



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

PUBLIC EDUCATION AND COMMUNICATION COMMITTEE

Rosalyn Hackworth, Chair
Albert Wong, PharmD, Professional Member
Ramon Castellblanch, PhD, Public Member
Allen Schaad, RPh, Professional Member
Stan Weisser, President

Report of the meetings held December 10, 2014 and January 13, 2015.

a. Summary of Presentation on the 43rd Annual Report of the Research Advisory Panel of California

Dr. Laurence R. Upjohn, Pharm.D., Chief with the Science and Education section of the California State Department of Public Health/Food and Drug Branch, spoke to the committee about the 43rd Annual Report of the Research Advisory Panel of California. California law, Health & Safety Code sections 11480 and 11481, requires proposed research projects using certain opioid, stimulant and hallucinogenic drugs classified as schedule I and schedule II controlled substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California. The Board of Pharmacy has an appointee on the panel. Dr. Upjohn said that projects come to the committee either through the institutional review panels or the US Food and Drug Administration.

The Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and the adequate security of the controlled substances used in the study. Panel members evaluate the scientific validity of each proposed project and may reject proposals where the research is poorly conceived would produce conclusions of little scientific value or would not justify the exposure of California subjects to the risk of research.

Dr. Upjohn said they meet every other month in San Francisco and that non-state committee members who live outside the area get reimbursed for travel. He said they've been having online and phone meetings because of the diminishing protocols. He said funding has been cut and many prevention studies have been curtailed, but they do see many phase 2 or 3 safety studies for new opioids and efficacy trials and post-marketing approvals, all submitted by private industry, with informed patient consent adhered to. He said there have been many studies for opioids with abuse deterrents.

The committee asked if the group pays special attention to opioid dependency studies that may be sponsored by pharmaceutical companies. Dr. Upjohn said every study now requires financial disclosures and it needs to be in the informed consent documents so the subject knows if a physician is being influenced by a pharmaceutical company.

b. Preparation for a Future Board Meeting Forum on Elements of Quality Patient Consultation

The importance of patient consultation by a pharmacist has been discussed by the board and committee and all agree that consultations are still not being conducted as they should be, despite studies that have shown there is better adherence to consultation requirements.

The committee noted that pharmacists are not always encouraged by their employers to conduct proper consultations because of time constraints, even though two chain pharmacies received large fines for their pharmacists failing to consult. Committee members reiterated that pharmacists are legally obligated to do consultation and the board has the ability to uphold that law and there are consequences if it is not done. It was discussed that pharmacies are evolving to become greater health care entities and the board is going to have to work on this evolution.

c. DISCUSSION AND POSSIBLE ACTION To Pursue Legislation Designed to Facilitate Implementation of Standardized Translations on Labels

Attachment 1

At its last two committee meetings, the committee discussed whether including the purpose or condition on a prescription label should be a general requirement. Comments reflected that patients can get confused over their medications and there may be better adherence to medication therapy if the patient understood the purpose or condition for which they are taking the medication. The committee noted that many physicians do not include purpose on the prescription document. During oral patient consultations, pharmacists discuss the purpose for which the medication is being taken, but they may be reluctant to include this information on the label because of liability issues; the committee also discussed a pharmacist's ability to exercise professional judgment when deciding whether or not to include the purpose on the prescription label. To that end, the committee discussed language drafted by staff – one as a legislative change, and the other as a regulatory change.

At its December 10, 2014, meeting the committee members discussed a draft legislative proposal to require translated "directions for use" utilizing the vetted translations that are available on the board's website. The standardized directions for use on the board's website are available in Chinese, Korean, Russian, Spanish, and Vietnamese.

At this and at previous meetings, the committee and board members discussed the benefits of providing patients with medication instructions printed in the patient's native language, as well as the issue of a pharmacist's liability if there is an error on the label and the pharmacist cannot read or write the translated language on the label or in ancillary information. The

committee discussed the mode of implementing such a proposal, be it via regulation or legislation. There was consensus that a starting point could be to require the use of the translated “directions for use” that are provided on the board’s website.

At the January 13, 2015 meeting, the committee continued its discussion of draft language to add section 4076.55 to the Business and Professions Code. The committee reached consensus on draft language and voted on a recommendation for the board’s consideration.

Committee Recommendation (Motion): Pursue legislation to add Business and Professions Code section 4076.55 as provided in Attachment 1.

d. Discussion of Additional Recommendations Designed to Facilitate Implementation of Standardized Translations on Labels

The committee discussed a regulation change to ask pharmacies to provide in their written policies that they not only show a means to provide interpretive services, but also translation services.

