



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
PUBLIC BOARD MEETING
MINUTES**

DATE: March 30, 2011

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Neil Badlani, RPh
Ryan Brooks, Public Member
Ramón Castellblanch, Public Member
Kenneth Schell, PharmD
Deborah Veale, RPh
Shirley Wheat, Public Member

BOARD MEMBERS

NOT PRESENT: Rosalyn Hackworth, Public Member
Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst

I. CLOSED SESSION

Pursuant to government code section 11126(c)(3), the board convened in closed session to deliberate on disciplinary decisions.

II. OPEN SESSION

President Stan Weisser called the meeting to order at 10:03 a.m.

President Weisser conducted a roll call. Board members Badlani, Wheat, Veale, Schell, Kajjoka, Lippe, Brooks, Castellblanch, and Weisser were present.

III. GENERAL ANNOUNCEMENTS

Ryan Brooks provided that he and President Weisser visited a Rite Aid Distribution Center in Woodland. He encouraged the other members of the board to do the same.

Executive Officer Virginia Herold announced that the meeting is being Web cast.

President Weisser requested that all public comment be limited to five minutes.

IV. LICENSING COMMITTEE

Discussion and Possible Approval to Award Continuing Education (CE) Credit for Attendees of a Drug Enforcement Administration Conference on Drug Security for Pharmacies to Be Held April 12, 2011 in Los Angeles

Report

President Weisser provided that on April 12, 2012, board staff will join with the DEA to host a day-long conference on pharmacy issues at the DEA's Los Angeles office. He stated that board licensees in the Los Angeles area will be invited to attend.

President Weisser provided that this conference is similar to a DEA conference held last June in San Diego that was well attended by San Diego licensees of the board.

President Weisser referenced the draft agenda for the conference provided in the meeting materials.

President Weisser provided that board staff request that the board consider awarding 5 hours of CE credit for those pharmacists and pharmacy technicians who attend this conference.

Discussion

Ken Schell offered a proposal to award five hours of CE credit for pharmacists and pharmacy technicians who attend the conference.

Ms. Herold provided an overview of the material that will be covered at the conference regarding drug diversion and theft.

Deborah Veale spoke in support of the proposal. She provided that the Licensing Committee has been discussing the issue of diversion as a possible area for mandatory CE.

Dr. Schell discussed that the content is substantially related to the practice of pharmacy and seems to meet the requirements of a CE program.

Mr. Brooks asked whether CE credit is awarded to the professional members of the board.

Ms. Herold provided board members are expected to attend board meetings as a function of their appointment to the board and are not awarded CE.

Kristy Shellans, DCA Staff Counsel, reviewed California Code of Regulations §1732.3 regarding requirements for CE courses. She advised that the board will need to evaluate the content of the conference against these criteria.

Ms. Veale sought clarification regarding whether the conference will include an assessment as required by §1732.3.

Ms. Herold stated that learning objectives will be provided to attendees at the beginning of the conference. She indicated that there will not be a post assessment.

President Weisser requested that an evaluation sheet be provided to attendees.

Public Comment

Steve Gray, representing Kaiser Permanente, provided comment in support of the proposal. He discussed that there is a lot of confusion with the DEA at the state and national level regarding what can be changed on a written prescription for schedule II drugs. He suggested that this issue be discussed and clarified prior to the meeting.

MOTION: Approval to award five (5) hours of continuing education credit for attendees of a Drug Enforcement Administration Conference on Drug Security for Pharmacies to be held April 12, 2011 in Los Angeles.

M/S: Schell/Lippe

Support: 9 Oppose: 0 Abstain: 0

V. ENFORCEMENT COMMITTEE

Discussion and Possible Action to Submit Comments to the Federal Food and Drug Administration Pursuant to Determination of System Attributes for Tracking and Tracing of Prescription Drugs; Public Workshop (Document ID FDA-2010-N-0633-001)

Report

Ms. Herold provided that California law has the strongest pharmaceutical supply chain security requirements of any state. She indicated that California's laws in this area were enacted in 2004, and amended in 2006 and 2008. Ms. Herold stated that the requirements will take effect over a 2.5 year period from 2015 through 2017.

Ms. Herold provided an overview of two major presentations given on behalf of the board regarding supply chain security and the board's efforts to ensure no counterfeit drugs are entering California's wholesalers and pharmacies, and that recalled drugs are appropriately removed. She stated that one of these presentations was at a two-day FDA workshop convened in mid February to collect information on developing federal standards for supply chain security.

