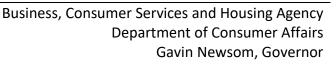


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COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Ricardo Sanchez, Public Member, Chairperson Jason Weisz, Public Member, Vice Chairperson Jose De La Paz, Public Member Kartikeya Jha, Licensee Member Kula Koenig, Public Member Nicole Thibeau, Licensee Member

During the meeting members will review a summary of the Committee's work at is February 6, 2023, meeting as well as updates for discussion and action as necessary.

a. Discussion and Consideration of FAQs about Mobile Units

<u>Background</u>

SB 872 (Dodd, Chapter 220, Statutes of 2022) allows a county, a city and county, or two special hospital authorities to operate a mobile unit as an extension of the pharmacy license held. The measure authorizes the mobile unit to dispense prescription medications (except controlled substances) under specified conditions and requires notification to the Board 30 days before beginning and 30 days before discontinuing use of a mobile unit.

To implement the law, staff has developed a standardized form for notifying the Board regarding operating a mobile unit. In addition, staff is developing FAQs to assist licensees in complying with the new law. Drafts of the standardized notification form and the FAQs are in **Attachment 1**.

<u>Summary of Committee Discussion and Action</u>
During the meeting members will receive an update on the discussion and action.

b. Update on Communication and Public Education Activities by Staff

1. The Script

The <u>January 2023 issue</u> of the Script is published on the Board's website. The newsletter includes articles about news pharmacy laws for 2022, the end of the COVID-19 state of emergency, sharps waste programs, revised USP chapters, and other topics.

Communication and Public Education Chair Report February 6-7, 2023 Board Meeting Page 1 of 2

2. Staff Outreach

A list of activities by individual staff members is in **Attachment 2**.

- i. Naloxone Education Materials Staff is researching possible educational materials. A link to naloxone materials currently on the Board's website is posted under "important Information for Licensees" on the homepage.
- ii. Public Aware Campaign on Treating Pharmacy Staff with Courtesy Staff is researching possible campaign materials and expects to report back at the next committee meeting.
- iii. Education Campaign Regarding ISMP Staff is researching possible educational materials and expects to report back at the next committee meeting.
- iv. Opioid, Heroin, Fentanyl, and Prescription Drug Abuse Awareness

 Month

The Legislature adopted a resolution declaring September 2022 as Opioid, Heroin, Fentanyl, and Prescription Drug Abuse Awareness Month. To raise public awareness, staff posted the resolution on the Board's website, issued a news subscriber alert, and launched a campaign tagged #DrugAbuseAwareness2022 on the Board's Twitter feed. The campaign included graphics with facts about drug abuse and links to find treatment, drug take-back locations, and other resources. The messages also were shared with DCA and other healing arts boards and bureaus. Campaign samples are included in **Attachment 3**.

3. News Media

News media inquiries received during the third and fourth quarters of 2022 are listed in **Attachment 4**.



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Business, Consumer Services and Housing Agency Department of Consumer Affairs Gavin Newsom, Governor



NOTIFICATION TO OPERATE OR DISCONTINUE OPERATING A MOBILE UNIT BPC 4110.5

This form is intended to assist in the notification to operate or discontinue operation of a mobile unit to provide prescription medication within its jurisdiction to those individuals without fixed addresses, individuals living in county-owned or city-and-county-owned housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority.

The mobile unit shall be operated as an extension of a pharmacy license held by the county, city and county, or special hospital authority as provided in Business and Professions Code section 4110.5.

As required, notification to the Board is required at least 30 days prior to commencing operation of a mobile unit. Notice is also required at least 30 days prior to discontinuing operation of a mobile unit.

| 1. | Enter the Date: Operation Date: | Discontinuance [| Oate: | |
|----|---|---------------------|-------------------------|--|
| 2. | Pharmacy Information | | | |
| | Pharmacy Name | | License Prefix & Number | |
| | Address Pharmacy: Street City | State | Zip Code | |
| | Name and License Number of the Pharmacist-in- | -Charge (PIC) | PIC email address | |
| 3. | The person(s) signing below must be identified on the pharmacy license and have the authority to bind the license. | | | |
| | I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made on this form including all supplementary statements. | | | |
| | Signature of Authorized Government Authority Listed on the License | Name (please print) | Date | |
| | I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representation made on this form including all supplementary statements. | | | |

Date Processed:

Processed by:

For Office Use Only

| Signature of Pharmacist-in-Charge | Name (please print) | Date |
|-----------------------------------|---------------------|------|
| | | |
| | | |

Mobile Units – Frequently Asked Questions

1. Q: What is the difference between a mobile unit and a mobile pharmacy?

A: A mobile unit is an extension of a pharmacy license held by the county, city and county, or special hospital authority that provides prescription medication within its jurisdiction to individuals without fixed addresses, individuals living in county-owned or city-and-county-owned housing facilities, and those enrolled in Medi-Cal plans operated by the county or a city and county, a health district, or a joint powers authority pursuant to Chapter 7 (commencing with Section 14000) or Chapter 8 (commencing with Section 14200) of Part 3 of Division 0 of the Welfare and Institutions Code.