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

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.

e. Update on *The Script*

The Board of Pharmacy newsletter *The Script* is in the review process and the issue highlights new laws, board enforcement actions, hospital drug diversion, the Medical Board’s release of their revised pain management guidelines and the board’s policy statement encouraging the elimination of tobacco products in pharmacies.

e. Update on the Future Redesign of the Board's Website

The board will be redirecting its IT person to redesign the website so it will be simpler to use with less information on each page. The redesign will take 4-6 months of the IT person's time spread out over a year. During the revision, old information on the site will be removed.

f. Summary of Discussion of National Association of Boards of Pharmacy's .Pharmacy Suffix for Online Pharmacies

The National Association of Boards of Pharmacy (NABP) launched the .pharmacy Top-Level Domain (TLD) to provide consumers around the world with a means for identifying safe, legal and ethical online pharmacies and related resources. Eligible trademark holders may apply to NABP for approval to register .*pharmacy* domain names and, once approved, will be able to register the domain.

During the initial application and registration phase, registration for .pharmacy domain names will be open to pharmacy websites that are accredited through the NABP Verified Internet Pharmacy Practice Sites[®] (VIPPS[®]) and Veterinary-Verified Internet Pharmacy Practice Sites^{CM} (Vet-VIPPS[®]) programs, as well as for pharmacy websites that have received approval through the NABP e-Advertiser Approval CM Program.

General availability will begin in June 2015, at which time all entities providing pharmacy-related products, services or information that meets .*pharmacy* eligibility standards will be able to apply to register for the domain.

The committee discussed that the new .pharmacy domain will apply to all pharmacies in the U.S. and internationally. For the first time, consumers will be able to tell if an online pharmacy is legitimate. Boards of pharmacy will also be able to have .pharmacy websites and the California Board already has a name reserved. In the future, the board will be able to post information there. Ms. Herold served on the NABP advisory committee.

A member of the public strongly encouraged that the board attend the upcoming NABP spring conference because important matters are discussed and voted on and last year California was the only pharmacy board not in attendance.

g. Update on Media Activity

At the December meeting, the committee reviewed and update on media activities that occurred between September and December.

h. Public Outreach Activities Conducted by the Board

At the December meeting, the committee reviewed the list of outreach activities that had occurred between September and December.

Copies of the minutes from December 10, 2014 and January 13, 2015 meetings are provided in **Attachment 2**.

Attachment 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.

Attachment 2



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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: December 10, 2014

Location: Department of Consumer Affairs
First Floor Hearing Room
1625 N Market Blvd.
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
Joyia Emard, Public Information Officer
Laura Hendricks, Staff Analyst

Call to Order

Committee Chair Rosalyn Hackworth called the meeting to order at 11:00 a.m. Committee members present were Rosalyn Hackworth, Chair, Ramon Castellblanch, Allen Schaad, Albert Wong, and Stan Weisser.

1. Presentation on the 43rd Annual Report of the Research Advisory Panel of California

Chair Rosalyn Hackworth said that at the last committee meeting, members requested that a presentation be made on the 43rd Annual Report of the Research Advisory Panel of California. She said California law, pursuant to Health and Safety Code sections 11480 and 11481, requires proposed research projects using certain opioid, stimulant and hallucinogenic drugs classified as schedule I and schedule II controlled substances as their main study drug(s), to be reviewed and authorized by the Research Advisory Panel of California in the Attorney General's Office. She reported that the Board of Pharmacy has an appointee on the panel.

She said the Research Advisory Panel primarily seeks to ensure the safety and protection of participating human research subjects and adequate security of the controlled substances used in the study. The Panel members evaluate the scientific validity of each proposed project and

may reject proposals where the research is poorly conceived, would produce conclusions of little scientific value or would not justify the exposure of California subjects to the risk of research.

Dr. Laurence R. Upjohn, Pharm.D., chief with the Science and Education Section of the California State Department of Public Health/Food and Drug Branch, asked the committee if they had any questions.

Discussion

Chair Hackworth asked Dr. Upjohn how frequently the Research Advisory Panel meets. Dr. Upjohn said that the panel meets every other month in San Francisco and that non-state committee members who live outside the area get reimbursed for travel. He said they've been having online and phone meetings because of the diminishing protocols. The panel's Executive Officer is Ed O'Brien, an attorney/retired annuitant. Dr. Upjohn said that due to cuts in funding many of the studies have been curtailed. He said they see many phase 2 or 3 safety studies for new opioids and efficacy trials and post-marketing approvals, all submitted by private industry, and with informed patient consent adhered to. He said there have been many studies for opioids with abuse deterrents.

