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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: March 23, 2017

Location: Department of Consumer Affairs
DCA Headquarters Building Two
1747 N. Market Blvd., Room 186
Sacramento, CA 95834

Committee Members Present: Victor Law, RPh, Chairperson
Debbie Veale, RPh, Vice Chairperson
Ryan Brooks, Public Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Debbie Damoth, Staff Services Manager
Bob Dávila, Public Information Officer

1. **Call to Order and Establishment of Quorum**

   Chairperson Law called the meeting to order at 9:10 a.m. Mr. Brooks arrived at 9:11 a.m. Roll call was taken, and a quorum was established.

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

   There was no public comment.

3. **Discussion and Consideration of Recommendations for Patient-Focused Labeling Changes to California Law**

   a. **Presentation and Proposal from Chapman University School of Pharmacy**

      Chairperson Law welcomed a group of faculty and students from Chapman University School of Pharmacy and invited the students to present their proposal

recommending changes in patient-focused labeling requirements. A copy of the students' proposal was included in Attachment 1.

Chapman student Michael Phan gave a presentation on the students' proposal. He said the group was recommending that the board include a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs. In response to a question from Ms. Veale about where about the symbol would be placed, Mr. Phan said the symbol should be somewhere on the main prescription label but not necessarily within the patient-centered area. He said the symbol should not be placed on a supplemental or auxiliary label.

Mr. Brooks noted that the board has already passed its regulation on prescription labeling. Ms. Freedman said the board could amend its regulation as long as it is consistent with statute. Ms. Veale asked if pharmacists currently could voluntarily put the symbol outside the patient-centered area, because the regulation only specifies what must be within the patient-centered area. Ms. Freedman said she believed a pharmacist could do that, but she added that she would research the issue and provide an answer in time for the chair report at the next board meeting. In response to a question from Mr. Brooks, Ms. Freedman said rulemaking would be required promulgating a rulemaking for the board to mandate the symbol on the label but would not be required for the symbol to be optional.

Mr. Phan noted that CCR section 1776 allows pharmacies voluntarily to provide prescription drug takeback programs for patients, but he noted that many takeback programs exclude hazardous drugs. He said providing a hazard symbol on the drug would help untrained persons identify dangerous drugs that must be separated from the normal was te-management process. He said a hazard symbol also would remind patients that these drugs need to be handled differently from ordinary drugs.

In response to committee members' questions, Ms. Freedman said that exclusions of dangerous drugs reflect federal regulations that restrict taking back dangerous drugs. Ms. Veale asked if the students were aware of any other states that currently require a hazard symbol on labels. One of Mr. Phan's fellow students replied that California regulations currently require that compounding drugs be identified as hazardous, and the students proposed that the requirement be applied to all medications.

Mr. Phan noted that oral chemotherapy medications in particular are growing in use and said they could present toxicity and cross-contamination problems for patients during home use. He said these medications generally are perceived by the patients to be less toxic than other drugs, and this misperception could lead to improper disposal. He said current guidelines issued by United States

Pharmacoepia, American Society of Health-Care Pharmacists, American Society of Clinical Oncology and the Oncology Nursing Society USP, ASHP, ASCO and ONS on handling these drugs cover only their uses in healthcare settings, not home settings. In response to a question from Ms. Veale, Mr. Phan explained that hospitals use separate waste containers for hazardous medications, which are sent to a separate facility for disposal.

Ms. Sodergren asked if the FDA requires drug manufacturers to include a hazard symbol on the medications. Mr. Phan said the FDA does not require it.

Mr. Phan said the students proposed mandating a hazard symbol on prescription labels to help overcome barriers to proper handling and disposal of hazardous drugs. He cited CCR sections 1707 and 1744 as examples of requirements for prescription labeling and said the students proposed a mandate similar to labeling requirements in BPC section 4076. He said pharmacies would be required to update their software to identify hazardous drugs listed by NIOSH and would be required to put a hazard symbol on the main prescription label.

Ms. Veale said that a hazard symbol outside the patient-centered area of the label might be too small to be noticed and suggested that using an auxiliary label would allow for a larger hazard symbol. A Chapman student replied that research indicates that auxiliary labels often are not used in pharmacies. In addition, she said that requiring the symbol on the main label would allow for pharmacy software to automatically include the hazard symbol and would eliminate an extra step for the pharmacist.

Professor Siu Fun Wong, the Chapman students' adviser, told the committee that her students had been actively researching the issue for more than a year and that they were in contact with other regional groups who are educating stakeholders promoting the same idea around the country. Ms. Veale said the committee would be interested in seeing the results of the students' research and surveys of drug manufacturers and other stakeholders about the issue.

