California State Board of Pharmacy
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COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Victor Law, Licensee Member, Chairperson
Deborah Veale, Licensee Member, Vice Chairperson
Ryan Brooks, Public Member

Report of the Communication and Public Education Committee meeting held March 23, 2017. A copy of the meeting minutes is included in **Attachment 1**.

a. Summary of Presentation and Proposal from Chapman University School of Pharmacy for Patient-Focused Labeling Changes to California Law

The committee heard a presentation from Chapman University School of Pharmacy students regarding patient-focused labeling changes to California law. In a presentation led by pharmacy student Michael Phan, the students proposed the board mandate a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs. A copy of the students' proposal is in **Attachment 2**.

Mr. Phan noted that oral chemotherapy medications in particular are growing in use. He said mandating a hazard symbol on prescription drug containers would help improve safe handling and proper disposal of hazardous drugs. The students asked that the symbol be required on the main prescription label, not as an auxiliary or supplemental label – but not necessarily within the patient-centered area of the label.

In response to questions from committee members and staff, the students said the FDA does not require a hazard symbol on medications and they were not aware of any states that require a hazard symbol on labels. However, they noted California requires that compounding drugs be identified as hazardous. The students said they spent a year researching the issue, and they are now working with other groups around the county to educate and promote the idea among pharmacies, drug manufacturers and other stakeholders.

Committee Discussion

Ms. Veale noted that adding a symbol to the main label might be too small to be noticed and suggested that an auxiliary label would allow a larger symbol to be used. The students said their research found that pharmacies often do not use auxiliary labels. They added that requiring the symbol to be located on the main label would allow for pharmacy software to automatically print out the symbol on the label and eliminate an extra step for pharmacists.

Ms. Veale asked if pharmacists currently could voluntarily put the symbol outside the patient-centered area, because the board's regulation specifies only what must be within the patient-centered area. Ms. Freedman said she believed a pharmacist could do that but

added that she would research the issue. In response to a question from Mr. Brooks, Ms. Freedman said rulemaking would be required for the board to mandate the symbol on the label but would not be required for the symbol to be optional.

Committee members thanked the students for their presentation and expressed support for their efforts to educate stakeholders about the proposal as a first step before possibly seeking regulations. Ms. Veale said the committee would be interested in seeing the results of the students' surveys of drug manufacturers about the issue. Ms. Herold invited the students to write an article about their proposal for *The Script.*

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

Background

The U.S. Department of Health and Human Services (HHS) issued a rule to implement Section 1557 of the Affordable Care Act (ACA) forbidding discrimination in health care on the basis of race, color, national origin, age, disability and sex. The rule took effect July 18, 2016.

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. Taglines are defined as short statements advising the public that interpreter and translation services are available free of charge.

At previous board and committee meetings, members requested information about Section 1557 to determine whether the federal rule would have an impact on California laws and regulations, including requirements for prescription label translations. At the December 2016 board meeting, staff reported a possible conflict between the tagline requirements of Section 1557 and the "Point to your language" requirements in CCR section 1707.6(c). President Gutierrez suggested the board refer the matter to the Communication and Public Education Committee to get answers to ambiguities in the federal rule.

Update

The committee heard a presentation about Section 1557 from Eric Press, an investigator in the HHS Office for Civil Rights. A copy of Mr. Press' presentation is in **Attachment 3**.

After giving a broad overview of Section 1557, Mr. Press discussed specific provisions for communicating with individuals with limited English proficiency (LEP). The provisions include a requirement that health care providers covered under the law must publish taglines in significant publications in the top 15 languages spoken by LEP individuals in the state. Covered entities also must post taglines in prominent locations and on their websites.

Mr. Press said covered entities also must post notices of nondiscrimination in physical locations where services are provided and in significant communications and publications. He said the notices must identify individuals' rights and the entity's obligations under Section 1557, and they must include taglines in the top 15 languages spoken by LEP individuals.

In addition, Mr. Press said a covered entity must post a nondiscrimination statement and two taglines in small-size communications and publications, such as postcards and brochures. To explain the difference between notices and statements, he said 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.

Mr. Press clarified 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 on a notice standing in front of a person in a pharmacy. He said it is not for face-to-face communication.

Mr. Press said he did not think the tagline requirement would apply for a prescription medication container, not for written material handed out with the container. He said the language assistance services would be provided at the pharmacy.

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

Committee members and staff asked questions about whether taglines would be required for other types of printed materials given to patients, including printed package inserts and "black box" warnings provided by the manufacturer. 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. Ms. Herold said the board may have specific questions later for OCR to ensure that California statutes and regulations comply with Section 1557.

In response to a question from Mr. Brooks about the potential viability of the federal rule, Mr. Press said repealing the ACA 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.

There was no public comment.

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

Background

The National Association of Boards of Pharmacy (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 stated that EpiPens and similar emergency-use products represent a unique category of medications that must be given special consideration regarding their expiration dates.

NABP noted 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 requested 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.

A copy of the NABP letter is in **Attachment 4**.

Committee Discussion

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 the board has said 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*.

d. Discussion and Consideration of Naloxone Matters

1. Update on Federal Legislation: US S. 524 – Comprehensive Addiction and Recovery Act of 2016 (CARA) – Provision Regarding Partial Fills for Schedule

Background

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).

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

Ms. Herold also 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 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.

There was no public comment.

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

Background
At the January 2017 board meeting, Dr. Rebecca Trotzky reported few pharmacies near Los Angeles County-USC Medical Center carry naloxone and most are not aware of laws allowing pharmacists to dispense naloxone without a prescription. She said that a survey by her medical students found that only 2 percent of independent pharmacies and about 30 percent of chain pharmacies carried naloxone in stock. She urged the board to provide more education and outreach to pharmacists about naloxone.

Because Dr. Trotzky spoke about a matter that was not on the board meeting agenda, President Gutierrez invited her to speak about this issue to the Communication and Public Education Committee.

Update
Dr. Trotzky addressed the committee by telephone from Los Angeles. She also provided a copy of her students' survey, which is included in **Attachment 5.**

Dr. Trotzky told the committee 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 when her students called to investigate, 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 said her students' survey was conducted in December 2016 and January 2017. 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.

Chairperson Law informed Dr. Trotzky of specific steps that board staff has taken to increase pharmacists' awareness of the naloxone since she spoke to the board in January, including:

- Emailing subscriber alerts reminding pharmacists about the protocol in March.
- Publishing an article about the protocol in a recent issue of *The Script* newsletter.
- Posting information for licensees about naloxone in the board's website.

He also noted that a training forum for pharmacists planned for March 11, 2017, included a session on naloxone.

Ms. Veale noted some pharmacists are not comfortable talking about naloxone with patients. Ms. Herold pointed out 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.

Chairperson Law said the board would take more steps to educate pharmacists about naloxone and to educate consumers about where they can find naloxone. 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, told the committee 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.

3. <u>Committee Recommendation on a Request from Walgreens to Use In-House Fact Sheet for Patients Receiving Naloxone</u>

<u>Background</u>
Walgreens sent a letter to the board requesting approval to use a Walgreens-specific naloxone fact sheet for patients receiving opioid antagonists. The fact sheet would be

provided to Walgreens patients 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.

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 board's online fact sheet in English, the Walgreens letter, and the Walgreens fact sheet are in **Attachment 6.**

Committee Discussion and Recommendation

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 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. 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.

Ms. Veale said she would prefer changing the section 1746.3(c)(6) to allow the board to approve alternative naloxone fact sheets rather than receiving individual requests from pharmacy chains to use their own fact sheets.

The committee discussed whether the Medical Board of California would have to review changes involving the naloxone fact sheet, because the Medical Board was involved in developing the protocol. After the committee meeting, Ms. Herold determined that the Medical Board would have to review any changes in the protocol but not in the public education materials.

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			

e. <u>Update on a Board-Developed Public Service Billboard Message and Related Communication Materials</u>

<u>Background</u>
At the September 2016 committee meeting, members reviewed proposed concepts for a bulletin board message developed by Mr. Brooks' firm. The committee recommended the board proceed with a proposal featuring drawings of pills around the message "Unattended Drugs are the Leading Killer of Kids."

At the October 2016 board meeting, members agreed with the committee recommendation and voted to sponsor the billboard message. The billboard is intended to encourage parents to talk to their children about prescription drug abuse.

<u>Committee Discussion</u>
Staff reached out to the Prescription Opioid Misuse and Overdose Prevention Workgroup, which is a joint effort among state agencies, is working to develop collaborative strategies to curb prescription drug overdose deaths and addiction in California. 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 asked if it might be more effective if the board participated in the outreach campaign being developed by the statewide task force rather than proceeding independently. Committee members expressed concern that process for the task force campaign process would take too long and recommended that the board's billboard project continue independently.

