



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

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

Rosalyn Hackworth, Chair

Albert Wong, PharmD, Professional Member

Ramon Castellblanch, PhD, Public Member

Allen Schaad, RPh, Professional Member

Stan Weisser, President

A report on the Public Education and Communication Committee meeting held on September 18, 2014, in Sacramento.

1. FOR INFORMATION: Parameters for Patient Consultation as Required by 16CCR Section 1707.2

Background

Requirements for patient consultation were adopted by the board in the early 1990s and have not been revised since.

Committee Discussion

The committee discussed the importance of patient consultation by a pharmacist and agreed that consultations are still not being conducted as they should be, despite studies that have shown there is better adherence with consultation.

They 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 a recitation of what is already printed on the label. They said pharmacists are in a position to dispel bad information that patients might find on the internet and since pharmacists are considered health care providers, the public expects more and pharmacists need to engage their patients.

They discussed that 25 years ago, when the board adopted patient consultation requirements, the board extended implementation by 18 months to allow for legislation that permits pharmacy technicians to "free" the pharmacist to perform consultation.

They said 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. A past study indicated that California pharmacists are not comfortable doing consultations because they weren't trained on how to do them and don't feel comfortable.

The committee discussed a California study that was conducted in the 1990s on consultation and the study showed there was a cost benefit for both a shotgun approach – where everyone was consulted – as well as targeted consultation for high-risk patients. The study showed that both groups benefited, but the high risk group benefited more.

The committee will keep this item on the agenda for future meetings.

2. **FOR DISCUSSION AND POSSIBLE ACTION: Development of the Draft of a Board Policy Statement Recommending the Elimination of Tobacco and E-Cigarette Sales from California Pharmacies**

Background

At the July 2014 board meeting, board members voted to adopt a policy to recommend the elimination of tobacco and e-cigarette sales from California pharmacies and referred the item to this committee for follow-up. At this meeting the committee was presented with two drafts of a recommendation.

Committee Discussion

The committee agreed that making a recommendation against tobacco sales in pharmacies was good for public health. However, they also discussed that the recommendation could encourage other groups in the future to demand that pharmacies stop selling items like alcohol and junk food.

They concluded that other products have some redeeming values, but tobacco and tobacco products do not. They also discussed whether the recommendation should also be directed at supermarkets and box stores that may sell tobacco in another part of the store and they decided those stores should also be included.

Committee Recommendation (Motion): Recommended that the board adopt a policy statement that: The California State Board of Pharmacy recognizes that pharmacists are health care providers and pharmacies are in the business of improving customer health; therefore the board recommends that pharmacies and chain stores that include pharmacies eliminate the sale of tobacco, e-cigarettes and tobacco products, as these products are known to cause cancer, heart disease, lung disease and other health problems.

Support: 5 Oppose: 0 Abstain: 0

3. FOR DISCUSSION AND POSSIBLE ACTION: Resumption of the Committee’s Assessment of California’s Patient-Centered Labeling Requirement

Background

Title 16 California Code of Regulations section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, there was much public comment from numerous stakeholders. As such, the board included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5, which directed the board to promulgate regulations for improved prescription container label design that would be patient-centered. Numerous presentations were made at the July 31, 2014, Patient-Centered Prescription Label Forum.

At the October 2013 board meeting, the board voted to amend two items of 1707.5(a) – requiring 12-point font for all elements of the patient centered label and an express prohibition that nothing but the designated patient-centered elements appear in the 50 percent of the label space dedicated to the patient-centered elements. At the January 2014 board meeting, these two changes were moved to notice for public comment to initiate a rulemaking and were not a part of the committee discussion.

The following items were considered for discussion and possible action.

a. Should Section 1707.5(a)(1)(B) Require Listing of the Manufacturer’s Name in the Patient-Centered Clustered Area of the Label When a Generic Drug Is Dispensed?

Background

Current statutory law for prescription container labels requires that if a generic drug is dispensed, then the manufacturer’s name must also appear somewhere on the label. If a brand name is dispensed, then no manufacturer’s name is required on the label.

In a prior meeting, the committee had recommended to the board the removal from the patient-centered area of the label in 1707.5 (a)(1)(B) of “and the name of the manufacturer” when a generic is dispensed.

The manufacturer’s name is still required by Business and Professions Code section 4076 to appear elsewhere on the label every time a generic is dispensed. At past board meetings, there was disagreement as to whether the manufacturer’s name needed to be in the patient-centered section.

Possible language to remove the manufacturer’s name from the patient-centered area (but it would still be required to appear elsewhere on the label) is:

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
- (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name ~~and the name of the manufacturer.~~

Committee Discussion

The committee discussed the importance of having the manufacturer’s name on the label because pill sizes, colors and shapes vary between manufacturers; and critical recalls would require knowing the manufacturer’s name.

They determined that while the manufacturer’s name needs to be on the label, it does not need to appear in the patient-centered portion of the label.

Committee Recommendation (Motion): The committee recommended: Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name. ~~and the name of the manufacturer.~~

Support: 5 Oppose: 0 Abstain: 0

- b. When a Generic Drug Is Dispensed, Should the Brand Name of the Generic Equivalent Be Included on the Label Phrased as “Generic for _____”?**

Background

The committee has previously discussed this issue, but has not taken action to require that when a generic drug is dispensed that “generic for [insert brand name]” is required on the label to ensure patients do not mistakenly take both forms of the medication. For example “Alendronate Tab 70 mg. generic for Fosamax.”