In response to a question from Ms. Sodergren, the students said their proposal for a hazard symbol on labels would apply to topical drugs as well as pills.

Chairman Law thanked the students for their presentation and said he supported their efforts to educate the public and pharmacists about the proposal. He said the board could send out subscriber alerts encouraging pharmacists to voluntarily include a hazard label on the prescription labels. Ms. Herold invited the students to write an article about their proposal for *The Script*.

Public comment: Paige Talley asked if the students' proposal would include all three tables from the NIOSH list, since California recognizes the medications on

only one of them, with the chemo drugs. Mr. Phan said the students are proposing that the pharmacy software recognize all the drugs from the NIOSH list, but the students want to speak with software vendors to see if it can be implemented. Ms. Sodergren said the students' proposal is still in the development stage and that questions about what drugs would be included would be decided later by the board as a policy matter.

Lori Hensic of Kaiser Permanente noted that the definition of hazardous drugs in CCR section 1735.1 differs from NIOSH and suggested the students keep that in mind as they develop their proposal. Ms. Herold pointed out that section 1735.1 applies only to compounding medications.

b. Next Steps

Committee members said they appreciated the students' research and efforts to reach out and educate stakeholders about their proposal to place hazard symbols on prescription labels for NIOSH-designated hazardous drugs. Ms. Veale said the education by the students and other supporters of hazard symbols on prescription labels is the first step of the process, and the second step is possible rulemaking later.

4. <u>Discussion and Consideration of Requirements Relating to Pharmacy Translations and Interpretations</u>

a. Presentation by Office for Civil Rights of U.S. Department of Health and Human Services on Final Rule Implementing Section 1557 of the Affordable Care Act (ACA) Regarding Nondiscrimination in Health Programs and Activities

Chairperson Law informed the committee that the U.S. Department of Health and Human Services (HHS) had issued a rule to implement Section 1557 of the Affordable Care Act, which forbids discrimination in health care on the basis of race, color, national origin, age, disability and sex.

Chairperson Law said the rule includes a requirement that health care providers that receive federal funding provide "meaningful access" to customers with limited English proficiency. The rule also requires providers to post taglines written in the top 15 languages spoken in the state by people with limited English proficiency. He explained that taglines are short statements advising the public that interpreter and translation services are available free of charge.

Chairperson Law noted that at previous board meetings, members requested information about Section 1557 to determine whether it would have an impact on California laws and regulations regarding requirements for prescription label

translations. He welcomed Eric Press, an investigator from the HHS Office for Civil Rights, who gave a presentation to the committee about Section 1557.

Copies of a draft board newsletter article about the rule, a sample tagline, and an APhA summary of Section 1557 were included in the meeting materials.

Mr. Press said entities that must comply with the law include all health programs and activities that have 15 or more employees and receive federal financial assistance. He gave a broad overview of Section 1557, including definitions and examples of discrimination based on sex, race, color and national origin.

Mr. Press also discussed specific requirements under Section 1557 for communicating with individuals with limited English proficiency (LEP), including:

- Covered entities must take reasonable steps to provide meaningful access to each individual with LEP.
- Covered entities must publish taglines – which are short statements in non-English languages informing individuals that language assistance services are available – in significant publications and must post taglines in prominent locations and on their websites. The taglines must be written in the top 15 languages spoken by LEP individuals in the state.
- Covered entities must offer qualified interpreters when oral interpretation is a reasonable step to provide meaningful access to a person with LEP.
- Language services must be provided free of charge and in a timely manner.
- Covered entities must follow certain quality standards in delivering language assistance services. For example, an entity may not require an LEP individual to provide his or her interpreter or rely on a minor child to interpret (except in a life-threatening emergency where no qualified interpreter is immediately available).

Ms. Veale noted that interpreters are not always available in pharmacies and that state regulations allow pharmacists to use telephone interpreter services. Mr. Press said the law allows flexibility on what is reasonable and using a phone interpreter service instead of an in-person interpreter might be acceptable.

Mr. Press said covered entities must post notices of nondiscrimination that identify individuals' rights and the entity's obligations under Section 1557 in physical locations where services are provided and in significant communications and publications. Notices must include taglines in the top 15 languages spoken in the state by LEP individuals. The notice requirement took effect Oct. 17, 2016.

Ms. Veale asked if the notices would have to be posted at every cash register. Mr. Press said notices at cash registers would meet the requirements, but the rule does not identify specific locations for their placement.

Mr. Press said a covered entity also must post a nondiscrimination statement (which is different from a notice of nondiscrimination) and two taglines in small-size communications and publications, such as postcards and brochures. He explained that notices of nondiscrimination would be appropriate for posting in physical locations in stores and hospitals and would include taglines in 15 languages, while nondiscrimination statements would be appropriate only for posting in small-size printed materials and would have two taglines.