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

There was no public comment.

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

Background
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 is included in **Attachment 7.**

Committee Discussion
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.

g. Update on Communication Plan for Reaching Consumers and Licensees

Background
At the September 2016 committee meeting, staff presented 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.

Update
Staff presented an updated plan reflecting specific communication and public education activities in progress or planned by the board, including publication of *The Script,* website improvements, subscriber alerts and CE. A copy of the plan is in **Attachment 8**.

1. Update on *The Script* Newsletter

Articles are undergoing legal review for publication, which is imminent.

2. Update on Media Activity

The board's executive officer (unless otherwise noted) participated in interviews 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.

3. Update on Public Outreach Activities Conducted by the Board

Major public outreach activities by the board's staff include:

Past events

- Jan. 28: Supervising Inspector Christine Acosta presented on new compounding regulations at Western University.
- Feb. 8: Supervising Inspector Christine Acosta presented on new compounding regulations to the San Diego Society of Health System Pharmacists.
- 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.
- April 3: Supervising Inspector Christine Acosta presented compounding regulations at Adventist Health in Roseville.
- April 20: Inspector Manisha Shafir presented on drug diversion and fraudulent prescriptions at Community Hospital of Monterey Peninsula.
- April 20: Ms. Herold discussed the opioid epidemic during a recorded appearance for the weekly "Studio Sacramento" program on KVIE.
- April 21: Supervising Inspector Christine Acosta presented on new compounding regulations to the South Bay-Long Beach Health System Pharmacists.
- April 21: Supervising Inspector Christine Acosta presented the new compounding requirements in a webinar with CDPH and OSHPD for CHA.
- May 3: Supervising Inspector Christine Acosta presented on new compounding regulations for a Western University of Health Sciences elective series.

<u>Future events</u>

- Oct. 8: Supervising Inspector Christine Acosta presenting at the California Council for the Advancement of Pharmacy annual meeting.

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.

Lori Hensic of Kaiser Permanente 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.

Chairperson Law asked if the website has a master calendar listing outreach activities organized by professional groups that people can plan to attend. Ms. Herold said the board often does not receive advance notice of events, and some are not open to the public. Ms. Sodergren said the board could create a calendar listing events sponsored by the board.

Update

Staff is the process of developing a mockup of a website calendar for the board's consideration. A copy of the mockup will be passed out as a handout at the board meeting.

Attachment 1

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

DRAFT 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. **Discussion and Consideration of Requirements Relating to Pharmacy Translations and Interpretations (Continued)**

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.

Attachment 2

Title 16
Oral Anticancer Chemotherapy Prescription Labeling Proposal

Chapman University School of Pharmacy (CUSP)

PharmD Candidates 2018: Michael Phan, Thien Huynh, Esther Shin, and Ani Haroutunyan
PharmD Candidates 2019: Priya Patel and Alexandra Corcoran

SCHOOL OF PHARMACY

CHAPMAN UNIVERSITY

We Propose:

The California Board of Pharmacy to include a standardized hazardous symbol on the main prescription label for the NIOSH designated hazardous drugs.

For Example:

Section 1707.5, Article 2, Division 17, Title 16

Prescription Labeling Requirement Modification:

- To include the brand name on prescription labels

Section 1744, Article 5, Division 17, Title 16

Written Labeling for:

1. Drugs that may impair a patient's ability to operate a vehicle
2. Drugs that pose a substantial risk when taken with alcohol

- Specific List of Drug Classes is mentioned
- Pharmacist's Professional judgement can be exercised

Section 1776, Article 9.1, Division 17, Title 16

Prescription Drug Take-Back Programs:

A. Pharmacies may provide take-back services
   - ❖ Voluntary
   - ❖ Mail back or collection receptacles

B. Skilled Nursing Facilities may participate

C. Reverse Distributors

Section 1776, Article 9.1, Division 17, Title 16

Prescription Drug Take-Back Programs:

KAISER PERMANENTE®

POLICE
CITY OF SACRAMENTO
FOUNDED IN 1849
™

However, HAZARDOUS DRUGS ARE EXCLUDED !!!!

How can our hazardous labeling proposal help?

- Easy Identification of Hazardous Drugs
- Remind Patients and Caregivers
- Promote Proper and Timely Education

A Growing Presence of Oral Chemotherapy

Pros

25% of New Chemotherapy in Development are Oral Agents

Growing Popularity in Use

Less Invasive → Improve QOL → Self Medicating → Home Setting

A Growing Presence of Oral Chemotherapy

- Carcinogenicity
- Reproductive Toxicity
- Genotoxicity

Cons

Hazardous Drugs

Cross Contamination at Home Setting

Misperceptions of Toxicity and Safety

Improper Disposal

Public Health Risks

Impact

Healthcare Setting vs Home Setting

Guidelines for the Healthcare Setting

- USP <800>
- ASHP (2006)
- ASCO (2013)
- ONS (2013)

No Guidelines for the Home Setting !!

Other Programs

Individual Institutions

- St. Jude Children's Research Hosp
- Benefit is limited geographically

International Programs are ahead of

- Canada & Australia
- Chemotherapy Take-Back

Water Treatment Centers

(Nikolau et al 2007)

Increase of drugs detected in water systems: seawater, groundwater, & sewage plants

EPA study 2013

50 large water plants tested, each detecting at least 1 pharmaceutical compound

One plant detected 43 pharmaceutical compounds

(Smith et al 2005)

Standard wastewater processes **DO NOT** filter drugs

(CMAJ-JAMC)

Predicted risks of cumulative water contamination

California County Ordinances

Alameda County Safe Drug Disposal Ordinance

- Supreme Court Ruling
- Manufacturers financially responsible
- Exelixis: Hazardous Drug Take-back

Product Stewardship Programs

- Based off of Extended Producer Responsibility
- San Mateo County, Santa Clara County, San Francisco County, City of Santa Cruz, Alameda County, Marin County
- Manufacturers financially responsible

Barriers and Challenges

- **Improper Labeling**
- Lack of Education
- Healthcare Provider Attitudes

- Polypharmacy is commonly seen in patients with cancer.
- Many psychosocial & treatment factors make recognition of handling and disposal precautions more difficult.
- Study reported **ONLY** 1 out of 110 prescriptions was properly labeled with an auxiliary label. (Wong et al 2016)

Barriers and Challenges

- Improper Labeling
- **Lack of Education**
- Healthcare Provider Attitudes

- Study also found that **NO** patient or caregiver received instructions for handling and disposal. (Wong et al 2016)

Barriers and Challenges

- Improper Labeling
- Lack of Education
- **Healthcare Provider Attitudes**

- Only **67.6%** of Healthcare Providers understand that oral agents should be treated the same as parenteral agents. (Johnson et al 2008)

How can our proposal help to overcome the barriers?

To Stay with Our Philosophy and Goals:

- ❖ Cost-Effective
- ❖ Automated Approach to Minimize Human Error
- ❖ Collaborative Effort of All Stakeholders

We Propose to Mandate Hazardous Symbol to the Main Prescription Label:

- ❖ Section 1707 & 1744 for Patient-centered Labeling
- ❖ Article 4, Section 4076

In Summary, We Propose:

Label Requirements

- Mandatory to be part of the Main Prescription Label and not the auxiliary label
- Automated approach to reduce human error

Pharmacy Software Update

- Identify drugs via NIOSH list
- Add standardized hazardous symbol

Pharmacy Practice

Outcomes

- Remind pharmacist counseling

In Summary, We Propose:

Label Requirements

- Mandatory to be part of the Main Prescription Label and not the auxiliary label
- Automated approach to reduce human error

Pharmacy Software Update

- Identify drugs via NIOSH list
- Add standardized hazardous symbol

Pharmacy Practice

Outcomes

- Remind pharmacist counseling
- Reduce unintended cross contamination at home

In Summary, We Propose:

Label Requirements

- Mandatory to be part of the Main Prescription Label and not the auxiliary label
- Automated approach to reduce human error

Pharmacy Software Update

- Identify drugs via NIOSH list
- Add standardized hazardous symbol

Pharmacy Practice

Outcomes

- Remind pharmacist counseling
- Reduce unintended cross contamination at home
- Improve waste management

Our Efforts

- **Capstone Research at CUSP:**
  - Assess knowledge, attitudes, and practice of handling and disposal of oral anticancer chemotherapy drugs:
    - Patients and Caregivers
    - Healthcare Providers
    - Manufacturers
  - Identify gaps and barriers
  - Propose best practice model
- **Policy Proposals to Professional Organizations**

Proposal to the California Board of Pharmacy!

