Member
Ramon Castellblanch, Public Member
Albert Wong, Professional Member

Committee Members Absent:

Ryan Brooks, Public Member (Chair)
Rosalyn Hackworth, Public Member
Shirley Wheat, Public Member

Staff Present:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Shellans, DCA Sr. Staff Counsel
Carolyn Klein, Manager
Laura Hendricks, Administrative Analyst

Stan Weisser, President of the Board, appointed himself to serve as Chair of the meeting for this date. He called the meeting to order at 12:33 p.m. and conducted a roll call of the members.

1. Review and Discussion of the 42nd Annual Report of the Research Advisory Panel of California

The Research Advisory Panel of California was established to oversee research involving use of controlled substances. Section 11213 provides that:

Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purposes of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled

substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Patrick R. Finley, Pharm.D., is the board's appointment to the seven member advisory panel. Mr. Weisser referenced the copy of the 42nd Annual Report of the Research Advisory Panel of California (July, 2012) provided with the meeting materials. He recommended that Dr. Finley come to a future meeting of the committee or board to tell them more about the Advisory Panel's activities and to share additional information on studies that may be of interest to the board or related to the pharmacy profession.

2. Discussion and Action on Requests from California Pharmacies for Exemption from 16 California Code of Regulations Section 1707.6(e) to Use Their Own Notice of Interpreter Availability Posters

Existing Board regulations require pharmacies to prominently post the "Notice to Consumers" required by 16 CCR section 1707.6. In addition, section 1707.6(c) requires every pharmacy to post or provide a "point to your language" notice so that consumers are aware that interpreter services will be provided to them at no cost. That subdivision specifies that the pharmacy shall use the standardized notice provided by the Board unless the pharmacy has received prior approval of another format or display methodology. The board has delegated to the Communication and Public Education Committee the authority to act on all requests to use another format or display methodology of these posters.

The committee discussed two requests from pharmacies to use their own Notices of Interpreter Availability. Sr. Staff Counsel Kristy Shellans advised the committee that neither request met the requirements of the regulation – in that neither contained the language required by subdivision (c) of section 1707.5: "Point to your language. Interpreter services will be provided to you upon request at no cost." Ms. Shellans noted that without the required language, she believes the committee does not have the authority to approve the notices. She reminded the committee that the board authorized the committee to approve alternate *formats* of the notice, but that each would need to meet the requirements of the regulation.

Dr. Albert Wong expressed concern over different posters, in that consumers may not be able to recognize it as a board-required notice if they were different. He approached the idea of having a company place their company's banner on the board-approved poster so that they would be consistent. Dr. Ramon Castellblanch stated that he looks for a state seal on any notice to determine if it is a mandated notice. Ms. Herold stated that the regulation requires the notice to be within easy reach of the consumer at the pharmacy counter. She stated that requesters would know what languages are needed in their settings, thus, adding languages (to the 12 required by the regulation) ultimately serves the consumer. She said a regulation change would be required if the board determined that only the board's notice, customized with an entity's banner, should be required.

Mr. Weisser asked counsel if adding a company's name to the board-approved poster is a deviation from the regulation. Ms. Shellans stated it was not a deviation; that the committee would just need to approve such a change.

Dr. Castellblanch asked if the board should require that the board logo be required to be on any notice posted pursuant to the regulation. Counsel stated that the current requirements do not require the board's logo on such a notice.

Counsel referenced a draft request form provided in the meeting materials. She stated she would like to see the form reference the required text that shall be on each notice.

Motion/Second (Castellblanch/Wong):

Do not approve the alternate formats presented by Walmart and Costco because the required language "Point to your language. Interpreter services will be provided to you upon request at no cost" is not on each of the alternate formats. In addition, the committee would like to see any alternate format notice submitted for the committee's approval to include the statement "This notice is required to be posted by the California Board of Pharmacy."

Public Comment: There was no public comment.

Support: 4 Oppose: 0 Abstain: 0

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

Mr. Weisser referred to the updated Emergency Contraception Fact Sheet provided in the meeting materials, adding that the board is currently securing bids to have the Fact Sheet reproduced in six languages: Chinese, Korean, Russian, Spanish, Tagalog and Vietnamese. These are the same six languages in which the board makes available its "Notice to Consumers" posters (upon request, or download). When available, the fact sheets will be available upon request, and will also be available for download from the board's web site.

There was no further committee or public comment on this matter.

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

Title 16 CCR section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, it included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code section 4076.5.

