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

LICENSING COMMITTEE REPORT

Debbie Veale, Licensee Member, Chairperson
Stan Weisser, Licensee Member, Vice-Chairperson
Allen Schaad, Licensee Member
Amjad Khan, Public Member
Lavanza Butler, Licensee Member
Albert Wong, Licensee Member

The Licensing Committee met on December 19, 2018.

a) <u>Pharmacy Services During a Declared State of Emergency</u>

Attachment 1

Pursuant to Business and Professions Code (BPC) section 4062, a pharmacy may 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.

Additionally, BPC 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.

Regrettably 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.

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.

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 (CDPH) 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).

1. **Summary of Presentation by the California Department of Public Health Regarding Provisions**

At the December 2018 committee meeting, Tom Ahrens, a pharmacist contracted with CDPH and currently working for UC Davis, and Mark Chew, pharmacist with Orange County Emergency Services as well as one of the respondents from the California Medical Assistance Team, provided a presentation on the emergency response to the Camp and Woolsey Fires.

Dr. Ahrens reported the 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). The committee was advised about the different entities that may establish shelters (e.g., The Red Cross, Salvation Army, local government, and religious organizations). However, Dr. Ahrens reported that problems exist in some shelters where medical care is not included (more commonly community shelters) and clarified that different problems exist in the different types of shelters.

Dr. Ahrens further explained some shelters provided medical care with some over-the-counter medications and limited prescriptions being provided to evacuees. In other cases, patients received a written prescription and then needed to find a pharmacy. If transportation was not available, filling the prescription was a problem. Dr. Ahrens advised the committee that this problem was aggravated because shelter managers are typically not healthcare providers. He 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 presentation identified a need for more healthcare providers to provide services to patients in shelters as well as more dispensing options available to patients in need of medications. The presenters also highlighted the 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. In addition, he explained another difficulty they faced was that wholesalers refused to delivery to remote unlicensed locations.

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.

In addition to the information provided by the presenters, the committee discussed some of the challenges patients and/or pharmacies experienced during the Camp Fire emergency as follows:

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 theft opportunities.
3. The board heard complaints early on that patients could not get their medications because they had no money to cover copays.

The committee discussed concerns and the challenges pharmacies face when seeking reimbursement from PBMs for a patient who was unable to provide insurance information during an emergency. As part of the discussion, it was identified that during emergencies PBMs provide information to pharmacies in the affected areas on how to use over-ride codes for patients who need medications and that pharmacists can also do an eligibility check of a patient through SureScripts to attempt to gather the information needed for reimbursement.

The committee discussed the 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 is only 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.

The committee discussed the development of a free, voluntary continuing education 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.

Further discussed by the committee was creating a specific blank prescription form to be used during emergencies and to mirror the current exemption in pharmacy

law for terminally ill patients and suggested that the board could use a similar exemption during declared emergencies.

The committee referred this item to the Communication and Public Education Committee and requested Dr. Chew and Dr. Ahrens to provide their presentation to the Communication and Public Education Committee on January 8, 2019, which they agreed.

2. Recommended Statutory Change Related to Controlled Substances Prescriptions

In response to some of the challenges discussed, the committee directed staff to work with committee's Chair to develop a statutory proposal to create an exemption from the security prescription forms requirement for patients unable to access controlled medication as a result of a declared state or federal emergency.

Recent Update

Following the meeting draft language was developed for the board's consideration. The draft language for Health and Safety Code section 11159.25 is provided in **Attachment 1**. Should the board agree with the proposed changes, the following motion could be used to initiate the statutory change.

Motion: Approve the proposed statutory language for Health and Safety Code section 11159.25 and to direct board staff to secure an author to sponsor the statutory change.

Attachment 1 includes a copy of the relevant law sections, all three subscriber alerts released, the handout from Tom Ahrens, and the draft proposed language for Health and Safety Code Section 11159.25.

b) Summary of Discussion of Inspections of Sterile Compounding Pharmacies Required as a Result of Remodeling of the Facility

Pursuant to BPC sections 4127.1 and 4127.2, a license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance. A fee is assessed for the issuance or renewal of a sterile compounding license.

At the October 2018 Board Meeting, at the recommendation of the Enforcement Committee, the board referred further discussion to the Licensing Committee and requested consideration of inspections for sterile compounding pharmacies that are required after a pharmacy remodel.

