



COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Ricardo Sanchez, Public Member, Chairperson
Valerie Muñoz, Public Member, Vice Chairperson
Ryan Brooks, Public Member
Shirley Kim, Public Member
Debbie Veale, Licensee Member

1. Call to Order and Establishment of Quorum

2. Public Comment for Items Not on the Agenda/Items for Future Meetings

The committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to place the matter on a future meeting agenda. [(Government Code sections 11125 & 11125.7(a))]

3. Discussion and Consideration of Proposed Language for a Policy Statement by the Board Regarding Proper Handling and Disposal of Oral Chemotherapy Drugs

Background

Pharmacy students and faculty from Chapman University have appeared before this committee previously to discuss proper handling and disposal of oral chemotherapy (OC) medications. The group has advocated requiring a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

Following the last presentation, in October 2018, the committee suggested the group focus on increasing awareness rather than seeking a mandated requirement for labels. Members also directed staff to develop a possible board policy statement regarding proper handling and disposal of OC drugs.

At this meeting

Staff has drafted a proposed policy statement regarding a hazardous drug symbol on prescription labels for oral chemotherapy medications. Staff requests the committee discuss and consider the draft language and provide direction. The proposed policy statement is in **Attachment 1**.

4. Staff Report on “Ask an Inspector” Program

Background

At the October 2018 committee meeting, members reviewed communication and public education goals identified in the board’s [Strategic Plan 2017-2021](#).

Under goal 4.2 (“Identify and use additional resources for public and licensee outreach services to implement the communication plan”), the committee requested a report on the “Ask an Inspector” program. Specifically, members asked about the number of calls received and the top 10 types of calls. The committee also directed staff to report annually on the program, starting in January 2019.

Staff report

Inspectors record and track details about inquiries – including calls, emails and faxes – to “Ask an Inspector” in a database. According to the database, inspectors responded to a total of 3,257 inquiries between Jan. 1 and Dec. 10, 2018.

Inquiries were classified by 77 types. The top 10 types are listed in the table below.

Type of inquiry	Count	Percentage of total
Controlled substances	730	22
Pharmacy practice	398	12
Other	367	11
Compounding	216	7
Pharmacy	154	5
Licensing	127	4
Prescription requirements	110	3
Prescription form	104	3
Wholesaler	61	2
Sterile compounding	53	2

Attachment 2 contains a list of all 77 categories and the number of inquiries received for each type of inquiry; and a draft copy of recent samples of questions and answers.

Based on this information, staff recommends compiling frequently asked questions (FAQs) and answers for publication in The Script. In addition, staff could create a library of FAQs on the board’s website for easy reference by licensees.

5. Staff Report on Surveys Performed after Pharmacy Inspections

Background

Under strategic goal 4.5 (“Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings”), the committee directed staff to report back on follow-up surveys of licensees that supervising inspectors perform after inspections. The committee also directed staff to report annually on the inspections, beginning in January 2019.

Staff report

In 2018, supervising inspectors surveyed 67 licensees post-inspection. The respondents were:

- Pharmacies (PHY) - 41
- Hospital pharmacies (HSP) - 2
- Sterile compounders (LSC) - 20

- Nonresident sterile compounders - 3
- Wholesalers - 1

The surveys ask pharmacies to rate the inspectors in five areas. Responses are summarized below.

The board inspector was ...	Agree or Strongly Agree	Disagree or Strongly Disagree	N/A*	Total
Courteous and professional	65 (97%)	2 (3%)	0	67 (100%)
Knowledgeable and demonstrated expertise	64 (95.5%)	2 (3%)	1 (1.5%)	67 (100%)
Educational and helpful	65 (97%)	1 (1.5%)	1 (1.5%)	67 (100%)
Organized and well prepared	66 (98.5%)	1 (1.5%)	0	67 (100%)
Reasonable and fair	62 (92.6%)	4 (6%)	1 (1.5%)	67 (100%)

*N/A reflects a neutral response or no response.

The surveys also seek comments from pharmacies on the inspection process, what went well, and what needs improvement. The comments are grouped by category. A copy of the comment groups and the survey form are in **Attachment 3**.

The board’s enforcement chiefs, Julia Ansel and Tom Lenox, have been invited to this meeting to discuss and answer questions about the survey process.

6. Discussion and Consideration of Current and Potential Public Educational Materials and Activities in Preparation for 2020 Sunset Review Report

Background

The Board of Pharmacy’s [Sunset Review Report 2016](#) described the internet as the primary means for educating the public and licensees about board activities and ways to participate in board activities. The report noted the board’s website received more than 2.8 million hits and was redesigned to improve ease of use. In addition, the report discussed specific resources and type of information available online.

A copy of the Public Information Policies from the sunset report is in **Attachment 4**.

At this meeting

In preparation for the next sunset review in 2020, staff is considering additional items the board may want to include in the report. For the committee’s discussion and consideration, staff has identified current and potential communication and public education activities and materials below.

Current activities/materials

- Webinars on law and ethics, naloxone training.

- CE training forums on drug abuse/drug diversion.
- Online search tool for drug take-back locations.
- CE for reading newsletter articles.
- Twitter social media account.
- Prescription drug abuse billboard.
- Holding board meetings outside Sacramento.
- Expanded email registration lists (including pharmacy technicians, intern pharmacists and designated representatives).
- Website calendar of board meetings and activities

Possible activities/materials

- Revised/updated brochures– Notice to Consumers, point to your language, etc.
- New brochures or videos – How to dispose of unwanted medications, how to prepare for a declared disaster, etc.
- Additional social media accounts – Facebook, Instagram, YouTube, etc.
- Additional CE webinars.
- A PowerPoint overview of the board for public outreach events.
- Staff presence with consumer brochures and other materials at community health fairs, senior events, other public gatherings.

Staff requests the committee discuss and consider the listed items and offer any comments, ideas or direction on any additional public information activities or materials for staff to develop.

7. Discussion and Consideration of Steps to Improve Emergency Response During Declared Disasters

Background

During declared disasters, the board immediately issues a subscriber alert advising licensees of provisions in the Business and Professions Code (BPC) intended to help pharmacists provide care for displaced patients:

- [BPC section 4062](#) authorizes pharmacies to furnish dangerous drugs in reasonable quantities without a prescription during a federal, state or local emergency. This section allows the board to waive any provision of pharmacy law the board believes is necessary to help care for patients or protect public health. Section 4062 also allows the use of a mobile pharmacy under specified conditions.
- [BPC section 4064](#) authorizes pharmacists to use their professional judgment in refilling a prescription for a dangerous drug or device without a prescriber’s authorization if failing to refill the prescription might interrupt ongoing care or have a significant adverse impact on the patient’s well-being.

In addition to subscriber alerts, the board’s duty inspector is available to answer questions and provide guidance to pharmacists caring for displaced patients.

Recent Experience

On Nov. 8, 2018, Acting Governor Gavin Newsom declared a state of emergency in Butte, Los

Angeles and Ventura counties due to wildfires. In Butte County, the Camp fire forced five pharmacies to close because they were destroyed or sustained significant damage. Six additional pharmacies closed temporarily because of poor air quality.

The board issued a subscriber alert Nov. 9 reminding licensees about BPC sections 4062 and 4064. On Nov. 20, in response to questions from pharmacists, the board issued an alert explaining that under BPC section 4062(b), the board waived requirements that may be impossible to meet in an emergency, including security prescription forms for controlled substances.

The Nov. 20 alert also directed pharmacists to the board's official Disaster Response Policy Statement regarding emergency care for patients in declared disasters. The statement was adopted by the board in October 2006 and published in the [2007 issue of The Script](#).

Board staff also collaborated with other state agencies, including the California Department of Public Health and the Office of Emergency Services. In addition, the board disseminated information via subscriber alerts Nov. 21 and Dec. 3 regarding the Emergency Prescription Assistance Program (EPAP). The program helps uninsured patients in disaster areas obtain prescription medications, medical equipment and supplies, and vaccinations at no cost.

At this meeting

At the December 19 Licensing Committee Meeting staff from the California Department of Public Health presented information regarding the provision of pharmacy services during a declared emergency. The Licensing Committee found the presentation to be very informative and asked that it also be provided at the Communication and Public Education Committee meeting as the committee would be well positioned to improve the board's communications during a declared state of emergency and to develop educational materials regarding pharmaceutical care during a state of emergency. Specifically, the Licensing Committee felt that the Communication and Public Education Committee may wish to consider the following during its meeting:

- The development of fact sheets for licensees and patients to refer to during a disaster.
- The development of a C.E. program on disaster preparedness.
- The development of a contact list of major chain pharmacies for board staff to use to disseminate information quickly during a disaster.

Attachment 5 includes the text of BPC sections 4062 and 4064; copies of four subscriber alerts issued during the recent declared disaster; an excerpt from the Licensing Committee minutes; and a copy of the board's Disaster Response Policy Statement published in [The Script](#).

8. Update on Communication and Public Education Activities by Board Staff

a. The Script

The current issue of the newsletter was published and posted online in December. The next issue will focus on new pharmacy laws. Publication is planned for January 2019.

b. Projects Update

As of Dec. 20, 2018, staff was waiting for Outfront Media to sign and return a no-cost contract for five billboards about prescription drug abuse. Staff will provide any additional information at the committee meeting.

A Twitter account has been established for the Board of Pharmacy. Staff will begin posting messages and will add a link to the Twitter account on the board's website in January.

c. News Media

The board's executive officer and public information officer participated in interviews or provided background information in response to media inquiries listed in **Attachment 6**.

d. Public Outreach

Board inspectors and staff provided training at the board's Dec. 8 CE forum on prescription drug abuse and drug diversion at Santa Barbara Community College in San Diego. A total of 94 pharmacists attended and received CE at the event. The board has tentatively scheduled the next forum for February 23 in Fresno and is working on scheduling another in San Diego in April.

Public outreach activities by board inspectors and staff are listed in **Attachment 7**.

9. Review and Discussion of News or Journal Articles

News articles on pharmacy issues that may be of interest to the committee have been provided in **Attachment 8**.

10. Future Meeting Dates

- Wednesday, April 10, 2019
- Tuesday, June 25, 2019
- Wednesday, Oct. 9, 2019

Minutes from the Oct. 11, 2018, Communication and Public Education Committee meeting are in **Attachment 9**.

