



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

MEETING MINUTES

Date: January 13, 2015

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

Committee Members Present: Rosalyn Hackworth, Chair
Ramon Castellblanch, PhD
Albert Wong, PharmD
Allen Schaad, RPh
Stan Weisser, RPh, President

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joyia Emard, Public Information Officer
Laura Hendricks, Staff Analyst
Michael Santiago, DCA Staff Counsel

Call to order

Committee Chair Rosalyn Hackworth called the meeting to order at 11:11 a.m. Committee members present were Rosalyn Hackworth, Chair, Ramon Castellblanch, Allen Schaad, Albert Wong, and Stan Weisser.

1. Resumption of the Committee's Assessment of California's Patient-Centered Labeling Requirement

a. Translation of Labels and the Use of Translated Directions Available on the Board's Website

The committee resumed its discussion of a draft proposal (also discussed on December 10, 2014) to require on a prescription label translated "directions for use" utilizing the vetted translations that are available in five non-English languages on the board's website, if a

translation is requested by the patient. These directions for use are available in Chinese, Korean, Russian, Spanish, and Vietnamese. A handout was provided of the draft language provided in the meeting materials. This draft also contained draft legislation that would provide pharmacists, who may not read or write the non-English language, immunity if there is an error in the translation.

Chair Hackworth summarized the committee's discussion on this item from the December 10 meeting, and noted that DCA Staff Counsel was present to answer the committee's questions. Ms. Hackworth reiterated the purpose of the meeting was to finalize a committee recommendation that could be considered at the January Board Meeting.

Chair Hackworth referred to the language provided in the meeting materials.

Discussion

Dr. Castellblanch stated that the first point that needs to be considered is a pharmacist's liability and he asked legal counsel to address that issue. Michael Santiago, DCA Staff Counsel, stated that any language addressing immunity from liability would have to be placed in the California Civil Code – not in the board's regulation or the Business and Professions Code, and that a statutory change would be required to implement such a provision.

Dr. Castellblanch said that given this information he is concerned that if the board sends it back to the legislature then the board will have failed to do what they were directed to do. He stated that the board could require pharmacies to have a written policy on what to do with transactions and – ultimately – language may have to be addressed legislatively.

Dr. Castellblanch suggested adding the following language:

“The pharmacy's policy and procedures for translation services should reasonably consider the needs of patients with limited English proficiency.”

He said this language would at least provide evidence that pharmacies are trying to provide translations. Chair Hackworth said she is disappointed that the board has to go the route of legislation, but she understands the pharmacists' need to address liability.

President Weisser said he is not sure how the board can encourage pharmacists to provide translations by having them put a policy in place on translations. He said if pharmacies are already providing translations, then the issue has come further along than anticipated without legislation and regulation. He said society is litigious and a pharmacist's liability must be considered.

Dr. Wong asked if anyone is using translator services. Ms. Herold said during inspections language interpretations are oral, translation is written. She said the information is being

gathered by inspectors, but is not yet available. Dr. Wong said the basic law of supply and demand means that pharmacies will provide translations when they are needed in order to keep their business. Dr. Castellblanch said the legislature already directed the board to do something about labels for people with limited English proficiency. He said it has been the law for eight years and the board is here to carry out the law. He said the board should at least mandate that there be policies in writing as the first step.

President Weisser moved that the board sponsor legislation using the draft language presented at the meeting. Dr. Castellblanch seconded.

Chair Hackworth asked if the board had any sponsor in mind and Ms. Herold said staff has a few in mind.

Public Comment

Mr. Brian Warren said that with respect to the civil code there is concern about using the “appropriate” translation in case a pharmacist accidentally uses the wrong translation item.

Committee members discussed whether that would be an error by the pharmacist or an error in translation. Dr. Wong said he believes that a pharmacy can do a better job with translations and that by requiring the use of the board translations they are limiting the pharmacist. Ms. Herold said that is covered in the language.

Mr. Warren reiterated that he wanted pharmacists protected from computer error.

Don Gilbert, Rite Aid, said they have no position at this time on the proposed language, but with respect to proposed regulations, he said a committee member stated that statute that compels the board to provide translations on the label; Mr. Gilbert asked what this statutory authority is. Dr. Castellblanch said there is no such law, but the board needs to consider the limited English proficient.