Ms. Herold asked why someone would come to them. He said either the institutional review panels have referred them or the FDA might direct them. He said the committee's greatest concern is that there is informed patient consent.

Ms. Herold asked him to give an example of when the committee would deny a study. He responded that he couldn't discuss specifics because of confidentiality, but they had a request to use MDMA to treat schizophrenia, and the person was going to use his own patients in the study and that would have been a denial. He said another denial or request for resubmission would be where companies coming from outside the state don't know about the patient bill of rights. He said sometimes they also get studies before they receive IRB approval and then they have to wait for the IRB approval.

Dr. Castellblanch asked if they pay attention to opioid dependency studies that may be sponsored by pharmaceutical companies. Dr. Upjohn said there are a number of studies that have been done on abuse. Dr. Castellblanch said he hopes those studies are independent from the pharmaceutical companies. Dr. Upjohn said every study now requires financial disclosures and it needs to be in the informed consent documents so the subject knows if a physician is being influenced by the pharmaceutical company.

2. Discussion of Social Media Participation by the Board of Pharmacy

The speaker was unable to attend because of a death in his family, so the item was tabled for another meeting.

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

a. Should Purpose or Condition Be a General Requirement For Labels?

Chair Hackworth reported that at the October Board Meeting, the addition of this component as a required element to the label was discussed.

She said board members, especially those who have cared for an elderly parent, concurred that it is important to have the "purpose" on the prescription label; however, prescribers are not required to include it and may choose not to because of off-label use of medications. She said discussion also included whether or not a pharmacist could include purpose on the label, even though the prescriber didn't include it, if the patient requests it. It was noted that pharmacists should ask patients the purpose of the medication because that could prevent a medication error; and that inclusion of purpose will be a new requirement for e-prescriptions. She said draft language was presented at the October Board Meeting to determine whether there should be regulation/legislation and to see if there was support to proceed. She said the draft language was below.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, ~~if requested by the patient or patients.~~ unless the patient requests that this information not be added to the prescription.

Ms. Hackworth said that at prior meetings it was discussed that someone with HIV may not want that on the label. She said legal counsel informed the board that if purpose was not provided by the prescriber, then the pharmacist would need to call the prescriber or talk to the patient to determine the purpose.

She said the board asked that this item be sent back to the committee for additional discussion.

Discussion

Ms. Herold said it was never intended to put the disease on the label – only the purpose, such as "for infection."

Dr. Castellblanch noted that the prescriber doesn't have to put it on the prescription and the patient may not want it on the label.

Chair Hackworth said there have been instances of the patient taking the same drug twice or not at all based on confusion over purpose. Dr. Castellblanch said there may be research to support this. Dr. Wong said he had a patient come in and during consult noted that the doctor told the patient the purpose was different than the one noted on the prescription. Mr. Schaad said it is not uncommon for a patient to be taking three medications for blood pressure, which

he said could cause more errors with “for blood pressure” on all three labels. He also said it would be time-consuming to chase the doctor down to get the purpose. Dr. Castellblanch said regulation would only apply if the prescriber put the purpose on the prescription. He said the pharmacy doesn’t have to try and get it from the prescriber.

President Weisser said it would be hard for a pharmacist to have a good patient consultation about the drug without knowing what the purpose of the drug is. He commented that he could not understand why pharmacists can talk about the drug purpose with a patient, but they don’t feel comfortable putting it on the label. Dr. Wong said the board should work with the Medical Board to encourage prescribers to include purpose on the prescription.

Dr. Steve Gray, pharmacist, said this item has been worked on for 20 years. He said there are a number of studies and there is anecdotal information to support including purpose on the label. He said the consultation requirement already has the language included about the importance of the medication. He said pharmacists are concerned about the deviation from prescription and the board needs to come up with the language that removes that excuse or the board needs to put in language that leaves it up to a pharmacist’s professional judgment. He said hospitals are trying to prevent readmission by contacting patients one week and then three weeks after discharge to be sure they are taking their medications properly because they are finding that patients are confused about taking them. He said this is a very serious issue that can result in death.

Sonja Frost, pharmacist, said it is important to put purpose on the label, but including professional judgment is also important because she said if it is required, pharmacists may delay filling the prescription until they get the purpose from the prescriber. She said she didn’t want medications for patients to be held up while pharmacists wait.