Committee Discussion

The committee discussed the importance of including the generic name on the label so that if a drug from a different manufacturer is dispensed and the patient has both the old and new version of the same drug that they don't take both by mistake. The committee requested that draft language be brought back to the board for discussion and possible action.

One solution could be to include "generic for _____" and include the brand name, and to require the brand name be listed for a period of time (e.g., five years after patent's expiration), or leave it up to the professional judgment of the pharmacist. Language to do this is provided below:

(1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface and listed in the following order:

(A) Name of the patient

(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for ____" where the brand name is inserted into the parentheses. If it has been at least five years since the expiration of the brand name's patent or if in the professional judgment of the pharmacist the brand name is no longer widely used, the label may list only the generic name of the drug and the name of the manufacturer.

c. Should Purpose or Condition Be a General Requirement for Labels?

Background

The addition of this component as a required element to the label has been discussed periodically for years.

Committee Discussion

Committee members, especially those who have cared for an elderly parent, concurred that it is important to have purpose on the label; however, prescribers are not required to include it and may choose not to because of off-label use of medications.

The committee also discussed whether or not a pharmacist could include purpose on the label, even though the prescriber didn't include it, if the patient requests it. This question was referred to legal counsel.

It was discussed that pharmacists should ask patients the purpose of the medication because that could prevent a medication error and the inclusion of purpose will be a new requirement for e-prescriptions.

The committee asked that draft language be presented at the next board meeting to determine whether there should be regulation/legislation and to see if there is support to proceed.

Draft language:

4040. Prescription; Content Requirements

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, his or her license classification, and his or her federal registry number, if a controlled substance is prescribed.

(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.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, podiatrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner

consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) “Electronic transmission prescription” includes both image and data prescriptions. “Electronic image transmission prescription” means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. “Electronic data transmission prescription” means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

(e) Nothing in the amendments made to this section (formerly Section 4036) at the 1969 Regular Session of the Legislature shall be construed as expanding or limiting the right that a chiropractor, while acting within the scope of his or her license, may have to prescribe a device.

d. Should the Existing Requirements for “Added Emphasis” in the Patient-Centered Area of the Prescription Label Be Modified?

Background

At the January 2014 committee meeting, there was no committee or public discussion on this item. It was included on the agenda to ensure the committee has no interest in modifications to this element.

Committee Discussion

The committee concurred that this element should be left as is.

e. Translations on Labels:

1. Translated Directions for Use Are Available on the Board’s Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?
2. Should There Be a Specific Requirement for Labels to Be Translated? If So, What Components Are Needed (e.g., Also printed in English, Only Directions, and Exemption from Liability for Translation Errors)?

Committee Discussion

The committee 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.

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.

There was also discussion about section 1716, which holds a pharmacist responsible for deviating from a prescription.

Committee Recommendation (Motion): Staff shall provide the board with recommendations for requiring translations with special consideration given to using the board website translations and providing pharmacist liability, and will consider Senator Corbett's proposed legislation on pharmacist liability.

Support: 5 Oppose: 0 Abstain: 0

These recommendations will be handed out at the board meeting.

f. Should the Board Adopt Liquid Measurement Standards as Recommended by NCPDP?

Background

The National Council for Prescription Drug Programs in March 2014 released liquid dosing instructions to provide recommendations and guidance for standardizing the dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies. The goal is to improve patient safety and outcomes by decreasing the potential for errors when patients and caregivers take and administer these medications.

Committee Discussion

The committee members noted that the board's regulations are silent on the issue of liquid dosing and proper liquid measurement is very important, especially for infants who are the most dose-sensitive.

Committee members said there are many different types of teaspoons available in the home that could mistakenly be used to dispense liquid medication. The committee

said, “Take one teaspoon” used to be a standardized direction, especially on pediatric prescriptions.

They said the use of syringes is a much more accurate means of measuring liquid doses. The committee said the standard is to use mLs, but parents don’t often have mLs measuring devices at home. The committee recognized that providing syringes with prescriptions adds time and expense; and syringes can take some sophistication on the patient’s part to use.

It was pointed out that if using mLs is required, then there will have to be certified conversions and there is no agreement on conversion rates between teaspoons to mLs.

The committee directed staff to include an article in the *Script* newsletter to begin to inform pharmacists about liquid measurements.

g. Should the Board Consider Technology Standards to Enhance the Patient-Centered Requirements?

Background

At past committee meetings, the committee has discussed that some pharmacies are able to provide pictures of the pill on the prescription label, instead of the verbal description of the medication -- which is a statutory requirement for all labels. The committee has not determined that requiring items like a picture of the pill on the label to replace the description is technologically feasible at many pharmacies.

Committee Discussion

The committee discussed that there is no standardization in technology available at different pharmacies to create requirements. For example, some pharmacies can use a color printer and can include a color photo of the pill on the label, while other pharmacies only have black and white printers.

There was no desire by the committee at this time to consider technology standards to enhance the patient-centered label. However, as technology evolves it may become feasible in the future.

4. FOR INFORMATION: Update on *The Script*

The next edition of *The Script* is expected to be completed this fall and will highlight new California laws.

5. FOR INFORMATION: Update on the Board’s Consumer Education Brochure on Counterfeit Drugs

Final edits were being made to a new brochure on counterfeit drugs and it would soon undergo legal review.

NOTE: The brochure is now completed.