Whereas a mobile pharmacy is used temporarily when a pharmacy is destroyed or damaged, and the mobile pharmacy is necessary to protect the health and safety of the public under specified conditions. The Board must be contacted to authorize approve the use of a mobile pharmacy and the pharmacy must provide the Board with records of the destruction of, or damage to, the pharmacy with an expected restoration date prior to operating a mobile pharmacy.

A mobile pharmacy can also be employed during a declared federal, state, or local emergency in impacted areas in order to ensure the continuity of patient care under specified conditions, including being located within the declared emergency or affected areas. An approved waiver from the Board is required to operate a mobile pharmacy during a declared emergency.

(BPC 4062(c), BPC 4110(c), BPC 4110.5)

Q: How many mobile units may a county, city and county, or special hospital authority pharmacy operate?

A: A county, city and county, or special hospital authority may only operate one mobile unit. (BPC 4110.5)

2. Q: What "special hospital authority" can operate a mobile unit?

A: The special hospital authority that may operate a mobile unit is limited to the Alameda Health System described in Chapter 5 (commencing with Section 101850) and the Kern County Hospital Authority Act describe in Chapter 5.5 (commencing with Section 101852 of Part 4 of Division 101 of the Health and Safety Code.

Note: A hospital pharmacy operating a mobile unit may furnish drugs to outpatients or employees of the hospital or to walk-in customers, provided the sales to walk-in customers do not exceed one (1%) of all the pharmacy's prescriptions.

(BPC 4110.5, HSC 101850, HSC 101852, BPC 4380(a)(3), CCR 1710)

3. Q: How can a county, city and county, or special hospital authority notify the Board of their intent to operate a mobile unit?

A: At least 30 days prior to commencing operations of a mobile unit, the county, city or county, or special hospital authority must notify the board of its intention to operate a mobile unit. To assist with notification requirements, the Board has developed a form that can be accessed here.

(BPC 4110.5(f)

4. Q: I am an independent retail pharmacy and would like to service my community by helping the homeless by providing better access in obtaining their medications. Can I operate a mobile unit?

A: No, only a county, city and county, or special hospital authority described in Chapter 5 commencing with HSC 101850 or Chapter 5.5 commencing with HSC 101852 may operate a mobile unit to provide prescription medications.

(BPC 4110.5)

5. Q: Can a clinic licensed by the Board pursuant to BPC 4180 qualify to operate a mobile unit?

A: No, a mobile unit can only be operated as an extension of a pharmacy license.

(BPC 4110.5)

6. Q: Our county operates a mobile unit. At the end of the day, can we park the mobile unit in a secured garage located where the pharmacy operating the mobile unit is located. Can we leave the drugs in the mobile unit if the garage has a security gate only accessible with a key fob by authorized personnel, the garage is well lit and there is a security guard that patrols the area.

A: No, dangerous drugs must not be left in the mobile unit during the hours the mobile unit is not in operation. Mobile units are extensions of the pharmacy when they are open for business and when not in use the stock of dangerous drugs and devices must be stored in the pharmacy.

(BP 4110.5(e))

7. Q: At the end of the day, where can the mobile unit be parked?

A: Pharmacy law does not specify where the mobile unit is required to be parked. However, when the mobile unit is not operating, the drugs cannot be left in the mobile unit. Therefore, the Board recommends the mobile unit be parked at or close to the address of the licensed

pharmacy since the drugs are required to be stored and secured at the licensed pharmacy operating the mobile unit.

(BPC 4110.5, CCR 1714(b)(d))

8. Q: If a county, city and county, or special hospital authority are planning to discontinue the use of a mobile unit, how should the Board be notified?

A: Notice must be given to the Board at least 30 days prior to discontinuing the operation of a mobile unit. To assist with notification requirements, the Board has development a form that can be accessed here.

(BPC 4110.5(f))

9. Q: Does the mobile unit require the Notice to Consumer poster to be posted in public view?

A: Yes, the mobile unit operates as an extension of a pharmacy license. Pharmacy law requires every pharmacy to prominently post in a place that is conspicuous and readable by a prescription drug consumer. The mobile unit must use the standardized poster available by the Board unless the pharmacy has received prior approval of another format or display methodology from the board. The mobile unit can also display the notice on a video screen. In addition to the English version required to be posted, the Notice to Consumer poster is also available in other languages from the board and may be printed from the board's website.