Ms. Herold discussed that California is viewed as the leader in this area, and the provisions in California law originate with a 2004 FDA Counterfeit Task Force Report. As such, she encouraged the board to submit comments to the FDA highlighting the components of California's requirements.

Discussion

Mr. Brooks suggested that the board's comments be reviewed by President Weisser prior to being submitted to the FDA.

Ms. Herold indicated that the comments are due by April 16, 2011 and will be signed by President Weisser.

Mr. Brooks requested that a copy of the board's comments also be provided to the members of the board.

Joshua Room, Deputy Attorney General, reminded the board that they will be unable to comment or respond to these comments.

MOTION: Direct board staff to draft a response to the FDA regarding the components of California's requirements for the tracking and tracing of prescription drugs to be reviewed by the board president, and upon completion, provide a copy to the members of the board.

M/S: Brooks/Lippe

Support: 9 Oppose: 0 Abstain: 0

VI. LEGISLATION AND REGULATION COMMITTEE

Discussion and Possible Action to Initiate a Rulemaking to Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels

Report

President Weisser provided that on January 1, 2011, the board's requirements for a patient-centered prescription drug container label took effect.

President Weisser provided that during the rulemaking process to adopt the prescription drug labeling requirements, the board decided to establish requirement(s) that consumers be notified of the availability of oral language interpretive services in pharmacies and of 12-point font, as specified in the regulation.

President Weisser provided that the board considered possible regulatory language for this at its July 2010 Board Meeting, and thereafter directed staff to develop new language. He stated that the board voted at that time to move the existing consumer notices from 16 CCR § 1702 to a new section that would also include any notice(s) regarding language interpretive services and larger font sizes.

President Weisser provided that at the October 2010 Board Meeting, the board continued its discussion of the possible regulation text and made modifications to subdivisions (a) and (b) of the draft text. He stated that at the February 2011 Board Meeting, the board generally discussed the requirements but did not modify the language.

President Weisser provided that at this meeting the board will be refining the requirement for the consolidated notice to consumers. He advised that if the board completes its work, the board can direct that staff release the draft proposal for the required 45-day initial notice period.

President Weisser provided an overview of the following draft text for discussion.

Draft Text for Discussion

This text reflects changes made at the October 2010 Board Meeting, along with staff recommendations. Line numbering is provided for reference.

This potential language incorporates changes made by the board at its October 2010 Board Meeting. Staff recommendations have a double underline or ~~strikethrough~~.

1 **Delete 16 CCR § 1707.2, subds. (g) and (g)**

2 **Add 16 CCR § 1707.6. Notices Required in Pharmacies.**

3

4 (a) In every pharmacy there shall be prominently posted, in a place conspicuous to and
5 readable by a prescription drug consumers, a notice containing the text in subdivision (b).
6 Each pharmacy shall use the standardized poster-sized notice provided or made available by
7 the board, unless the pharmacy has received prior approval of another format or display
8 methodology from the board. The board may delegate authority to a committee or to the
9 Executive Officer to give the ~~such~~ approval ~~to a committee of the Executive Officer~~. As an
10 alternative to a printed notice, the pharmacy may also or instead display the notice on a
11 video screen located in a place conspicuous to and readable by prescription drug
12 consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2)
13 The pharmacy utilizes the video image notice provided by the board; (3) The text of the
14 notice remains on the screen for a minimum of 60 seconds; and (4) No more than five
15 minutes elapses between displays of any notice on the screen, as measured between the
16 time that a one-screen notice or the final screen of a multi-screen notice ceases to display
17 and the time that the first or only page of that notice re-displays.

18 (b) The notice shall contain the following text

19

20 NOTICE TO CONSUMERS

21

22 You may ask this pharmacy to use 12-point font on prescription drug labels.

23

24 Oral language services are available to you at no cost.

25

26 Before taking your medicine, be sure you know: the name of the medicine and what it
27 does; how and when to take it, for how long, and what to do if you miss a does; possible
28 side effects and what you should do if they occur; whether the new medicine will work
29 safely with other medicines or supplements; and what foods, drinks, or activities should be
30 avoided while taking the medicine. Ask the pharmacist if you have any questions.