6. FOR INFORMATION: Public Continuing Education Training Session by the California State Board of Pharmacy and DEA Held September 2 and 3, 2014, in Santa Barbara

Background

The Board of Pharmacy and the DEA held two continuing education training sessions on September 2 and 3 in Santa Barbara on diversion prevention titled “Pharmacy Diversion Awareness Conference.” The event was attended by 142 people – 81 on the first day and 61 on the second day.

Committee Discussion

The committee discussed that the board continues to have a demand for these training sessions and the board is also registering pharmacists into CURES at these events. The committee noted that for the first time at one of these educational programs, 75-80 percent of the attendees raised their hands when asked who was registered to use CURES.

7. FOR INFORMATION: Update on Media Activity

A report on recent media contacts handled by board staff was presented. Media coverage included advanced practice pharmacy, patient-centered labels, prescription drug abuse, compounding pharmacies and board enforcement cases. Media outlets covering these issues included the *Los Angeles Times*, *Sacramento Bee*, *National Public Radio* and television stations.

A complete list of media activity is available in the attached minutes.

8. FOR INFORMATION: Public Outreach Activities Conducted by the Board

Background

The board continues to participate in community outreach events that inform consumers about such issues as prescription drug abuse and concerns for seniors. The board also participated in informative meetings with government officials on advanced practice pharmacists and prescription drug abuse prevention.

Of note is the board's participation in a state work group that is working to create a unified message on prescription drug abuse and overdose prevention.

A full list of public outreach activities is included in the attached meeting minutes.

Committee Discussion

Committee members discussed that the Board of Pharmacy and the Medical Board teamed up to provide a presentation for the dental association on prescription drug abuse, as dentists are one of the top three prescribers of hydrocodone.

Staff said there is great concern regarding the rescheduling of hydrocodone because patients may present at pharmacies and request refills that may no longer be available. Staff said the board sent a subscriber alert in advance of the Oct. 6 rescheduling of hydrocodone to educate licensees.

9. FOR REVIEW AND DISCUSSION: Articles on Issues of Interest

Background

Many articles of interest were included in the meeting attachments and the committee noted those articles included informative pieces on the "100 Most Prescribed Drugs;" and an article on how seniors are medicated in nursing homes.

10. FOR REVIEW AND DISCUSSION: The 43rd Annual Report of the Research Advisory Panel of California

Background

California law, pursuant to Health & Safety Code sections §11480 & §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. The Board of Pharmacy has an appointee on the panel.

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.

During 2013, the panel reviewed 32 research study submissions. Twenty-eight were approved by the panel. Among the approved studies, 10 studies were academic research studies, nine studies were substance abuse treatment research protocols and nine studies were multi-clinical drug trial research studies. At the end of 2013, the panel was monitoring 89 research projects.

Committee Discussion

The committee members said they wanted to hear a full presentation of this item and directed staff to add it to an upcoming agenda and invite guest speakers.

The next meeting will be held on December 10, 2014.

Meeting minutes from the September 18 meeting are provided in **Attachment 1**.

Attachment 1



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GOVERNOR EDMUND G. BROWN JR.

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

DATE: September 18, 2014

LOCATION: Department of Consumer Affairs
1625 N. Market Blvd., 1st Floor Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS Rosalyn Hackworth, Chair
PRESENT: Ramon Castellblanch, PhD
Albert Wong, PharmD
Allen Schaad, R.Ph.
Stan Weisser, R.Ph., President

STAFF Virginia Herold, Executive Officer
PRESENT: Anne Sodergren, Assistant Executive Officer
Joyia Emard, Public Information Officer

Call to Order

Chair Rosalyn Hackworth called the meeting to order at 10:05 a.m. Committee members present were: Ramon Castellblanch, Albert Wong, Allen Schaad and Stan Weisser.

1. FOR DISCUSSION: Parameters for Patient Consultation as Required by 16CCR Section 1707.2

Chair Hackworth explained that requirements for patient consultation were adopted by the board in the early 1990s and have not been revised since.

Chair Hackworth read the regulation and asked how often pharmacists give instruction about storage. President Weiser said there are some medications, such as pediatric medications and suppositories, which require refrigeration. Mr. Schaad said he believes that pharmacists do address that issue.

Chair Hackworth asked about refills. Mr. Schaad said refill information is on the bottle, but Chair Hackworth said she's never had a pharmacist tell her how many refills are left during consultation. President Weisser said he doesn't see refill information as an important part of a consultation. Ms. Virginia Herold said there is no specific regulation for requiring that refill information appear on the label. She said she does not believe patients are receiving proper consultation. She said the

requirement is that pharmacists initiate a consultation with patients, not that patients be asked if they want a consultation. Ms. Herold said the board is working with three California district attorney offices and conducting undercover operations. When instances of failure to consult are found, they are using the unfair business practices, Business and Profession Code 17200, to file charges. Two major pharmacy chains have been fined almost \$500,000 each. After 25 years, she said, the board should be better positioned so that patients know about and value a consultation and it should never be a recitation of just what is on the label. She said it has been a disservice to the public that consultation isn't done more often because a pharmacist has valuable information to share with the patient. She said that pharmacists are also in a position to dispel bad information that patients might find on the internet.

Chair Hackworth said she often finds that pharmacists are too busy to help and that patients may feel they are bothering the pharmacist if they ask questions. President Weisser said since pharmacists are considered health care providers, the public expects more and pharmacists need to engage their patients. Dr. Ramon Castellblanch asked what research has been done as to best practices and Chair Hackworth asked what other states are doing.