Brian Warren, from the California Pharmacists Association, said pharmacists would want purpose on the prescription in order to put it on the label and he supported adding the words “in a pharmacist’s professional judgment” to the regulation.

President Weisser asked Mr. Warren how he felt about the pharmacist including purpose during oral consultation. Mr. Warren said during oral consultation a pharmacist uses his or her professional judgment, but printing purpose on the label is different because a pharmacist becomes liable when it is included on the label.

Ms. Herold said staff would work with legal staff on the language.

Mr. Warren said it would be good to hear what pharmacists think “purpose” means.

Tony Wong, pharmacist, said Dr. Gray had to leave the room but asked him to tell the committee that Dr. Gray would not recommend changing section 4040, but rather modify section 1716 (regulation) instead – and that pharmacists could exercise their professional judgment.

The committee instructed staff to continue to work on the language.

4. Preparation for a Future Board Forum on Elements of Quality Patient Consultation

Chair Hackworth said that it was discussed at the last committee meeting and at the October Board Meeting that requirements for patient consultation were adopted by the board in the early 1990s and have not been revised since. She said the importance of patient consultation by a pharmacist was discussed and it was agreed that consultations are still not being conducted as they should be, despite studies that have shown there is better adherence with consultation.

She said the committee discussed that consultation should include items of importance that aren't always on the label, such as storage requirements and number of refills left; and should never be just reciting what is already printed on the label. She said the committee felt pharmacists are in a position to dispel bad information that patients might find on the internet and since pharmacists are health care providers, pharmacists need to engage their patients.

She noted that the committee discussed that 25 years ago when the board adopted patient consultation requirements, the board extended implementation by 18 months to allow for enactment of legislation that permitted pharmacy technicians to work in pharmacies to "free" the pharmacist to perform consultation. She said that during the board meeting, it was stated that pharmacy schools must do more to train their students on how to do a proper consultation and not leave it up to the students to learn during their internships. She said preceptors don't always have the time to train interns on this. Evidence of this is a past study that indicated California pharmacists are not comfortable doing consultations because they weren't trained on how to do them.

She said the committee further discussed that many improvements are needed in the area of pharmacist consultation. She said the board requested that patient consultation and the elements of quality consultation be further discussed by the committee and that a future board meeting discussion be scheduled with California school of pharmacy deans to discuss how schools are educating students to perform patient consultation. She said the deans might also be asked about purpose on the label and how they describe purpose.

Discussion

Dr. Castellblanch said pharmacists don't always have the time to do the consultations and he said a good consultation may also get a pharmacist in trouble because it adds to their workload. Chair Hackworth agreed. President Weisser said two chain pharmacies received hefty fines for their pharmacists failing to consult. He said pharmacists are legally obligated to do the consultation and the board has the ability to uphold that law; he added that there are consequences if it is not done. Dr. Wong said the board keeps creating regulations that add responsibility to pharmacists and the pharmacists aren't compensated for it. He said consultation is important and insurance companies should compensate for it. Chair Hackworth

disagreed and said there should not be compensation for consultation. She said pharmacists should want to inform and educate their patients and doesn't think they should be paid for it. Dr. Wong said he'd like to have a tour of a pharmacy set up for the board members to show the public members what is involved in filling a prescription. He said reimbursements are very low. Chair Hackworth said she is familiar with pharmacy procedures. President Weisser said pharmacies are evolving to become greater health care entities and the board is going to have to work on this evolution.

2b. Translation of Labels and the Use of Translated Directions Available on the Board's Website

This item was taken out of order to accommodate Dr. Anandi Law's schedule.

Dr. Law, B.Pharm., MS, PhD, FAACP, FAPhA, is a professor and chair of the Department of Pharmacy Practice and Administration; and director of ACCP-peer reviewed Fellowship in Health Outcomes at the College of Pharmacy, Western University of Health Sciences. She narrated a PowerPoint presentation by phone titled "Updates on Why We Need Prescription Translations."

Excerpts from the presentation follow.