31

32 This pharmacy must provide any medicine or device legally prescribed for you, unless: it is
33 not covered by your insurance; you are unable to pay the cost of a copayment; or the
34 pharmacist determines doing so would be against the law or potentially harmful to health.
35 If a medicine or device is not immediately available, the pharmacy will work with you to
36 ensure that you get your medicine or device in a timely manner.

37

38 You may ask this pharmacy for information on drug pricing and use of generic drugs.

39

40 (c) Every pharmacy, in a place conspicuous to and readable by a prescription drug
41 consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are
42 dispensed or furnished, shall post or provide a notice containing the following text repeated
43 in English and in each of the languages for which interpretive services are available, printed
44 in at least an 18-point boldface type in a color that sharply contrasts with the background
45 color of the notice, with each repetition enclosed in a box with at least a ¼ inch clear
46 space between adjacent boxes:

47

48 Point to your language. Language assistance will be provided at not cost to you.

49

50 This text shall be repeated in at least fourteen (14) languages, to include all of the non-
51 English languages now or hereafter identified by the Medi-Cal Managed Care Division,
52 Department of Health Care Services, for translation of vital documents, as well as any other
53 primary languages for groups of ten thousand (10,000) or more limited-English-proficient
54 persons in California.

55

56 The pharmacy may post this notice in paper form or on a video screen meeting the
57 requirements of subdivision (a) if the posted notice or video screen is positioned so that a
58 consumer can easily point to and touch the statement identifying the language in which he
59 or she requests assistance. Otherwise, the notice shall be made available on a cardstock
60 flyer or handout clearly visible from and kept within easy reach of each counter in the
61 pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the
62 pharmacy is open. The flyer/handout shall be at least 8 ½ inches by 11 inches, shall be
63 printed on durable cardstock, and may be laminated.

Discussion

Dr. Schell offered a proposal to direct staff to take all steps necessary to initiate the formal rulemaking process to text at 16 CCR 1707.6, and to amend 16 CCR Section 1707.2, authorize the executive officer to make any non-substantive changes to the

rulemaking package, provide the proposed language for a 45-day public comment period, and set a public hearing for the proposed regulation.

The board discussed the draft text and reviewed specific concerns by line number.

Line 22

Ramón Castellblanch expressed concern regarding the language in line 22. He discussed that this language should indicate to the consumer that they have the right to ask for and receive their prescription label in a 12-point font.

The board discussed possible amendments to this language.

Dr. Castellblanch offered a proposal for alternate language.

Public Comment: Line 22

Carol Bailey, representing the California Alliance for Retired Americans (CARA), recommended that the language be changed from “this pharmacy” to “any pharmacy.”

David Williams, representing CARA, suggested that the general public may not know what “12-point font” means. He encouraged that this term be changed to clarify that a larger size of lettering can be requested.

Mr. Brooks suggested that Dr. Castellblanch incorporate Ms. Bailey’s suggested change into his proposed language.

Dr. Castellblanch accepted this friendly amendment to his proposal.

MOTION: Amend line 22 of the draft text to read as follows:

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font. ~~may ask this pharmacy to use 12-point font on prescription drug labels.~~

M/S: Castellblanch/Schell

Support: 9 Oppose: 0 Abstain: 0

Line 24

Dr. Castellblanch offered a proposal to change the term “oral language services” to “interpreter services.”

Dr. Schell offered a friendly amendment to clarify that these services are upon request.

Shirley Wheat reminded the board that adding additional language will make it more challenging to fit all of the notice language on the notice.

The board discussed whether this additional language is necessary or whether requesting this service is implicit to consumers. It was emphasized that the board should focus on maintaining the readability of the notice while communicating the most important information to the consumers.

Public Comment: Line 24

Nan Brasmer, representing CARA, discussed that it is difficult to read lengthy wording. She suggested that the information be provided in a bullet point format.

Mr. Room explained that not all of the language lends itself to the bulleting format; and as such, paragraphs are required.

Nancy Tilcock, representing CARA, discussed that some consumers may be afraid or hesitant to request these services. She suggested that the notice include a variety of colors to emphasize information as well as a header (e.g. "You have a right") with bulleted information followed by an explanatory paragraph at the bottom of the notice. Ms. Tilcock also suggested that notices be posted lower so that people are not forced to strain their heads to read the information.