Dr. Gray, pharmacist, noted the draft language in subsection (b) states “a dispenser may select the appropriate translated standardized direction for use from those established in subdivision (b) and append it to the label.” He said in the New York model, they provide translations on a separate piece of paper and he said that is what “append” means. He said the intent of the directive is unclear. He asked if the board had considered the label size when putting the translation on the label. He said putting the translation on a separate piece of paper would be easier than putting on it the label and may be met with less resistance.

Dr. Wong said when a translation is on a separate piece of paper it could cause more problems if patients get their papers mixed up. Dr. Gray said he did not think so. He said the interface is not available in pharmacy computer systems to have the translations. Dr. Gray said an unintended consequence of a mandate is that it could limit access because if a pharmacy can’t translate, do they have to turn the patient away? He said the issue has not been fully vetted. He

asked that the board reconsider what is likely to get enacted and what is likely to get resistance. He suggested the New York model.

Mr. Weisser said in order for the board to proceed with legislation it has to be a collaborative effort. He said the English version on a translated label would be exempt from the 12 pt. font and would be on the label for the benefit of the pharmacist, health care workers and emergency responders. Dr. Gray said the font size would be important and questioned what size font would be acceptable for that purpose.

Kimberly Chen, from California Pan-Ethnic Health Network, asked if in Section (a), for “dangerous drugs” the reference could be made clear to mean prescription drugs because it may not be clear to legislators. She was told pharmacists understand that language.

Ms. Herold gave an overview of patient-centered labels. She said the purpose of the legislation is to provide pharmacist liability protection while utilizing the vetted translations already done on the board website. She said it doesn’t solve all of the problems, but it is a first step. She said software providers have to make changes periodically and may have to make them for CURES. She said she was recently asked some very hard questions by the governor’s office on why this is so difficult for the board to proceed on. She said the proposed legislation is an easy solution. Dr. Wong again stated he does not like the idea of translations being mandatory. Chair Hackworth told him he is already doing it, so what is the difference.

Committee Recommendation (Motion): Pursue legislation to add Business and Professions Code section 4076.55 as presented follows:

M/S Weisser/Castellblanch

Support: 3 Oppose: 1 Abstain: 1

Name	Support	Oppose	Abstain
Castellblanch	X		
Hackworth	X		
Schaad			X
Weisser	X		
Wong		X	
Total	3	1	1

4076.55 Standardized Directions for Use and Translations of Directions for Use on Labels

(a) For all dangerous drugs dispensed to patients in California, whenever possible, a dispenser shall use a standardized direction for use on the label of the prescription container from the list that appears in California Code of Regulations, Title 16, section 1707.5(a).

(b) The board shall make available translations of the standardized directions for use that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least the five most frequently spoken non-English languages in California. These translations shall be approved by state-certified translators.

These translated standardized directions for use shall be posted on the board's website. (c) Upon the request of a patient, a dispenser may select the appropriate translated standardized direction for use from those established in subdivision (b) and append it to the label on the patient's prescription container. Whenever a translated direction for use appears on a prescription container label, the English version of this direction must also appear on the label. The translated direction for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area. (d) A dispenser shall not be liable for any error that results from a dispenser's inability to understand the non-English language translation made available under subdivision (b), unless gross negligence has been committed by the dispenser.

(e) A dispenser may provide his or her own translated directions as an alternative to the process identified in this section. The translated directions for use shall appear in the patient-centered area of the label pursuant to California Code of Regulations, Title 16, section 1707.5(a). The English version must appear in other areas of the label outside this patient-centered area.

The committee also addressed possible regulation changes to section 1707.5 of Title 16 CCR. Dr. Castellblanch made a motion to amend section 1707.5(d) to insert the words "and translation" as shown below, so that, at minimum, a pharmacy will have a policy and procedure in place to address translation services:

1707.5 (d) The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language

are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

President Weisser seconded the motion.

There was no public comment.

Committee Recommendation (Motion): Amend board regulation at Title 16 CCR section 1707.5(d) to insert the words “and translation” as reflected in these minutes.

Support: 4 Oppose: 0 Abstain: 1

Name	Support	Oppose	Abstain
Castellblanch	X		
Hackworth	X		
Schaad	X		
Weisser	x		
Wong			X
Total	4	0	1

2. Public Comment for Items Not on the Agenda, Matters for Future Meetings*

Ms. Herold advised the committee and public that the Office of Administrative Law recently approved the board’s rulemaking to require a minimum 12-point font on patient-centered prescription labels, and that the regulation will be effective on April 1, 2015.

There was no additional public comment.

Chair Person Hackworth adjourned the meeting at 12:19 p.m.