While there is no requirement in pharmacy law for the board to conduct an inspection of the sterile compounding pharmacy after a remodel, the board is mandated by law to ensure that sterile compounding pharmacies are in compliance with pharmacy law, and as such a remodel inspection is conducted to confirm compliance. Such reinspection is necessary to reassess the compounding conditions and compliance with pharmacy law and to ensure that changes do not pose a safety threat to consumers. This process is similar to CETA guidelines that establish recertification of equipment when changes are made to certain types of equipment used. However, under current law, the board does not have the authority to assess a fee for such an inspection. The board must immediately respond to perform such remodel inspections because a delay could impact patient care.

Since July 1, 2015, the board has completed approximately 65 sterile compounding remodel inspections. This number is expected to increase as sterile compounding pharmacies remodel for compliance with the new USP chapters.

The scope of a remodel ranges from simple projects to a full remodel or an expansion. There are several reasons that a remodel may trigger an inspection such as:

- unforeseen damage (e.g., flood, fire);
- planned upgrades (e.g., replacement of a PEC, addition of a PEC, repairing walls, floors, ceilings); and
- expansion of a facility.

Currently, when board staff is notified of a pending remodel to a sterile compounding facility, the board attempts to conduct an inspection as soon as possible after receiving the notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. Travel costs and inspector time for remodel inspections are currently being absorbed by the board.

<u>Committee Discussion and Action</u>

The committee discussed the board's mandate to conduct inspections of sterile compounding pharmacies to confirm the facility is in compliance with pharmacy law and agreed that an inspection is required after a remodel. The committee discussed establishing notification parameters for advising the board when a remodel is planned and possible consideration to develop a remodel application for the facility to submit in order to be notified if an inspection will be required at the conclusion of the remodel.

The discussion included establishing parameters as well when an inspection fee would be assessed. The committee noted that an inspection is required prior to the expiration of the license as the board is mandated to conduct an inspection of a sterile

compounding pharmacy prior to issuance and renewal of the license. The committee noted that the board does not have the authority to postpone conducting an inspection after the expiration date of the license. Additionally, a sterile compounding pharmacy license renewal period runs congruent with the underlying primary pharmacy or hospital license and as such the expiration date for the sterile compounding pharmacy cannot be altered. The committee agreed that placing parameters in law to specify that if a remodel inspection occurs within 90 days of the expiration of the license then the inspection would also serve as the renewal inspection.

The committee requested staff to develop language with legal to establish remodel inspection parameters and fees for review and consideration at the next licensing committee meeting.

c) <u>Discussion and Consideration of Proposed Regulation Regarding the Self-Assessment Requirement for Automated Drug Delivery Systems</u>

Attachment 2

In 2018, Governor Brown signed AB 2037 and SB 1447, both relating to the licensure and use of Automated Drug Delivery Systems (ADDS). Both measures require the operating pharmacy to complete an annual self-assessment to ensure compliance with pharmacy law as it relates to the use of the ADDS.

To facilitate implementation of this requirement, promulgation of regulations is necessary. Similar to the approach the board is taking with the pharmacy self-assessment process, board staff recommends detailing the specific reporting elements in the regulation language while also incorporating a self-assessment form by reference.

<u>Committee Discussion and Action</u>
The committee discussed and reviewed the proposed draft self-assessment of an ADDS by a pharmacist-in-charge regulation and the proposed draft ADDS self-assessment and made the following changes to the language. The committee added a comma and the word "or" at the end of paragraph (2) of subdivision (b).

Draft Regulation to read as follows: § 17##. Self-Assessment of an Automated Drug Delivery System by Pharmacist-in-Charge.

(a) A pharmacy holding an automated drug delivery system (ADDS) license as defined under section 4119.11, 4187.5 or section 4427.2 of the Business and Professions Code shall complete a self-assessment of compliance with federal and state pharmacy law for each location where an ADDS license is granted. The assessment shall be performed by the pharmacist-in-charge annually before July 1 of every year.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new ADDS license has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge, or

(3) There is a change in the licensed location of an ADDS to a new address.

Committee Recommendation (Motion): Recommend to the full board to approve the draft language with the addition of the ", or" after (b)(2) and to direct staff to initiate the rulemaking with the intent to have the regulation in place by May 1, 2020.

The committee discussed and reviewed the proposed draft ADDS self-assessment and made the following changes to the assessment.