Why We Need It

Limited English proficiency (LEP): one of the barriers for patients to understand medical instructions

- 44% of California residents speak languages other than English at home
- Nearly half of Latino adults in the US report that they speak English "less than very well"
- Latino patients found to be more likely to misunderstand directions on medication use

Where We Are Now

Methods of Translation

- Computer programs (86%): Google translates to programs
- Lay staff members (11%): someone in the pharmacy who speaks the language
- Professional interpreter (3%): more for counseling

Access

- 43% of pharmacies across the country report availability of translations; 21% report limited service; 35% report no service

Currently Available Languages

- California Board of Pharmacy website offers translations of common instructions in Spanish, Chinese, Vietnamese, Korean, and Russian (top 5 common non-English languages in California)

Challenges with Label Translation

Regulations and liability

- Concerns with pharmacists not being able to verify the label instruction for accuracy before dispensing

Accuracy

- Literature: overall error rate in Spanish-labels: 50% (Bronx, New York); there is access for Spanish labels, but it may not be correct. There are liability issues for pharmacists

Literacy of the patient

- Some patients may not be literate in reading their own language
- For other healthcare providers
Emergency situation requiring paramedics to understand patient's drug labels; needs to be in English, also

Standardization

- There are not completely understandable, patient-centered labels, even in English

Dr. Law also presented a revised sample label which included a timetable for when to take the medication.

Discussion

President Weisser asked Dr. Law what errors were made in Spanish in the Bronx and New York study. Dr. Castellblanch asked about the citation for the study and noted that the information was from 2010, which was before the state law in New York was enacted that required larger pharmacies to provide written language translations. Dr. Law said the errors in Spanish were for incomplete instructions; English and Spanish languages mixed; and errors in spelling and grammar. Dr. Castellblanch emphasized that the information was four years old. He wanted to see the study because he said it is dated. President Weisser asked Dr. Law if she was creating a translated label that would include English. Dr. Law said that the translation may not be as important if the focus is on what the patient really needs and she asked how many language translations would be provided. She suggested just translating the table in her presentation instead of the entire label.

Sarah de Guia, with California PanEthnic Health Network, asked if Dr. Law tested the label in other languages. Dr. Law said they are currently testing the label in Korean. Ms. de Guia asked if the testing was being done for multiple drugs or one specific drug. Dr. Law said they are testing a senior population on the five most commonly used drugs, including hydrocodone for pain. They found that giving the seniors a consultation on how to read labels improved comprehension. She said subjects who did not receive the consultation did not have any improvement. She said the study results are being published.

Dr. Gray asked her how many languages were offered by the 43% of pharmacies that are offering translations and if only translating in one language qualified a pharmacist as part of the 43 percent. Dr. Law said translating in at least one language qualified a pharmacy as providing translations. He said many pharmacies offer only Spanish translations. She agreed and said Spanish-only translations qualified a pharmacy to be included.

Chair Hackworth stated that at the last committee meeting, committee members agreed that patients benefit when translated instructions are provided in their native language; however, there are liability issues for pharmacists when they cannot read or write the language on the label or in ancillary information.

She said the committee discussed that requiring translations could first begin by requiring the use of the vetted instructions on the board's website, which appear in English and five different languages; and then addressing the issue of liability through legislation. She said there was also discussion about section 1716, which holds a pharmacist responsible for deviating from a prescriber's prescription order.

Chair Hackworth said that at the October Board Meeting, discussion included comments that requiring complete translations in all languages could be difficult for many pharmacies and could negatively affect the workflow. She said it was noted that a board survey indicated that approximately 70% of the pharmacies indicated they already had a system in place to provide translations. Concerns were also raised about law enforcement or emergency medical workers needing to have the label printed in English, such as a paramedic or police officer. She said it was explained that the initial intent of the proposal is to have pharmacists use the standardized directions for use, which are on the board's website and are translated into five languages.

Chair Hackworth also said it was stated that the goal of the proposed language was not to provide translations for every language and for every possible type of prescription with complicated directions for use, i.e., Prednisone, but that the goal was to provide translations for the 90% of medications that are dispensed with standard directions for use in the top five non-English languages spoken by Californians. She said during the full board meeting, that board members were provided with draft language to consider, it was noted that the language specifically took the liability off pharmacists if they used the translations provided on the board's website. She stated the board asked that the item be brought back to the committee for further discussion and that the draft language be revised.

Chair Hackworth read the following revised draft language:

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 the use of dangerous drugs that are listed in California Code of Regulations, Title 16, section 1707.5(a) in at least the four most frequently spoken foreign languages in California. These translations shall be approved by state-certified translators. These translated 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 of use from those established in subdivision (b) and append it to 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 established in California Code of Regulations, Title 16, section 1707.5(a). The English version may appear in other areas of the label outside this patient-centered area.

(d) A dispenser shall not be liable for an error which results from a dispenser's inability to understand the foreign language translation made available under subdivision (b), unless gross negligence has been committed by the dispenser.