Attachment 1

California State Board of Pharmacy
Proposed Policy Statement
Regarding Warning Labels on Prescription Labels for Oral Chemotherapy Medications

The California State Board of Pharmacy recognizes that oral chemotherapy (OC) treatment is increasingly popular among cancer patients and health care providers. However, these medications pose serious risks to humans and the environment if improperly handled or disposed of. Many patients, caregivers and even health care providers may not recognize these drugs or be aware of their hazardous nature.

The board supports voluntary efforts by pharmacies and clinics to improve awareness and education about OC medications. In addition, the board encourages pharmacists to provide specific counseling to patients and their caregivers on proper handling and disposal of OC medications.

To help patients, caregivers and health care providers recognize these medications as hazardous, the board encourages pharmacies to affix a standardized “hazardous drug” symbol to prescription labels when appropriate. The addition of the symbol would serve as an important reminder to patients and caregivers about the proper handling and disposal of the drugs.

The following represents an appropriate warning symbol:



Attachment 2

“Ask an Inspector” Inquiry Counts by Type – January 1 through December 10, 2018

Type of question	Count
Controlled Substances	730
PHARMACY PRACTICE	398
OTHER	367
Compounding	216
PHARMACY	154
LICENSING	127
PRESCRIPTION REQUIREMENTS	110
PRESCRIPTION FORM	104
WHOLESALER	61
STERILE COMPOUNDING	53
IMMUNIZATIONS	52
LABELING	47
CLINIC	46
Technician Duties	45
REGULATORY COMPLIANCE	36
PHARMCY PRACTICE	36
PERMITTED ACTIVITIES BY RPH	35
SECURITY PADS	34
COMPLAINT	33
CORRESPONDING RESPONSIBILITY	32
RECORD KEEPING	31
AUTOMATIC DISPENSING DEVICES	28
DELIVERY	26
Out of State CS	25
PHARMACY RECORDS	24
PHYSICIAN DISPENSING	22
EPRESCRIBING	22
VETERINARY	19
PHARMACY CONSTRUCTION	16
NON RESIDENT PHARMACY	15
DRUG PURCHASES	14
SELF-ASSESSMENT	13
DRUG TAKE BACK PROGRAM	13
SAMPLES	12
DRUG STOCK	12
BILLING	12

Type of question	Count
REFILL LIMITS	12
PDMP/CURES	12
OVER THE COUNTER	12
SYRINGES	11
HOSPICE PRESCRIPTIONS	11
INSURANCE	11
PSEUDOEPHEDRINE SALES	10
TELEHEALTH	9
MEDICATION	9
EXPIRATION DATING	8
RPH DUTIES / RESPONSIBILITIES	8
CONSULTANT PHARMACIST	8
ELECTRONIC RECORDS	8
PHARMACY INSPECTION	8
INTERN	7
MANUFACTURING	6
VACCINATIONS	6
MEDICAL DEVICE	6
REPORTING	6
OWNERSHIP	6
HIPAA	6
REMOTE VERIFICATION	6
CENTRAL FILL	5
SHIPPING	5
PHYSICIAN ASSISTANT	5
LONG TERM CARE FACILITY	5
PRESCRIBER'S AGENT	4
MAIL ORDER PHARMACY	4
DESIGNATED REPRESENTATIVE	3
WASTE DISPOSAL	3
OUTSOURCING FACILITY	3
BLISTER PACKING	2
DENTAL PRESCRIBING	2
ADVERTISING	2
CURES	2
CHANGE OF LOCATION	1
DEXTROMETHORPHAN	1
AUTO REFILL PROGRAM	1
DRUG ALLERGIES	1

Type of question	Count
EPEDIGREE	1
DONATED DRUGS	1
Grand Total	3257

DRAFT Sample “Ask an Inspector” Question and Answers

1. Controlled substance

Question: Do we have to treat the mandatory CURES check annotated on the prescription as a required element of the prescription? Will board inspectors give citations if this is missing on the prescription?

Answer: On October 2, 2018, pursuant Health and Safety Code section 11165.4, a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance must consult the CURES database to review a patient’s controlled substance history before prescribing a Schedule II, III or IV controlled substance to the patient for the first time and at least once every four months thereafter if the controlled substance remains part of the treatment of the patient. Pharmacist who are prescribing a Schedule II, III, or IV controlled substance, pursuant to Business and Professions Code sections 4052(a)(5), 4052.1, 4052.2 or 4052.6 and are registered with the DEA, are required to consult the CURES database to review the patient’s drug history. Although HSC 11165.4 does not specify the prescriber make an annotation of their review of the CURES database, best practices suggest a pharmacist prescribing a controlled substance document their review and remind pharmacist of their corresponding responsibility pursuant to Health and Safety Code section 11153.

2. Controlled substance

Question: Can you please confirm whether or not pharmacies in California can fill out of state electronic CII prescriptions (where the signature is digitally verified)?

Answer: In the July 2007, the board printed in the SCRIPT Newsletter an article titled “*When can a pharmacy fill a prescription written by an out-of-state prescriber*” which referenced Health and Safety Code section 11164.1. In addition, Schedule II controlled substance prescriptions that are electronically transmitted (e-Scripts) must meet the federal requirements as listed in Title 21 Code of Federal Regulations Part 1311 Subpart C. As a reminder, pharmacies transferring, selling, or delivering dangerous drugs or dangerous devices to a person outside of California, must do so in compliance with the laws of California and of the United States and of the state or country to which the dangerous drug or dangerous device is to be transferred, sold or delivered. This includes obtaining any required licensure prior to transferring, selling and delivering any dangerous drug or dangerous device into the other country or state.

3. Controlled substance

Question: My name is _____ from _____ Pharmacy. I would like clarification on whether partial filling of a C3-5 would be considered a complete "fill"; so that we can follow the maximum of 5 refills rule. Do we count each partial refill as a fill or would it be 2 partial fill of #15 would constitute a full fill?

Let's say a prescription is written for #30 with 4 refills:

Original Fill - Quantity #30 / 30 Day Supply

1st Refill - Quantity #15 / 15 Day Supply

2nd Refill - Quantity #15 / 15 Day Supply

3rd Refill - Quantity #15 / 15 Day Supply

4th Refill - Quantity #15 / 15 Day Supply

5th Refill - Quantity #30 / 30 Day Supply (If we count each partial fill as a complete fill, then the refills would stop here)

6th Refill - Quantity #30 / 30 Day Supply (But if we don't consider each partial fill as a complete fill, then we can continue filling until we reach the max of 120 days supply?)

Answer: See BPC 4063, HSC 11200, 21 CFR 1306.22 and 21 CFR 1306.23.

The original quantity of the controlled substance prescription is considered one fill. If the pharmacy dispenses smaller quantities than the original quantity on the prescription, those are not considered a refill for purposes of the regulation. Filling less than the original quantity is considered a partial fill. 21CFR 1306.22/1306.23

No dispensing of the controlled substance prescription including refills can occur after 6 months from the date the prescription was written. Additionally, Schedule 3 & 4 controlled substance shall not be refilled more than 5 times and the refills shall not exceed a 120-day supply. HSC 11200.

4. Controlled substance

Question: I was wondering if there were day supply limits on dispensing of schedule II prescriptions?

Answer: No regulation that specify. Please consider CCR 1761, HSC 11153 and CFR 1306.4 for corresponding responsibility. Thank you.

5. Pharmacy practice

Question: Can I dispense/sell 10 tablets of Halcion to a dentist for office use?

Answer: A pharmacy may provide a dentist a controlled substance, such as Halcion, under sales and purchase records (an invoice) provided the following information is listed, the date, the names and addresses of the supplier (pharmacy) and buyer (dentist), the drug or device, and its quantity, pursuant to Business and Professions Code section 4059(b). In addition, federal law states a prescription may not be issued in order for an individual practitioner (dentist) to obtain controlled substances for supplying the individual practitioners for the purpose of general dispensing to patients, 21 CFR 1306.04(b).

6. Pharmacy practice

Question: Caller had two questions:

1. Clarification regarding SB 1442 and how it will change his business.

2. RPH received a prescription for high dose opioid and MD refused to provide adequate justification. He denied filling the prescription and wanted to discuss laws supporting his decision.

Answers:

1. Unfortunately, at this time, the board has no additional information other than what is written in the bill as stated below. BOP will provide more info when it's written in pharmacy law. Section 4113.5 is added to the Business and Professions Code, to read:

(a) A community pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located, is made available to assist the pharmacist at all times.

2. Discussed pharmacist's right to exercise corresponding responsibility. Recommended pharmacist to keep documentation of his refusal to fill prescriptions.

7. Pharmacy practice

Question: Caller had three questions.

1. Clarify if pharmacist on lunch but in the building, if technicians can fill during temporary absence of pharmacist.
2. Questions on transfers of non-controlled medications which have never been filled before
3. Discuss ratios of pharmacist to intern and pharmacist to technicians.

Answers:

1. A pharmacy staffed with a single pharmacist may leave the pharmacy temporarily for breaks and meal period, limited to 30 minutes, without closing the pharmacy and removing ancillary staff from the pharmacy if the pharmacist reasonably believes that the security of the dangerous drugs and devices will be maintained in his or her absence. During the temporary absence of the pharmacist, the ancillary staff may continue to perform non-discretionary duties (removing drug from stock, counting, pouring, or mixing pharmaceuticals, placing the production into a container, packaging and repackaging. (BPC 4115, BPC 4116, CCR 1714.1, CCR 1793.2)
2. Business and Professions Code section 4052(a)(2) allows a pharmacist to transmit a valid prescription to another pharmacist.
3. Ratio for Pharmacist to pharmacy technician, pharmacy technician trainee and intern pharmacist.