Questions, Concerns, or Suggestions

Thank You

Attachment 3

Section 1557 of the Affordable Care Act

A Civil Rights Training for Health Providers and Employees of Health Programs and Health Insurance Issuers

Content provided by the U.S. Department of Health and Human Services,
Office for Civil Rights

March 2017

What is the Office for Civil Rights (OCR)?

- OCR enforces regulations prohibiting discrimination on the basis of:
  - Race, color, national origin, disability, age and sex, by recipients of HHS Federal financial assistance
  - Disability by health and social service programs of State and local governments
  - Enforces the HIPAA Privacy and Security Rules and the privilege and confidentiality protections of the Patient Safety Act

Training objectives

During this training, participants will learn:

1. Background on Section 1557 of the Affordable Care Act (ACA)

2. Section 1557's nondiscrimination requirements

3. Federal enforcement and Section 1557 resources

BACKGROUND

What is Section 1557?

- Section 1557 is the nondiscrimination provision in the ACA.
- Section 1557 is important to achieving the ACA's goals of expanding access to health care and coverage, eliminating barriers, and reducing health disparities.
- Section 1557 **prohibits discrimination on the basis of race, color, national origin, sex, age, or disability** in certain health programs and activities.
- Section 1557 builds upon longstanding nondiscrimination laws and provides new civil rights protections.

What are some of the notable provisions of Section 1557?

- Section 1557 is the ***FIRST*** Federal civil rights law to broadly prohibit sex discrimination in health programs and activities.
  - Sex discrimination includes, but is not limited to, discrimination based on an individual's sex, including sex stereotypes and sexual harassment. Sex stereotypes means stereotypical notions of masculinity or femininity.
  - NOTE: The U.S. District Court for the Northern District of Texas issued an opinion and order on December 31, 2016 in *Franciscan Alliance, Inc. et al v. Burwell.* The order preliminarily enjoins HHS from enforcing, on a nationwide basis, the provisions of the regulation implementing Section 1557 that prohibit discrimination based on gender identity or termination of pregnancy.
  - OCR will not enforce these provisions until the resolution of the litigation.

- Section 1557 applies to the Health Insurance Marketplaces and to all health plans offered by health insurance companies that participate in the Marketplaces.

REQUIREMENTS

7

Who must comply with HHS's Section 1557 regulation?

- All health programs and activities that receive Federal financial assistance from HHS.
  - Examples: hospitals, health clinics, physicians' practices, community health centers, nursing homes, rehabilitation centers, health insurance issuers, State Medicaid agencies, etc.
  - Federal financial assistance includes grants, property, Medicaid, Medicare Parts A, C and D payments, and tax credits and cost-sharing subsidies under Title I of the ACA. (Medicare Part B is not included.)
- All health programs and activities administered by entities created under Title I of the ACA (i.e., State-based and Federally-facilitated Health Insurance Marketplaces).
- All health programs and activities administered by HHS (e.g., Medicare Program, Federally-facilitated Marketplaces).
- Where an entity is principally engaged in health services or health coverage, ***ALL*** of the entity's operations are considered part of the health program or activity and must be in compliance with Section 1557 (e.g., a hospital's medical departments, as well as its cafeteria and gift shop).
- The rule does not apply to employment practices, such as hiring or firing, except that covered employers are responsible for their employee health benefit programs in certain circumstances.

Discrimination based on an individual's race, color or national origin is prohibited

- Under Section 1557, a covered entity may **not**:
  - Segregate, delay or deny services or benefits based on an individual's race, color or national origin. For example,
    - A covered entity may not assign patients to patient rooms based on race.
    - A covered entity may not require a mother to disclose her citizenship or immigration status when she applies for health services for her eligible child.
  - Delay or deny effective language assistance services to individuals with limited English proficiency (LEP)
    - The term "national origin" includes, but is not limited to, an individual's, or his or her ancestor's, place of origin (such as a country), or physical, cultural, or linguistic characteristics of a national origin group.
- Section 1557 protects individuals in the United States, whether lawfully or not, who experience discrimination based on any of Section 1557's prohibited bases.

Requirements for communicating with LEP individuals

- A covered entity **must** take reasonable steps to provide meaningful access to each individual with LEP eligible to be served or likely to be encountered in its health programs and activities. Reasonable steps may include the provision of language assistance services, such as oral language assistance or written translations.
- A covered entity **must** publish taglines, which are short statements in non-English languages, in significant publications and post in prominent locations and on its website, to notify the individual about the availability of language assistance services.
- A covered entity **must** offer a qualified interpreter when oral interpretation is a reasonable step to provide an individual with meaningful access.
- Where language services are required, they **must** be provided free of charge and in a timely manner.

Requirements for communicating with LEP individuals (cont.)

- A covered entity **must** adhere to certain quality standards in delivering language assistance services.

- For instance, a covered entity **may not**:

  - Require an individual to provide his or her own interpreter
  - Rely on a minor child to interpret, except in a life threatening emergency where there is no qualified interpreter immediately available
  - Rely on interpreters that the individual prefers when there are competency, confidentiality or other concerns
  - Rely on unqualified bilingual or multilingual staff
  - Use low-quality video remote interpreting services

Examples of race, color or national origin discrimination

- A physician at a hospital's emergency department denied a mother with LEP a Spanish interpreter when she requested language assistance. Instead, the physician used the mother's 13-year-old son as the interpreter, while he was being treated for a dog bite. The hospital also failed to translate or orally explain the discharge instructions in Spanish.
- A nurse ignored an African-American female, who needed medical attention, and made her wait in the lobby for close to an hour. While she was waiting, a Caucasian male arrived for his appointment with the same health provider. Although he did not have a health emergency, he waited less than five minutes before the nurse called him for a patient room. Computer records verified that the woman had arrived 15 minutes early for her appointment and that her appointment was scheduled before his. The clinic did not have a legitimate, nondiscriminatory reason for treating the Caucasian male first.

Procedural Requirements

Coordinator & Grievance Procedure

- Effective July 18, 2016
- Applies to covered entities with 15 or more employees
- Requires the covered entity to designate an employee to serve as the entity's compliance coordinator
  - Must investigate grievances
- Requires the covered entity to adopt a grievance procedure
  - Must afford due process and prompt and equitable resolution of grievances
  - Appendix C to the final rule is a sample

Coordinator & Grievance Procedure (cont.)

- Preamble discussion (not binding but explanatory)
  - A covered entity may designate existing staff to perform coordinator duties
  - A covered entity may combine the Section 1557 grievance procedure with other grievance procedures (even unrelated to civil rights)
  - An individual does not have to exhaust a covered entity's grievance procedure prior to filing with OCR
  - Covered entities with fewer than 15 employees may implement the coordinator and grievance procedure

Notice Requirement

- Effective Oct. 17, 2016
- Applies to all covered entities
- Must post a nondiscrimination notice
  - Seven elements required in the notice
  - May combine the content of the notice with other notices
- Must post at least 15 taglines
- Posting requirements
  - In significant publications and significant communications (except those that are small-size)
  - In conspicuous physical locations where the covered entity interacts with the public
  - On the covered entity's website, accessible from the home page

Notice Requirement (cont.)

- Seven elements required in the nondiscrimination notice

1. The covered entity does not discriminate on the basis of race, color, national origin, sex, age, or disability in its health programs and activities
2. The covered entity provides appropriate auxiliary aids and services
3. The covered entity provides language assistance services
4. How to obtain auxiliary aids and services and language assistance services
5. If applicable, the name and contact information for the compliance coordinator
6. If applicable, the availability of the covered entity's grievance procedure and how to file a grievance
7. How to file a discrimination complaint with OCR

Notice Requirement (cont.)

- In small-size significant publications and significant communications, each covered entity must post:
  - A nondiscrimination statement
  - At least 2 taglines
- Appendix A to the final rule - sample notice of nondiscrimination and nondiscrimination statement
- Appendix B to the final rule - sample tagline

Notice Requirement (cont.)

- Preamble discussion (not binding but explanatory)
  - A covered entity has flexibility to implement requirements as long as the covered entity does not compromise the intent to clearly inform individuals of their Section 1557 rights.
  - The provision of the notice and taglines is effective if the content is sufficiently conspicuous and visible that an individual could reasonably be expected to see and be able to read the information.
  - A covered entity may post nondiscrimination notices and statements in non-English languages (OCR has these and taglines in 64 languages, http://www.hhs.gov/civil-rights/for-individuals/section-1557/translated-resources/index.html).
  - A covered entity may satisfy the web posting requirement on its home page by posting an English-language link for the nondiscrimination notice and 15 "in-language" links for each tagline.