The committee reviewed the factors considered when developing the current regulatory requirements, as well as the board's efforts to date to review the patient-centered requirements, which was initiated by the committee in April 2013. The committee discussed

the USP guidelines published in November 2012, noting the close resemblance to the board's requirements. Ms. Herold indicated that staff continues to search for medical literacy research regarding standardized directions for use, noting the goal of such standardized directions is to increase patient understanding, adherence to medication instructions and improving health outcomes. She stated she has been trying to build support among groups by highlighting the benefits of utilizing standardized directions for use, and that there may be educational opportunities to work with the prescribing boards to this end. One of the recommendations in the NCPDP White Paper is to implement the use of universal medication instructions in an effort to help get the e-prescribing directions for use standardized. In its surveys, the board has looked at the use of font sizes, how interpretive services requirements are being implemented, patient satisfaction (a general framework of what patients are thinking) – noting they want larger font, and the purpose on the label. Mr. Weisser discussed the distribution of these surveys, noting that the board had the survey translated and CPEHN had it distributed among limited English and other groups. Dr. Wong indicated the survey was available in Chinese in his pharmacy. Ms. Herold provided the results of a recent survey conducted by the board on translations, the results of which will be appended to the minutes of the meeting.

Should the board modify what is considered “patient-centered”?

Regulations currently require that “patient-centered” items be clustered into one area of the label that comprises at least 50 percent of the label:

1. Name of the patient
2. Name of the drug and strength of the drug
3. The directions for use
4. The condition or purpose, if it is indicated on the prescription.

Ms. Herold noted that in addition to these required elements, some pharmacies include additional information within the 50% clustered area, such as the patient's address, expiration dates of drugs, or other information. She asked the committee to clarify exactly what they intend be included within the patient-centered clustered area. Dr. Castellblanch spoke in support of having “only the four items” (specified at Section 1707.5(a)(1)(A)-(D)) – and nothing else – within the clustered area.

Motion/Second (Castellblanch/Butler): Recommend that Section 1707.5(a)(1) be modified to read as follows to indicate the prominence of the patient-centered clustered items:

- (1) Each of the following items, and only those 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:

There was no public comment.

Support: 4 Oppose: 0 Abstain: 0

Does the committee wish to discuss any changes to the requirement that the “name of the patient” be in the patient-centered cluster portion of the label?

There was no committee or public discussion for changing this requirement.

Should changes be made to 1707.5(a)(1)(B) regarding the “name of the drug and strength of the drug”? Is it worthwhile to list the name of the manufacturer in the patient-centered portion of the label?

Current regulations at section 1707.5(a)(1)(B) specify that the name of the drug and strength of the drug be in the patient-centered portion of the label and that “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.” The committee discussed the value of having the manufacturer’s name as one of the patient-centered elements. Dr. Wong stated his support of having the manufacturer’s name on the label, but not necessarily within the patient-centered elements.

Ms. Herold noted recommendations provided in the research:

- USP suggests that the drug name be spelled out fully (brand AND the generic name) – no abbreviations.
- NABP suggests inclusion of suffixes (CD, SR, XL, XR, etc.)

It was the consensus of the committee that having both the trade/brand name and the generic name fully spelled out was needed. In addition, there was consensus that the suffixes referenced in the NABP recommendation were part of the drug name and should be used.

- NABP suggests that if a prescription is written for a brand name and a generic drug is dispensed then “generic for [brand name]” appear on the label.

Ms. Herold clarified it is required that the manufacturer’s name be on a prescription label, and that the committee is considering whether or not it should be within the patient-centered cluster or not.

Public Comment

Dr. Steve Gray speaking for CSHP and as an individual/pharmacist noted that CSHP and CHA had a joint task force on “transitions for care” which addressed medication reconciliation. The task force noted too high a percentage of confusion among patients and their care givers regarding the names of drugs. He provided examples where brand names were prescribed and where generic substitutions were made (and communicated to the patient). He provided an example of a verbal consult where a patient is told that hydrochlorothiazide is substituted for Hydrodiuril, and the patient goes home with a prescription label that indicates hydrochlorothiazide. When the patient gets home, they also have a vial of Hydrodiuril (previous Rx) and they take both and have an adverse event – because they didn’t know they should have taken only one of those. He supported the use of “Generic for…” on the label so that the patient or care giver would not be confused as to what medication should be taken. He said *something* needs to change, and that the board may want to look into this further by having others address the board. He also spoke in support of prescription labels that are formatted the same, using a “check book” example (where specific items are always found in the same place no matter the bank).

With regard to directions for use, Dr. Gray provided that the name and *strength of the drug* is important to emergency personnel.

It was the consensus of the committee that the “suffixes” referenced in the research are a part of the drug name and should be on the label.

The committee discussed the use of generic drug names (when a generic is substituted for a trade name drug, or when a generic is prescribed) and reached consensus that when a generic is dispensed for a trade name drug that the label specify “Generic for *(trade name)*.” Dr. Wong conveyed the importance of having the manufacturer’s name, because that information was important to persons who might have drug allergies to a particular generic.