Carry Sanders, representing the California Pan-Ethnic Health Network (CPEHN), provided comment in support of the proposal. She stated that "interpreter services" has more resonance with the patients who need this service. Ms. Sanders discussed a notice developed by the Department of Managed Health Care (DMHC) that provides information regarding available interpreter services for consumers in 12 different languages. A copy of this document was provided to the board and is also attached, following this meeting summary. Ms. Sanders encouraged a vetting process and stated that it is important to inform consumers that they have the right to interpreter services at no cost.

Dr. Schell provided an overview of the vetting process for this issue and indicated that the public will have an opportunity to provide comment during the rulemaking process.

MOTION: Amend line 24 of the draft text to read as follows:

Interpreter ~~ora~~-language services are available to you upon request at no cost.

M/S: Castellblanch/Wheat

Support: 9 Oppose: 0 Abstain: 0

Lines 35-36

Mr. Room offered to share alternative language to replace lines 35 and 36 that he was directed by the board to draft regarding conscientious objection.

Dr. Castellblanch stated that he believes providing new language during the middle of a meeting is problematic. He requested prior notice of such amendments for consideration.

Greg Lippe discussed that new alternative language was just approved by the board in lines 22 and 24. He encouraged the board to hear the language that was drafted by Mr. Room.

Ms. Veale provided that the board requested this alternative language in response to public comment concerning the simplification of information regarding a pharmacist's right to decline to fill a prescription for ethical, moral or religious reasons.

Mr. Room read the following alternative language for lines 35-36:

A medicine or device may not be immediately available, if it is not in stock or if the pharmacist has an ethical, moral, or religious objection to providing it to you. In either case, the pharmacy will work with you to help you get the medicine or device in a timely manner.

Mr. Lippe expressed concern regarding the length of this alternative language.

Mr. Room discussed that the alternative language is intended to clarify conscientious objection as there was concern that the condensed information in the current draft did not acknowledge ethical, moral, or religious objection.

Ms. Wheat discussed that this information was condensed because it was felt that this notice should be directed towards the consumer, and not the rights of the pharmacist.

Ms. Veale offered a proposal to replace lines 35 and 36 of the draft language with the alternative language drafted by Mr. Room.

Public Comment: Lines 35-36

An unidentified member of the public asked for assurance that the consumer will be directed to where they can get the service or medicine they need.

President Weisser provided that the alternative language states that the pharmacy will work with the consumer to help them get the medicine or device in a timely manner.

Steve Gray, representing Kaiser Permanente, expressed concern regarding the term “ensure” as used in the draft language.

President Weisser clarified that the alternative language uses “help” instead of “ensure.”

Mr. Lippe spoke in support of maintaining the current draft language. He discussed that the alternative language is too lengthy.

MOTION: Amend lines 35 and 36 of the draft text to read as follows:

~~If a medicine or device is not immediately available, the pharmacy will work with you to ensure that you get your medicine or device in a timely manner. A~~
medicine or device may not be immediately available, if it is not in stock or if the pharmacist has an ethical, moral, or religious objection to providing it to you. In either case, the pharmacy will work with you to help you get the medicine or device in a timely manner.

M/S: Veale/Brooks

Support: 2 Oppose: 4 Abstain: 2

Ms. Wheat offered a proposal to replace “ensure that” with “help” on line 36 of the draft language. She stated that pharmacies can not ensure that other pharmacies will have the medication or devices available.

Ms. Veale provided that in some cases, certain products are not available anywhere.

Mr. Room provided that Section 733 uses the term “ensure,” but in a slightly different manner. He stated that using “help” instead would not be inaccurate.

No additional public comment was provided on this proposal.

MOTION: Amend lines 35 and 36 of the draft text to read as follows:

If a medicine or device is not immediately available, the pharmacy will work with you to ~~ensure that~~ help you get your medicine or device in a timely manner.

M/S: Wheat/Schell

Support: 9 Oppose: 0 Abstain: 0

Subdivision (c) – Interpreter Services

Dr. Castellblanch offered a proposal to replace any reference to “interpretive services” or “language assistance” in the draft language with “interpreter services.” He stated that this will be consistent with the amendment to line 24.

Public Comment: Subdivision (c) – Interpreter Services

David Williams, representing CARA, asked whether interpreter services also refers to services provided to those who are hearing, speech, or sight impaired.

Dr. Schell clarified that these services are already mandated by the American Disabilities Act (ADA).