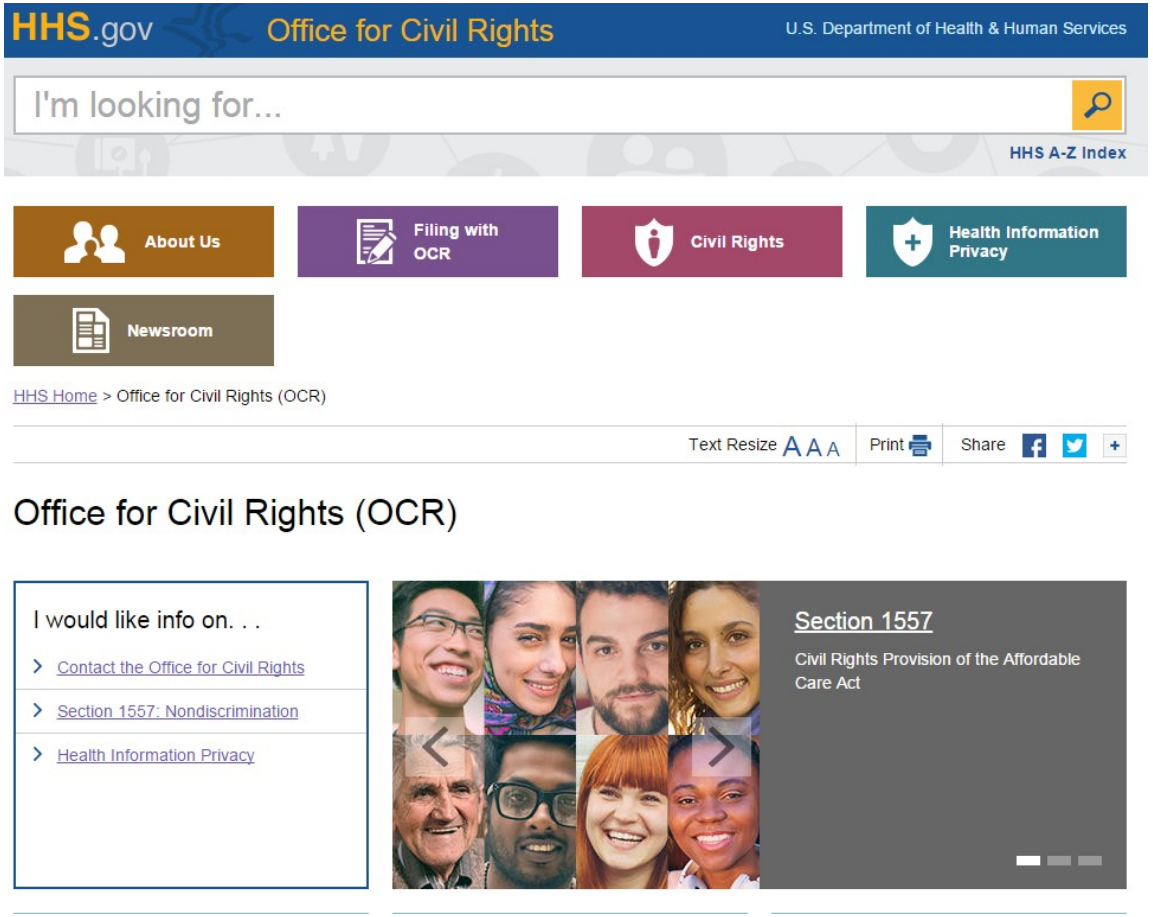
ENFORCEMENT

Federal Enforcement

- The U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR) enforces Section 1557 as to programs that receive funding from HHS.
- OCR is a neutral, fact-finding agency that receives, investigates and resolves thousands of complaints from the public alleging discrimination in health services and health coverage.
- When OCR finds violations, a covered entity will be required to take corrective actions, which may include revising policies and procedures and implementing training and monitoring programs. Covered entities may also be required to pay compensatory damages.
- When a covered entity refuses to take corrective actions, OCR may undertake proceedings to suspend or terminate Federal financial assistance from HHS. OCR may also refer the matter to the U.S. Department of Justice for possible enforcement proceedings.
- Section 1557 also provides individuals the right to sue covered entities in court for discrimination if the program or activity receives Federal financial assistance from HHS or is a State-based Marketplace℠.

VISIT OUR WEBSITE!

www.hhs.gov/ocr



On OCR's website….

- Read about civil rights and HIPAA laws
- Download fact sheets
- Access sample policies and resources in English and other languages
- File a complaint
- Contact us!

Office for Civil Rights
U.S. Department of Health and Human Services

200 Independence Avenue, SW
Room 509F, HHH Building
Washington, DC 20201

Website: www.hhs.gov/ocr
Email: 1557@hhs.gov

Toll Free: (800) 368-1019

TDD Toll-Free: (800) 537-7697

Attachment 4

NABP
National Association of Boards of Pharmacy
www.nabp.pharmacy

1600 Feehanville Drive
Mount Prospect, IL 60056
T) 847/391-4406
F) 847/375-1114

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Carmen A. Catizone, Executive Director/Secretary

DATE: October 13, 2016

RE: Labeling Requirements for Emergency-Use Medications

As you are aware, there have been numerous reports related to the increasing price of epinephrine products and the impact on patient access; ie, EpiPen®. In an effort to further protect the public health and not place an undue financial burden on patients, NABP is respectfully urging state boards of pharmacy to review their current requirements regarding the labeling of epinephrine auto-injectors and other similar emergency-administration medications by dispensing pharmacies.

EpiPen auto-injectors, and other similar emergency-use medications, represent a unique category of medications for which special consideration must be given regarding the products' expiration dates. Many state laws or rules 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. In situations where an EpiPen has not been removed from the original packaging and has been stored under appropriate conditions, as determined by the pharmacist, NABP requests that 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.

NABP encourages state boards of pharmacy to adopt the above position or modify their position on labeling requirements for emergency-use medications. NABP also respectfully requests that if such allowances can be made that the information be shared with licensees and the public. NABP suggests including such information in the next state newsletter. Additionally, *NABP e-News* can serve as a vehicle to convey this information. NABP would be glad to work with states to provide such notice to their licensees and the public regarding pharmacy-labeled and manufacturer-applied expiration dates for these products.

cc: NABP Executive Committee

Attachment 5

Narcan on Demand: Non-Prescription Naloxone Availability in LA County

Report Summary:

- 100 pharmacies from Los Angeles County zip codes stratified by median household income were randomly selected and surveyed
- Though Narcan was available at 49 pharmacies, it was only in stock at 12 pharmacies, of which 2 required prescriptions. 33 pharmacies required prescriptions to pick up/order Narcan. Only 16 of the 100 surveyed pharmacies were compliant with California Assembly Bill No. 1535 (AB1535) permitting patients access to non-prescription Naloxone.
- Even when pharmacies abide by AB1525, there is still an array of additional barriers patients requesting Narcan have to overcome. Patients picking up Narcan without a prescription need to be over 18, fill out documentation as to why they required the medication, and pay for the medication with cash (as insurance “does not cover” the medication unless the person buying the medication was the person it was intended to be used for). Several pharmacists commented on the high price of the medication.
- There is only a 34% chance of finding a AB1535 compliant chain pharmacy and a 2% chance of finding a AB1535 compliant community pharmacy. The most likely hurdle a patient will encounter at a chain pharmacy is lack of awareness of AB1535, at a community pharmacy a patient will unable to order Narcan at all.
- There is no evidence of median regional income affecting Narcan availability.
- There is evidence that demand for Narcan in LA County is low
- 10 of 16 AB1535 compliant pharmacies were branches of CVS

Conclusion:

There is significant non-compliance with California Assembly Bill No. 1535. There are a significant number of hurdles preventing patients, or family members of patients with substance abuse, from obtaining Narcan without a prescription. Chain pharmacies are more likely than community pharmacies to have Narcan available. There is no evidence of median regional income affecting Narcan availability. There is evidence suggesting low Narcan demand in LA county.

100+ pharmacies from several regions of LA were surveyed. However, there were two prominent methodological flaws.