Ms. Freedman added that Section 1557 requires nondiscrimination statements for printed materials provided to patients – not for prescription labels.

Ms. Veale asked if the board would have to change the "Point to your language" tagline. Mr. Press said the sample taglines provided in Appendix B of the final rule are not intended to be binding as long as taglines meet the requirements of the rule by directing patients where to go to get language-assistance services. Ms. Veale and Ms. Herold said the "Point to your language" tagline meets the rule's requirement.

Mr. Press said the "Point to your language" tagline is different from the taglines in the federal rule, which are taglines printed on pamphlets, trifolds, postcards and anything that is mailed out to patients – not to a notice standing in front of a person in a pharmacy. He said it is not for face-to-face communication.

Ms. Herold asked if the federal law requires a tagline provided in 15 languages for a prescription medication container, not for written material handed out with the container. Mr. Press said he did not think the tagline requirement would apply in that situation. He said the language assistance services would be provided at the pharmacy.

Ms. Veale and Ms. Herold asked whether taglines would be required for printed package inserts that have additional information about medications and that are handed to patients with the receipt. They noted that some information is mandatory for patients, but Ms. Veale asked if a pharmacist has an obligation to include a tagline if the pharmacist voluntarily gives out the package information.

Mr. Press said he could not answer specific questions about what documents would require taglines under Section 1557. He referred questions about Section 1557 to the Office for Civil Rights website, www.hhs.gov/ocr.

Chairperson Law asked if OCR was already enforcing the federal rule. Mr. Press said there was no "honeymoon" period and that OCR is currently investigating cases involving Section 1557.

Ms. Sodergren noted that pharmacies sometimes dispense medication to a patient with "black box" warnings that has been provided by the drug manufacturer. She asked what is the pharmacy's responsibility under Section 1557, because the manufacturer would not be a covered entity. Mr. Press said if the information is something the patient needs to know, the covered entity would be required to take reasonable steps to provide the information to the LEP patient – but what is reasonable depends on the situation.

In response to a question from Mr. Brooks about the potential viability of the federal rule, Mr. Press said repealing the Affordable Care Act also would repeal Section 1557. He added that whatever legislation replaces the ACA probably would retain the less controversial provisions of Section 1557, including the LEP requirements and procedural requirements of Section 1557.

There was no public comment.

The committee recessed for a break at 10:43 a.m. and returned at 10:57 a.m.

5. <u>Discussion and Consideration of Naloxone Matters</u>

a. Availability of Naloxone at Pharmacies in Specific Communities, including Los Angeles County

Chairperson Law welcomed Dr. Rebecca Trotzky, who addressed the committee by telephone from Los Angeles. She said that at the January 2017 board meeting, Dr. Trotzky reported problems for patients with opioid use disorders who were trying to obtain naloxone at Los Angeles County pharmacies.

Dr. Trotzky told the committee that many pharmacies do not stock naloxone or are not aware of California laws and regulations that authorize pharmacists to furnish naloxone without a prescription. She said that when she prescribed naloxone to ER patients at LA County-USC Medical Center, many reported they could not get it from local pharmacies. She said that when her students called to investigate for a survey, they learned pharmacies were telling patients that they could not give naloxone without a prescription, that they did not have naloxone in stock, that patients had to pay cash for it, and other responses that prevented patients from obtaining naloxone.

Dr. Trotzky provided a copy of the students' survey, which was conducted in December 2016 and January 2017. She said the survey found that only 2 percent

of independent pharmacies and about 30 percent of chain pharmacies in Los Angeles County carried naloxone in stock. She said she wanted to work with the board to increase awareness among pharmacists about naloxone and to increase the availability of naloxone to patients without a prescription.

In response to a question from Ms. Veale, Dr. Trotzky said that her students who called pharmacists asked for naloxone by both its generic name as well as the brand name Narcan.

Chairperson Law told Dr. Trotzky that the board has taken several steps to increase pharmacists' awareness of the naloxone protocol since she addressed the board meeting in January 2017. He said board staff emailed subscriber alerts reminding pharmacists about the protocol in March, published an article about the protocol in a recent issue of *The Script* newsletter, and posted information for licensees about naloxone in the board's website. Chairperson Law also noted that a training forum for pharmacists planned for March 11, 2017, would include a session on naloxone.

Chairperson Law added that some pharmacists who have never received a naloxone prescription might not stock it because of inventory costs. He added that even if a pharmacy does not have naloxone in stock, the medication can be ordered and usually delivered to the pharmacy within the same day.