Pharmacy setting:	Ratio:	Reference:
Community pharmacy with one pharmacist	1 Pharmacist to 1 Pharmacy technician	BPC 4115(f)(1)

Pharmacy setting:	Ratio:	Reference:
Community pharmacy with more than one pharmacist	First Pharmacist to 1 Pharmacy technician Second Pharmacist to 2 Pharmacy technicians	BPC 4115(f)(1)
Inpatient licensed health facility	1 Pharmacist to 2 Pharmacy technicians	CCR 1793.7(f)
Licensed home health agency	1 Pharmacist to 2 Pharmacy technicians	CCR 1793.7(f)
Correctional facility of the Department of Youth Authority	At a minimum: First Pharmacist to 1 Pharmacy technician Second Pharmacist to 2 Pharmacy technicians	BPC 4115(f)(2) CCR 1793.7(f)
Department of Corrections	At a minimum: First Pharmacist to 1 Pharmacy technician Second Pharmacist to 2 Pharmacy technicians	BPC 4115(f)(2) CCR 1793.7(f)
State Department of Mental health	At a minimum: First Pharmacist to 1 Pharmacy technician Second Pharmacist to 2 Pharmacy technicians	BPC 4115(f)(2) CCR 1793.7(f)
State Department of Developmental Services	At a minimum: First Pharmacist to 1 Pharmacy technician Second Pharmacist to 2 Pharmacy technicians	BPC 4115(f)(2) CCR 1793.7(f)
Department of Veteran Affairs	At a minimum: First Pharmacist to 1 Pharmacy technician Second Pharmacist to 2 Pharmacy technicians	BPC 4115(f)(2) CCR 1793.7(f)
All settings	1 pharmacist to 1 pharmacy technician trainee (completing externship)	BPC 4115.5(b)(4)
All settings	1 pharmacist to 2 intern pharmacists	BPC 4114(b)

8. Other

Question: I am writing to ask about requirements for disposing narcotic medication in the state of CA. We currently have medications that are patient specific, patients are gone and need to dispose. I have asked our corporate pharmacy and they indicated that I need to pop each pill into the appropriate container with a witness and update our redbook. The

pharmacist suggested I contacted CA pharmacy board to inquire whether an inspector needed to be present.

Answer: In the October 2017 The Script Newsletter, the board of pharmacy published an article titled, “New Drug Take-Back Rules Include Key Requirements” regarding the new drug take back regulations that took effect June 6, 2017. In addition to the article, the board recommends the following:

- **Community setting:** Pharmacies interested in assisting the public in disposing unused and unwanted drugs may register with the Board of Pharmacy and install a collection receptacle where the consumer directly deposits their drugs into the receptacle. Pharmacies may also provide mail-back envelopes or packages that are pre-addressed to a location registered with DEA as a collector. Pharmacies cannot accept any mail back packages or envelopes unless the pharmacy is registered as a collector with DEA and have an onsite method of destruction that complies with the DEA requirements.
- **Skilled Nursing Facilities (SNF):** To dispose unused and unwanted drugs from patients residing or no longer residing at a SNF, 1) the SNF may dispose unwanted and unused drugs using mail back envelopes or packages, 2) deposit the drugs into a drug take back receptacle if one was installed by their contracted pharmacy, 3) donate the drugs to a County Repository and Distribution Program, or 4) destroyed at the SNF pursuant to 22 CCR §72371. Drugs listed under Schedule II, III or IV must be destroyed by the SNF in the presence of a pharmacist and registered nurse. Drugs not listed under Schedule II, III or IV must be destroyed at the SNF in the presence of a pharmacist or licensed nurse.
- **Board and Care (B/C) and Assisted Living Facilities (ALF):** Unwanted and unused drugs from a B/C or ALF may be disposed using mail back packages or envelopes or directly depositing the drugs in a registered drug take back receptacle located at a pharmacy. Pharmacies can no longer pick up unused or unwanted drugs back from a B/C or ALF, unless during the delivery of a new prescription, the drugs are refused at the time of the delivery. The B/C and ALF can also refer to the guidelines published by the FDA on their website at www.fda.gov regarding drug take-back options, drug take back events provided by the U.S. DEA, locations of permanent collection sites, and other methods of disposal.
- **Hospitals:** Discontinued patient’s drugs not supplied by the hospital but remains in the hospital after discharge are destroyed pursuant to 22 CCR §70263(q) (11) which requires the destruction of Schedule II, III, IV controlled substances in the presence of two pharmacists or a pharmacist and a registered nurse. Drugs not listed as a Schedule II, III or IV controlled substance must be destroyed in the presence of a pharmacist.

9. Other

Question: How many CE hours are required every two years for the smoking cessation CE requirement? The rule (1746.2. Protocol for Pharmacists Furnishing Nicotine Replacement Products) says ongoing CE focused on smoking cessation therapy from an approved provider once every two years is required but it does not give an hour requirement.

Answer: Pharmacists furnishing nicotine replacement products pursuant to Business and Professions Code section 4052.9 and California Code of Regulations section 1746.2 are required to complete one hour of CE focused on smoking cessation therapy biennially.

10. Other

Question: RPH _____ called today at 11:43 asking whether a doctor (urologist) can write a Rx out of their normal practice. Urologist wrote a Rx for compounded derma medication.

Answer: As discussed, you must use your professional judgement as to whether it is appropriate for a physician to be prescribing out of their scope of practice. The duty inspector cannot provide legal advice or approve business plans. You should review BPC 733, CCR 1761, BPC 4040, HSC 11150 regarding uncertain prescriptions, dispensing, and prescription requirements. If the prescription contains a controlled substance, then review that CCR 1761(b) and HSC 11153 requires that the prescription not be dispensed if you have a reason to know it was not issued for a legitimate medical purpose.

11. Compounding

Question: I am a RN who works in the Operating Room and our staff have questions regarding compounding medications. I contacted the BRN and was directed to contacting the pharmacy board for clarification. Below are a few scenarios that nurses are questioning if this is considered compounding:

Adding epinephrine to Lidocaine or Marcaine to become 1:100,000 units of per ml or 1:200,000 units per ml.

Mixing Exparel with Marcaine and Normal saline injection

Mixing vasopressin with IV saline for injection

Adding Ancef, and Gentamycin in saline solution of the field for irrigation or soaking of implants

Mixing a 50/50 solution of Marcaine and Lidocaine for injection

Answer: Note the Board of Pharmacy does not regulate nurses or physicians. The Board defines compounding in CCR 1735

12. Compounding

Question: I had a question regarding disinfectant products that I was hoping that you would be able to help clarify. When cleaning the PEC, we use Peridox and Opticide RTU (ready-to-use) products. However, we were wondering if it was acceptable to use tap water when diluting disinfectant when cleaning floors, shelving, walls, and ceilings in the buffer room and anteroom or does it also need to be with sterile water?

Answer: Refer to California Code of Regulations section 1751.4(d) which states cleaning shall be done using a germicidal detergent **and sterile water**. This would include all ISO Class 5 surfaces, work table surfaces, carts, counters and cleanroom floors that are cleaned

at least daily and walls, ceilings, storage shelving, tables, stools and all other items in the ISO Class 7 or ISO Class 8 environment cleaned at least monthly.

13. Pharmacy

Question: RPH wants to close on Black Friday because wasn't busy last year. Does he need to notify Board.

Answer: If the pharmacy is closed for one day, the pharmacy is not required to notify the board. However, for consumer protection, the board recommends pharmacies not open during their normal hours of operations to provide notification to the consumers when to pick up their medications to avoid missing any doses. As a reminder, Business and Professions Code section 4312(e) defines "closed" to mean not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120-day period.

14. Licensing

Question: I am inquiring about the license requirements for laboratories. For them to receive Rx products and/or devices, are they required by the state to hold a pharmacy license or will their CLINICAL LABORATORY IMPROVEMENT AMENDMENTS certificate be enough? This question has come up for SUN CLINICAL LABORATORIES but is needed in regards to all laboratories.

Answer: Please review the following regulations:

BPC 4031 defines "laboratory" in part to mean a research, teaching or testing laboratory not engaged in the dispensing or furnishing of drugs or devices but using dangerous drugs or dangerous devices for scientific or teaching purposes.

BPC 4059.5(d) which states: Notwithstanding any other law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device. I would recommend contacting CDPH regarding labs specifics.

15. Wholesaler

Question: We are a pharmaceutical wholesaler and we are looking for a new space to lease. Our current location has a locked area and we have been putting our prescription products there. The new location is more of a warehouse setting and we want to be compliant in making a "secured and lockable area" for our products. We only have Class II medical devices and do not store any drugs at our facility.

1. Your requirements say: "(a) A wholesaler shall store dangerous drugs in a secured and lockable area." We are under the assumption that Class II prescription medical devices are treated the same as "dangerous drugs". Is that correct?

2. The location we are looking at has a 22-foot ceiling in the warehouse. Would the fence need to go all the way to the ceiling? Is there a minimum height? Could razor wire or any other "securing" system work?
3. Are there any guidelines for the type of fence/wall/doors/gates that need to be used? We would appreciate any guidelines before we can lease and move into our next location.

Answers:

1. Yes, dangerous devices are treated the same as dangerous drugs
2. Although California law does not specify the height of the fence, to be a secured and lockable area, the fence can either be 1) floor to ceiling of the building or 2) a fenced area with a roof or ceiling added to the fenced area to be completely enclosed.
3. There are not separate guidelines from CCR 1780. You may also wish to review the wholesaler self-assessment and application located at: <https://www.pharmacy.ca.gov/applicants/wls.shtml> and https://www.pharmacy.ca.gov/forms/17m_26_draft.pdf. Please note the duty inspector cannot provide legal advice or approve business plans.

16. Labeling

Question: Can you please answer a question for me? I see in the law Business and Professions Code section 4076[a][9] that the expiration date on the label in a retail pharmacy states:

(9) The expiration date of the effectiveness of the drug dispensed.

However, it has also been said that this is for stock bottles that are not opened. I have read that for stock bottles that are opened, and the contents are transferred to a regular prescription vial that the expiration is "not later than (a) the expiration date on the manufacturer's container or (b) one year from the date the drug is dispensed, whichever is earlier."

Answer: The pharmacist is to use their professional judgement in regard to labeling the expiration date on the prescription vial regarding the effectiveness of the drug dispensed. The important thing is to ensure the patient receives an effective drug. A slightly newer Script article addresses your question regarding the confusion from the 7/2001 article you provided below. See page 9: https://www.pharmacy.ca.gov/publications/02_jan_script.pdf

17. Technician duties

Question: I was seeing when it will become mandatory for technicians to become certified?

Answer: Currently, all pharmacy technicians are not required to be certified. However, to apply for a pharmacy technician license, in addition to, being a high school graduate or possessing a general educational development certificate equivalent, one of the qualifying requirements is being certified by a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board. Currently, the Pharmacy Technician Certification Board (PTCB) and the Exam for the Certification of Pharmacy Technicians (ExCPT) offered by the National Healthcareer

Association (NHA) are approved by the Board. Pharmacy technicians who are certified by PTCB or ExCPT only must apply for a pharmacy technician license in California to practice in California, pursuant to Business and Professions Code section 4202.