MOTION: Amend the draft text to replace any references to “interpretive services” or “language assistance” with “interpreter services.”

M/S: Castellblanch/Lippe

Support: 9 Oppose: 0 Abstain: 0

Lines 53-54

Mr. Room provided that the board has discussed at previous meetings whether a certain number of languages should be specified or whether an external source listing specified languages should be identified. He stated that as directed, staff has begun research in this area and has identified an All Plan Letter dated June 7, 2002 by the Medi-Cal Managed Care Division (MMCD) of the Department of Health Care Services (previously Department of Health Services) regarding 13 threshold standard languages as well as a 2010 document listing 10 threshold languages by Health Plan. (These documents are attached, following this meeting summary.) Mr. Room advised that staff is still currently researching to determine whether these documents are appropriate for this purpose.

Ms. Shellans advised that, as Mr. Room has discussed, the board should either list the languages in the text of the regulation or refer to an external document in order to avoid a clarity challenge.

President Weisser asked if there is a difference between the languages listed in the MMCD documents and the 14 languages referred to on line 50 of the draft text.

Mr. Room provided that the language in the draft text was taken directly from Senator Ellen Corbett’s bill, SB 1390. He discussed that it is unclear what document the bill refers to. Mr. Room explained that he contacted MMCD and was referred to the 2002 and 2010 documents.

Mr. Room discussed that it may be easier to list the required languages within the regulation rather than referring to a document. He stated that this may eliminate confusion with regards to identifying updated and current versions of the document.

Dr. Castellblanch stated that he originally discussed the 14 languages referenced in the draft text with the board. He advised that he may have inadvertently misstated the actual number of identified threshold languages.

Ms. Veale provided that she supports referencing a static number of languages. She expressed concern regarding the reference in lines 52-54 to “any other primary languages for groups of ten thousand (10,000) or more limited-English-proficient persons in California.” She explained that this can be a moving target and may be difficult to manage. Ms. Veale recommended that this language be struck.

Ms. Shellans discussed that lines 52-54 of the current draft language may not meet the clarity standard. She again suggested that the board either list each required language or incorporate a document by reference and make amendments to the regulation as changes are needed.

Dr. Schell discussed that the board should establish a methodology for updating the list of languages as the regulatory process can be lengthy.

Mr. Lippe suggested that the required languages be based upon the specific demographics for each pharmacy location.

Ms. Shellans advised that this option does not establish a clear standard and would not pass approval by the Office of Administrative Law.

Ms. Herold encouraged the board to use the available documents as data to help identify specific languages to list in the regulation. She stated that the board may need to periodically review this list.

Mr. Brooks sought information regarding the prevalence of interpreter services in the pharmacy setting. He asked whether the board is attempting to find a solution for a problem that does not exist.

Ms. Veale discussed that pharmacies tend to hire employees from the surrounding neighborhood but may not be able to accommodate all languages in a specific area. She stated that services such as Language Line are not highly utilized. Ms. Veale reminded the board that these services are required by legislation.

Mr. Lippe discussed that the board has received a lot of testimony advocating for services in this area.

Dr. Schell discussed that while there is not a significant problem in this area, there is a potential for problems. He provided an example of services needed when a patient travels.

Dr. Castellblanch provided that language options are commonly provided today. He recommended that the specific languages be listed in the regulation.

Ms. Veale reviewed available census data regarding the ten main languages in California. She indicated that Spanish and English cover 85 percent of Californians. Ms. Veale asked whether the board can include in the regulation that the board will revisit the list of languages at a specified time.

Ms. Shellans provided that the board can revisit the languages and advised that there would not be an extended regulatory process to modify the languages listed in the regulation.

Ms. Veale offered a proposal to include a list of 12 languages by amending lines 50-54 to require that the “point to your language” text be repeated in the languages listed in the MMCD 2002 document.

Public Comment: Lines 53-54

Carry Sanders, representing the California Pan-Ethnic Health Network (CPEHN), spoke in opposition to the proposal because it does not address California’s changing demographics. She suggested that the board use more broad data from the US Census to define a threshold rather than referencing Medi-Cal data.

Ms. Sanders suggested that the board refer to the Dymally-Alatorre Bilingual Services Act which requires services for a “substantial number of non-English-speaking people” who comprise five percent or more of the people of a service area. Ms. Sanders also discussed AB 922 which will specify a threshold of 20,000 or more limited-English-proficient persons.