Ms. Veale said some pharmacists are not comfortable talking about naloxone with patients. She said pharmacists need help being proactive instead of waiting for patients to ask about naloxone. Ms. Herold noted that the protocol includes specific questions for pharmacists to ask patients. She said CE providers could emphasize training for pharmacists on asking questions and communicating with patients about naloxone.

Chairman Law said the board would take more steps to education pharmacists about naloxone and to educate consumers about where they can find naloxone in pharmacies. Dr. Trotzky thanked the committee and said she might conduct another survey in a year to see if the situation improved.

Jonathan Bloomfield of Adapt Pharma, the manufacturer of Narcan nasal spray, said pharmacists nationwide often are not proactive about furnishing naloxone because of the amount of time they are required to spend training patients or lack of reimbursement.

b. Walgreens Request to Use In-House Fact Sheet for Patients Receiving Naloxone

Chairperson Law informed the committee that Walgreens sent a letter to the board requesting approval to use a Walgreens-specific naloxone fact sheet for

patients receiving opioid antagonists whose primary language is English. For patients whose primary language is not English, Walgreens would provide materials printed in alternate languages that are on the board's website.

Chairman Law noted that CCR section 1746.3(c)(6) requires pharmacists to provide naloxone recipients with "a copy of the current naloxone fact sheet approved by the Board of Pharmacy. This fact sheet shall be made available in alternate languages for patients whose primary language is not English."

Copies of the Walgreens letter, the Walgreens fact sheet and the board's online fact sheet in English were included in the meeting materials.

Lori Walmsley of the pharmacy affairs department of Walgreens told the committee that Walgreens would like to use the Walgreens branded fact sheet that it uses in all other states to improve workflow. She said the Walgreens sheet contained all the same elements in the board's website fact sheet. She said the Walgreens sheet is automatically printed anytime an opioid antagonist is sold.

Ms. Freedman informed the committee that section 1746.3(c)(6) requires a single fact sheet that is to be made available on the board's website. She said Walgreens could submit the fact sheet for board approval and posting on the website, but Walgreens would have to give copyright approval for its fact sheet to be posted and made available for use by other pharmacies. Alternatively, Ms. Freedman said, the board could modify the section 1746.3(c)(6) to allow the board to approve alternate versions of the fact sheet.

Ms. Walmsley told the committee that she would have to get corporate approval from Walgreens on the copyright issue.

Ms. Veale noted that the board allows pharmacists to develop their own language for "Point to your language" notices or to produce their own videos for the Notice to Consumers. Ms. Herold pointed out that the regulation specifically allows for alternative forms and for videos for the Notice to Consumers. Ms. Veale said she would prefer changing the regulation to allow the board to approve alternative naloxone fact sheets rather than receiving individual requests from pharmacy chains to use their own fact sheets.

Ms. Veale asked about including fact sheets for other medications, such as hormonal contraceptives. Ms. Herold pointed out that the Medical Board of California is involved in protocols for those medications, so any changes also would have to go to the Medical Board as well.

Ms. Herold asked if Walgreens would be open to using the current fact sheet on the board's website if CDPH gave approval for Walgreens to load the fact sheet

in the company's software. Ms. Walmsley said Walgreens does not have the ability to automatically print different fact sheets for different states.

Committee recommendation: Change CCR section 1746.3(c)(6) to authorize the executive officer to approve substantially similar fact sheets for use so that individual pharmacies can use them.

M/S: Veale/Brooks

Support: 3 Oppose: 0 Abstain: 0

Name	Support	Oppose	Abstain	Not Present
Brooks	x			
Law	x			
Veale	x			

As a short-term solution, Ms. Veale suggested that Walgreens allow the board to post the Walgreens fact sheet on the board's website. Ms. Freedman and Ms. Herold said posting the Walgreens sheet on the board's website would present liability issues for the board. In response to a question from Mr. Brooks, Ms. Herold explained that by approving the Walgreens fact sheet, the board would just be giving Walgreens permission to use its own fact sheet instead of the board's version, which was created by CDPH.

Ms. Herold added that the Medical Board would have to approve changing the naloxone fact sheet requirement as part of the protocol requirement. At Ms. Veale's request, Ms. Herold said she would consult with the Medical Board executive officer about changing the fact sheet.

c. SB 833 (Committee on Budget and Fiscal Review, Health, Chapter 30, Statutes of 2016)

Chairman Law said that at the September 2016 committee meeting, staff reported that SB 833 requires the California Department of Public Health to award funding to local health departments, local government agencies, community-based organizations or regional opioid prevention coalitions to support or establish programs that provide naloxone to first responders and at-risk opioid users through programs that serve at-risk drug users. Committee members discussed the possibility that pharmacist organizations might be eligible for SB 833 funding to increase naloxone availability.