(e) Dispensers that wish to provide their own translated directions FOR use as an alternative to the process identified in this section may do so should they so choose.

Dr. Castellblanch said he felt the draft language answered the concerns that were raised at prior meetings. He asked what the definition of "dangerous drug" is. Chair Hackworth also echoed his question. Ms. Herold said that "dangerous drugs" are defined in Section 4022 of the Business and Professions Code. She said that term is used because patients don't understand prescription drugs are dangerous drugs. She said dangerous drugs and prescription drugs are the same thing.

Dr. Castellblanch pointed out that there are five translations instead of the four stated in subdivision (b) of the draft language.

Ms. Herold said some corrections needed to be made. She said in subdivision (c) the sentence "The English version may appear in other areas of the label outside this patient-centered area," the word "may" should be changed to "must." She said that is not conditional, that has to be a requirement.

Ms. Herold said that subdivision (e) would read better as "Dispensers that wish to provide their own translated directions FOR use MAY DO SO as an alternative to the process identified in this section ~~may do so should they so choose.~~"

Dr. Castellblanch made a motion to approve the draft with the changes discussed at this meeting.

Ms. Herold pointed out that this would be a legislative change, not a regulation change. Dr. Castellblanch stated that the Legislature already gave the board the authority to regulate the issue. Ms. Herold pointed out that the board cannot regulate civil liability issues, such as holding pharmacists harmless for translation errors. She said the language proposed as legislation would apply to all dispensers, not just pharmacists.

Dr. Castellblanch said that going through the legislative process could take years and asked if the board could use the New York solution. He said in New York, pharmacies use their own translation service, but in New York the third party translator would be liable. He said he didn't know if the New York language would remove the liability issue, but he said that sending the item back to the legislature would be a shame. He asked what board counsel said about the issue. Ms. Herold said that at the last board meeting, counsel said the board would have to go with legislation to remove civil liability of a pharmacy because the board can't remove it with a regulation. She said counsel said the board needed to do a statute change and legal staff was involved in drafting the language presented at this meeting. Ms. Herold pointed out that if the board did a regulation it would only apply to pharmacies and not all dispensers.

Dr. Castellblanch asked what the difference is between a pharmacy and a dispenser. President Weisser said physicians and clinics also dispense medications and that a regulation would not apply to them.

Dr. Castellblanch said he viewed returning the issue to the legislature as giving up because it can take years and he believes the Legislature already told the board what to do. He wanted to know whether New York did translations as a regulation or legislation. He wanted to check legal counsel's opinion that legislation would be required.

Dr. Albert Wong said that 70% of the pharmacies are already providing translations. He said requiring language translations will cause delays at pharmacies. He said he supports translations, but said if a pharmacy needs to do translations, it will. He said the market should be able to sort it out for itself.

Chair Hackworth said she disagreed and said there are times when a patient, who may not speak or read English, would need a translation and the pharmacy needed to be able to provide it. Dr. Wong asked if that was the case then why limit translations to five languages. Chair Hackworth said it is a place to start.

Ms. Herold clarified that the board asked the committee to develop language for a statutory modification that mandated the use of standardized directions for use and the translated directions for use. However, at the last meeting two board meetings, some board members were very clear that their pharmacies already provided translations and they didn't want to have to be bound to provide only the standardized directions for use. She said this is why subdivision (e) was added at the end of the draft language. Ms. Herold said the goal was to provide a transition from not providing any translations at all to providing translations that have been fully vetted in the communities where the languages are spoken. She said no one is using those translations on the board website because there is no waiver from potential

liability. She said the board wasn't looking at requiring full translations, but was looking at using what is already readily available as a first step.

Dr. Wong said the board should encourage translations and work with computer software that translations could be made from, instead of mandating translations. Dr. Castellblanch said that 35% of pharmacies provide no translations at all and that he is sure those pharmacies serve patients who need translations. He said this is a serious health hazard. He said what the legislature told the board is that the board shall promulgate regulations that require that there are standardized patient-centered prescription drug labels on all prescription medicines distributed in California. He said he interprets this to mean that if the board is supposed to require people to do it, then the board has to deal with the liability issue. He said the committee should proceed with regulations and he is strongly opposed to sending it back to the legislature.

Dr. Castellblanch said he had looked up and found the study Dr. Law included in her presentation about the 50% of New York Spanish translations being wrong and he said the study was from 2007 and it was seven years old and done before New York required language translations for prescriptions. He said it is not an indicator of what is now going on with translation services in New York.