1.) Survey design- the initial survey design was woefully inappropriate for this task. 13/15 initially contacted pharmacies declined to take part in the survey. This warranted a change in survey methodology and the survey was changed to more reflect the interaction a patient looking for narcan may have with a pharmacy. However, further problems continued with one of the new survey items, “Have any other patients requested non-prescription Narcan/Naloxone?” I could not ask this question regularly because a.) pharmacist staff (community especially) were interested in ending the phone conversation as promptly as possible and b.) not all pharmacy staff were willing/interested/able to quantify how many patients had also asked for this medication. Moreover, the initial survey was aimed at pharmacists but often they survey was administered to pharmacy technicians who often not as familiar with their pharmacy's formulary or drug protocols as the pharmacy’s pharmacist.
2.) Survey method- the initial survey was designed to assess Narcan availability in different regions of LA stratified by median income. A listing of median income by zip code was stratified and randomly sampled from. However, a problem came up while selecting pharmacies because there were often not enough pharmacies in each zip code. This led to pharmacies being selected from nearby zip codes and introducing an uncontrolled neighborhood median income variability in the sample.

Gross analysis:

Of 100 surveyed pharmacies, only 12 had Narcan available in the store at the time of the call. Of those 12, 2 said that a prescription was needed to pick up the medication. Among the 10 that did not require a prescription there were an array of additional barriers patients requesting Narcan had to overcome. Patients picking up Narcan without a prescription needed to be over 18 (verbally endorsed by 2/12 but likely required by all), needed to fill out documentation as to why they required the medication, and needed to pay for the medication with cash (2/12 - as insurance “did not cover” the medication unless it was the person buying the medication was the person it was intended to be used on). Of note, several pharmacists commented on the high price of the medication.

Of the 100 surveyed pharmacies, 37 pharmacies did not have Narcan available in the store at the time of the call but were willing to order it. 29 pharmacies said that prescriptions were required to order and pickup Narcan and 2 pharmacies said they could order it but said Narcan would be more readily available at another pharmacy. 6 pharmacies said that Narcan could be ordered and picked up without a prescription.

Of the 100 surveyed pharmacies, 51 pharmacies did not have any narcan available and had no intention or ordering any. Pharmacies often referred to Narcan as a “specialty drug” and said that it was not on their drug list and that they were unable to order it (38/51). 6 pharmacies said they were able to order the drug but “chose not to,” 2 pharmacies hung up when asked if they could “order Narcan”, and 2 pharmacies said they could not order Narcan because their pharmacy did not have a protocol to order it in place yet. 1 pharmacy did not disclose why they

were unable to order Narcan. Of note, 2 pharmacies that did not carry Narcan referred me to a place where they thought it was available.

In summary: Though Narcan was available at 49 pharmacies, it was only in stock at 12 pharmacies, of which 2 required prescriptions. Only 16% of pharmacies were compliant with California Assembly Bill No. 1535 (AB1535) permitting patients access to non-prescription Naloxone.

In-depth analysis:

Community vs. Chain Pharmacy

Pharmacy	Do.you.have.intranasal.Narcan.		Can.you.order.it.for.me.	
	No	Yes	No	Yes
Chain	33	12	7	38
Community	55	0	44	11

As can be eye-balled, community pharmacies are much less likely to have/order Narcan. This can in part be explained by Narcan being considered a “specialty drug (70% of community pharmacies as opposed to 6% of chain pharmacies said they do not carry Narcan).” Both differences are statistically significant by chi-squared analysis (p-value = < 0 & < 0). Because only chains can typically order Narcan they were much more likely to ask for a prescription (20% of community pharmacies and 42% of chain pharmacies said they do not carry Narcan).

In summary, there is only a 34% chance of finding a AB1535 compliant chain pharmacy and a 2% chance of finding a AB1535 compliant community pharmacy. The most likely hurdle a patient will encounter at a chain pharmacy is lack of awareness about AB1535 and inaccessibility of Narcan at a community pharmacy.

Income Stratification:*

Eyeballing Table 1, there is no gross difference in Narcan availability, both in terms of immediate Narcan availability and willingness of pharmacies to order Narcan, by median income. Statistical testing confirms this with p-values of 0.61 and 0.71 respectively.

Analysis is limited by the small numbers when sub-categorizing pharmacies by income but no gross trends are apparent.

Eyeballing Table 1, there is no gross difference in Narcan availability, both in terms of immediate Narcan availability and willingness of pharmacies to order Narcan, by zip codes earning split down the middle. Statistical testing is not necessary.

Table 1: Stratified Income vs. Narcan Availability

Median Income ($)	Do.you.have.intranasal.Narcan.		Can.you.order.it.for.me.	
	No	Yes	No	Yes
13576	9	1	6	4
25028	8	2	6	4
41592	9	1	6	4
42849	8	2	4	6
51345	10	0	7	3
73030	8	2	5	5
75690	8	2	4	6
86826	8	2	6	4
146510	10	0	3	7
182270	10	0	4	6

Table 2: Collapsed Income vs. Narcan Availability

Median Income	Do.you.have.intranasal.Narcan.		Can.you.order.it.for.me.	
	No	Yes	No	Yes
Bottom 50%	44	6	29	21
Top 50%	44	6	22	28

In summary, there is no evidence of median regional income affecting Narcan availability.

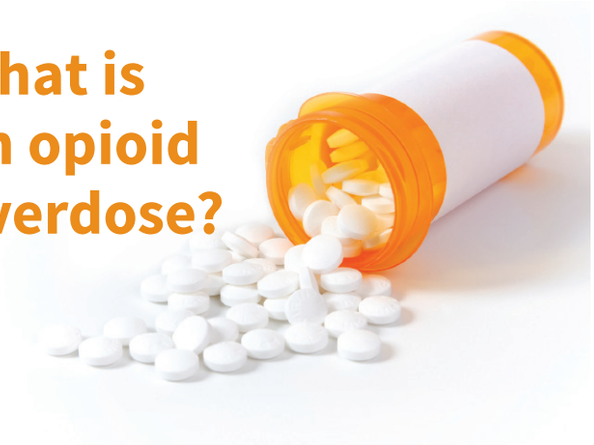
*- as noted in the intro, this assessment may be severely affected by survey methodology

Narcan Demand:

Though data is of poor quality, there is some evidence to suggest that areas of median income extremes ($182270 - $146510 & $25028 - $13576) have higher demand for Narcan as indicated by responses to the survey question, “How many other patients have asked about this medication?” **Only 4/100 pharmacies endorsed that other patients had asked about this medication** though. Despite the poor implementation of this question, see intro, it can be conservatively concluded that there is some merit to this assessment as many pharmacy staff were either unfamiliar with drug Narcan/Naloxone or had to look up their protocols regarding it.

Attachment 6

What is an opioid overdose?



Opioids can cause bad reactions that make your breathing slow or even stop. This can happen if your body can't handle the opioids that you take that day.

TO AVOID AN ACCIDENTAL OPIOID OVERDOSE:

- Try not to mix your opioids with alcohol, benzodiazepines (Xanax, Ativan, Klonopin, Valium), or medicines that make you sleepy.
- Be extra careful if you miss or change doses, feel ill, or start new medications.

Now that you have naloxone…

Tell someone where it is and how to use it.

Common opioids include:

GENERIC	BRAND NAME
Hydrocodone	Vicodin, Lorcet, Lortab, Norco, Zohydro
Oxycodone	Percocet, OxyContin, Roxicodone, Percodan
Morphine	MSContin, Kadian, Embeda, Avinza
Codeine	Tylenol with Codeine, TyCo, Tylenol #3
Fentanyl	Duragesic, Actiq
Hydromorphone	Dilaudid
Oxymorphone	Opana
Meperidine	Demerol
Methadone	Dolophine, Methadose
Buprenorphine	Suboxone, Subutex, Zubsolv, Bunavail, Butrans

* Heroin is also an opioid.

For patient education, videos and additional materials, please visit
www.prescribetoprevent.org

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

2016

Opioid safety and how to use naloxone

A GUIDE FOR PATIENTS AND CAREGIVERS

SAN FRANCISCO DEPARTMENT OF PUBLIC HEALTH

In case of overdose:

1 Check reponsiveness

Look for any of the following:

- No reponse even if you shake them or say their name
- Breathing slows or stops
- Lips and fingernails turn blue or gray
- Skin gets pale or clammy

2 Call 911 and give naloxone

If no reaction in 3 minutes, give second naloxone dose

3 Do rescue breathing and/or chest compressions

Follow 911 dispatcher instructions

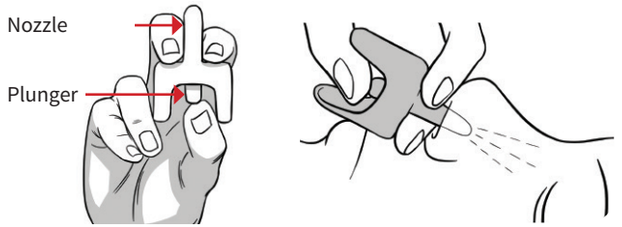
>> STAY WITH PERSON UNTIL HELP ARRIVES.