In an update, Chairman Law informed the committee that staff contacted CDPH to ask whether pharmacies might be eligible to apply for SB 833 grants. He said Holly Sisneros of the Prescription Drug Overdose Prevention Initiative at CDPH informed staff that CDPH is currently working to implement SB 833. Ms. Sisneros

added that the funds would most likely go to local health departments so that they can distribute naloxone to eligible agencies within their jurisdictions. Chairman Law said pharmacies likely would not be eligible for funding.

There was no public comment.

d. Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016 (CARA) – Provisions Regarding Partial Fills for Schedule II

Chairman Law reported that at the September 2016 committee meeting, members discussed a potential conflict between Section 702 (f)(2)(A)(ii) of CARA and California law. At the October 2016 board meeting, staff provided the following clarification from legal counsel:

> Pursuant to the Comprehensive Addiction and Recovery Act of 2016 (CARA), 21 USC §829(f) would be another situation where partial filling of a Schedule II controlled substance would be allowed provided the prescription is a valid prescription and the pharmacist exercises their corresponding responsibility when filling a controlled substance prescription:
>
> (1) If requested by the patient or practitioner with no fill after 30 days from date written (21 USC §829[f]).
>
> (2) For a terminally ill patient marked as "terminally ill," tendered within 60 days from date issued and no more dispensing after 60 days from date of issuance (CCR 1745[a][2] and [c], H&SC11159.2, 21CFR1306.13[b]).
>
> (3) For a Long Term Care Facility patient marked as "LTCF", tendered within 60 days from date issued and no more dispensing after 60 days from date of issuance (CCR 1745[a][1] and [c], 21 CFR 1306.13[b]).
>
> (4) When a pharmacy doesn't have enough, dispenses a partial with the balance within 72 hours (21 CFR 1306.13[a] and CCR 1745).

Chairman Law reported that an article about this topic is planned for *The Script* scheduled for print in Summer 2017.

Ms. Herold informed the committee that the California Pharmacists Association is putting amendments into AB 1048 this year to amend state law to partial filling for 30 days. She stated that even if the ACA and the federal provisions are repealed, the bill would allow partial filling for up to 30 days. Ms. Herold noted that HSC section 11159.2 exemption allows pharmacies special handling for hospice or terminally ill patients, and they do not have to use security forms. She

added that the board will be asked to take a position on the bill at the May board meeting.

There was no public comment.

e. Outreach Efforts to Licensees Regarding Naloxone Protocol and Training/CE Requirements

Chairman Law said that at the September 2016 committee meeting, Ms. Veale reported that many pharmacies are not dispensing naloxone. She suggested the board send out periodic subscriber alerts to remind pharmacists they can dispense naloxone and to direct them to information on the board's website.

Chairman Law said that since then, staff has taken outreach steps to help improve awareness of laws and regulations related to dispensing naloxone:

- Subscriber alerts were sent in October 2016 and March 2017 reminding pharmacists about the protocol in CCR section 1746.3, which authorizes pharmacists to furnish naloxone without a prescription. Staff will continue to issue reminder alerts periodically.
- A detailed article about the protocol, including requirements for CE training before dispensing naloxone, was published in the Summer 2016 issue of *The Script*.
- Ms. Herold sent information letters about the naloxone protocol to executive officers of the healing arts boards in October 2016.
- An easy-to-read chart summarizing training and CE required by protocols for naloxone, self-administered hormonal contraception, nicotine replacement therapy, and initiating and administer vaccinations has been posted on the board's website.
- Information about naloxone on the website has been reorganized for easier access, including a single Naloxone webpage under "Important Information for Licensees." The webpage contains links to information and press releases about the protocol, fact sheets, screening questions and the text of CCR section 1746.3.
- Staff cohosted a training forum on drug abuse topics March 11, 2017, in La Jolla, including a session on providing naloxone pursuant to the state protocol. Pharmacists who attended the day-long event received an extra hour of CE credit to fulfill the requirements of the naloxone protocol.

Chairman Law discussed the staff's outreach efforts at the meeting during discussion of agenda item **5.a. Availability of Naloxone at Pharmacies in Specific Communities, including Los Angeles County**.

4. **<u>Discussion and Consideration of Requirements Relating to Pharmacy Translations and Interpretations (Continued)</u>**

   b. United States Access Board's Recommendations Related to Prescription Labels for Visually Impaired and Elderly Patients

   Chairperson Law said that at the May 2016 committee meeting, members discussed a set of recommended best practices for making information on prescription drug labels accessible to people who are blind, visually impaired or elderly. The recommendations were developed by a working group of stakeholders convened by the U.S. Access Board, a federal agency that promotes equality in access for people with disabilities.