Ms. Herold said some pharmacy schools actually have contests for consultation. She said studies have shown there is better adherence with consultation. She said all states require that pharmacists offer consultation, but California's law states pharmacists must consult – this is not an offer to consult.

President Weisser said there is a rumor that the large pharmacy chains don't encourage pharmacists to find the time to consult and the board has fined pharmacies because of it. Chair Hackworth said pharmacists finding the time has been a bone of contention. Ms. Herold said both pharmacy chains fined for lack of consultation signed consent agreements that they will have their pharmacists provide consultations.

Mr. Schaad said there is no shortage of pharmacists to justify not doing consultations. Dr. Wong said the Legislature and the board keep adding tasks for pharmacists, but there is no financial incentive for pharmacists to comply. Ms. Herold said she thinks that the board supports arguments that pharmacists should be compensated, but the board doesn't have the power to make that decision.

Dennis McAllistair, R.Ph., D.Ph., said in 2003 Arizona eliminated the pharmacist-to-technician ratio and certified techs could be behind the counter and pharmacists could do consultation. He said last year Texas eliminated their ratio, as did Florida and New Mexico. Changing the ratio would allow pharmacists more time for consultation. He said 18 states have no ratios.

Ms. Herold said that 25 years ago, when they adopted patient consultation requirements, the board extended implementation by 18 months to allow for legislation that permits pharmacy technicians to "free" the pharmacist to perform consultation.

Steve Gray, representing Kaiser, said the former Pharmacy Foundation of California got behind the issue of patient consultation. He said they conducted studies to find out why consultation wasn't

done. He said they found that pharmacists blame it on their bosses not allowing the time, but the study showed the reason is because pharmacists aren't well-trained and don't feel confident. He said some schools said their students should get consultation training during their internships, but interning is usually done by an alumni of the same school who didn't get the training either. He said out-of-state pharmacy students received much better training on consultation. Dr. Gray stated California pharmacy school students could do 30-minute consultations very well, but could not do them well in two minutes or less. He said he gave Ms. Herold a "Be Smart" guide on consultations. Dr. Gray said in the early 1990s, Kaiser conducted a \$2-million-study with USC on consultation and the study showed there was a cost benefit for both a shotgun approach – where everyone was consulted – as well as targeted consultation for a high-risk patient approach. He said the study showed that both groups benefited, but the high risk group benefited more. He said a few years ago, the board made consultation a priority. He said an increase or elimination in the ratio of techs versus pharmacists has not resulted in more compliance with consultation.

Dr. Gray specifically noted that board inspectors in San Diego asked the pharmacists to conduct a consultation with them on a popular drug. He said the No. 1 one thing pharmacists forgot to mention during consultation was storage information. He said pharmacists mistakenly assume patients understand about storage. He said refill information was also not given and refill information is not always on the label because it is not required to be. He said there are problems with adherence when people don't realize they have refills available or have no refills left. He said discussions need to be held with the pharmacy schools on consultation.

Dr. Gray said hospitals are now penalized for 30-day readmissions and they found that discharge consultations are practically worthless because there is too much going on at discharge, so hospitals are paying for pharmacists to consult with the patients later. He asked that if consultation is still the No. 1 goal of the board, then why isn't there mandatory continuing education.

Sarah de Guia, executive director of CPEHN, said it would be helpful to link the requirement of consultation with the oral language translation requirement because they are in separate areas of pharmacy law and there needs to be some sort of connection between the two.

Dr. Wong said there should be more continuing education courses offered and completing them could be a requirement for license renewal.

Dr. McAllister said the PTCB exam was formed to set a bar of minimum level for pharmacy technician training and in 2020 the technician must graduate from an ATC-accredited school to help standardize the training of technicians.

The committee directed staff to keep this item on the agenda for future meetings.

2. FOR DISCUSSION AND POSSIBLE ACTION: Development of the Draft of a Board Policy Statement Recommending the Elimination of Tobacco and E-Cigarette Sales from California Pharmacies

Chair Hackworth said that at the July 2014 board meeting, board members voted to adopt a policy to recommend the elimination of tobacco and e-cigarette sales from California pharmacies and referred the item to this committee for follow-up.

Chair Hackworth presented drafts of two possible statements that the committee could use as a starting point for discussion.

Dr. Castellblanch said that the board taking a stance against tobacco sales in pharmacies is a good step forward for public health.

President Weisser said he supports the stance in general, but some supermarkets and big box stores have tobacco products available in the front of the store and not in the pharmacies.

Dr. Gray said he didn't think that the board would accomplish what they wanted by just saying "in pharmacies" and allowing tobacco to be sold in another part of the store. He said he thought the intent was to follow what Marin County and San Francisco did, which was whether it was a chain store with cigarettes locked up in the front of the store or a Costco, if the facility wants to have a retail pharmacy then they cannot have tobacco products anywhere in that store. He said if the board isn't specific about their meaning, then a supermarket could say, "You are only talking about pharmacies, you are not talking about me."

Dr. Castellblanch said this is just a recommendation, not a ban. Dr. Gray said there are distinctions being brought up in court.

Fred Mayer said in Canada, Walmart challenged the ban on tobacco in pharmacies and Walmart lost. He said he wants to be sure this applies to all box stores and the chain stores – any facility with a pharmacy in it would not be allowed to sell tobacco products.