How to give naloxone:

There are 4 common naloxone products. Follow the instructions for the type you have.

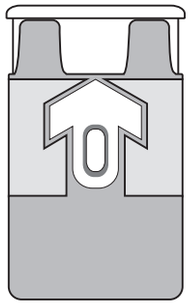
Nasal spray

This nasal spray needs no assembly and can be sprayed up one nostril by pushing the plunger.



Auto-injector

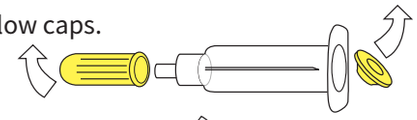
The naloxone auto-injector needs no assembly and can be injected into the outer thigh, even through clothing. It contains a speaker that provides step-by-step instructions.



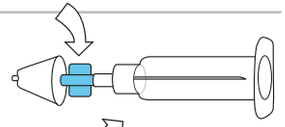
Nasal spray with assembly

This requires assembly. Follow the instructions below.

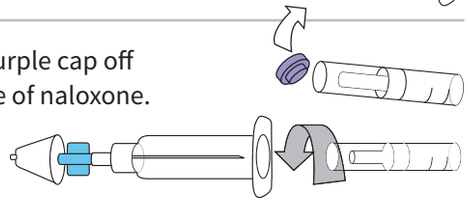
1 Take off yellow caps.



2 Screw on white cone.



3 Take purple cap off capsule of naloxone.



4 Gently screw capsule of naloxone into barrel of syringe.

5 Insert white cone into nostril; **give a short, strong push** on end of capsule to spray naloxone into nose: **ONE HALF OF THE CAPSULE INTO EACH NOSTRIL.**

Push to spray.

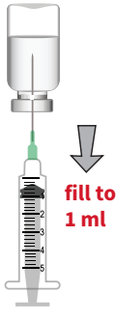
6 If no reaction in 3 minutes, give second dose.

Injectable naloxone

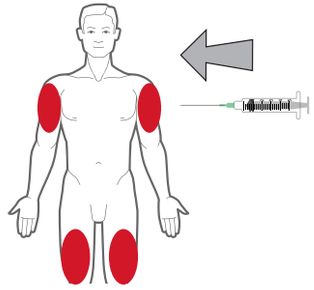
This requires assembly. Follow the instructions below.

1 Remove cap from naloxone vial and uncover the needle.

2 Insert needle through rubber plug with vial upside down. Pull back on plunger and take up 1 ml.



3 Inject 1 ml of naloxone into an upper arm or thigh muscle.



4 If no reaction in 3 minutes, give second dose.

Lorri Walmsley, RPh
Senior Manager, Professional Affairs
Walgreen Company
5330 E. Washington St., D-105
Phoenix, AZ 85034
P 602-214-6618

January 3, 2017

Virginia Herold
Executive Officer
California State Board of Pharmacy
1625 North Market Blvd.
Sacramento, CA 95834

Via Email: Virginia.Herold@dca.ca.gov

Dear Ms. Herold and the California State Board of Pharmacy,

Walgreen Co. intends to begin furnishing opioid antagonists at its locations in California in early 2017. Pursuant to California §1746.3(b) (6), I am writing to request approval from the California State Board of Pharmacy to utilize our Walgreen specific naloxone fact sheet for patients.

Walgreen Co. is currently providing opioid antagonists via pharmacist prescriptive authority or protocol in 34 other states and the District of Columbia. Our policy and procedure is to provide a patient medication leaflet along with a patient education fact sheet (enclosed) that auto-prints when the prescription is filled. This automated process for providing patient education materials has proven to be effective in the other locations where it has been implemented and has ensured that the patient has sufficient education materials once leaving the pharmacy.

We are proposing to use this same procedure for patients in California whose primary language is English. In order to fulfill the requirement for patients whose primary language is not English we intend to provide access through our intranet system to your website to print the materials in alternate languages.

I would welcome the opportunity to personally meet with you and all the members of the California State Board of Pharmacy in order to review this request. Also, I would send representation to a full board meeting to discuss further if that would be helpful. Your timely attention to this matter will be greatly appreciated.

Kindest Regards,

Lorri Walmsley

Lorri Walmsley, RPh
Senior Manager, Pharmacy Affairs

Enclosure: Naloxone Guide for Patients and Caregivers

Naloxone Guide for Patients and Caregivers

Walgreens at the corner of happy & healthy

The information provided below outlines how to recognize an opioid overdose and what do to if it ever occurs. It is important for you to share this with your family and friends. Create a plan of action so everyone knows the steps to follow in case of an emergency overdose situation. Notify family and friends where you plan to store naloxone so they can easily access the kit in case of an emergency.

What are opioids?

Opioids are generally prescribed to treat pain. When opioids are taken in high doses or abused, they can cause feelings of euphoria, relaxation, drowsiness, and warmth. If the individual takes too many opioids or combines them with other drugs or alcohol, this may cause problems such as difficulty breathing, loss of consciousness, cardiac arrest and even death.

What is naloxone?

Naloxone is an antidote for opioid overdose and reverses the effects of opioids. Naloxone only works if there are opioids present in the body and has no effect on other drugs or alcohol.

It usually takes 3-5 minutes for the medicine to work and lasts 30-90 minutes.

It is available for use during opioid emergency situations.

Common opioids include:

Buprenorphine	Suboxone, Subutex
Codeine	Tylenol #3
Fentanyl patch	Actiq, Duragesic
Hydrocodone	Vicodin, Norco
Hydromorphone	Dilaudid
Meperidine	Demerol
Methadone	Methadose
Morphine	MS Contin
Oxycodone	Oxycontin, Percocet
Oxymorphone	Opana

*Heroin is also an opioid.

Risk Factors for Overdose Anyone who uses prescription opioids or heroin are at risk for overdose. Other factors that may increase a person's risk include: switching between opioids, having a history of substance abuse or mental illness, mixing opioids with certain medications, taking opioids or heroin alone, recent emergency medical care after opioid intoxication, or having decreased tolerance but a high risk of relapse (i.e. recently completing a mandatory opioid detoxification or having abstained from use for a long period of time).

How to Avoid an Accidental Overdose:

- Do not adjust your own dose, skip doses, or take any extra doses.
- Do not abuse prescription opioids.
- Do not mix with other drugs and/or alcohol. *For Example*: anti-anxiety drugs like Xanax, Ambien, Ativan, Klonopin; anti-depressants; or cocaine.

STEPS to respond to an Overdose:

ACT IMMEDIATELY!

1. Recognize overdose
2. Call 9-1-1
3. Rescue breathing
4. Administer naloxone
5. Stay with person and continue rescue breathing until medical personnel arrive.

How to Identify an Opioid Overdose:

- Difficulty breathing, struggling to breathe, gurgling for breath, making deep snoring sounds
- Bluish lips and/or fingertips
- Pale, clammy skin
- Awake but unable to talk
- Small pupils
- Body very limp

STEP 1. Recognizing an Opioid Overdose

When an individual takes too many opioids the drug may block their ability to breathe, which may lead to coma or death.

1. Shout to see if the victim responds and gently shake their shoulder.
2. Rub your knuckles on their upper lip or up and down the front of their rib cage (**sternal rub**).
3. If patient is unresponsive, **CALL 9-1-1.**

STEP 2. Calling 9-1-1

When calling 9-1-1, it is important to share the following information:

1. Individual's breathing has stopped and they are unresponsive.
2. Exact location of the individual.
3. Whether or not naloxone has been given to the individual and if that helped.

STEP 3. Rescue Breathing

1. Place the individual on their back. Place one hand on their forehead and the other under their chin.
2. Tilt their chin up gently to open the airway.
3. Check to see if there is anything in their mouth blocking their airway, such as gum, toothpick, undissolved pills, syringe cap, fentanyl patch, etc. If so, remove it.
4. Pinch their nose with one hand and keep chin tilted up with the other hand. Create an airtight mouth-to-mouth seal and give 2 even, regular-sized breaths. Blow enough air into their lungs to make their chest rise. If the chest does not rise, make sure you pinch their nose and tilt their head back with each breath.
5. Give one breath every 5 seconds.