Motion/Second (Wong/Castellblanch): Modify section 1707.5(a)(1)(B) to remove the requirement that the manufacturer be in the “patient-centered” clustered items (knowing the manufacturer name will be elsewhere on the label); and amend the language where a generic is dispensed to say “generic for” (the trade name). Staff will work with counsel to bring back languages that would accomplish this recommendation.

There was no additional public comment on this item.

Support: 4 Oppose: 0 Abstain: 0

Should Purpose or Condition be in the patient-centered clustered items?

There was wide consensus that the purpose or condition should be on the prescription label within the clustered patient-centered items. Staff counsel commented that a statutory change may be needed, as Section 4076 states it is required to be on the label only if it is specified on the prescription.

Public Comment

Dr. Gray stated that a pharmacist may indicate the purpose or condition on the label if the patient requests it. He suggested a modification to the regulation that would clarify that a pharmacist can use professional judgment as to whether or not the purpose or condition should be on the label. With regard to patient consultation, a pharmacist needs to know what the drug is being used for in order to provide a full consultation, so the pharmacist has to figure that out somehow. Ms. Anne Sodergren, AEO, sought the committee’s input on suggesting a statutory amendment, and noted challenges in previous years when trying to make a statutory change to require the purpose or condition on the prescription label. Jonathan Nelson, CSHP, spoke in support of having the purpose or condition on the label, within the patient-centered clustered area. Dr. Gray suggested modifying the regulation language that would more clearly indicate that a pharmacist could use his or her professional judgment to include the purpose or condition on the label.

Motion/Second (Butler/Castellblanch): Direct staff to work with legal counsel to draft language to either amend Section 1707.5(a) (1)(D) to allow the purpose or condition to be included in the patient-centered clustered items.

Dr. Steve Gray, Kaiser Permanente, and Jonathan Nelson, CSHP, spoke in support of having the “purpose or condition” as one of the patient-centered required items.

Support: 4 Oppose: 0 Abstain: 0

What Font Size is Appropriate?

Stan Weisser read the Governor’s recent veto letter for SB 205 related to the minimum font size on a prescription label, indicating the Governor’s preference to wait for the findings of the board’s review before making a statutory change to the font size on a prescription label.

Ms. Herold reviewed the current requirement for font size (10 point minimum, with 12 point required if requested by the patient) and as previously discussed at this meeting pharmacies, by a wide preponderance, are using 12 point font as the primary font on prescription labels. It was the consensus of the committee that the regulation should be modified to require a minimum 12 point font.

Dr. Castellblanch recognized the many reports, research, and legislative efforts to address the minimum font size on prescription labels.

Motion/Second (Castellblanch/Butler): Modify Section 1707.5(a)(1) to read as follows:

(1) Each of the following 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:

Public Comment

Mandy Lee, California Retailers Association, expressed concern that if translations will be required at some point, and that if the patient-centered items are required to be printed in 12-point font, there could be issues with fitting everything on the label.

Jonathan Nelson, CSHP, sought clarification on exactly which patient-centered items would be impacted by the motion. Counsel referred to the four items currently referenced in Section 1707.5(a)(1)(A) – (D).

Support: 4 Oppose: 0 Abstain: 0

Should the existing requirements for “added emphasis” be modified?

Current regulation at Section 1707.5(a)(2) states “For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).”

Ms. Herold noted that there is not much available in the research that addresses these items, however, there is a recommendation in the research that sentence casing not be in all capital letters.

There was no further committee or public discussion on this item.

Translations

Ms. Sarah de Guia, CPEHN, thanked the board for its efforts to encourage translations for prescription labels. She noted that translation services are provided in health care settings on a regular basis. She expressed concern over the survey results that indicated that pharmacies were using on-line translation services, such as Google Translations. Ms. de Guia spoke in support of the professional field of translators that are certified to provide these

services. She requested that as the board moves forward that it considers the use of such certified translators, and that where CPEHN can provide additional information to let her know. She said CPEHN is concerned about the quality of translations that are being provided. She spoke in support of establishing standards for providing translations.

Dr. Castellblanch asked how the board has been advising pharmacies of the patient-centered requirements. Ms. Herold noted that the board has utilized its newsletter, *The Script*, as well as e-mail subscriber alerts.

Ms. Mandy Lee, California Retailers Association, indicated they are not aware that any of their member pharmacies that use on-line translations, as described at the meeting.

Ms. Herold indicated that two member pharmacies indicated they used “on-line computer software” to provide the translations. Ms. Sodergren asked if Ms. Lee might be able to survey their members to clarify the types of services that are used for the purpose of translating prescription drug labels.