Draft Automated Drug Delivery System Self-Assessment form

- Include in the assessment form the hours of the ADDS as required in the draft regulation in (c)(1)(D) and add if the hours of the ADDS are different than the pharmacy, what are they and why?
- Need to reference to sign the certification on page 34 for the ADDS listed under sections 4, 5, 6, 7, and 8 after completing the assessment.
- Correct if the ADDS is either an AUDS and/or an APDS in Section 1 and to provide instruction that there are two different types of ADDS.

Committee Recommendation: Direct staff to make the necessary changes as discussed in the draft regulation and draft assessment for ADDS to bring forward to the full board.

Attachment 2 contains the updated draft regulation language and the draft self-assessment form.

d) Discussion and Consideration of a Policy Statement and Strategic Steps to Authorize a Pharmacist to Provide Medication-Assisted Treatment

Attachment 3

Background

There is a huge nationwide opioid crisis. One of the recommended solutions to address the crisis is to provide medication-assisted treatment (MAT) to help wean patients from opioids. There are three main medications used for this -- methadone, buprenorphine and naltrexone.

The California Legislature declares pharmacists to be health care providers who have the authority to provide health care services. Pharmacists are medication specialists who are skilled in the assessment and management of substance related disorders such as opioid addiction. Today pharmacists have six to eight years of

collegiate education with focused experience in performing medication management. Increasingly this also includes additional residency experience. For a number of years under California law and in conjunction with collaborative practice agreements with prescribers, pharmacists have had the ability to:

1. Design treatment plans;
2. Initiate medications;
3. Monitor patient progress;
4. Order and review necessary laboratory tests;
5. Coordinate care with other medical providers; and
6. Serve as expert consultants to support prescribers in making medication decisions for patients with opioid addiction and co-occurring conditions.

Pharmacists with this skill set are well positioned to provide direct care to patients with opioid addiction and assist other medical providers in caring for this population, thereby expanding access to treatment for consumers. Additionally, in California, pharmacists with appropriate education and experience may secure an additional pharmacist's license, that of Advanced Practice Pharmacist, which authorizes collaborative practice with primary care providers.

Currently, federal laws prevent a pharmacist from prescribing MAT for opioid addiction. A pharmacist is not eligible to obtain a federal DATA 2000 waiver to prescribe buprenorphine. Pursuant to federal regulation, the only health care providers who can obtain this authority currently are physicians, nurse practitioners, and physician assistants. Expanding this authority to pharmacists would allow pharmacists to fully exercise their pharmaceutical education and experience in this area of health care services as a health care practitioner in California. Additionally, expanding this authority to pharmacists increases the number and availability of health care providers for Californians.

During the October 2018 Board Meeting, the board directed staff to draft a policy statement supporting the role of pharmacists in providing MAT services as well as develop options for advocating changes in federal law to allow such services to occur.

<u>Committee Discussion and Action</u>
The committee discussed the draft policy statement and possible ways to advocate this policy. The discussion included encouraging the National Association of Boards of Pharmacy (NABP) to adopt this policy as they are the national organization and should be advocating for pharmacists to be a part of the list of providers federally.

The committee also discussed the need to work with a coalition of groups on this policy including: the American Pharmacist Association (APHA), the NABP, the California Healthcare Foundation, the California Pharmacists Association (CPHA), the

California Society of Health-System Pharmacists, schools of pharmacy and other interested parties.

The committee heard comment from the public in support of the policy and support for adopting this policy statement and to move forward with legislation at the state level which will ultimately prepare the board to initiate this change once it's approved at the federal level.

Committee Recommendation (Motion): Recommend to the board to adopt this policy statement; encourage the NABP establish this policy language as a model law for all states nationwide; and work with APHA, CPHA and other national organizations to implement this in federal law.

The committee directed staff to work with legal counsel to determine if a change in statute is necessary at the state level.

Attachment 3 contains a copy of the draft policy statement.

e) Review of Licensing Statistics

Licensing statistics for July 1-December 31, 2018, are provided in **Attachment 4**.

As of December 31, 2018, the board has received 8,992 initial applications, including:

- 1,681 intern pharmacists.
- 1,035 pharmacist exam applications.
- 132 advanced practice pharmacists.
- 2,639 pharmacy technicians.