(BPC 4110.5, CCR 1707.6)

10. Q: Is the mobile unit required to have hot and cold running water?

A: Yes, the mobile unit operates as an extension of a pharmacy license. Therefore, the mobile unit is required to have a sink with hot and cold running water for pharmaceutical purposes.

(BPC 4110.5, CCR 1714(c))

11. Q: Who can possess the keys to the mobile unit:

A: The mobile unit operates as an extension of a pharmacy license. When drugs are stored in the mobile unit, the key to the mobile unit is restricted to a pharmacist. The pharmacy owner (the county, city and county, or the special hospital authority) may possess a key to the mobile unit that is maintained in a tamper evident container for the purposes of 1) delivering the key to a pharmacist or 2) providing access in case of emergency that would include fire, flood or earthquake. The signature of the pharmacist-in-charge must be present in such a way that the pharmacist may readily determine whether the key was removed from the container.

(BPC 4110.5, CCR 1714(d)(e))

12. Q: Can the County pharmacy operate a mobile unit to assist the County's methadone program to dispense methadone to better serve the homeless population?

A: No, methadone is classified as a Schedule II controlled substance and a mobile unit cannot carry or dispense controlled substances.

(BPC 4110.5(d))

13. Q: What are the staffing limitations for a mobile unit?

A: A mobile unit operates as an extension of a pharmacy. Therefore, if the pharmacy operating the mobile unit has a community pharmacy license (PHY or PHE), then the pharmacy with only one pharmacist must have no more than one pharmacy technician performing the tasks specified in BPC 4115(a). Any additional pharmacist, the ratio of pharmacy technicians to pharmacist shall not exceed 2:1.

(BPC 4110.5, BPC 4115(f)(1))

14. Q: Can a pharmacist working on a mobile unit provide vaccine administration?

A: Yes, the pharmacist may provide vaccine administration. In addition to dispensing prescriptions, the pharmacist may perform activities consistent with pharmacy law listed in Article 3 commencing with BPC 4050.

(BPC 4110.5(b), BPC 4050-4068)

- 15. Q: During the temporary absence of a pharmacist for their 30-minute meal break, can the pharmacist leave the mobile unit leaving the pharmacy technicians and clerks in the mobile unit and continue to fill prescriptions?
 - A: The decision to keep the mobile unit open resides with the pharmacist working in the mobile unit. As part of the decision making, the pharmacy must reasonably believe that the security of the dangerous drugs and devised will be maintained in the pharmacist's absence.

If the mobile unit remains open during any temporary absence of the pharmacist no prescription medications may be provided to the patient or patient's agent unless the prescription medication is a refill medication that the pharmacist checked and released for furnishing to the patient and the pharmacist determined that a consultation was not required. The ancillary staff may continue to perform the non-discretionary duties authorized by pharmacy law.

During the temporary absence of the pharmacist, an intern pharmacist may not perform any discretionary duties nor otherwise act as a pharmacist. However, the intern pharmacist may perform non-discretionary tasks such as removing the drugs from stock, counting, pouring, or mixing pharmaceuticals, placing the product into a container, packaging and repackaging.

Note: To operate a mobile unit, a licensed pharmacist must be on the premises and the the mobile unit must be under the control and management of a pharmacist except during the pharmacist duty free breaks and 30-minute meal break. Medications should not be dispensed while a pharmacist is on break except for refills released by the pharmacist that do not require a patient consultation.

(BPC 4110.5(a), CCR 1714.1(a)(b)(c)(d)), CCR 1793.2

16. Q: Our mobile unit has very limited storage space. Where can a mobile unit store its records?

A: All records required by BPC 4081 and 4105 may be temporarily stored in the mobile unit while in operations. At the end of the day, when the mobile unit is not in operation, all records required by BPC 4081 and 4105 must be transferred and maintained on and/or at the licensed pharmacy premises that is operating the mobile unit. All required records must be preserved for at least three years from the date of making. If the licensed pharmacy has an approved waiver for storing records offsite from the board, the records from the mobile unit for non-controlled substances are required to be stored on on the mobile unit or the licensed pharmacy premise for a period of one year from the date of making. The records beyond one year from the date of making may be stored at the approved offsite storage location.

Note: A mobile unit cannot carry or dispense controlled substances. Therefore, the mobile unit should not have any records for controlled substances.