President Weisser asked Dr. Mayer what his motivation was to do this. Dr. Mayer said pharmacists are health care providers and shouldn't be selling cigarettes. Chair Hackworth asked if he plans to try and ban cigarette sales in pharmacies. Mayer said he is not sure what the next step would be – perhaps to go to the legislature to achieve a ban. President Weisser said he agrees with everything Dr. Mayer said, but asked what would prevent Dr. Mayer from coming back in a year and asking for a recommendation that pharmacies and stores with pharmacies not sell alcohol. He said his concern is that there may not be an end to people coming to the board to ban what they consider unhealthy. He thought it would be opening a Pandora's box. Dr. Mayer said California's pharmacy board would be the first to tell pharmacists it is not acceptable to sell tobacco products. He said if the board really represents the consumer then pharmacies should not be selling tobacco; and if the board's mission statement is to protect public health, then pharmacists shouldn't be selling cigarettes.

Dr. Aglaia Panos, president of Marin County Pharmacists Association, said there is proof that nicotine is the gateway drug to all other drugs. She said the *New England Journal of Medicine* reported there is an increase in child poisoning from e-cigarette vials.

Dr. Gray said CHSP and CPHA have policies on the books that support this recommendation. He said President Weisser asked a very good question about whether alcohol will be next. He said science shows there is redeeming value in alcohol, but not tobacco. Tobacco has no redeeming qualities. He said it is a red herring argument that other items will be next after tobacco.

Mandi Lee, with the California Retailers Association, expressed her disappointment with the board taking this position and said she had stated the association's opposition before. She said the board is going down a very slippery slope with this recommendation. She said it is getting into dangerous space with the Board of Pharmacy dictating the business operations of pharmacies. She asked if alcohol, sugary drinks and junk food are going to be next.

Committee Recommendation (Motion): Recommended that the board adopt a policy statement that: The California State Board of Pharmacy recognizes that pharmacists are health care providers and pharmacies are in the business of improving customer health; therefore the board recommends that pharmacies and chain stores that include pharmacies eliminate the sale of tobacco, e-cigarettes and tobacco products, as these products are known to cause cancer, heart disease, lung disease and other health problems.

Support: 5 Oppose: 0 Abstain: 0

3. FOR DISCUSSION AND POSSIBLE ACTION: Resumption of the Committee's Assessment of California's Patient-Centered Labeling Requirement

Chair Hackworth explained that Title 16 California Code of Regulations section 1707.5 specifies requirements for patient-centered labels for prescription drug containers. When the board promulgated these requirements, there was much public comment from numerous stakeholders. As such, the board included in subdivision (e) a requirement that the board re-evaluate the requirements by December 2013 to ensure optimal conformance with Business and Professions Code Section 4076.5, which directed the board to promulgate regulations for improved prescription container label design that would be patient-centered.

She said numerous presentations were made at the July 31, 2014, Patient-Centered Prescription Label Forum and a portion of this meeting will include discussion of the information provided at the July meeting.

Chair Hackworth said at the October 2013 board meeting, the board voted to amend two items of 1707.5(a) – requiring 12-point font for all elements of the patient centered label and an express prohibition that nothing but the designated patient-centered elements appear in the 50 percent of the label space dedicated to the patient-centered elements. She said at the January 2014 board meeting, these two changes were moved to notice for public comment to initiate a rulemaking, and were not a part of the discussion scheduled for this committee meeting.

The following items were considered for discussion and possible action.

a. Should Section 1707.5(a)(1)(B) Require Listing of the Manufacturer’s Name in the Patient-Centered Clustered Area of the Label When a Generic Drug Is Dispensed?

Chair Hackworth said current statutory law for prescription container labels requires that if a generic drug is dispensed, then the manufacturer’s name must also appear somewhere on the label. If a brand name is dispensed, then no manufacturer’s name is required on the label.

She said in a prior meeting, the committee had recommended to the board the removal from the patient-centered area of the label in 1707.5 (a)(1)(B) of “and the name of the manufacturer” when a generic is dispensed.

Chair Hackworth said the manufacturer’s name is still required by Business and Professions Code section 4076 to appear elsewhere on the label every time a generic is dispensed. At past board meetings, there was disagreement as to whether the manufacturer’s name needed to be in the patient-centered section.

Possible language to remove the manufacturer’s name from the patient-centered area (but it would still be required to appear elsewhere on the label) is:

- (a) Labels on drug containers dispensed to patients in California shall conform to the following format:
 - (1) Each of the following items shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12-point sans serif typeface and listed in the following order:
 - (A) Name of the patient
 - (B) Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name ~~and the name of the manufacturer.~~

Dr. Castellblanch said he doesn’t know of any research that indicates it’s important for the manufacturer name to be on the label and it may make more room on the label for other items. Chair Hackworth agreed. Dr. Wong said it is important to him as a pharmacist because when a patient comes back for a refill he tries to give the patient the same manufacturer’s drug because pill sizes, colors and shapes vary between manufacturers. He said the manufacturer needs to be somewhere on the label, but it doesn’t have to be in the patient-centered section of the label. President Weisser said having the pill description somewhere on the label with the manufacturer name is important, but not in the patient-centered section of the label. Mr. Schaad concurred.

Dr. Mayer said there was recently a manufacturer recall of a Coumadin drug and said the recall was a matter of life and death and the manufacturer’s name needs to be readable to consumers. Ms. Herold said it is up to the pharmacy to contact patients when there is a recall. She said it is a professional obligation. Dr. Mayer said he wasn’t aware of a law to require that. Ms. Herold and President Weisser both said that no law should be required to have a pharmacist fulfill his or her professional duty to patients in the event of a recall.