18. Regulatory compliance

Question: Hi Inspector. I would like to know where I can find the pharmacy regulations surrounding when to consult CURES prior to dispensing Scheduled drugs in the Pharmacy Law Book. I am not clear whether this regulation only applies to Schedule II drugs or all Schedules. Also, does it apply to patients who live in an Assisted Living facility? I know that it doesn't apply to SNF patients. I would also like to clarify the frequency of which I need to consult CURES prior to dispensing these narcotics.

Answer: Effective July 1, 2016, all California-licensed pharmacist and all California-licensed prescribers with DEA numbers must be registered to access CURES. Effective October 2, 2018, prior to prescribing, ordering, administering, or furnishing a Schedule II, III, and IV controlled substances, prescribers are mandated to consult CURES. This includes the following:

- The first time a patient is prescribed, ordered, administered, or furnished a controlled substance, unless one of the exemptions apply.
- Within the twenty-four-hour period, or the previous business day, before prescribing, ordering, administering, or furnishing a controlled substance, unless on the exemptions apply.
- Before subsequently prescribing a controlled substance, if previously exempt.
- At least once every four months if the controlled substances remain a part of the patient's treatment plan.

Pharmacists who are registered with DEA and are prescribing, ordering, administering, or furnishing a Schedule II, III, and IV controlled substances pursuant to Business and Professions Code sections 4052(a), 4052.1, 4052.2, 4052.6 are required to consult CURES as listed.

Pharmacist who are only dispensing Scheduled II, III, and IV controlled substances are encouraged to consult CURES when exercising their corresponding responsibility pursuant to Health and Safety Code section 11153 and in determining the validity of prescription that may be erroneous or uncertain, pursuant to California Code of Regulations section 1761.

For further guidance, refer to the following available on the Board's website:

<http://www.pharmacy.ca.gov/licensees/cures.shtml>

http://www.pharmacy.ca.gov/publications/corresponding_responsibility.pdf

http://www.pharmacy.ca.gov/licensees/med_bd_cures_flyer.pdf

http://www.pharmacy.ca.gov/pulications/faq_askinspector.pdf

Attachment 3



California State Board of Pharmacy

1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

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

Pharmacy Name: _____ License Number: _____

Date of Inspection: _____ Inspector: _____

Name and title of person providing this information:

_____ Phone _____

1. The board's inspector was courteous and professional:
Strongly Agree _____ Agree _____ Disagree _____ Strongly Disagree _____

Comment: _____

2. The board's inspector was knowledgeable and demonstrated expertise:
Strongly Agree _____ Agree _____ Disagree _____ Strongly Disagree _____

Comment: _____

3. The board's inspector was educational and helpful:
Strongly Agree _____ Agree _____ Disagree _____ Strongly Disagree _____

Comment: _____

4. The board's inspector was organized and well prepared:
Strongly Agree _____ Agree _____ Disagree _____ Strongly Disagree _____

Comment: _____

5. The board's inspector was reasonable and fair:
Strongly Agree _____ Agree _____ Disagree _____ Strongly Disagree _____

Comment: _____

6. What comments do you have on the board's inspection process? What went well? What needs improvement?

SI completing form: _____

date

Overall Positive Comments

Informative, educational, one of the best inspectors - they want her back!

Inspection went well/ new laws provided and new CE requirement/ very helpful

Explain the process

Inspector was great, proactive

Approachable/ Helpful/ less stressful/ respectful

Fair /Informative/ professional

Good at explaining laws and regs/ explained how to be successful for future inspections

Educational, helpful, always keeps us updated on the laws.

Clear explanation/ education on new laws

Inspector was "cool" - I had heard bad things about the board/ inspector was helpful and not frightening

Educational

x4

Most thorough inspection/ firm and fair/ nervous at first but eased fears after explaining everything

Nervous at first but inspector alleviated fears/ able to continue working without disrupting workflow

Very good/ no improvement needed

Provided good practice judgment

Helpful

x3

Love the board/ **insurance reimbursement poor for independent phys**

Inspectors was nice

Courteous & helpful

Everything was perfect/ Satisfied 110%

Impressed/ Inspector professional

Helpful, board should be more considerate of pharmacists who graduated long ago.

Good feedback from inspector

helpful, knowledgeable, relatable. Inspections can be stressful, inspector was able to make it more relaxed.

Time

Educational, fair, Compounding *renewals should be every 2 years for locations that are consistently compliant*

Improvement *could be more frequent inspections*

Appear to have had multiple inspections/contact with Board

One of the better inspectors/ very good

Improved drastically over the past few years. Inspectors more apt to help licensees get into compliance

Licensee has seen 4 different inspectors/ always learns something

Scheduling/Pharmacy Operations

Inspector was respectful of pharmacy operations

Did not hinder pharmacy ops/ learned a lot

Inspection was rushed but comments were all strongly agree or agree

Inspector came on Monday before Thanksgiving/ if possible avoid busy day

Would be better if it was scheduled

Inspection should be quicker/ Application process s/b quicker

Too much focus on process

Negative

PBMs & Ins Companies need more regulation/ 5 inspections in two years between 2 pharmacies/ overregulated/ unlike med board

Rude/ abusive/ educational/ reviewed invoices in a disorganized fashion/ if records are looked at, replace in the correct folder. (4/18comment)

Semi-Negative/area to address w/ Staff

Different inspectors have differing opinions/ some more lenient than others. Inspector was "very neutral" but trying very hard to find something wrong. WLS had 3 inspections with differing opinions on who is able to possess a key to the business. WLS is now following advice given from latest inspection.

Different inspectors have difference areas of focus

???????

It would be helpful to have a handout when the inspector comes in, showing what documents are needed.

Handout of new laws to keep us updated/ clear reason why they are at the pharmacy, be honest and truthful to calm us down.

No Animosity

Attachment 4

Section 6

Public Information Policies



BE AWARE AND TAKE CARE:
Talk to your pharmacist!
CALIFORNIA STATE BOARD OF PHARMACY

Public Access Via Internet

The internet is the primary means by which the board educates and informs the public and licensees in general about board activities, and methods to participate in board activities. Whereas letters, calls, emails, in-person discussions and public presentations do compose a proportion of staff workdays, we reach more individuals through our email blasts, and through the information placed online than via any other method.

Over the past four fiscal years, the board received over 2.8 million hits to its website. The board works hard to ensure its website is relevant to consumers, applicants, and licensees alike. The board is currently in the process of redesigning its website to improve ease of use for licensees and consumers alike.

Internet Hits			
FY 2011/12	FY 2012/13	FY 2013/14	FY 2014/15
586,147	629,277	799,697	787,839

The board posts meeting agendas online at least 10 days before a public meeting, and sends a subscriber alert advisory when the agenda is posted. Usually about five days before a meeting the board, the board posts meeting materials online.

The board has online meeting agendas and minutes from March 1999 to March 2003. Additionally, the board has meeting agendas, minutes, and meeting materials from April 2003 to present. The board has webcasts of board meetings posted online from July 2012 to present.

The board posts minutes from prior meetings online. Board meeting minutes are posted under the “minutes” column on the board’s website after they have been reviewed and approved by the board. Action to review and approve the prior meeting’s minutes is agenzized at board meetings. Draft copies of the board meeting minutes that will be acted upon during a board meeting are provided as drafts in the meeting materials. The approved minutes are posted following the meeting.

For committee meetings, meeting summaries are provided at the back of each committee report segment in a board packet. Following a board meeting, the committee summaries are posted on the board’s website in the column for committee meeting agendas, meeting materials and summaries to allow for easy reference. The committee meeting summaries are provided for reference. They are not specifically approved by the committee or board.

It can sometimes be difficult to locate new information on a website. The board has a listserv that alerts interested parties when new materials are added to the website. All licensed locations are mandated to subscribe to the board's listserv (Business and Professions Code section 4013), and the board encourages all licensees, individuals and health care facilities to subscribe. The board also uses the listserv as a quick and efficient way to disseminate important notices and alerts to subscribers. The purpose is to ensure that pharmacies and wholesalers and other interested parties receive notice immediately of recalls of prescription medication and devices where the recall directs the removal of the product from dispensers or from patients – essentially removing the product from the market. Recalls are not issued routinely by drug manufacturers and pharmacies; these are significant events we believe warrant this attention and emphasis. Over the four year reporting period the board has released 1,061 recall notices at the pharmacy or patient level. Additionally, the recall notices are posted to the board's website for future reference and access.

Webcasting

The board routinely webcasts its board meetings. The board relies upon the staff of the Department of Consumer Affairs to provide the webcast services, and is grateful for this support.

The board has provided webcasts of committee meetings when there is likely to be broad interest in the subjects discussed. For example, while the board was working on e-pedigree implementation, E-Pedigree Committee Meetings were webcast once webcast services were available. The most recent SB 493 Implementation Committee meeting was webcast, given that there was much interest in board and public discussion around this issue. Webcasting is done on an "as available" basis when DCA staff are available to provide such services.

At this time webcasted meetings are available online. This is still relatively new and as such the board does not have a formal retention policy for this specific function in its approved records retention policy.

Annual Meeting Schedule

The board creates its board meeting schedule and approves it during the April or July Board Meetings for the following calendar year. The board meeting schedule through 2016 is available online. Periodically the board needs to schedule additional meetings in

response to an emergent issue; these additional meetings are posted online as soon as the dates are established. (The board sends out a subscriber alert to ensure interested parties are provided with such changes to the board's schedule.)

Committee meetings typically occur once per quarter, between board meetings. Committee meeting dates are posted once the dates are established. The board also sends out a subscriber alert once a committee meeting date is set so interested parties can reserve the date if they are interested in attending.

Complaint Disclosure Policy

The board's complaint disclosure policy follows the *DCA's Recommended Minimum Standards for Consumer Complaint Disclosure*.

The board uses its website to post a number of important materials of public interest. The board posts accusations and disciplinary actions online. It also posts interim suspension orders, Penal Code section 23 orders, and suspension for incarceration orders. For sterile injectable compounding pharmacies, cease and desist orders are also posted. Such information is posted under a single tab section to identify licensees and facilities that have restricted or bars from practicing. These orders are also specifically linked to the online license verification function of the board, so that when someone accesses license verification for any licensee, any restrictions on the license are visible as well.