Dr. Castellblanch withdrew his motion.

President Weisser asked how the board should deal with the liability issue. Ms. Herold said patients sue under the civil code and the board has no jurisdiction over the civil code. Dr. Wong asked about the New York translation law and he was told that in New York, the translation is not on the prescription container label, it is on an additional piece of paper that is given to the patient. Dr. Wong asked if there is even room on the label for translations. Dr. Castellblanch said he is sure there is room for both. He said to hand patients who don't understand or read English a pill bottle in English is dangerous and irresponsible. Chair Hackworth agreed.

President Weisser said the board is trying to deal with this, but there are differences of opinion on how to do it. He said during the New York translation presentation that one of the big issues was liability. Dr. Castellblanch said he thought the board could deal with liability in a regulation. He asked that the committee direct staff to find out from legal counsel if the board could do a regulation (not legislation) for the liability issue. Ms. Herold said that legal counsel was involved in drafting the proposed language and they drafted it for legislation, not regulation. She said staff would go back to counsel and see if there was another way to deal with liability.

Ms. Herold pointed out that the deadline to submit legislative proposals (language) to Legislative Counsel is at the end of January 2015, which coincides with the next full board meeting. She said the board could possibly draft the language and possibly find someone to back the bill. She said the options are to go ahead and draft legislation just in case, or take it back to the next committee or board meeting. Dr. Castellblanch said the bill has gotten "blown

up” every time it has gone to the legislature and he is not very optimistic about taking the legislative route. He suggested the committee have a ‘Plan A’ and a ‘Plan B’ to cover both legislative and regulatory solutions. Chair Hackworth said her concern is that if the board doesn’t do something about translations then someone else will do it for the board and it may not look anything like what the board wants it to.

The committee discussed having another committee meeting to discuss translations with legal counsel present before the January Board Meeting. Ms. Herold said staff could check if there is an alternative process to provide pharmacists with liability immunity, but expressed concern that if the committee is as divided on which approach to take, then the same concerns would be mirrored at the board meeting. She said it was thought that the committee would resolve those issues at this meeting. She said staff could try and find an author for the legislation without having to commit to that option until after a board decision is made.

President Weisser said he wanted a recommendation from the committee to come to the board at their next meeting and it was clear that they needed legal counsel’s presence and input.

Sarah de Guia, with Pan-Ethnic Health Network, thanked the committee for their work and said she thought it was a good idea to have a ‘Plan A’ and ‘Plan B’. She said there are a number of consumer groups that are willing to offer their support. She also said that the comments made about definition of the term “dangerous drugs” were important and suggested there may be a way to connect back to that definition so that consumers understand. She said her organization understands the concerns of pharmacists, who don’t speak or write other languages, and she wants to be sure they are protected for doing the right thing. She said the biggest concern is subdivision (e) and said her organization supports translations, but questions the quality of them. She said the translations on the board website went through a very good review process. She said there is uncertainty as to the translation source for the 70% of pharmacies that said they are providing translations. She wanted to ensure that there is information collected as to how pharmacies are doing those translations. She also said that patients shouldn’t have to ask for the translations and it should be up to the pharmacy because patients don’t know they have those rights. She said that instead of using the term “foreign language” that “non-English languages” is the correct term that should be used.

Mr. Warren said the draft was excellent and it reflected committee and board discussions as to using the board’s standardized instructions available on the board website. He suggested in subdivision (a) to replace “whenever possible” to “when deemed appropriate in the professional judgment of the dispenser.” He said there are instances when a pharmacist may need to use his professional judgment to determine if the standardized instructions are appropriate.

Regarding subdivision (d), Mr. Warren said he had just confirmed with his association’s legal counsel that the board has the authority to provide pharmacists with immunity from regulatory liability, but not immunity from civil or criminal liability. He suggested the wording from the

Good Samaritan Law in regards to Naloxone be used because it is broader. He said it contains more explicit language that could be used to protect a pharmacist, who in good faith is trying to give patients instructions in their language.

Dr. Castellblanch asked Mr. Warren to provide that information to staff in writing and he said he would provide it to Ms. Herold. Mr. Warren said he thought the changes could be made more quickly in statute instead of with regulation changes. Mr. Warren said his association would support the legislation because it gives a pharmacist liability protection. Dr. Castellblanch asked him why, if statute changes could be done faster, do the bills keep getting killed. Mr. Warren answered that the other bills were for different provisions.