There was no further discussion on this item.

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

Ms. Herold stated that the committee goals need to be augmented.

6. Update on The Script

Mr. Weisser referred to the update provided in the meeting materials.

7. Public Outreach Activities Conducted by the Board

A listing of public outreach activities are appended to these minutes.

8. Public Comment for Items Not on the Agenda

There were no public comments.

Mr. Weisser adjourned the meeting at 2:25 p.m.

TABULATION OF SURVEY RESULTS

Survey Results Regarding Pharmacy Compliance With Translated Labels and Interpreter Availability

A total of 239 surveys were collected by Board inspectors. The results are as follows:

1. Do you provide prescription container labels with translated directions?

a) Yes 185 (77.4%) b) No 54 (22.6%)

Individual Comments:

Limited Spanish

No occasion has arisen

Spanish/French Canadian on label and as counseling information

Spanish

Spanish only

2. How do you provide the translation of the directions for use?

a) Pharmacy staff translates the labels: 69 (37.3%)

Individual Comment: Spanish Only

b) The pharmacy uses the Board of Pharmacy's online translated directions for use: 5 (2.7%)

c) The pharmacy uses computer software or online programs: 151 (81.67%)

Comments: Spanish only; by Sigs only; no free-form Sigs can be translated on label.

d) The pharmacy uses other means of providing translations (describe): 12 (6.5%)

Individual Responses:

1. Third party Language Line, although the occasion has never arisen

2. Language Line

3. Store employees (Spanish only). No other language translations have ever come up

3. If you translate the labels, do you also provide the English language equivalent on the label?

a) Yes 47 (26%) b) No 134 (74%)

Individual Comments:

Optional

If the software is used correctly an additional leaflet prints in English, with label information and medication information

No room/space for both

Hard copy is in English

RPh translates based on Spanish experience
Some prescribers write both English and the foreign language, so the pharmacy puts both on the label
Has never come up
Don't use often
Don't know if label provides English translation.

4. If you do not provide translated directions on the label, why?

- a) The pharmacy has no requests for translated labels 28 (51.9%)
- b) The pharmacy has too many patients with diverse language needs 4 (7.4%)
- c) The pharmacy's software will not print in foreign language fonts 18 (33.3%)
- d) The pharmacy is concerned that errors on the label will go undetected 14 (25.9%)
- e) Other:

Individual Responses:

Pharmacy has not contracted with any software vendor to provide labels yet (new pharmacy).

Pharmacy has no prescription processing software at this time (new pharmacy).

5. How does the pharmacy comply with the interpreter requirements?

- a) Uses pharmacy staff at this or other pharmacies to interpret 138 (57.7%)
- b) Uses a telephone language service 190 (77.5%)
- c) Is not compliant with current requirements to have access to an interpreter 15 (6.3%)

Individual Comments:

Is not in full compliance. Only has Spanish-speaking staff.
Both staff and rarely Language Line

PUBLIC OUTREACH ACTIVITIES (July – September 2013)

The following are public outreach activities we have participated in since the July report to the board:

- July 25, 2013: The Board of Pharmacy, in conjunction with the Los Angeles Field Division of the Drug Enforcement Administration, co-hosts a seminar for pharmacists on July 26 in Downey, CA. The seminar focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminar was well attended, with approximately 220 in attendance.
- August 13, 2013: Executive Officer Herold provides a webinar on e-Pedigree requirements at to a webinar audience hosted by the FDAnews.
- August 16, 17, 18, 19: The Board of Pharmacy, in conjunction with Washington Headquarters of the Drug Enforcement Administration, co-hosts four day-long seminars for pharmacists. Two were held in San Diego, and two in San Jose. The seminars focused on prescription drug abuse, corresponding responsibility of pharmacists, and other issues related to curtailing drug diversion. The seminars were well attended, with at least 300 individuals in attendance each day.
- August 25: Supervising Inspector Janice Dang provides a presentation on corresponding responsibility of pharmacies to physicians attending the Napa Pain Conference.
- August 26: Executive Officer Herold provides a presentation via telephone connection to the New Mexico Board of Pharmacy on virtual wholesalers and wholesaler brokers and drug diversion.
- September 17: Executive Officer Herold provides a presentation via telephone connection on California's e-pedigree regulations to 300 attendees of a LogiPharma conference in Princeton, NJ.
- September 17: Executive Officer Herold provides a webinar on California's requirements for serialization to attendees of a PricewaterhouseCoopers virtual meeting.
- October 2: Executive Officer Herold provides a presentation on California's e-pedigree regulations to attendees at a GS1 conference held in San Francisco.