Dr. Gray said there needs to be some discussion on the readability of the rest of the label. He also suggested that common manufacturer’s identity rather than the manufacturer’s name would be

better to use. He said the identity is usually a commonly known, abbreviated form of the name. He suggested changing the wording in the regulation from “name” to “identity.” He said pharmacists know the manufacturer identity and it is important to them.

Committee Recommendation (Motion): Name of the drug and strength of the drug. For the purposes of this section, “name of the drug” means either the manufacturer’s trade name of the drug, or the generic name. ~~and the name of the manufacturer.~~

Support: 5 Oppose: 0 Abstain: 0

b. When a Generic Drug Is Dispensed, Should the Brand Name of the Generic Equivalent Be Included on the Label Phrased as “Generic for _____”?

Chair Hackworth said the committee has previously discussed this issue, but has not taken action to require that when a generic drug is dispensed that “generic for [insert brand name]” is required on the label to ensure patients do not mistakenly take both forms of the medication. For example “Alendronate Tab 70 mg. generic for Fosamax.”

Chair Hackworth said she thinks it is very important to include the generic name on the label so that if a drug from a different manufacturer is dispensed and the patient has both the old and new version of the same drug that they don’t take both by mistake. President Weisser and Dr. Castellblanch agreed, but wanted to have a draft of the language before voting on it. Ms. Herold said there were drafts on past agendas and they would be brought back to the board at the next meeting.

c. Should Purpose or Condition Be a General Requirement for Labels?

Chair Hackworth reported that the addition of this component as a required element to the label has been discussed periodically for years.

Chair Hackworth said she supports this and as a caregiver for an older parent, realizes it is important to have purpose on the label of her mother’s medication. Dr. Castellblanch agreed and pointed out that it is up to the medical profession to agree to include this on prescriptions and they sometimes don’t like to include it because they may be using a medication off label. Both President Weisser and Dr. Wong asked if the patient requests this information be on the label and the prescriber did not include it, can pharmacists include it. Ms. Herold said in order to do that the statute would need to be amended. She said at one time there was a provision to do that, but it was amended to be what is included here. Dr. Wong said this was proposed at one time and there was resistance. Ms. Herold said if the patient wants it on the label and requests it then there is no reason a pharmacist shouldn’t be able to do that. Dr. Castellblanch suggested that legal counsel research this question as to whether a pharmacist can include purpose on the label if the prescriber didn’t indicate it.

Dr. Gray said the legislation was trying to mandate that the prescriber include the purpose on the prescription, the compromise was to have it on label if it was included on the prescription.

He said it shouldn't be a problem, it is a minimum requirement. He said prescribers have used the off-label argument to leave it off the prescription. He said pharmacists should ask the patient what the medication is prescribed to treat as that could prevent a medication error. He said schools are teaching their pharmacy students differently on this topic. He said it needs to be clarified that pharmacists use their professional judgment as to whether or not to put it on the label, even if it is not included. He said new requirements on e-prescriptions will move this forward. He recommended the board proceed with the regulation. He said CMS is going to make it mandatory in the future, but it is proceeding slowly. He said this is the No. 1 item missing from the label.

Ms. Herold said the board needs to do serious work with the prescribers in order to be successful. Dr. Castellblanch said research indicates that up to 20 percent of prescriptions are for off-label uses. Dr. Gray said the Medical Board supported that purpose be on the label and California Association of Physician Groups (CAPG) agreed this would help prevent problems with patients. He said he believes things are different from 10 years ago and that there would now be more support and there are more study results that support having purpose or condition on the label.

The committee asked that staff draft language for the next board meeting to determine whether there should be regulation/legislation and to see if there is support to proceed and if there is documentary evidence that can be provided.

d. Should the Existing Requirements for "Added Emphasis" in the Patient-Centered Area of the Prescription Label Be Modified?

Chair Hackworth said that at the January 2014 committee meeting, there was no committee or public discussion on this item. It is repeated here just to ensure the committee has no interest in modifications to this element.

She said she is opposed to it because if you emphasize too much information on the label, then patients won't pay attention to any of it. Dr. Castellblanch agreed. The committee concurred that this element is fine as is.

e. Translations on Labels:

1. Translated Directions for Use Are Available on the Board's Website. Should the Board Require Use of Them to Aid Patients with Limited English Proficiency?
2. Should There Be a Specific Requirement for Labels to Be Translated? If So, What Components Are Needed (e.g., Also printed in English, Only Directions, and Exemption from Liability for Translation Errors)?

Chair Hackworth said the board has translated instructions on its website and verbal translations at consultation don't carry over to the home. She believes it would be good for patients to have written directions in their native language. President Weisser agreed, but

said the board needs to encourage the use of the standardized instructions already available. He said once there are standards, then there can be translations. He said there is also the issue of liability. Chair Hackworth said pharmacists she spoke to are concerned about the accuracy of the translations when they don't read or speak the language and want some protection for liability. Dr. Castellblanch said it is time to proceed with mandating translations and New York is already doing this. He said it is practical as all the major chains are already doing this in New York. He said a colleague of his said in Paris she received a prescription label that was in five languages, including Braille. He said if the French can do it, then so can the board. Dr. Wong said he supports label translations and his pharmacy has been doing this for 30 years. However, he is concerned about liability if translations become required.

Chair Hackworth asked if there is committee support to require translations on labels. President Weisser said if the board requires translations, then there has to be some provisions for liability.

Ms. Herold said requiring translations can be started slowly by first requiring the use of the vetted instructions on the board's website. She said the issue of liability has to be addressed through legislation.