As of December 31, 2018, the board has issued 6,608 licenses, renewed 33,193 licenses and has 140,820 active licenses, including:

- 7,005 intern pharmacists.
- 47,053 pharmacists.
- 456 advanced practice pharmacists.
- 71,138 pharmacy technicians.
- 6,437 community pharmacies.
- 408 hospital pharmacies

Processing Times

The general application and deficiency mail processing times by license type are provided below reflecting data current as of January 11, 2019. The data reflects the

time from when an application or deficiency response is received by the board through to the time it is processed by licensing staff.

Currently, there are three site license types that are outside the standard 30-day processing performance standards for applications and that are outside the standard 10-day processing performance standards for deficiency mail. Management continues to prioritize the workload to ensure that mission critical site applications are being processed and issued in a timely manner.

Premises Application Types	Application Processing Times	Deficiency Mail Processing Times
Pharmacy	35	39
Nonresident Pharmacy	35	37
Sterile Compounding	32	10
Nonresident Sterile Compounding	Current	Current
Outsourcing	Current	Current
Nonresident Outsourcing	15	Current
Hospital	32	Included w/PHY
Clinic	22	Current
Wholesaler	16	Current
Nonresident Wholesaler	22	Current
Third-Party Logistics Provider	Current	Current
Nonresident Third-Party Logistics Provider	Current	Current

The individual license types are within the standard processing times for both applications and deficiency mail.

Individual Application Type	Application Processing Times	Deficiency Mail Processing Times
Pharmacist Examination	30	7
Pharmacist Initial Licensure	7	N/A
Advanced Practice Pharmacist	18	Current
Intern Pharmacist	18	9
Pharmacy Technician	24	7
Designated Representative	29	7
Designated Represenative-3PL	7	4

f) <u>Future Committee Meeting Dates</u>

The 2019 Licensing Committee dates are as follows:

- April 3, 2019
- June 26, 2019
- October 2, 2019

The draft meeting minutes from the December 19, 2018, committee meeting have been provided in **Attachment 5**.

Attachment 1

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 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.
(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.

Drug Dispensing During Emergencies

Discussion Points/Considerations for the Board of Pharmacy

Access to medication issues

1. Prescribers were often in short supply at shelters.

2. When prescriptions were written by Cal Mat prescribers, they only had blank prescription forms to use so all information had to be handwritten on the prescription. Some local pharmacies objected to the lack of preprinted info.

3. Although the Board of Pharmacy did repeatedly email everyone on the emergency dispensing statutes, many of the community pharmacists were either unaware, and some treated the emergency dispensing statutes as an option. These actions are based upon fear of Board of Pharmacy violations.

4. Some pharmacies faced corporate & third party payer obstacles to dispensing during the emergency. Such obstacles included inability to authorize early refills, waive copays and not providing sufficient pharmacy staff to service the increased patient load.

5. Most prescribers and pharmacists lack knowledge of the federal Emergency Prescription Assistance Program (EPAP) which was activated during the November 2018 wildfires. EPAP helps people affected by a disaster who do not have health insurance. The program provides free access to prescription drugs, vaccinations, medical supplies, and equipment.

6. Some patients on Medication Assisted Therapy (be it methadone or others) lacked access to their counselors and medications. In some cases retail pharmacy was expected, but was unable to fill the gap.

7. Some prescribers had problems with pharmacies denying electronic prescriptions.

8. Some shelters did not anticipate the need to send a staff member to local pharmacies to drop off and pick up medications. Who is authorized to fill this role? Does this authorization change if controlled substances are involved?

Recommendations

1. Ask the Board of Pharmacy to consider requiring mandatory CE on disaster regulations.

2. During emergencies, waive BPC 4076.5 regarding standardized, patient-centered prescription labels as many of the labels utilized within the shelter were actually handwritten and could not meet all the requirements of this code.

3. Request that pharmacy inspectors be deployed and utilized to give guidance to pharmacists and pharmacies in the impacted areas.

4. Is there a role for expanded use of pharmacists as prescribers in shelter settings?

5. Allow wholesaler delivery to remote unlicensed locations that are extensions of a licensed pharmacy or wholesaler (similar to how mobile pharmacies are allowed based on their connection to a licensed pharmacy).

6. In order to augment the availability of emergency response pharmacy personnel, inquire as to the possibility of allowing pharmacy inspectors to work/volunteer at shelters or remote locations as part of the response (i.e., not as inspectors). Are pharmacy inspectors allowed to participate in the California Disaster Healthcare Volunteer (DHV) system?