STEP 4. Administer Naloxone

- Follow the directions below to give either nasal spray naloxone or injectable naloxone.
- **Caution**: The naloxone medicine vial is glass so use hands to gently pry cap off.
- **Nasal naloxone note:** When twisting the glass medicine vial into bottom of plastic syringe, stop when you feel slight resistance. Naloxone will start to spray out the top of the white spray top. STOP!
- Remember to continue to give rescue breaths until emergency medical personnel arrive.
- Naloxone lasts for 30-90 minutes. Naloxone may wear off before the effects of the opioids are gone. The individual may experience overdose symptoms again if this happens.

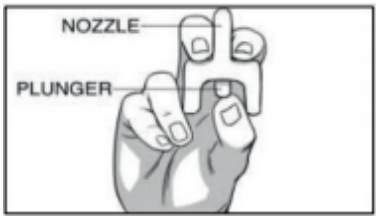
Narcan® Nasal spray

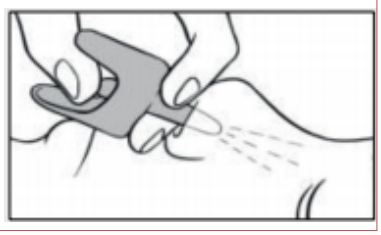
1. Remove Narcan nasal spray from the box. Peel back the tab with the circle to open the Narcan nasal spray.

2. Hold the Narcan nasal spray with your thumb on the bottom of the plunger and your first and middle fingers on either side of the nozzle.

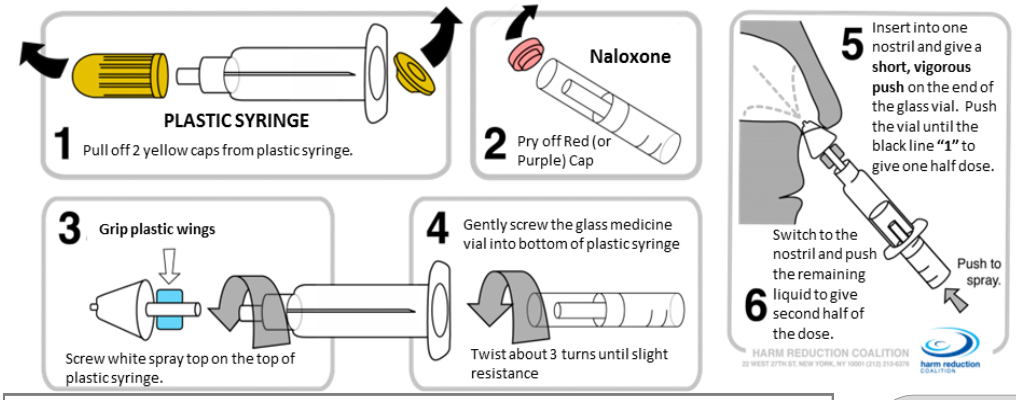
3. Gently insert the tip of the nozzle into either nostril. Tilt the person's head back and provide support under the neck with your hand. Gently insert the tip of the nozzle into one nostril, until your fingers on either side of the nozzle are against the bottom of the person's nose.

4. Press the plunger firmly to give the dose of Narcan nasal spray. Remove the Narcan nasal spray from the nostril after giving the dose.

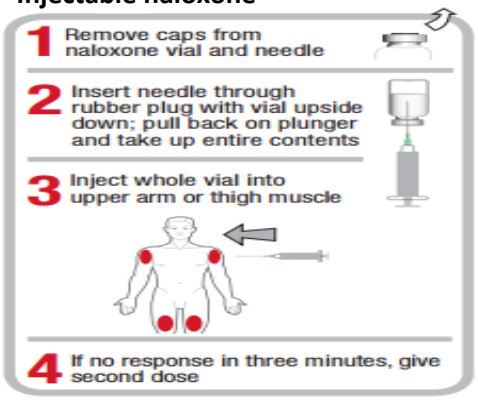




Nasal spray naloxone with atomizer



Injectable naloxone



Administering a second dose:

- If the naloxone did not work after you waited 2-5 minutes, you may give a second dose of medication.

⇒**Narcan Nasal Spray**: repeat step 2 every **2-3 minutes** until the person responds or emergency medical help is received.

⇒**Intranasal with atomizer**: if there is no change in **3-5 minutes**, remove the second naloxone medication from a new box and a new white spray top and repeat steps 1-4 to assemble. Then give the victim a second dose by giving one half of the dose in each nostril following steps 5-6.

⇒**Injectable naloxone**: if there is no change in **2-3 minutes**, repeat steps 1-4 to administer a second dose.

Recovery Position

If you have to leave the individual, even for a moment to call for help or to get naloxone, make sure to roll the individual over on their side with their top leg and arm crossed over their body. This position will help maintain an open airway. If they happen to vomit, this position will lessen the risk that they choke on their vomit.

Naloxone Storage Naloxone should be stored at room temperature and protected from light.

Important Resources:

Poison Control: 800-222-1222
Walgreens Pharmacy: 1-800-WALGREENS (800-925-4733)
www.prescribetoprevent.org
Information on local drug addiction treatment programs can be found by calling 877-SAMHSA-7 or by logging into: https://findtreatment.samhsa.gov/

Auto-injector:

The naloxone auto-injector, Evzio, is FDA approved for use in opioid emergencies. It comes with visual and voice instructions for injection into the thigh through clothing if necessary. The kit comes as a twin pack with 2 auto-injectors if a second dose is needed.

Signs of Withdrawal

If the naloxone is successful in overdose reversal the patient may experience withdrawal symptoms. Comfort the individual and keep them calm. An individual may experience withdrawal symptoms if the naloxone works to block the opioid in their system.

How to recognize Opioid Withdrawal:

- Dilated pupils
- Nausea, vomiting
- Agitation and anxiety
- Sweating

Walgreens
at the corner of happy & healthy

References: 1.) Massachusetts Department of Public Health. Opioid Overdose Education and Naloxone Distribution.
2.) Harm Reduction Coalition. Chicago Recovery Alliance. 3) San Francisco Department of Public Health. Opioid Safety and How to Use Naloxone.

Attachment 7

WHERE IN THE WORLD IS **AMAZON**MEDICA?

Amazon Medica, an online drugs distributor, is **illegally and fraudulently selling into the U.S. non-FDA approved** injectable pharmaceuticals for treating arthritic joint pain, chronic migraines, bladder dysfunction, upper limb spasticity, cervical dystonia, primary axillary hyperhidrosis, blepharospasm and strabismus, and for cosmetic use.

Amazon Medica claims as "Our Brands": Allergan; Merz Aesthetics; Q-Med (Galderma); Sanofi (Aventis, Genzyme); Ferring Pharmaceuticals; Fidia Farmaceutici; and Zimmer Biomet.

+ Claims to be **GREAT BRITAIN'S #1 pharmaceutical wholesaler** with affiliated UK pharmacy
+ Office listed in **LOS ANGELES** – **NO OFFICE EXISTS**
+ Name servers registered in **AMSTERDAM**
+ Site server registered in **SINGAPORE**
+ Domain registered by proxy company in **AUCKLAND, NZ**
+ Owner of website based in **KUALA LUMPUR**
  - Same owner founded **MagicGroup Asia** & **MagicLabs**
  - MagicGroup Asia & MagicLabs **specialize in digital advertising**

Product Protection Update

Allergan

Amazon Medica: Illegal seller of Allergan Aesthetics products

The situation

Amazon Medica is a foreign and unauthorized criminal entity that is illegally selling Allergan Aesthetics products, including BOTOX® Cosmetic (onabotulinumtoxinA) and JUVÉDERM® XC. Not only is the authenticity of the products Amazon Medica sells in question, but the "JUVEDERM ULTRA 2, JUVEDERM ULTRA 3, and JUVEDERM ULTRA 4" products it promotes and sells are not FDA approved for use and distribution in the United States. Any and all sales of Allergan Aesthetics products through Amazon Medica—counterfeit, compromised, or otherwise—is illegal. **This is a violation of federal law and, more importantly, puts patients' safety at risk.**

What Allergan is doing

Allergan is doing everything in its power to educate providers and patients, and to shut down Amazon Medica (see inside).

Please see specific actions that Allergan has taken against Amazon Medica on the following page.

BOTOX® Cosmetic (onabotulinumtoxinA) Important Information

Indications

Glabellar Lines

BOTOX® Cosmetic (onabotulinumtoxinA) for injection is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

Lateral Canthal Lines

BOTOX® Cosmetic is indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines associated with orbicularis oculi activity in adult patients.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX® Cosmetic and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and upper limb spasticity and at lower doses.

Please see additional Important Safety Information on following pages.