President Weisser asked Mr. Warren what he thought the timeline for passage would be. Mr. Warren said it could be passed in one year because there isn't going to be opposition from the pharmacy community that had been present for past legislation. Ms. Herold said the first question asked when seeking legislation is "who is going to oppose this?" She said the fact that the pharmacy community would be solidly behind this would help.

President Weisser asked what kind of a degree of difficulty would be added if all dispensers are included. Mr. Warren said his group supports having it apply to all dispensers, not just pharmacies. He said it could draw opposition from the medical community, but that he couldn't speak to how the medical community would react.

Dr. Wong asked for clarification on what would be required. Ms. Herold said it would be the standardized directions for use on the board's website available in five translated languages. She said this is a start. Dr. Wong again reiterated that he supported "encouraging" the use of those items, but not requiring it. He also said he supports only translating in the five languages and not requiring translating the information into all languages.

Ms. Herold said staff would confer with legal counsel on what could be done to provide pharmacist immunity with regulations and statutes and another committee meeting would be scheduled in January prior to the board meeting.

5. Update on *The Script*

Chair Hackworth said the Board of Pharmacy newsletter *The Script* is in the review process. She said the issue highlights new laws, board enforcement actions, hospital drug diversion, the Medical Board's release of their revised pain management guidelines and the board's recommendation on no tobacco sales in pharmacies.

6. Redesign of the Board's Website

Ms. Herold said the board is going to redirect its IT person to redesign the website so it will be simpler to use with less information on each page. She said it will take 4-6 months of the IT person's time to complete. Chair Hackworth said there is old information on the site and

Ms. Herold said that will be removed. Dr. Castellblanch said years ago he was on a subcommittee to redesign the website and he'd try to find the information. He said he feels the website redesign is very important.

7. Discussion of National Association of Boards of Pharmacy's .Pharmacy Suffix for Online Pharmacies

Chair Hackworth said the National Association of Boards of Pharmacy (NABP) launched the **.pharmacy** Top-Level Domain (TLD) to provide consumers around the world with a means for identifying safe, legal and ethical online pharmacies and related resources. She said during the initial application and registration phase, eligible trademark holders who have logged their brand names in the ICANN TMCH may apply to NABP for approval to register **.pharmacy** domain names that exactly match their trademark names. She said once approved, these organizations will be able to register the domain with an approved registrar. The initial application phase will begin immediately following a special members-only registration period for NABP's member boards of pharmacy, she said.

Chair Hackworth reported that following the initial application and registration phase, registration for **.pharmacy** domain names will be open to pharmacy websites that are accredited through the NABP Verified Internet Pharmacy Practice Sites® (VIPPS®) and Veterinary-Verified Internet Pharmacy Practice Sites CM (Vet-VIPPS®) programs, as well as for pharmacy websites that have received approval through the NABP e-Advertiser Approval CM Program.

Chair Hackworth said applications from other dispensing pharmacies will be accepted beginning in mid-2015. General availability will begin in June 2015, at which time all entities providing pharmacy-related products, services or information that meet **.pharmacy** eligibility standards will be able to apply to register for the domain. She reported that the **.pharmacy** domain application would be available at **www.dotpharmacy.net** beginning December 19, 2014. Additional information about the **.pharmacy** TLD Program, as well as NABP's most recent research on rogue online drug sellers is also available on the site.

Discussion

Dr. Castellblanch asked if foreign pharmacies would be included. Ms. Herold said this will apply to all pharmacies in the world. Ms. Herold said that the **.pharmacy** domain will also be available to boards of pharmacy so the board has an opportunity to be connected through this. She said the board has a name reserved and in the future the board can post information there. Ms. Herold said she was on the advisory committee and said she will have more information. She said the program will allow patients to tell if a pharmacy site is legitimate.

Dr. Gray, individual, said he hoped Ms. Herold could attend the NABP conference in spring because at the last conference California was the only pharmacy board not in attendance.

8. Update on Media Activity

Chair Hackworth noted some of the items of interest in the attachment.

9. Public Outreach Activities Conducted by the Board

Chair Hackworth commended staff on participating in outreach. Ms. Herold said an item not included on the list was a San Diego presentation she was invited to participate in by the DEA.

10. Review and Discussion of Articles on Issues of Interest

Chair Hackworth noted articles of interest.

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

There were no items for public comment not on the agenda.

Chair Person Hackworth adjourned the meeting.



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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

	Support	Oppose	Abstain
	X		
Hackworth	X		
			X
Weisser	X		
		X	
	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.