   The group developed more than a dozen specific recommendations, including:
   - Follow universal patient-centered prescription drug container label standards.
   - Make labels available in audible, braille and large-print formats.
   - Ensure that duplicate labels preserve the integrity of the print prescription label.
   - Do not impose an extra fee to cover the cost of providing an accessible label.

   The group also reported a variety of technologies for providing accessible label information, including:
   - Hard-copy labels printed in large type or braille.
   - Digital voice or text-to-speech recorders.
   - Radio Frequency Identification Device (RFID) tags.
   - Smart devices and computers equipped with electronic braille, large text and audio technology.

   Chairman Law said that at the committee's request, staff developed a summary of the recommended best practices on the board's website. Staff also published the summary as an article in the summer 2016 issue of *The Script*. Copies of the brochure and *The Script* article were included in meeting materials.

   Chairman Law said the information was provided to the committee for discussion and consideration in recommending to the board possible changes in laws and regulations related to prescription drug labels. Ms. Veale said the list was very comprehensive.

   There was no public comment.

   c. NABP Request to Boards of Pharmacy Regarding Labeling Requirements for Emergency-Use Medications

Chairman Law stated NABP sent a letter asking state boards of pharmacy to review their requirements regarding the labeling of epinephrine auto-injectors and other similar emergency-administration medications by dispensing pharmacies. NABP states that EpiPens and similar emergency-use products represent a unique category of medications that must be given special consideration regarding their expiration dates.

Chairman Law said the letter notes that many states require pharmacies to label dispensed prescription medications with a one-year expiration date or with the manufacturer-applied expiration date if less than one year from the date of dispensing. NABP requests that in situations where an EpiPen has not been removed from the original packaging, states allow a waiver for the EpiPen to be maintained and administered beyond the labeled one-year expiration date through the manufacturer-applied expiration date.

Chairman Law said the committee had an opportunity to discuss the NABP letter and consider what recommendations, if any, to make to the board. For the committee's reference, CCR section 1718.1 states:

> 1718.1. Manufacturer's Expiration Date.
> All prescription drugs not bearing a manufacturer's expiration date pursuant to Title 21, Code of Federal Regulations, section 211.137 are deemed to have expired and may not be manufactured, distributed, held for sale, or dispensed by any manufacturer, distributor, pharmacist, pharmacy or other persons authorized to dispense such drugs in California.

Business and Professions Code section 4119.3 establishes labeling requirements for epinephrine auto-injectors. BPC section 4076(a)(9) requires that prescription container labels include "the expiration date of the effectiveness of the drug dispensed."

Copies of the NABP letter and BPC sections 4119.3 and 4076 were included in the meeting materials.

Ms. Veale and Ms. Herold noted that the board does not have a one-year expiration requirement that is mentioned by NABP. She pointed out that that the board has said that pharmacists cannot put an expiration date on compounding medications that is later than any of the ingredients in the compounded medication, or any date later than the date listed on a container by a manufacturer.

Ms. Herold said that as a matter of professional judgment, pharmacists know that if they have an EpiPen in a box that has never been opened, it can be used up to the manufacturer's date – even if it is outside one year. She said the issue of expiration dates could be covered in a brief article in *The Script*.

Lori Hensic of Kaiser Permanente asked that the article point out that the expiration date issue applies to all medications, not just EpiPens. She said some inspectors have noted that it is not appropriate to use the manufacturer's date if the date is more than one year.

d. Necessary Modifications to Pharmacy Law or Regulations Relating to Translation and Interpretation Services, If Any

Chairperson Law told the committee that at previous board meetings, members requested information about Section 1557 of the Affordable Care Act to determine whether it would have an impact on California laws and regulations regarding requirements for prescription label translations. At the December 2016 board meeting, staff reported that a cursory review indicated a possible conflict between the tagline requirements of Section 1557 of the Affordable Care Act and the "Point to your language" requirements in CCR section 1707.6(c).

Mr. Press of the HHS Office for Civil Rights told committee members that the "Point to your language" requirement is different from the taglines required by Section 1557. But he added that he could not answer specific questions about what documents would require taglines under Section 1557. He referred questions about Section 1557 to the Office for Civil Rights website, www.hhs.gov/ocr.

Ms. Herold said the board may have specific questions later for OCR to ensure that California statutes and regulations are in compliance with Section 1557 of the Affordable Care Act.

6. <u>Update and Discussion of Development of FAQs for SB 493 Items</u>

Chairperson Law said at the April 2016 board meeting, the Communication and Public Education Committee was asked to coordinate the development of a Frequently Asked Questions (FAQs) document for SB 493 related items.