License History and Status Information

The availability of license status information ensures that consumers have ready access to information about their care providers, and allows employers, other government agencies and other licensees to quickly access license status information about any licensee. The board's "verify a license" feature is a valuable tool to reduce unlicensed activity and provides consumers with status information about their community pharmacy and pharmacist. License verification is routinely used by drug wholesalers to ensure that facilities that wholesalers ship to are licensed and in good standing. Years ago the board sponsored legislation to specify that verification of licensure from the board's website is proof of licensure.

Further, for pharmacists, pharmacy technicians and designated representatives, the board provides name, type of license, license number, status of license, expiration date and issue data of license, and address of record. The website provides the same information for pharmacist interns except there is no address of record listed for these licensees.

For licensed sites, the same information is provided, and where a responsible individual must be linked to the facility (e.g., pharmacist-in-charge for a pharmacy), there is a cross link to the individual's license.

Any formal discipline taken against the individual or facility will be listed, along with a link to the public documents.

To supplement the information available on the website, the board also responds to requests for information in writing. Such public information includes what is available on our website, but also includes some information that is not posted on the website.

The board does not provide additional personal information about licensees regarding their education, degree, etc.

Consumer Outreach

The board reaches consumers in various ways. We rely on our website as a primary means to communicate with the public, but also use in-person presentations and telephone services to assist with inquiries in our jurisdiction. The board also uses press releases and the department's social media to deliver information to consumers.

The board's website contains materials for consumers, in both written and video forms. In the last two years, in response to the opioid epidemic, the board also has developed a specific webpage for the public with links to informational materials and resources for those seeking information about prescription drug abuse.

A new consumer safeguard for those who use the internet to purchase drugs is the .pharmacy (called dot pharmacy) suffix, which is a top level domain that has been recently introduced so that the public can readily identify legitimate from illegal websites involving pharmacy and drug sales. The board is an early adopter of this concept and possesses the www.CAboard.pharmacy website name that currently links directly to the board's website at www.pharmacy.ca.gov. About half of the US boards of pharmacy have a similar link to their websites, and pharmacies and pharmaceutical companies are among others who possess .pharmacy websites. The board is partnering with the National Association of Boards of Pharmacy to educate the public about this new form of internet safety.

Pharmacy law is complex with components scattered in numerous federal and state codes. Thus, researching answers is sometimes difficult. To assist the public, licensees and others in finding answers to their questions, the board now redirects one pharmacist inspector to assist these individuals. On Tuesdays and Thursdays, one board inspector is

available to respond to telephone inquiries, and the inspector responds to written, emailed and faxed questions on the other days. The inspector does not provide legal advice or research, but does provide referral to specific laws or provides problem resolution where possible. All inspectors perform this function for one week. The board also has office staff available to provide general guidance and direction to individuals who call the board. Since August 2015 the board has assisted 356 callers.

Upon request, the board's inspectors or staff will provide information to the public on prescription drug abuse, information about the board including filing a complaint, preventing medication errors or buying drugs online. This is information that will aid patients in becoming more knowledgeable about the importance of appropriate drug therapy and adherence.

Attachment)

Business and Professions Code - BPC § 4062

- (a) Notwithstanding [Section 4059](#) or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding [Section 4060](#) or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.
- (b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.
- (c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:
 - (1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.
 - (2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).
 - (3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.
 - (4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.
 - (5) The mobile pharmacy is located within the declared emergency area or affected areas.
 - (6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

Business and Professions Code - BPC § 4062

- (a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.
- (b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.
- (c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.
- (d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.
- (e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.
- (f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> **On Behalf Of** Pharmacy_Subscriberlist@DCA
Sent: Monday, December 3, 2018 11:35 AM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Information to Assist Pharmacy Patients in Declared Disaster Areas

The National Council for Prescription Drug Programs (NCPDP) and the NCPDP Foundation have issued information for pharmacy patients affected by declared disasters in Butte, Los Angeles and Ventura counties.

NCPDP Emergency Preparedness Update: HHS Activates Aid for Uninsured Californians in Need of Medications Lost in Wildfires

[EPAP has been activated](#). Uninsured citizens in California's Butte, Los Angeles and Ventura counties are eligible for no-cost replacements of critical medications lost or damaged by the current wildfires in those counties.

Additional information and resources are below:

- EPAP Hotline for patients (to register or learn eligibility): (855) 793-7470
- EPAP allows uninsured patients to receive a 30-day supply of select prescriptions and DME at *no cost*
- A [list of items covered by EPAP](#)

Emergency Preparedness Refill Too Soon Edit Override

NCPDP members approved the most effective method for overriding refill too soon type reject during a disaster: using the Submission Clarification Code 13 - Payer-Recognized Emergency/Disaster Assistance Request. The pharmacist is indicating that an override is needed based on an emergency/disaster situation recognized by the payer. Download more information on our Emergency Preparedness Task Group in the [NCPDP Collaborative Workspace](#), under MC: Maintenance and Control.

Rx Open

Healthcare Ready's [Rx Open](#), an interactive map that helps patients and providers find nearby open pharmacies in areas impacted by disaster, was activated for Louisiana, Arkansas and Texas. The map will be updated daily throughout the federally declared disaster. If pharmacies find their status is not consistent with what is shown on Rx Open, please notify Healthcare Ready at ContactUs@HealthcareReady.org.

From: Board of Pharmacy Pharmacists <PHARM-RPH@DCALISTS.CA.GOV> **On Behalf Of** Pharmacy_Subscriberlist@DCA
Sent: Wednesday, November 21, 2018 5:17 PM
To: PHARM-RPH@DCALISTS.CA.GOV
Subject: Emergency Prescription Assistance for Patients in Declared Disaster Areas

Pharmacies in Butte, Los Angeles and Ventura counties are urged to advise patients about the Emergency Prescription Assistance Program (EPAP), which helps people in declared disaster

areas who don't have health insurance obtain access to prescription medicine, medical equipment, medical supplies, and vaccinations.

At 1:00p.m. PST, November 21, 2018, the Emergency Prescription Assistance Program (EPAP) was activated for specific areas affected by the fires in Northern California (Camp Fire) and Southern California (Woolsey and Hill fires).

The prescription medications covered by EPAP can be found at www.phe.gov/Preparedness/planning/epap/Pages/epap-covered-items.aspx.

A searchable list of EPAP pharmacies can be found at www.phe.gov/Preparedness/planning/national-plus/Pages/NationalPlus.aspx.

To determine if you qualify for EPAP, residents in fire-impacted zip codes should call the EPAP Help Line at **1-855-793-7470**; EPAP hours of operation are 24/7, including holidays.

For more information about EPAP, visit www.PHE.gov/EPAP.

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> **On Behalf Of** Pharmacy_Subscriberlist@DCA
Sent: Tuesday, November 20, 2018 4:34 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Subject: Filling Prescriptions during a Declared Disaster

Under a declared state of emergency because of ongoing fires in Butte, Los Angeles and Ventura counties, the Board of Pharmacy reminds pharmacies of state laws intended to help pharmacists provide prescription drugs – including controlled substances – for residents displaced because of emergency evacuation.

Pursuant to California Business and Professions Code (BPC) [section 4062\(b\)](#), the Board of Pharmacy permits pharmacies to provide care by waiving requirements that may be impossible to meet during an emergency – including requirements for prescription forms, record-keeping, labeling, and other standard pharmacy practices and duties. Pharmacists should document “**dispensed pursuant to BPC 4062(b)**” on the prescription form in case of audit by the board or an insurance company.

In addition, BPC [section 4064](#) authorizes pharmacists to use professional judgment to refill a prescription for a dangerous drug or device without a prescriber’s authorization if failure to refill the prescription might interrupt ongoing care or have a significant adverse impact on the patient’s well-being.

The board’s formal policy for filling prescriptions during an emergency is spelled out in paragraph 5 of the newsletter article “Disaster Response Policy Statement” on Page 5 in the [January 2007 issue of The Script](#).

Below is the text of an alert issued to pharmacies by the board Nov. 9, 2018, including the full text of BPC sections 4062 and 4064:

Under the state of emergency declared by Acting Governor Gavin Newsom on November 8, 2018, in Butte County, Los Angeles County, and Ventura County, the California State Board of Pharmacy reminds pharmacists of state laws that can help in caring for patients displaced by emergency relocations. Below are requirements for furnishing prescription drugs, providing emergency refills without prescriber authorization, and operating a mobile pharmacy in a declared emergency area from California Business and Professions Code (BPC) sections 4062 and 4064.

Section 4062. Furnishing Dangerous Drugs during Emergency; Mobile Pharmacy

(a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy shares common ownership with at least one currently licensed pharmacy in good standing.

(2) The mobile pharmacy retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist is on the premises and the mobile pharmacy is under the control and management of a pharmacist while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy.

(5) The mobile pharmacy is located within the declared emergency area or affected areas.

(6) The mobile pharmacy ceases the provision of services within 48 hours following the termination of the declared emergency.

Section 4064. Emergency Refill of Prescription without Prescriber Authorization

(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this

section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

For additional information, contact the Board of Pharmacy at (916) 574-7900 or visit the board's website at www.pharmacy.ca.gov.

From: General Board of Pharmacy Subscriber List <PHARM-GENERAL@DCALISTS.CA.GOV> **On Behalf Of** Pharmacy_Subscriberlist@DCA

Sent: Friday, November 9, 2018 12:42 PM

To: PHARM-GENERAL@DCALISTS.CA.GOV

Subject: State of Emergency Declared in Butte County, Los Angeles County, and Ventura County

Under the state of emergency declared by Acting Governor Gavin Newsom on November 8, 2018, in Butte County, Los Angeles County, and Ventura County, the California State Board of Pharmacy reminds pharmacists of state laws that can help in caring for patients displaced by emergency relocations.

Below are requirements for furnishing prescription drugs, providing emergency refills without prescriber authorization, and operating a mobile pharmacy in a declared emergency area from California Business and Professions Code (BPC) sections 4062 and 4064.

[Section 4062](#). Furnishing Dangerous Drugs during Emergency; Mobile Pharmacy

(a) Notwithstanding Section 4059 or any other provision of law, a pharmacist may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other provision of law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

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- (c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.
- (d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.
- (e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.
- (f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

For additional information, contact the Board of Pharmacy at (916) 574-7900 or visit the board's website at www.pharmacy.ca.gov.