7. Encourage corporate pharmacy chains to modify software to allow for the timely processing of prescriptions for emergency dispensing.

8. Request the Board of Pharmacy to clarify emergency dispensing of controlled drugs.

Prescription Form Standards for a Controlled Substance During a Declared Emergency – DRAFT language (2019 1 7)

HEALTH AND SAFETY CODE - HSC

DIVISION 10. UNIFORM CONTROLLED SUBSTANCES ACT [11000 - 11651]

CHAPTER 4. Prescriptions [11150 - 11209]

ARTICLE 1. Requirements of Prescriptions [11150 - 11180]

(Article 1 added by Stats. 1972, Ch. 1407.)

Proposal to add Health and Safety Code Section 11159.25 as follows

(a) Notwithstanding any other provision of law, if the California State Board of Pharmacy issues an notification pursuant to BPC section 4062, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of a declared state or federal emergency, regardless of whether the prescription form meets the requirements of Section 11162.1, if the prescription meets the following requirements:

(1) Contains the information specified in subdivision (a) of Section 11164.

(2) Indicates that the patient is affected by a declared emergency by the words “11159.25 exemption.”

(c) A pharmacist filling such a prescription must review the patient’s activity report from the Prescription Drug Monitoring Program prior to dispensing the medication.

Attachment 2

Title 16. Board of Pharmacy
Proposed DRAFT Regulation

Proposal to amend §17## of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 17##. Self-Assessment of an Automated Drug Delivery System by Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed annually before July 1 of every year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new automated drug delivery system permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system, or

(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form ##X-## (Rev 12/18) entitled "Automated Drug Delivery System Self-Assessment". Form ##X-## shall be used for all automated drug delivery systems and is hereby incorporated by reference.

(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:

(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);

(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;

(C) DEA registration number, expiration date and date of most recent DEA inventory;

(D) Hours of operation of the pharmacy; and

(3) The pharmacist-in-charge shall respond “yes”, “no” or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.

(4) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink on the self-assessment form.

(6) The pharmacist-in-charge shall certify on the last page of the self-assessment that he or she has completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink on the self-assessment form.

(7) The automated drug delivery system owner shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system’s license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment. An automated drug delivery system shall correct any non-compliance as specified in the assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.1, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, and 4333, 4400, 4427, 4427.1, 4427.2 4427.3, 4427.4, and 4427.5 Business and Professions Code.

California State Board of Pharmacy
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www.pharmacy.ca.gov

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

DRAFT AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 17## of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2, California Code of Regulations (CCR) are to Title 16, and 21 Code of Federal Regulations (21CFR) to Title 22 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy Permit: _____
Expiration Date: _____
DEA Registration: _____
DEA Expiration Date: _____
DEA Inventory Date: _____
Last C2 Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____ **Saturday** _____ **Sunday** _____
PIC: _____ **RPH#** _____

ADDS Permit: _____
ADDS Address: _____
City: _____
ADDS Hours: **M-F:**_____**Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. (BPC 4119.11(b) 1), 4017.3 (a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)2), BPC 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)3, BPC 4017.3(b)]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined, that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the conditions are met. "Covered entity" as defined by Section 256(b) of Title 42 of United Sates Code. [BPC 4119.11(a)]

☐☐☐ 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

☐☐☐ 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

☐☐☐ 2.4 Provides pharmacy services through **a clinic** licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

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Yes No N/A

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [(BPC 4187.1, BPC 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office**. [(BPC 4427.3(b)(5), BPC 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in Section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), BPC 4427.4(a)]

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- Use of the ADDS is consistent with legal requirements.
- The proposed location for installation of the ADDS met the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
- The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

☐☐☐ 3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]
List dates of pre-license inspections:

_____
_____
_____

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Yes No N/A

☐☐☐ 3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premise address, at a location approved by the board. [BPC 4427.3(a)]

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS

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located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

Yes No N/A

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under Section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5)

☐☐☐ 3.20 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CHECK OFF THE TYPE OF ADDS USE BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Please Note: The Pharmacist-in-Charge of the pharmacy and the owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.