In an update for the committee, Chairman Law said the FAQs drafted by staff, reviewed by counsel and posted on the board's website. A copy of the FAQs was included in the meeting materials**.**

Ms. Veale said staff did a good job in covering the most important questions and providing accurate answers. Ms. Herold thanked Ms. Freedman for reviewing the FAQs.

Chairman Law noted that the FAQs incorrectly indicate that the advanced practice pharmacist regulations are pending. Ms. Herold noted that the FAQs were done in December 2016, before the APH regulations took effect. Ms. Veale suggested that the FAQs be corrected and returned to the committee for review.

There was no public comment.

7. <u>Update and Discussion of a Board-Developed Public Service Billboard Message and Related Communication Materials</u>

Chairman Law said at the September 2016 committee meeting, members reviewed proposed concepts for a bulletin board message developed by staff at Mr. Brooks' firm. The billboard is intended to encourage parents to talk to their children about prescription drug abuse. The committee recommended that the board proceed with a proposal featuring drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids."

Chairman Law said at the October 2016 board meeting, members agreed with the committee's recommendation and voted to sponsor the billboard message. Mr. Brooks said his firm would work with the executive officer to finalize the billboard message, identify locations and perhaps generate additional media exposure.

In an update to the committee, Chairman Law said staff had reached out to the Prescription Opioid Misuse and Overdose Prevention Workgroup, which is a joint effort among state agencies (including the Board of Pharmacy) to develop collaborative strategies to curb prescription drug overdose deaths and addiction in California. He said staff is working to ensure that the board's billboard project is consistent with communication strategies being developed by the workgroup's Communication and Outreach Taskforce.

Ms. Herold thanked Mr. Brooks again for donating the billboard. She added that it might be more effective if the board participated in the public outreach campaign being developed by the statewide task force rather than proceeding independently. She said any decision to join the statewide effort would have to be made by the board.

Mr. Brooks expressed concern that the process required to participate in the task force campaign would take too long. He recommended that the board move forward with the billboard project. Chairman Law and Ms. Veale agreed with Mr. Brooks.

Ms. Freedman asked if Mr. Brooks firms had any concerns about sharing its intellectual property with state agencies. Mr. Brooks said there were no concerns.

There was no public comment.

8. **Update and Discussion on Development and Implementation of Communication Plan for Reaching Consumers and Licensees**

Chairman Law said at the September 2016 committee meeting, members received copies of a draft communication plan that included aspects for both consumers and licensees. Staff developed the draft in accordance with the board's Strategic Plan. The committee approved the plan with continued modifications and updates. A copy of the updated plan was included in the meeting materials.

Chairman Law noted staff is working on many items listed on the updated plan, including subscriber alerts and CE. He thanked staff for its work.

9. **Discussion of Efforts by Drug Manufacturers to Stop Illegal Sales of Non-FDA Approved Products**

Chairman Law noted the sale of drug products from unlicensed sources – foreign or domestic – is a major for patients, pharmacists, prescribers and drug manufacturers. According to the Food and Drug Administration, there is a growing network of rogue wholesale drug distributors selling potentially unsafe drugs in the U.S. market.

Chairman Law informed the committee that representatives of Allergan met recently and discussed with board staff their concerns about the illegal importation of non-FDA approved products. They described Allergan's efforts to shut down Amazon Medica, a foreign and unauthorized entity reported to be illegally selling Allergan Aesthetics products, including counterfeit products that are not FDA approved for use or distribution in the United States.

Copies of information about Allergan's efforts against Amazon Medica was included inin the meeting materials**.**

Note: Mr. Brooks left at 11:59 a.m., depriving the meeting of a quorum.

Ms. Sodergren said the board is aware the problem also is happening with other manufacturers. She said the board would be considering legislation dealing with this problem.

There was no public comment.

10. **Update on the Status and Implementation of the Approved Regulation Title 16, CCR section 1707.5, Regarding Patient-Centered Labels for Prescription Drug Containers**

Chairman Law reported the Office of Administrative Law has approved proposed amendments to CCR section 1707.5, regarding patient-centered labels. The amended regulation takes effect July 1, 2017.

Chairman Law said the change requires require pharmacists dispensing a generic drug to list the generic name and the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. An exemption is allowed when, in the professional judgment of the pharmacist, the brand name is no longer widely used – in which case the patient-centered portion of the label may list only the generic name, while the manufacturer's name may be included inside or outside the patient-centered area of the label.

Chairman Law said information about the amended regulation was emailed to subscribers on March 7, 2017, and an article would be published in the *The Script*.

There was no public comment.