Disaster Response Policy Statement

Advance planning and preparation for disaster and emergency response are important activities for individuals, as well as all Board licensees. The Board has begun working on such preparedness with the federal and state government, and to this end, in October 2006, the Board adopted the following policy statement.

The California State Board of Pharmacy wishes to ensure complete preparation for, and effective response to, any local, state, or national disaster, state of emergency, or other circumstance requiring expedited health system and/or public response. The skills, training, and capacities of board licensees, including wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians, will be an invaluable resource to those affected and responding. The Board also wishes to encourage an adequate response to any such circumstance affecting residents of California, by welcoming wholesalers, pharmacies, pharmacists, intern pharmacists, and pharmacy technicians licensed in good standing in other states to assist with health system and/or public response to residents of California.

The Board encourages its licensees to volunteer and become involved in local, state, and national emergency and disaster preparedness efforts. City or county health departments, fire departments, or other first responders can provide information on local opportunities. The Emergency Preparedness Office of the California Department of Health Services is a lead agency overseeing emergency preparedness and response in California, particularly regarding health system response, drug distribution and dispensing, and/or immunization and prophylaxis in the event of an emergency. At the federal level, lead contact agencies include the Department of Health and Human Services, the Centers for Disease Control, and/or the Department of Homeland Security and its Federal Emergency Management Agency (FEMA). Potential volunteers are encouraged to register and get information at www.medicalvolunteer.ca.gov (California) and www.medicalreservecorps.gov (federal).

The Board also continues to be actively involved in such planning efforts, at every level. The Board further encourages its licensees to assist in any way they can in any emergency circumstance or disaster. Under such conditions, the priority must be protection of public health and provision of essential patient care by the most expeditious and efficient means. Where declared emergency conditions exist, the Board recognizes that it may be difficult or impossible for licensees in affected areas to fully comply with regulatory requirements governing pharmacy practice or the distribution or dispensing of lifesaving medications.

In the event of a declared disaster or emergency, the Board expects to utilize its authority under the California Business and Professions Code, including section 4062, subdivision (b) thereof, to encourage and permit emergency provision of care to affected patients and areas, including by waiver of requirements that it may be implausible to meet under these circumstances, such as prescription requirements, record-keeping requirements, labeling requirements, employee ratio requirements, consultation requirements, or other standard pharmacy practices and duties that may interfere with the most efficient response to those affected. The Board encourages its licensees to assist, and follow directions from, local, state, and national health officials. The Board expects licensees to apply their judgment and training to providing medication to patients in the best interests of the patients, with circumstances on the ground dictating the extent to which regulatory requirements can be met in affected areas. The Board further expects that during such emergency, the highest standard of care possible will be provided, and that once the emergency has dissipated, its licensees will return to practices conforming to state and federal requirements.

Furthermore, during a declared disaster or emergency affecting residents of California, the Board hopes that persons outside of California will assist the residents of California. To facilitate such assistance, in the event of a declared California disaster or emergency, the Board expects to use its powers under the California Business and Professions Code, including section 900 and section 4062, subdivision (b) thereof, to allow any pharmacists, intern pharmacists, or pharmacy technicians, who are not licensed in California but who are licensed in good standing in another state, including those presently serving military or civilian duty, to provide emergency pharmacy services in California. The Board also expects to allow nonresident pharmacies or wholesalers that are not licensed in California but that are licensed in good standing in another state to ship medications to pharmacies, health professionals or other wholesalers in California.

Finally, the Board also expects to allow use of temporary facilities to facilitate drug distribution during a declared disaster or state of emergency. The Board expects that its licensees will similarly respond outside of the state to disasters or emergencies affecting populations outside California, and will pursue whatever steps may be necessary to encourage that sort of licensee response.

¹Expanded powers in the event of a disaster are also granted to the Governor and/or other chief executives or governing bodies within California by the California Emergency Services Act [Cal. Gov. Code, §§ 8550-8668] and the California Disaster Assistance Act [Cal. Gov. Code, §§ 8680-8690.7], among others. Section 8571 of the Government Code, for instance, permits the Governor to suspend any regulatory statute during a state of war or emergency where strict compliance therewith would prevent, hinder, or delay mitigation.

²See also the Interstate Civil Defense and Disaster Compact [Cal. Gov. Code, §§ 177-178], the Emergency Management Assistance Compact [Cal. Gov. Code, §§ 179-179.5], and the California Disaster and Civil Defense Master Mutual Aid Agreement [executed 1950], regarding cooperation among the states.

Excerpt from the **Draft** December 19 Licensing Committee Minutes

Presentation by the California Department of Public Health Regarding Provisions for Pharmacy Services During a Declared State of Emergency and Possible Next Steps

Chairperson Veale explained that Business and Professions Code section 4062 establishes the authority for a pharmacy to furnish dangerous drugs in reasonable quantities without a prescription during a federal, state or local emergency. This section allows the board to waive application of any provisions of pharmacy law if, in the board's opinion, the waiver will aid the provision of patient care or the protection of public health. Further, under this section, provisions exist to allow for the use of a mobile pharmacy under specified conditions.

Chairperson Veale also explained that Business and Professions Code section 4064 provides that a prescription may be refilled by a pharmacist without prescriber authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgement, failure to refill the prescription might interrupt the patient's ongoing care.

Chairperson Veale stated that in recent years the number of declared state of emergencies in California have grown both in frequency and scope. The board has relied upon both its strong policy and legislative authority during such emergencies to guide pharmacists in helping displaced patients.

Chairperson Veale reported that when such an event occurs, the board uses its subscriber alert system to remind pharmacists about authorities provided in the law. Further, the board's duty inspector provides real time guidance. During the most recent declared emergency resulting from the Camp Fire, in addition to mandatory evacuations and loss of homes, five pharmacies were closed because the business either burned down or sustained significant fire damage. An additional six pharmacies closed for limited time due to air quality concerns.

Chairperson Veale noted that in addition to working with licensees, board staff also collaborates with other state agencies involved in disaster response, most notably the California Department of Public Health and the Office of Emergency Services. During this most recent emergency the board disseminated information on a pharmacist's ability to care for patients under emergency conditions via the subscriber alert system. For the first time the board also shared reimbursement procedures for pharmacies providing emergency dispensing through the Emergency Prescription Assistance Program (EPAP).

Chairperson Veale stated that during this meeting, the committee will have an opportunity to hear a presentation from the California Department of Public Health on the provision of pharmacy services during a declared state of emergency.

Chairperson Veale explained that board staff has reported some challenges that patients and/or pharmacies experienced during the Camp Fire emergency that may be appropriate for the committee to discuss.

1. Methadone patients were in some cases unable to get their prescribed doses of methadone. A call to DHCS solved this.
2. A pharmacy in an evacuation area that had not been destroyed was being watched for possible drug thefts opportunities.
3. Early on that patients could not get their medications because they had no money to cover copays.

Tom Ahrens, a pharmacist from CDPH, and Mark Chew, pharmacist with LA County Emergency Services, provided a presentation on the emergency response to the Camp and Woolsey Fires.

Dr. Ahrens stated that Camp Fire required a larger response than past fires due to the large number of individuals displaced and the significant damage to infrastructure and health care facilities (including pharmacies). As part of the presentation the committee was advised about the different entities that may establish shelters, e.g., The Red Cross, Salvation Army, and religious organizations. However, the presenters stated that problems exist in some shelters where medical care is not included (this occurs more typically in community shelters). The presenter clarified that different problems exist in the different types of shelters.

The presenters explained that shelters provided medical care with some over-the-counter medications and limited prescriptions being provided to evacuees. In other cases, patients received a prescription and needed to find a pharmacy. If transportation was not available, filling the prescription was a problem. It was noted that this problem was aggravated because shelter managers are typically not healthcare providers. It was also noted that even if a patient could find transportation to a pharmacy, many lacked the ability to cover copays and did not have insurance information.

The presenters stated that there is a need for more healthcare providers in shelters as well as more dispensing options available to patients in need of medications. The presenters also highlighted that challenges that exist in transporting prescription drugs to shelters, especially for controlled substances.

Dr. Chew reported that he performed dispensing functions during the recent disaster. He noted that one of the most frustrating issues is that pharmacists don't read the statements issued by the board or are hesitant to follow the directions provided by the board.

Note: The presenters provided a handout to the committee and the public which highlighted the issues faced by shelters and the recommendations from CDPH to the board. The document has been provided following these minutes.

Committee member Stanley Weisser expressed concerns with the challenges pharmacies face when seeking reimbursement from PBMs for a patient who was unable to provide insurance information during an emergency.

Chairperson Veale noted during emergencies PBMs provide information to pharmacies in the affected areas on how to use over-ride codes for patients who need medications. Ms. Veale noted that pharmacists can also do an eligibility check of a patient through SureScripts to attempt to gather the information needed for reimbursement.

Committee member Dr. Albert Wong suggested that the state should consider guaranteeing payments to pharmacies who provide medications to patients during a declared state of emergency.

The committee discussed the Emergency Prescription Assistance Program, or EPAP, which helps people in a federally-identified disaster area who do not have health insurance get the prescription drugs, vaccinations, medical supplies, and equipment that they need. Dr. Chew stated that this program is helpful, but it only is available if a federal disaster is declared and if the patient has **ZERO** insurance. Dr. Chew noted that only six patients were able to use the program during the wildfires. Board staff offered to research options regarding co-pays and reimbursements.

Committee member Lavanza Butler asked if there were any problems with the board communicating with pharmacies. Ms. Herold stated that she took phone calls as well as the duty inspector. She added that there is always room to improve the board's outreach and education. Dr. Wong suggested that the board's inspectors proactively reach out to pharmacies in the disaster area to see if they need assistance.

The committee discussed the development of a free, voluntary CE program regarding disaster response as well as a contact list for chain pharmacies so that the board can use it to provide information quickly during a disaster. The committee also discussed the development of a fact sheet for pharmacies. Ms. Veale volunteer to provide information on performing eligibility checks to include on the fact sheet for pharmacies. The committee noted that these items would be best handled by the Communication and Public Education Committee.

Dr. Wong suggested that the board create a specific blank prescription form to be used during emergencies. Ms. Sodergren explained that there is currently an exemption in pharmacy law for terminally ill patients and suggested that the board could use a similar exemption during declared emergencies.

Dr. Chew explained another difficulty they faced was that wholesalers refused to delivery to remote unlicensed locations. Ms. Herold stated that the board will reach out to the wholesalers to discuss operations during a declared state of emergency.