- ☐ SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5 – ADDS adjacent to the secured pharmacy area and Medical Offices.
- ☐ SECTION 6 – ADDS in a health facility pursuant to HSC 1250
- ☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190
- ☐ SECTION 8 – ADDS operated by a correctional clinic

SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 4.1 Covered Entity May Contract with Pharmacy to Provide Services- The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC Section 4126 to provide those pharmacy services through the use of the APDS. (BPC 4119.11(a)2)

☐☐☐ 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by Health Resources and Services Administration and are available for inspection by Board during normal business hours. (BPC 4126(a))

☐☐☐ 4.3 Drugs purchased and received pursuant to Section 256b of Title 42 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. (BPC 4126(b))

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. (BPC 4126(b))

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. (BPC 4126(c))

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. (BPC 4126(d))

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CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site (BPC 4119.11(a) 1).

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license) (BPC 4119.11(a)1), BPC 4119.11(a)8, BPC 4107

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. (BPC 4119.11(a) 9)

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated (BPC 4119.11(a)9)

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. (BPC 4119.11(a)9 & 11)

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated) (BPC 4119.11(a)10)

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. (BPC 4119.11(d)10). List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

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9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

Yes No N/A

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. (BPC 4119.11(d)11)

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. (BPC 4119.11(i))

Date of Last Self-Assessment: _____

☐☐☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. (BPC 4119.11(j))

☐☐☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. (BPC 4119.11(a)3)

☐☐☐ 4.18 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. (BPC 4119.11(a)5)
- The operation of the APDS. (BPC 4119.11(a)5)
- The maintenance of the APDS. (BPC 4119.11(a)5
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. (BPC 4119.11(a)6)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. (BPC 4119.11(a)7). Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used the stocking of the APDS may be done outside of the facility if the following conditions are met: (BPC 4119.11(g)

☐☐☐ 4.21 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. (BPC 4119.11(g)(1)

☐☐☐ 4.22 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. (BPC 4119.11(g)(2)

☐☐☐ 4.23 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. (BPC 4119.11(g)(3)

☐☐☐ 4.24 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. (BPC 4119.11(h))

Date of Last Inspection: _____

☐☐☐ 4.25 The APDS dispenses medications **directly** to the patient ONLY if all the following are met: (BPC 4119.11(d)1 & 2)

☐☐☐ 4.26 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. (BPC 4119.11(d)4)

☐☐☐ 4.27 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. (BPC 4119.11(d)5)

☐☐☐ 4.28 The pharmacist consulted patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a **Board licensed pharmacist** via telecommunication link that has two-way audio and video capabilities. (BPC 4119.11(d)6)

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Yes No N/A

☐☐☐ 4.29 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the [CCR 1715.65(h)]:

- All controlled substances added to the ADDS/APDS are accounted for:
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.30 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. (BPC 4119.11(e))

☐☐☐ 4.31 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. (BPC 4119.11(f))

☐☐☐ 4.32 Drugs stored in an APDS are a part of the inventory of the operating pharmacy and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. (BPC 4119.11(a)3)

☐☐☐ 4.33 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. (BPC 4119.11(c)1)

☐☐☐ 4.34 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. (BPC 4119.11(c)2)

☐☐☐ 4.35 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: (BPC 4119.11(d)1 & 2)

☐☐☐ 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies shall be reviewed annually:

Date of Last Policy Review: _____

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Yes No N/A

☐☐☐ 4.37 Maintaining the security of the APDS and dangerous drug and devices within the APDS. (BPC 4119.11(d)1)A)

☐☐☐ 4.38 Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients. (BPC 4119.11(d)(1)B)

☐☐☐ 4.39 Ensuring patients are aware that consultation with a pharmacist is available for any Prescription medication including those delivered via APDS. (BPC 4119.11(d)(1)C)

☐☐☐ 4.40 Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS. (BPC 4119.11 (d)(1)D)

☐☐☐ 4.41 Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the SPDS does not interfere with the delivery of drugs and devices. (BPC 4119.11 (d)(1)E)

☐☐☐ 4.42 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions. (BPC 4119.11 (d)(1)F)

☐☐☐ 4.43 Only used for patient who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach copy of consent form. (BPC 4119.11 (d)2)

☐☐☐ 4.44 The device shall a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. (BPC 4119.11 (d)3)

☐☐☐ 4.45 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. (BPC 4119.11 (d)4)

☐☐☐ 4.46 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. (BPC 4119.11 (d)5)

☐☐☐ 4.47 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. (BPC 4119.11 (d)6)