(BPC 4110.5, BPC 4081, BPC 4105)

17. Q: Are the prescription labels dispensed by the mobile unit required to have patient centered labeling?

A: Yes, all prescription medication dispensed by the mobile unit must comply with all labeling requirements applicable to a California licensed pharmacy, including all the requirements for patient centered labeling. Also, upon request of the patient or patient's representative, the mobile unit must provide translated directions for use printed on the prescription container, label, or on a supplemental document.

(BPC 4076, BPC 4076.5, CCR 1707.5)

18. Q: Are pharmacists required to provide consultation for new prescriptions dispensed from the mobile unit?

A: Yes, the mobile unit is an extension of the licensed pharmacy. Therefore, the same requirements for consultation pursuant to CCR 1707.2 applies for patient consultation.

(BPC 4110.5 CCR 1714)

19. Q: If a physician is practicing in the mobile unit, writes a new prescription for the patient and consults the patient on how to take the new medication, is the pharmacist also required to provide consultation to the patient when the mobile unit dispenses the new prescription to the patient?

A: Yes, the pharmacist is still responsible to provide patient consultation pursuant to CCR 1707.2.

(BPC 4110.5, CCR 1711)

20. Q: Does a board inspector have the authority to inspect a mobile unit?

A: Yes. Inspectors employed by the board may inspect during business hours all pharmacies or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(BPC 4008)

21. Q: When the mobile unit is in use, what security and maintenance measures are required for the drugs stocked and patient confidential records in the mobile unit?

A: The mobile unit is an extension of the pharmacy. Therefore, the mobile unit is required to maintain its facility, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The mobile unit, fixtures and equipment must be maintained in a clean and orderly condition. The mobile unit must be dry, well-ventilated, free from rodents and insects, and properly lighted. Each pharmacist while on duty is responsible for the security of the prescription drugs on the mobile unit, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records. When the mobile unit is not in use, the dangerous drugs and patient confidential records must be safely removed from the mobile unit to the licensed pharmacy.

To ensure security of the drug stock and patient confidential records, the board recommends the mobile unit to consider the following:

- When the mobile unit is in operation, the drugs are secured to prevent drugs from being displaced while the mobile unit is in motion.
- Use of a secured and lockable storage unit for the dangerous drugs and devices, and patient confidential records that is easily transferrable to the licensed pharmacy at the end of the day.
- Coordinating breaks and meal breaks if the pharmacist leaves the mobile unit and the pharmacy technician(s) remain in the mobile unit.
- Relocating the mobile unit to a safe area during meal breaks.

(CCR 1714(b)(c)(d))

Staff Outreach Activities

Board staff reported the following outreach activities:

- November 1, 2022: Board inspectors participated in "CE training: Inspection Expectations, Diversion Trends, Loss Prevention, Legal Updates, and CURES."
- November 16, 2022: Inspector Brandon Mutrux made a presentation on how to prepare for a Board inspection to the San Diego Pharmacists Association.

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Public Awareness Campaign – Opioid, Heroin, Fentanyl, and Prescription Drug Abuse Awareness Month (September 2022)







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Looking for help with drug abuse? The Substance Abuse and Mental Health Services Administration operates a 24-hour helpline and referral service for drug abuse treatment programs: 1-800-662-HELP (4357). Get more info at samhsa.gov.

#DrugAbuseAwareness2022



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News Media Inquiries

Board staff responded to the following news media inquiries in the second half of 2022:

- July 12, 2022: Daniel Moritz-Rabson, Pro Publica, regarding pharmacist licensee Daniel Buffington.
- July 22, 2022: Candice Nguyen, NBC Bay Area, regarding complaints related to pharmacists prescribing Paxlovid.
- August 2, 2022: Brandon Richardson, Long Beach Business Journal, regarding consumer complaint filed against Memorial Care/Long Beach Medical Center.
- September 1, 2022: Josh Slowiczek, CBS 13 (Sacramento), regarding any limits on quantity of controlled substance prescriptions pharmacies are allowed to fill.
- September 6, 2022: Yesenia Amaro, Fresno Bee, regarding status of students graduating from unaccredited pharmacy school.
- November 15, 2022: Robert Benincasa, NPR, regarding data on volumes of drugs prescribed in California in 2022.
- November 16, 2022: Rae Ellen Bichell, Kaiser Health News, regarding canceled license of former licensee.
- November 18, 2022: Kristen Hwang, CalMatters, regarding status of pharmacy law waiver allowing pharmacists to order and dispense Paxlovid when the state's declaration of emergency expires.
- December 7, 2022: Blake Dodge, Business Insider, regarding pharmacies reportedly declining to fill prescriptions issued by clinicians with telehealth provider Cerebral.
- December 21, 2022: Ed Silverman, STAT, regarding status of disciplinary hearing for CVS Caremark mail order pharmacy.

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