Dr. Chew again stated that a major problem during disasters is the lack of health care professionals available to assist evacuees. He explained that there is a disaster healthcare volunteer system and encouraged pharmacists to join (including the board's inspectors).

A representative from Walgreens commended that the board has a good communication plan in place for emergencies. She indicated that Walgreens is able to provide information to stores quickly after receiving a subscriber alert sent by the board. It was also noted that Walgreens felt the board's communication were clear and did not have any problems interpreting the board's laws during declared emergencies.

Pharmacist Steve Gray noted that other states have not had to deal with disaster responses and commended the board for their efforts in the area. Dr. Gray stated that when people are evacuated they often travel to other areas of the state. He recommended changing the working of the waiver notice to make it clear that the waivers are state wide not limited to the disaster area itself. Dr. Gray also recommended that the board work with neighboring states as well so that patients who leave the state when they are evacuated can still receive care.

Paige Tally explained the difficulties that skilled nursing facilities faced when they had to evacuate their patients. She asked if CDPH assists with evacuations. Dr. Chew stated that CDPH does help track where patients are evacuated so they can continue to receive medical care.

Chairperson Veale asked if Dr. Chew and Dr. Ahrens would provide their presentation to the Communication and Public Education Committee. Dr. Chew and Dr. Ahrens agreed to present at the January 8th committee meeting.

Committee Recommendation: Authorize the Chair to work with staff to develop a statutory proposal for the board to consider regarding the issues related to controlled substances that occurred during the recent declared state of emergency.

M/S: Weisser/Butler

Support: 5 Oppose: 0 Abstain: 0

Attachment 6

News Media Activity

The board's executive officer and public information officer participated in interviews or provided background information in response to the following media inquiries:

- **San Diego Union-Tribune**, Aug. 7: Paul Sisson, lidocaine and drug shortages in California
- **Palm Springs Desert Sun**, Aug. 10: Geraldine Estevez, availability of hormonal contraception
- **KPIX**, Aug. 23: Julie Watts, Kaiser restriction on EpiPen prescriptions
- **STAT**, Aug. 27: Ed Silverman, update on Pharmedium license cancellation
- **News 10 San Diego**, Sept. 5: Jennifer Kastner, complaint about improperly stored Kaiser insulin
- **Outpatient Surgery Magazine**, Sept. 20: Desiree Ifft, compounding regulations for ambulatory surgery centers.
- **STAT Pharmalot**, Oct. 10: Ed Silverman, board accusation against McKesson in DEA case.
- **USA Today**, Nov. 17-28: Steve Reilly, PRA request for NABP Disciplinary Clearinghouse Reports.
- **Capitol Morning Report**, Dec. 13: Gianna Miller, background on board meeting discussion of fee increases.

Attachment 7

Public Outreach Activities

Board inspectors and staff reported the following public outreach activities:

- October 3: Enforcement Chief Tom Lenox spoke about prescription drug abuse in the pharmacy to 30 students at California Northstate University School of Pharmacy.
- October 6: Enforcement Chief Tom Lenox, Supervising Inspector Christine Acosta and Executive Officer Virginia Herold spoke about 2019 new laws at CSHP in San Diego.
- October 6: Enforcement Chief Tom Lenox spoke about prescription drug abuse trends at the American Osteopathic Association Conference in San Diego.
- Nov. 8: Executive Officer Virginia Herold spoke about the role of PIC to managerial pharmacy staff of the California Department of Corrections.
- Nov. 17: Executive Officer Virginia Herold presented 2018 pharmacy laws at University of California, San Diego.
- Nov. 28: Inspector Louisa Tsoi presented on corresponding responsibility at the Semi-Annual Monterey County Prescription Drug Abuse & Diversion Summit
- Dec. 8: Executive Officer Virginia Herold; Enforcement Chief Tom Lenox; Supervising Inspectors Janice Dang and Tony Ngondara; and Inspectors Steven Kyle and Noelle Randall presented on prescription drug abuse and drug diversion at Board of Pharmacy CE training in Santa Barbara.
- Dec. 17: Executive Officer Virginia Herold presented 2018 pharmacy laws at the Sacramento Chapter meeting of CSHP.

Attachment ,

Review and Discussion of News or Journal Articles

News articles on pharmacy issues that may be of interest to the committee are listed below.

[Pharmacist holds up Danville CVS at gunpoint for pills, authorities say](#)

San Francisco Chronicle

Nov. 29, 2018

A registered pharmacist was charged with second-degree robbery after he allegedly stole narcotics from a CVS pharmacy in Danville while brandishing a gun and wearing a blue surgical mask, officials said Thursday. Jonathan Szkotak was arrested April 3 after he approached a pharmacy counter with a firearm and stole clonazepam and buprenorphine, according to the Contra Costa County district attorney's office.

[Generic drugmaker to sell alternative to EpiPen injectors](#)

Associated Press

Dec. 6, 2018

Generic drugmaker Sandoz announced plans Thursday to start selling an alternative to the EpiPen in the U.S. early next year. The EpiPen injector is used to halt life-threatening allergic reactions to insect bites, nuts and other foods. Brand-name EpiPen, which dominates the market, has been in short supply since spring because of production problems.

[The Opioid Epidemic's First Corporate Casualty May Be a Drugmaker That Helped Fuel the Crisis](#)

Bloomberg

Dec. 4, 2018

Insys could become the first corporate casualty of the opioid epidemic. Its sales have plunged as it spends millions of dollars on legal defenses of its former executives, including billionaire founder and ex-chief executive John Kapoor. In a desperate bid to save itself, Insys's new managers are trying to sell off its main pain drug to a corporate buyer to raise money. They hope to use the proceeds to pivot out of the opioid business into something slightly less controversial – cannabis-derived drugs.

['The Numbers Are So Staggering.' Overdose Deaths Set a Record Last Year.](#)

New York Times

Nov. 29, 2018

A class of synthetic drugs has replaced heroin in many major American drug markets, ushering in a more deadly phase of the opioid epidemic. New numbers Thursday from the Centers for Disease Control and Prevention show that drug overdoses killed more than 70,000 Americans in 2017, a record. Overdose deaths are higher than deaths from H.I.V., car crashes or gun violence at their peaks. The data also show that the increased deaths correspond strongly with the use of synthetic opioids known as fentanyl.

[Virginia moves to limit mail-order specialty pharmacies following concerns of mishandling medicines for complex conditions](#)

Richmond Times-Dispatch

Nov. 28, 2018

Virginia regulators are seeking greater control over the delivery of the medications from specialty pharmacies to a practitioner's office or directly to a patient's home. The state's Board of Pharmacy gave initial approval Wednesday to several rule changes aimed at reducing the chance of medication being mishandled due to delivery mishaps, including requiring delivering pharmacies to inform hospitals and doctors' offices of expected arrival time and storage instructions for medicines, banning the delivery of drugs requiring special storage directly to the patient's home, and mandating that the specialty pharmacy provide a return procedure for medications that are not delivered or administered.

Attachment -



DRAFT COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MEETING MINUTES

Date: October 11, 2018

Location: Department of Consumer Affairs
DCA Headquarters Building
1625 N. Market Blvd., 1st Floor Hearing Room
Sacramento, CA 95834

Committee Members Present: Ricardo Sanchez, Public Member, Chairperson
Valerie Muñoz, Public Member, Vice Chairperson
Deborah Veale, Licensee Member

Committee Members Not Present: Ryan Brooks, Public Member
Shirley Kim, Public Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kelsey Pruden, DCA Staff Counsel
Debbie Damoth, Administrative Manager
Bob Dávila, Public Information Officer

1. Call to Order and Establishment of Quorum

Chairperson Sanchez called the meeting to order at 9:03 a.m. Roll call established a quorum.

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

There was no public comment.

3. Approval of the January 31, 2018, Committee Meeting Minutes

Motion: Approve the minutes for the January 31, 2018, Communication and Public Education Committee meeting.

M/S: Muñoz/Veale

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Kim				X
Muñoz	X			
Sanchez	X			
Veale	X			

4. Discussion and Consideration of a Presentation and Proposal by the Chapman University School of Pharmacy Group Regarding a Warning Label on Prescription Containers for Chemotherapy Medications

Chairperson Sanchez reminded the committee that Chapman University pharmacy students and faculty presented research about proper handling and disposal of oral chemotherapy medications at the March 2017 committee meeting. The group proposed requiring a standardized hazard symbol on prescription labels for NIOSH-designated hazardous drugs.

Chairperson Sanchez noted the group returned at the September 2017 committee meeting with early findings from a survey of health care professionals on use and handling of oral chemotherapy drugs. The group also said it was preparing a similar survey for patients.

Using a PowerPoint presentation, the Chapman group informed the committee that it had surveyed 24 pharmacists and 12 patients about their knowledge, awareness and practices in handling and disposing of oral chemotherapy drugs. In summary, the findings indicated an important need for more education in these areas for pharmacists and patients. A copy of the Chapman presentation is attached to the minutes for this meeting. (A copy of the PowerPoint is attached to these minutes.)

The committee expressed concern about the lack of public awareness and education revealed by the surveys. Members suggested a larger survey sample with more respondents is needed to better understand the scope of the problem and possible solutions.

The committee urged the students to focus on increasing awareness and education about safe handling and drug disposal rather than seeking a mandated requirement for adding a hazard symbol to prescription labels. The committee also suggested advocates work with pharmacies that are willing voluntarily to add the hazard symbol to labels. The committee indicated this will help to demonstrate the need and effectiveness of the hazard symbol added to prescription labels.

The committee directed staff to develop and return to the committee with a policy statement for the board to consider regarding proper handling and disposal of oral chemotherapy drugs.

Danny Martinez indicated CPhA was willing to work with the Chapman students on licensee

awareness and education. He also urged the board to work with CPhA on a unified message to pharmacists before considering a possible regulation.

5. Update on the Proposal for a Public Service Billboard Message and Related Communications Materials on Prescription Drug Abuse

Chairperson Sanchez reminded the committee that Outfront Media is donating five bulletin boards to the Board of Pharmacy for a public service message about prescription drug abuse. The committee approved a design and chose "Use, Don't Abuse" as the theme. The board reviewed the design and message in February 2018.

Staff reported a no-cost contract for five billboards has been sent to Outfront Media for approval and signature. As of Oct. 11, staff was waiting for Outfront to respond. Ms. Herold said delays on both sides resulted in the contract process taking longer than expected.