11. Update on *The Script* Newsletter

Chairman Law reported staff is preparing articles for the next issue, which is set for publication in April 2017.

12. Update on Media Activity

Chairman Law directed committee members to the following list of interviews with the board's executive officer (unless otherwise noted) and requests for information from the news media:

- **Glendale News Press,** Sept. 6, 2016: Alene Tchekmedyian, disciplinary case against Kenneth Road Pharmacy in Glendale
- **The Hollywood Reporter,** Sept. 21, 2016: Peter Flax, pharmacy law re providing false information for prescriptions
- **Chicago Tribune,** Oct. 6, 2016: Ray Long, patient consultation requirements
- **Wall Street Journal,** Oct. 14, 2016: Arian Campo-Flores, synthetic opioid U-47700
- **Kurtis Productions,** Oct. 21, 2016: Chris Tamalunas, precedential decision re Pacifica Pharmacy
- **Los Angeles Times,** Oct. 21, 2016: Soumya Karlamanga, hormonal contraception regulation
- **KTLA,** Oct. 25, 2016: Irving Last, UCLA Medical Center pharmacy
- **USC School of Journalism,** Nov. 1, 2016: Katie Giacobbe, self-administered hormonal contraception
- **ABC 7 News,** Nov. 1, 2016: Justin Mendoza, generic prescription drug prices

- **Pharmacy Today,** Nov. 30, 2016: Rachel Balick, pending drug take-back regulations
- **Noozhound,** Jan. 18, 2017: Sam Goldman, L.M. Caldwell Pharmacist
- **Santa Barbara Independent,** Jan. 18, 2017: Kelsey Brugger, L.M. Caldwell Pharmacist
- **Chicago Tribune,** Feb. 2, 2017: Ray Long, pharmacist duty to consult patients
- **KPIX,** Feb. 6, 2017: Molly McCrea, Naloxone sales in California
- **North Bay Business Journal,** Feb. 13, 2017: Cynthia Sweeney, automated drug-dispensing systems
- **Veterinary Information Network News Service,** Feb. 14, 2017: Edie Lau, compounding law changes affecting veterinarians.
- **California Health Report,** March 6, 2017: Jessica Portner, update on label translations requirements in AB 1073.

13. <u>Update on Public Outreach Activities by the Board</u>

Chairman Law directed committee members to the following list of major public outreach activities provided by the board's staff:

<u>Past events:</u>

- Feb. 24: Ms. Herold presented on Pharmacy Law to 350 pharmacists at a CPhA event.
- March 7: Ms. Herold presented on the Board of Pharmacy to 80 pharmacy students at Touro University.
- March 8: Supervising Inspector Janice Dang presented on "Surviving as a PIC" to fourth-year students at Western University School of Pharmacy.
- March 11: Supervising Inspector Antony Ngondara presented on "Preventing Drug Thefts and Diversion from Pharmacies" during an educational forum cohosted by the board, DEA and UC San Diego Skaggs School of Pharmacy.

<u>Future events:</u>

- Future events are scheduled based on request and availability. There are currently no scheduled future events.

At Chairman Law's request, Ms. Herold provided an update on the March 11 forum at UC San Diego. She said 225 people attended the event, and the board offered seven CE units to participants. In addition, 132 participants received naloxone certification.

Ms. Herold said participants asked good questions and that the ratings were good. She said the event was videotaped and was being put online. In addition, she said organizers were asked to do the forum again, probably in Northern California.

Chairman Law asked when the next event would be announced. Ms. Herold said the board is waiting for the arrival of a speaker who works for the DEA but is joining the board staff.

Chairman Law also asked if the website has a master calendar listing educational activities and events that people can plan to attend. Ms. Sodergren said the board could create a calendar for board-sponsored events. Ms. Herold said the board often does not receive advance notice of public forums and events.

Lori Hensic of Kaiser Permanente suggested that the board contact the March 11 participants who received naloxone certification and ask if they are using it to dispense naloxone. She said the information could be used to demonstrate efforts to increase the numbers of pharmacists providing naloxone to the public.

Ms. Hensic also asked if the board could provide an event like the March 11 forum specifically for an employer or other organization. Ms. Herold said the board would want to open the event up. Ms. Sodergren added that any request to the board for an educational event must be made in writing.

14. Review and Discussion of News or Journal Articles

Chairman Law directed committee members to the following summary of articles of interest. Copies of the articles were included in the meeting materials**.**
There was no public comment.

15. Future Meeting Dates in 2017

Chairman Law announced the following meeting dates for the Communication and Public Education Committee:

- June 28
- Sept. 20
- Dec. 13

The meeting adjourned at 12:10 p.m.