Amazon Medica: Illegal seller of Allergan Aesthetics products

What Allergan is doing (continued)

Actions that Allergan has taken:

- Notified Amazon Medica and its known employees that their activity violates federal law and endangers patients
- Working with organizations and companies to impede Amazon Medica's ability to do business
- Successfully removed Amazon Medica's promotional video from *YouTube*®

Risks for you, your practice, and your patients

- Federal law prohibits non-FDA–approved drug importation
  - These products may be counterfeit or compromised, and can pose a health risk to your patients. The identity, purity, and source of these products are unknown

What you can do

- **Continue to let us know about any intelligence** you receive on Amazon Medica. Please send information to your Allergan representative
- **Rest assured** that Allergan is doing everything in its power to protect patients and providers by shutting down Amazon Medica in the same manner that Gallant Pharma, Medical Device King/Pharmalogical, and other foreign and unlicensed suppliers have been shut down
  - Read more about Gallant Pharma, Medical Device King, and the legal consequences of violating FDA regulations:
    - **Physician Guilty of Illegal Importation of Non-FDA-Approved Products:** www.fda.gov/ICECI/CriminalInvestigations/ucm397123.htm
    - **Pharmaceuticals President Sentenced to 60 Months in Prison:** Justice.gov/usao-edny/pr/president-pharmaceutical-companies-sentenced-60-months-prison-long-running-scheme-sell
    - **Convicted—$3.4M in Restitution and 3 Years Imprisonment for Gallant Head:** Justice.gov/usao-edva/pr/co-leader-illegal-drug-company-gallant-pharma-sentenced-3-years

Together, we can help protect our patients and the industry from illegal suppliers.

IMPORTANT SAFETY INFORMATION (continued)
CONTRAINDICATIONS
BOTOX® Cosmetic (onabotulinumtoxinA) is contraindicated in the presence of infection at the proposed injection site(s) and in individuals with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation.

WARNINGS AND PRECAUTIONS
Lack of Interchangeability between Botulinum Toxin Products

The potency units of BOTOX® Cosmetic are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX® Cosmetic cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method.

Please see additional Important Safety Information on following page.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)
Spread of Toxin Effect
Please refer to Boxed Warning for Distant Spread of Toxin Effect.

No definitive serious adverse event reports of distant spread of toxin effect associated with dermatologic use of BOTOX® Cosmetic (onabotulinumtoxinA) at the labeled dose of 20 Units (for glabellar lines), 24 Units (for lateral canthal lines), 44 Units (for simultaneous treatment of lateral canthal lines and glabellar lines) have been reported.

Serious Adverse Reactions With Unapproved Use
Serious adverse reactions, including excessive weakness, dysphagia, and aspiration pneumonia, with some adverse reactions associated with fatal outcomes, have been reported in patients who received BOTOX® injections for unapproved uses. In these cases, the adverse reactions were not necessarily related to distant spread of toxin, but may have resulted from the administration of BOTOX® to the site of injection and/or adjacent structures. In several of the cases, patients had pre-existing dysphagia or other significant disabilities. There is insufficient information to identify factors associated with an increased risk for adverse reactions associated with the unapproved uses of BOTOX®. The safety and effectiveness of BOTOX® for unapproved uses have not been established.

Hypersensitivity Reactions
Serious and/or immediate hypersensitivity reactions have been reported. These reactions include anaphylaxis, serum sickness, urticaria, soft-tissue edema, and dyspnea. If such reactions occur, further injection of BOTOX® Cosmetic should be discontinued and appropriate medical therapy immediately instituted. One fatal case of anaphylaxis has been reported in which lidocaine was used as the diluent and, consequently, the causal agent cannot be reliably determined.

Cardiovascular System
There have been reports following administration of BOTOX® of adverse events involving the cardiovascular system, including arrhythmia and myocardial infarction, some with fatal outcomes. Some of these patients had risk factors including pre-existing cardiovascular disease. Use caution when administering to patients with pre-existing cardiovascular disease.

Pre-existing Neuromuscular Disorders
Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junction disorders (eg, myasthenia gravis or Lambert-Eaton syndrome) should be monitored when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including generalized muscle weakness, diplopia, ptosis, dysphonia, dysarthria, severe dysphagia, and respiratory compromise from onabotulinumtoxinA (see *Warnings and Precautions*).

Dysphagia and Breathing Difficulties
Treatment with BOTOX® and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or oropharyngeal muscles that control swallowing or breathing (see *Boxed Warning*).

Pre-existing Conditions at the Injection Site
Caution should be used when BOTOX® Cosmetic treatment is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle(s).

Human Albumin and Transmission of Viral Diseases
This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

ADVERSE REACTIONS
The most frequently reported adverse event following injection of BOTOX® Cosmetic for glabellar lines was eyelid ptosis (3%).

The most frequently reported adverse event following injection of BOTOX® Cosmetic for lateral canthal lines was eyelid edema (1%).

DRUG INTERACTIONS
Co-administration of BOTOX® Cosmetic and aminoglycosides or other agents interfering with neuromuscular transmission (eg, curare-like compounds) should only be performed with caution as the effect of the toxin may be potentiated. Use of anticholinergic drugs after administration of BOTOX® Cosmetic may potentiate systemic anticholinergic effects.

The effect of administering different botulinum neurotoxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of BOTOX® Cosmetic.

USE IN SPECIFIC POPULATIONS
BOTOX® Cosmetic is not recommended for use in children or pregnant women. It is not known whether BOTOX® Cosmetic is excreted in human milk. Caution should be exercised when BOTOX® Cosmetic is administered to a nursing woman.

Please see accompanying full Prescribing Information including Boxed Warning and Medication Guide.

BotoxCosmetic.com 1-800-BOTOXMD BCT101925 09/16 163109

Attachment 8

Communication and Public Education Communication Plan

The Board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

2017-2021

4.1 Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Develop plan and bring to committee for approval	Licensees and Consumers	List of tasks with corresponding: audiences, content/method, purpose , responsible parties and timing	To improve communication and keep stakeholders better informed	Staff, C&PE Committee	Completed September 2016
b. Provide direction and new assignments	Staff	Board, committee requests at meetings	To carry out board, committee requests to communicate with licensees, public	Board, C&PE Committee, Staff	Ongoing
c. Explore ways to engage more directly with licenses	Licensees	Solicit pharmacist input at board meetings, events	Foster dialogue, communication between licensees and board	Board, C&PE Committee, Staff	Ongoing

4.2 Identify and use additional resources for public and licensee outreach services to implement a communication plan.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Website	Licensees and Consumers	Post news, announcements online	Communicate immediate information to licensees, public	Staff	Ongoing
b. Newsletter	Licensees and Consumers	Publish news, announcements in formatted publication	Communicate to licensees, public	Staff	Quarterly
c. Subscriber alerts	Licensees and Consumers	Notices of recalls, regulations, news, important information	Communicate instantly to licensee, public	Staff	Ongoing
d. News archive	Licensees, Consumers	Website announcements, Script articles	Permanently archive web announcements in easy-to-find place	Staff	Completed January 2017
e. Topic pages	Licensees	Important information for licensees	Organize information by topic on easy-to-find webpages	Staff	Completed February 2017

4.3 Establish a process to collect email addresses and mobile numbers for text messaging, from all licensees for better ability to improve communications.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Research means to collect email addresses	Licensees	Mechanism to collect email addresses	To distribute information to licensees	Board staff C&PE Committee	TBD
b. Research means to collect mobile telephone numbers	Licensees	Mechanism to collect mobile telephone numbers	To distribute information to licensees	Board staff C&PE Committee	TBD

4.4 Educate licensees about the board's regulations by publishing summaries of all newly issued regulations and explain implementation tactics.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Inform licensees of new regulations	Licensees	Website Subscriber alert Newsletter	Disseminate information about new regulations	Board staff	TBD
b. Cohost training forum on drug abuse topics	Licensees	Training at live event	CE for licensees	Staff, DEA, UCSD School of Pharmacy	Completed March 2017
c. Produce CE courses	Licensees	Live sessions, webinar	Educate licensees on Pharmacy Law	Staff	2017

4.5 Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Inspect pharmacies at least once every four years	Licensee – pharmacies	Inspection	Forum for licensee-inspector interaction	Inspectors Board staff	TBD

4.6 Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Naloxone availability at pharmacies	Consumers	Website	Inform the public	Board staff	TBD

4.7 Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.

Task	Audience	Content/Methods	Purpose	Responsible Parties	Timing
a. Notice to Consumers	Consumers	Update regulation language	Inform consumers of rights	Board staff C&PE Committee	TBD
b. Point-to-your-language notice	Consumer	Update regulation language	Inform consumers of rights	Board staff C&PE Committee	TBD