The committee directed staff to ask Outfront how long it would take to get the billboards printed and where they will be erected. Committee members said staff should use data on drug abuse to identify locations where the signs would be most effective.

6. Discussion and Consideration of Educational Materials Regarding Drug Take-Back Collection Receptacles and Providing Public Access to Such Information

Chairperson Sanchez reminded the committee that the board directed staff in July 2017 to develop consumer information on accessing drug take-back programs. At the February 2018 board meeting, staff demonstrated an online search tool being developed to help consumers find locations for drug take-back collection receptacles.

Staff gave a brief demonstration of a new search tool for drug take-back services on the board's website. The online tool enables consumers to find pharmacies and clinics that have registered with the board to provide drug take-back services. Staff reported a total of 233 receptacle locations were registered with the board as of Sept. 25, 2018.

Staff noted the online search tool includes only take-back locations that are registered with the board and is not a comprehensive list of all collection sites in California. Staff added that the board's website includes links to search tools for other take-back locations operated by DEA, Don't Rush to Flush, and the California Department of Public Health.

Staff also reported the Department of Public Health has received \$3 million to fund grants to pharmacies for drug take-back services. In addition, staff said the Governor recently had signed SB 212, which will require manufacturers and distributors of drugs or sharps to form stewardship programs to operate and pay for take-back programs for drugs and sharps. The law requires CalRecycle to promulgate regulations to implement the law by Jan. 1, 2021.

Staff reported the board will be involved with CalRecycle in developing the regulations for

SB 212. Staff said the new law will not change the board's current take-back regulations.

Danny Martinez of CPhA asked why sharps are treated separately from needles and if pharmacies are liable in case someone is accidentally pricked by a needle. Ms. Herold explained that sharps are separated from pills as a safety measure and because they are incinerated while pills are destroyed by a different means. She also said provisions in the Civil Code protect pharmacies from needle accidents.

7. Update on the Development of a Webinar Course to Satisfy the Education Requirement for Pharmacists to Furnish Naloxone

Chairperson Sanchez noted that a protocol adopted by the board in [California Code of Regulations, title 16, section 1746.3](#) requires pharmacists to complete one hour of training in an approved CE course before they can begin furnishing naloxone. He reminded the committee that the board in February 2018 approved the committee's recommendation to create a webinar course that would satisfy the naloxone training requirement.

Staff reported DCA's SOLID unit was finalizing the voice-over and closed-captioning for the webinar. In addition, staff said SOLID was asked to set up the webinar to prevent users from fast-forwarding through the video to the quiz at the end. Staff said the webinar was expected to be available on the website in October.

Staff noted the webinar quiz does not require a passing score. Instead, if a user chooses the wrong answer, the quiz indicates the answer is incorrect and shows the correct answer. It was noted that the Licensing Committee is looking into a possible requirement for users to earn a passing score on webinars. In addition, staff said technology could be used to prevent fast forwarding and to improve future versions of board webinars.

Danny Martinez of CPhA said the Department of Health Care Services is expected to begin reimbursing Medi-Cal pharmacists for services performed under SB 493 as well as furnishing naloxone on April 1, 2019.

8. Discussion and Consideration of Proposal to Establish a Twitter Account for the Board of Pharmacy

Chairperson Sanchez noted the board's 2017-2021 Strategic Plan calls for the board to "identify and use additional resources for public and licensee outreach services."

Staff proposed using Twitter as a communication tool for outreach to the public. It was noted that the board currently has several channels for communicating directly with licensees – including subscriber alerts, the newsletter, site inspections, etc. – but none that is widely accessible to the public.

Staff gave a PowerPoint presentation about how Twitter could help the board:

- Reach and engage consumers directly.
- Reach news media.
- Deliver timely information immediately.
- Create links with other organizations.
- Promote public awareness of the board’s activities and brand.
- Increase public awareness and support for the board’s mission and activities.

Staff also discussed types of information the board could communicate to the public via Twitter – including upcoming board meetings and events, recalls, regulations, news releases, and links to consumer resources.

The committee expressed support for using Twitter as a public communication channel. Vice Chairperson Muñoz noted that millions of Americans rely on Twitter to receive news and information, mostly on their cell phones, rather than traditional news media.

The committee asked about using other social media in addition to Twitter, such as Facebook and Instagram. Staff recommended starting with Twitter because it is easiest to use. In addition, staff could collect and present data on its effectiveness to help the board determine whether to add other social media accounts.

Members of the public said they supported the board using Twitter but expressed concern about how the board would handle hostile messages that target licensees or other individuals. Speakers also asked if private messages sent on Twitter would be subject to Public Records Act requests. Counsel said these issues would require legal research.

Committee recommendation: Recommend that the board approve the establishment and use of a Twitter account to communicate with the public and direct staff to report on its usage in the committee’s quarterly report to the board. In addition, direct staff to research other social media for possible use.

M/S: Veale/Muñoz

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Kim				X
Muñoz	X			
Sanchez	X			
Veale	X			

9. Discussion and Consideration of Frequently Asked Questions Relating to Inventory Reconciliation Reports of Controlled Substances (California Code of Regulations, title 16, section 1715.65)

Chairperson Sanchez noted that [California Code of Regulations, title 16, section 1715.65](#) took effect April 1, 2018. He said many licensees have expressed questions about how to comply with the regulation.

Staff reported on several steps being taken to help licensees understand and comply with the new regulation. Staff said a list of [frequently asked questions \(FAQs\)](#) and answers about the regulation has been posted on the board's website. In addition, the FAQs were updated and published in the [July 2018 issue](#) of The Script.

Staff said a follow-up FAQ article was planned for the next Script. In addition, training on the new regulation was provided at a board-sponsored CE forum on Sept. 22 in Buena Park. Ms. Veale complimented the FAQs and said they were comprehensive. Ms. Herold said the regulation enabled one pharmacy to uncover a major loss of controlled substance pills early.

10. Discussion and Consideration of Granting CE Credit for Reading The Script

Chairperson Sanchez noted the board in November 2017 directed the committee to consider awarding CE credit for reading The Script. The committee suggested pharmacists could earn one CE credit for reading each newsletter, up to a maximum of two credits per renewal cycle (every two years).

Chairperson Sanchez said the board directed the committee to pursue options for awarding CE for The Script that would apply to the required two hours of board-provided CE in law and ethics every renewal cycle. The board also asked staff to research ways to keep costs and required staff time for the CE to a minimum.

Staff presented the following possible options for awarding CE for The Script:

1. **Require pharmacists to self-certify reading The Script.** Users could click on a link in the newsletter that would take them to a site to certify they have read the newsletter. Estimated staff time to process each CE unit: one minute.
2. **Require pharmacists to pass a quiz to be included with The Script.** Users would answer multiple-choice or true-false questions prepared by staff. Estimated staff time to process each CE unit: one minute.
3. **Require pharmacists to complete learning objectives after reading The Script.** Users would write a brief description of what they learned from reading articles. Estimated staff time to process each CE unit: five to 15 minutes.

The committee supported requiring pharmacists to pass a quiz to earn CE. Members said it is important to provide CE that genuinely improves pharmacists' professional competence.

Speakers supported the quiz option and stressed the importance of having CE requirements that improve professional competence. It also was suggested that staff invite pharmacy school faculty to write articles and quizzes for the newsletter.

Committee recommendation: Recommend that the board allow pharmacists who pass a quiz based on Script articles to earn one hour of CE credit per newsletter, up to a maximum of two credits per renewal period, as fulfillment of the two units of CE required to be earned from completion of board-provided CE to renew a pharmacist license.

M/S: Veale/Sanchez

Name	Support	Oppose	Abstain	Not Present
Brooks				X
Kim				X
Muñoz	X			
Sanchez	X			
Veale	X			

11. Discussion and Consideration of FDA Draft Guidance “Indications and Usage Section of Labeling for Human Prescription and Biological Products – Content and Format”

Chairperson Sanchez informed the committee that FDA regulations require a manufacturer's drug labels to include an “Indications and Usage” section. This section must state the drug is indicated for the treatment, prevention, mitigation, cure or diagnosis of a disease or condition; or for the relief of the disease's or condition's symptoms.

Chairperson Sanchez said the FDA issued a draft guidance for industry, “[Indications and Usage Section of Labeling for Human Prescription and Biological Products – Content and Format](#).” He said the guidance describes the FDA's recommendations for how to clearly convey such information.

Staff presented the guidance document for the committee's information. There was no action or public comment.

12. Discussion and Consideration of Strategic Goals for the Communication and Public Education Committee

The committee reviewed and discussed strategic goals for communication and public education as identified in the board's [Strategic Plan 2017-2021](#). Members recommended keeping the current goals, noting that activities and programs intended to carry out the

goals are still in progress. Members also directed staff to provide updates on efforts to achieve the strategic goals at future committee meetings.

Regarding goal 4.2 (Identify and use additional resources for public and licensee outreach services to implement the communication plan), the committee directed staff to report back annually on the “Ask an Inspector” program – including number of calls, the nature of calls, the top 10 types of calls – starting in January 2019.

Regarding goal 4.3, committee members suggested that the board may not need to collect mobile numbers for texting licensees because the board can use other communication tools, including email, address of record and social media.

Regarding goal 4.5 (Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings), the committee also directed staff to report back annually on the follow-up surveys that supervisors do with pharmacies after inspections – starting in January 2019.

Regarding goal 4.7, the committee directed staff to review consumer education materials and revise or refresh them as needed.

13. Update and Discussion of Communication and Public Education Activities by Board Staff

a. The Script

Staff reported the next newsletter is expected to be published in October. Staff said it would include articles about the inventory reconciliation regulation, applying to be an inspector, counseling patients over 50 about opioids, the executive officer’s retirement and new board members.

b. News Media

The committee received a list of recent media interviews and information requests handled by Ms. Herold and Mr. Dávila.

c. Public Outreach

The committee received a list of recent public outreach activities by staff.

14. Review and Discussion of News or Journal Articles

The committee received summaries of several recent news articles about pharmacy issues.

15. Future Meeting Dates

Chairperson Sanchez announced the committee’s meeting schedule for 2019:

- Tuesday, Jan. 8, 2019
- Wednesday, April 10, 2019

- Tuesday, June 25, 2019
- Wednesday, Oct. 9, 2019

The meeting adjourned at 11:24 am.

DRAFT