Dr. Wong said mandatory translations of labels could be difficult and dangerous. Dr. Castellblanch said Mike Wolf tested a number of directions and came up with the ones on the website and then they were translated. He said it was never the intention to translate complicated prescriptions, but only the simpler ones. Dr. Wong said legislation is not needed. He said there is software available to do the translations and the board should spend their energy to have software with standardized translations available instead of creating more legislation. Chair Hackworth said she talked to New York pharmacists who said the software is not cost prohibitive. Ms. Herold said during inspections the board found that 70 percent of pharmacies said they are providing translations, but only one pharmacy said it is using the board's translations from the website. She said of those pharmacies doing translations, 37 percent had staff do some translations and 82 percent used computer software or went online.

Dr. Mayer said medication errors are the most common type of errors and the second highest cause of emergency admission. He asked the board to look at translation errors and Braille for the blind and something for the hard-of-hearing. He thanked the board for the 12-point font requirement. He said his organization is in favor of what the board is doing and wants to work with the board.

Ms. de Guia said CPEHN is very supportive of the proposal. She added they are not sure of the quality of the translations currently being provided by pharmacists. She also said that English as a second language speakers don't understand their rights. She said providing translations is doable.

Brian Warren, with the California Pharmacists Association, echoed the liability concerns with providing translations. He said the SB 204 language was not very comprehensive and New

York's law requires a court to determine whether or not a pharmacist made a reasonable effort. He said it is often more cost effective to just settle out of court than to try to fight to prove a pharmacist took reasonable action. He said those settlements get reported to the Board of Pharmacy and could lead to increases in malpractice insurance costs. He asked that any translation requirements not be effective until liability legislation is enacted. He also said there is a need for standardized language in regulations that prohibit a pharmacist from deviating from the prescription and whether they have the legal ability to do that. He stated that language is needed to say that a pharmacist does have that ability. Ms. Herold agreed that it is often less expensive to settle than fight. She invited Mr. Warren to bring specific language of what they have in mind to the board.

Dr. Gray concurred with Mr. Warren. He said the board needs to look at section 1716, which holds a pharmacist responsible for deviating from a prescription. He said unless that is changed, it provides an excuse for pharmacists not to do it. He said that regulation is the most frequently cited in citations and fines. Ms. Herold said the regulation is how the board cites for medication errors. She said it's cited for wrong dosages, wrong drug or wrong number of pills. Dr. Gray said the threshold for pharmacies reporting settled claims is \$3,000 or more, but for physicians the threshold is \$30,000. Ms. Herold said not everyone is reporting their settlements and when the board finds out they are fined.

Dr. Panos asked how this this would relate to the 20 percent of prescriptions that are mail order. Ms. Herold said that is why a statutory mandate is required to be sure that every patient in California receives translated labels.

Committee Recommendation (Motion): Staff will provide the board with recommendations for requiring translations with special consideration given to using the board website translations and providing pharmacist liability, and will consider Senator Corbett's proposed legislation on pharmacist liability.

Support: 5 Oppose: 0 Abstain: 0

f. Should the Board Adopt Liquid Measurement Standards as Recommended by NCPDP?

Chair Hackworth said the National Council for Prescription Drug Programs in March 2014 released liquid dosing instructions to provide recommendations and guidance for standardizing the dosing designation (the amount and volumetric units) used on prescription container labels of oral liquid medications dispensed from community pharmacies. The goal is to improve patient safety and outcomes by decreasing the potential for errors when patients and caregivers take and administer these medications.

She said the board's existing regulation is silent on liquid dosing instructions.

President Weisser said the board's regulations are silent on this at best and there are lots of different types of teaspoons available in the home. He said "Take one teaspoon" was a standardized direction, especially on pediatric prescriptions. He said providing syringes with

prescriptions adds time and expense; and syringes take some sophistication on the patient's part to use. He said syringes are much more accurate and biometrics are better. Dr. Wong said at his pharmacy, he gives syringes. Ms. Herold said the standard is to use mLs and only mLs, Dr. Wong said parents don't often have mLs measuring devices at home.

Dr. Gray said "teaspoon" means different things in different cultures and different countries and pharmacies should provide the measurement items. Dr. Ruth Conroy, from Walgreens, agreed with Dr. Gray and said Walgreens encourages their pharmacists to use mLs instead of teaspoons or tablespoons.

Ms. Herold said liquid measurement is an area for errors, especially for infants who are the most dose-sensitive.

Dr. Wong said if you require mLs then you will have to have certified conversions. Dr. Gray said there is no agreement on conversion rates between teaspoons to mLs.

Staff will include an article in the *Script* newsletter to begin to inform pharmacists about liquid measurements.

g. Should the Board Consider Technology Standards to Enhance the Patient-Centered Requirements?

Chair Hackworth said at past committee meetings, the committee has discussed that some pharmacies are able to provide pictures of the pill on the prescription label, instead of the verbal description of the medication -- which is a statutory requirement for all labels. The committee has not determined that requiring items like a picture of the pill on the label to replace the description is technologically feasible at many pharmacies.

Dr. Wong said this is all voluntary and said if there is a demand then pharmacists will provide it. Chair Hackworth asked what happens when the manufacturer changes the pill and who ensures the pill description is the same as on the label. She said she is not in favor of this.

Dr. Gray said the statute requires that the board consider this and that the pill description and photos are readily available on a national level from a recognized provider. Dr. Conroy said a lot of pharmacies have black and white printers so photos of colored pills are meaningless.