Ms. Sanders provided that CPEHN would like an opportunity to work with the board to identify a strong threshold to include in the regulation.

Dr. Castellblanch requested more information regarding the Dymally-Alatorre Bilingual Services Act and invited CPEHN to participate in this process.

Jennifer Snyder, representing the National Association of Chain Drug Stores (NACDS), expressed concern regarding consistency in compliance from the pharmacy perspective. She encouraged the board to develop and provide the notice for the pharmacies to use to ensure that all pharmacies are using the same notice.

Steve Gray, representing Kaiser Permanente, urged the board to list the languages in the regulation. He provided comment regarding the Dymally-Alatorre Bilingual Services

Act and indicated that it applies to government agencies and not necessarily private entities.

David Williams, representing CARA, clarified that the proposal specifies “at least” the following languages. He suggested that the language also include “and not limited to” to allow for flexibility.

Al Carter, representing Walgreens, spoke in support of this initiative moving forward. He reviewed efforts in New York City in this area and indicated that they placed the responsibility on the pharmacies to provide the translated languages which has resulted in inaccuracies and inconsistencies. Mr. Carter recommended that the board develop the translated language to provide to the pharmacies.

Nancy Tilcock, representing CARA, spoke in support of the proposal to change “ensure” to “help.” She sought clarification regarding the struck language on pages six and seven of the draft text.

Ms. Herold provided that this text has been moved to the front of the new notice.

Dr. Kajioka suggested that Language Line or others who provide interpretive services be invited to present to the board to ensure that services are available in the languages that will be listed in the regulation.

President Weisser discussed that demand will ensure that services are provided in these specific languages if they are not already provided.

Ms. Veale provided that she believes that services are already provided in these languages as they are threshold languages for Medi-Cal patients.

Mr. Room provided that the board may receive comments during the comment period regarding any services that are not currently provided.

Ms. Sanders confirmed that services are available in these languages as well as many others.

MOTION: Amend lines 50-54 of the draft text to read as follows:

This text shall be repeated in at least ~~fourteen (14) languages, to include all of the non-English languages now or hereafter identified by the Medic-Cal Managed Care Division, Department of Health Care Services, for translation of vital documents, as well as any other primary languages for groups of ten thousand (10,000) or more limited-English proficient persons in California.~~ the following

languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese.

M/S: Veale/Castellblanch

Support: 9 Oppose: 0 Abstain: 0

Subdivision (c)

Dr. Castellblanch sought clarification regarding the video screen that would display the notice. Specifically, he asked where the screen would be located so that consumers can utilize it as a touch screen.

Ms. Veale discussed that the video is an option that could be installed with a swing arm to allow patients to point to their language on the screen within a close proximity.

Mr. Room clarified that touch screen capabilities are not required; instead, the screen must be close enough that patients can point to their language on the screen.

Ms. Veale suggested that the board provide the translated text in the 12 languages to pharmacies. She also recommended that lines 6-9 of the draft text also be incorporated to this section to allow for an alternative methodology.

Mr. Room discussed that if the board were to provide these translations, it would need to decide on whether it will provide a poster, handout, or PDF document.

The board discussed the development of a PDF to be made available on the board's Web site and how the translations on the document will be vetted. It was also discussed how pharmacies would utilize this document with services such as Language Line.

Ms. Veale recommended that the board provide a PDF document. She suggested that the requirements on line 63 regarding durable cardstock and lamination be eliminated.

Mr. Brooks asked if there is an available model from another state to use as an example in the development of this document.

Ms. Herold provided that California is the first state to do mandatory patient-centered prescription labels and to require interpreter services. She stated that California is seemingly setting the national standard in this area.

Public Comment – Subdivision (c)

Steve Gray, representing Kaiser Permanente, discussed that the requirements in subdivision (a) regarding the poster are not easily incorporated into this section. He

discussed that patients tend to not like handouts printed on cardstock and suggested that the requirements in lines 63 be eliminated.

The board discussed possible modifications to this section of the regulation. It was suggested that the board take a break to allow staff to draft possible modifications for consideration.

The board recessed for a break at 12:23 p.m.

The board reconvened at 1:05 p.m.

Mr. Room reviewed incorporated changes to the draft text based on the board's discussion. A copy of the revised document was provided to the board and the members of the public in attendance. (This document is attached, following this meeting summary.)