4. FOR INFORMATION: Update on *The Script*

Chair Hackworth reported that the next edition of *The Script* is expected to be completed this fall. It will highlight new California laws.

5. FOR INFORMATION: Update on the Board's Consumer Education Brochure on Counterfeit Drugs

Chair Hackworth said final edits are being made to a new brochure on counterfeit drugs and it will soon undergo legal review.

6. FOR INFORMATION: Public Continuing Education Training Session by the California State Board of Pharmacy and DEA Held September 2 and 3, 2014, in Santa Barbara

Chair Hackworth informed the committee that the Board of Pharmacy and the DEA held two continuing education training sessions on September 2 and 3 in Santa Barbara on diversion prevention titled "Pharmacy Diversion Awareness Conference." The event was attended by 142 people – 81 on the first day and 61 on the second day.

Ms. Herold said the board continues to have a demand for these training sessions. She said the board is also registering pharmacists into CURES at these events and for the first time at one of these educational programs, 75-80 percent of the attendees raised their hands when asked who was registered to use CURES.

7. FOR INFORMATION: Update on Media Activity

A report on recent media contacts handled by the office were presented at the meeting.

Advanced Practice Pharmacy

6/5/14: Bakersfield Californian, Courtney Edlhart

Glendale pharmacy license suspended

6/19: L.A. Times, David Lazarus

6/20: Glendale News Press, Mark Kellam

Pharmacists refusing to fill oral contraceptive prescriptions

7/18: Legal Daily Journal, Emily Green

Patient Centered Labels

6/20: California Healthline, Staff

7/31: Sacramento Bee, Sammy Caiola

7/28: NPR KQED San Francisco, April Dembosky

7/29: NBC San Luis Obispo, LeeLee Tan

Translated Labels

9/6: Pharmacy Today, Sonya Collins

Prescription Drug Abuse

6/26: KGO Radio, Beth Houston

CURES

9/5: Jason Smith, freelance writer

Prescription Drug Abuse Subcommittee Meeting

8/26: Auburn Journal, Eyragon Eidam

Compounding

9/12: Work Comp Central, Ben Miller

Substitutions Made by Pharmacists

6/26 Journal of the American Veterinary Medical Association, Staff

Orange County Compounding Pharmacies Involved in Toddler Death

August ongoing: NPR Southern California, Karen Foshay and Denise Guerra

Ms. Herold reported most media activity is reactive as opposed to proactive, but she expects that to change with the board working in controversial areas.

8. FOR INFORMATION: Public Outreach Activities Conducted by the Board

- July 10, August 29: Executive Officer Virginia Herold and Public Information Officer Joyia Emard attended the California Prescription Drug Abuse Work Group meetings
- July 15: Board Inspector Brandon Mutrux, PharmD, spoke on prescription drug abuse and other pharmacy issues at a Senior Scam Stopper program held in Southern California
- August 21: Executive Officer Virginia Herold provided a presentation at the California Conference of Local Health Officers monthly meeting regarding the board's implementation of SB 493 and the state's immunization registry
- August 25: Executive Officer Virginia Herold provided a presentation about the board's activities regarding prescription drug abuse to the first meeting of the Dental Board of California's prescription drug abuse committee
- August 28: Board Member Dr. Ramon Castellblanch presented at the Generation Rx educational event at Touro University, in Vallejo
- September 11: Public Information Officer Joyia Emard attended the Overdose Prevention Messaging Workshop

Ms. Herold said the Dental Board requested that the Pharmacy Board and Medical Board come in and do a presentation for their association on prescription drug abuse. She said dentists are one of the top three prescribers of hydrocodone. She said this was a timely event because two days later those drugs were rescheduled and will be Schedule II drugs on October 6.

Ms. Herold said staff is greatly concerned as the rescheduling of hydrocodone goes into effect that patients will present at pharmacies and request refills. She said they may be denied because of the rescheduling issue. The board has sent a subscriber alert to educate licensees.

Dr. Castellblanch asked what dentists are going to do about the rescheduling as he's had dental work and been given a 30-count pain medication prescription with no complaint of pain and said he was told to start taking the pills even before he had pain. Ms. Herold said at the

presentation, a board member advised that this is what they were taught in dental school. Chair Hackworth agreed that it is common practice for pain pill prescriptions to be given out after dental work.

9. FOR REVIEW AND DISCUSSION: Articles on Issues of Interest

Chair Hackworth said she found many articles of interest in the attachments including the “100 Most Prescribed Drugs;” an article on nursing homes and how seniors are medicated and she encouraged the reading of the articles.

10. FOR REVIEW AND DISCUSSION: The 43rd Annual Report of the Research Advisory Panel of California

Chair Hackworth said California law, pursuant to Health & Safety Code sections §11480 & §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. 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.

She reported that during 2013, the panel reviewed 32 research study submissions. Twenty-eight were approved by the panel. Among the approved studies, 10 studies were academic research studies, nine studies were substance abuse treatment research protocols and nine studies were multi-clinical drug trial research studies. At the end of 2013, the panel was monitoring 89 research projects.

Ms. Herold asked the committee if there was any interest in hearing a full presentation and she received affirmation. Ms. Herold said staff will add this to an upcoming agenda and invite guest speakers.

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

Next committee meeting is December 10, 2014.

Dr. Gray asked to hear reports on research in California on medical marijuana.

Dr. Gray also asked for the board position on medication take-back regulations recently approved by the DEA.

Adjournment

3 p.m.