Mr. Room explained that lines 4-11 of the draft text have now been incorporated into the first section of subdivision (c) of the revised text on lines 41-47. He stated that minor modifications were made to eliminate references to the poster, and instead emphasizes the notice.

Ms. Veale offered a proposal to amend the draft text to incorporate the revised text drafted by Mr. Room.

The board discussed inconsistencies with incorporating language from subdivision (a) into subdivision (c). It was recommended that specific references to requirements of subdivision (a) be eliminated.

Ms. Veale accepted these friendly amendments to her proposal.

Public Comment – Subdivision (c)

Carry Sanders, representing the California Pan-Ethnic Health Network (CPEHN), provided that the proposal does not include a reference to where the 12 languages were derived and how often they will be updated. She sought clarification regarding where the PDF was incorporated in the revised text.

Ms. Shellans referred Ms. Sanders to line 44 of the revised draft text.

Nan Brasmer, representing CARA, discussed that the language is confusing with regards to the options for video screens. She identified a typo in line 5.

Mr. Brooks agreed with Ms. Brasmer and suggested that this be clarified in the language.

Ms. Herold clarified that each subdivision of the regulation requires a separate notice.

Ms. Shellans reminded the board that there will be opportunity to make modifications to the language during the rulemaking process.

Dr. Kajioka provided that he believes the language regarding the video screens is clear. He encouraged the board to maintain flexibility for pharmacies with this video screen option.

Dr. Castellblanch encouraged the board to move forward.

Mr. Lippe spoke in support of the revised text regarding the video screens.

MOTION: Amend subdivision (c) of the draft text to read as follows:

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 ~~repeated in English and in each of the languages for which interpretive services are available, printed in at least an 18-point boldface type in a color that sharply contrasts with the background color of the notice, with each repetition enclosed in a box with at least a ¼ inch clear space between adjacent boxes:~~ Point to your language. Language assistance Interpreter services will be provided to you upon request at no cost to you.

~~This text shall be repeated in at least fourteen (14) languages, to include all of the non-English languages now or hereafter identified by the Medic-Cal Managed Care Division, Department of Health Care Services, for translation of vital documents, as well as any other primary languages for groups of ten thousand (10,000) or more limited-English-proficient persons in California. 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 ~~meeting the requirements of subdivision (a)~~ 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 ~~cardstock~~ 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/handout shall be at least 8 ½ inches by 11 inches, ~~shall be printed on durable cardstock, and may be laminated.~~

M/S: Veale/Castellblanch

Support: 9 Oppose: 0 Abstain: 0

President Weisser offered the public an opportunity to provide general comments relative to the proposal.

Public Comment

Nan Brasmer, representing CARA, asked what consumers can do if pharmacies do not comply with the patient-centered label requirements.

President Weisser provided that consumers should file a complaint with the board. He discussed that licensees that are found to violate the requirements are subject to disciplinary action.

Ms. Herold provided that the board's contact information is available on the Notice to Consumers.

Carol Bailey, representing CARA, provided comments regarding the entire process for this rulemaking. She stated that a member of the board accused seniors of thinking they needed special treatment. Ms. Bailey stated that she found this offensive. Ms. Bailey asked how it would have cost pharmacies three cents per prescription to provide labels in a 12-point font.

The board returned to the Dr. Schell's initial proposal regarding the rulemaking.

MOTION: To direct staff to take all steps necessary to initiate the formal rulemaking process to text at 16 CCR 1707.6, and to amend 16 CCR Section 1707.2, authorize the executive officer to make any non-substantive changes to the rulemaking package,

provide the proposed language for a 45-day public comment period, and set a public hearing for the proposed regulation.

M/S: Schell/Lippe

Support: 9 Oppose: 0 Abstain: 0

Final Language

Title 16. Board of Pharmacy Proposed Language

To Add §1707.6. to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumers, 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.

(b) The notice shall contain the following text:

NOTICE TO CONSUMERS

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font.

Interpreter services are available to you upon request at no cost.

Before taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions.

This pharmacy must provide any medicine or device legally prescribed for you, unless: it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner.

You may ask this pharmacy for information on drug pricing and use of generic drugs.

(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/handout shall be at least 8 ½ inches by 11 inches.

Public Comment for Items Not on the Agenda

No public comments were provided.

The public board meeting was adjourned at 1:43 p.m.