☐☐☐ 4.48 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy (BPC 4119.11 (d)7)

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Yes No N/A

☐☐☐ 4.49 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. (BPC 4119.11 (d)8)

☐☐☐ 4.50 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's Quality Assurance program pursuant to BPC 4125. (BPC 4119.11 (d)9)

☐☐☐ 4.51 The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 4.52 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 4.53 Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 4.54 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 4.55 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 4.56 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. (BPC 4119.11(j))

☐☐☐ 4.57 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. (BPC 4119.11(a)4)

☐☐☐ 4.58 The APDS transaction information will be maintained in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. (BPC 4119.11(c)2

☐☐☐ 4.59 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and

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electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

Yes No N/A

☐☐☐ 4.60 The Records of drugs purchased and received pursuant to Section 256b of Title 42 USC shall be readily retrievable in a form separate from the pharmacy's other records. (BPC 4126(b)

☐☐☐ 4.61 The pharmacy reports drug losses as required by law. (BPC 4105.5(c), CCR 1715.6, 21CFR 1301.76, & BPC 4104)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.62 The APDS will dispense medications directly to the patient if all the following are met: [BPC 4119.11(d)(1)(2)]. The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.63 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. (BPC 4105.5(c))

☐☐☐ 4.64 The pharmacy reports drug losses as required by law. (BPC 4105.5(c), CCR 1715.6, 21CFR 1301.76, & BPC 4104)

Last Reported Drug Loss: _____

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CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA AND IN MEDICAL OFFICES.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS (BPC 4427.6 (l)).

☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS policy and procedures pertaining to the APDS, including: (BPC 4427.6 (a)).

- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
- Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. (BPC 4427.6 (k)). List of current APDS licenses:

1._____2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

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9._____10._____

11. _____ 12._____

13._____14. _____

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CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation (BPC 4427.6 (d)).

☐☐☐ 5.5. Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions (BPC 4427.6 (e)).

☐☐☐ 5.6. A board licensed pharmacist performs consultation via a telecommunication link that has two-way audio and video for all drugs and devices dispensed to a patient from the APDS for the first time (BPC 4427.6(f)).

The Pharmacist-in-Charge of the offsite ADDS/APDS has ensured that (CCR 1715.65(h)):

☐☐☐ 5.7. All controlled substances added to the ADDS/APDS are accounted for;

☐☐☐ 5.8. Access to ADDS/APDS is limited to authorized facility personnel;

☐☐☐ 5.9. An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and

☐☐☐ 5.10. Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 5.11 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist (BPC 4427.4 (e)(1)).

☐☐☐ 5.12. Access to the APDS is controlled and tracked using an identification or password system or biosensor (BPC 4427.4 (e)(2)).

☐☐☐ 5.13. The APDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system (BPC 4427.4(e)(3)).

☐☐☐ 5.14 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages (BPC 4427.4 (f)).

☐☐☐ 5.15 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy (BPC 4427.4 (d)).

☐☐☐ 5.16 The APDS is only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets established inclusion criteria (BPC 4427.6 (b)).

☐☐☐ 5.17 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent (BPC 4427.6(c)).

☐☐☐ 5.18. A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation (BPC 4427.6 (d)).

☐☐☐ 5.19 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions (BPC 4427.6 (e)).

☐☐☐ 5.20. A board licensed pharmacist performs consultation via a telecommunication link that has two-way audio and video for all drugs and devices dispensed to a patient from the APDS for the first time (BPC 4427.6(f)).

☐☐☐ 5.21. The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy (BPC 4427.6 (g)).

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Yes No N/A

☐☐☐ 5.22. Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125 (BPC 4427.6 (i)).

☐☐☐ 5.23. If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice (BPC 4427.6(j)).

☐☐☐ 5.24. The pharmacy has developed and implemented written policies and procedures with respect to the APDS use and the policies shall be reviewed annually (BPC 4427.6 (a)).

Date of Last Policy Review: _____

☐☐☐ 5.25. The labels on all drugs and devices dispensed by the APDS comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations (BPC 4427.6(h)).

☐☐☐ 5.26. The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 5.27. Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 5.28. Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 5.29. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 5.30. Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 5.31. Any incident involving the APDS where a complaint, error, or omission occurs is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125 (BPC 4427.6 (i)).

☐☐☐ 5.32. The pharmacy reports drug losses as required by law. (CCR 1715.6, 21 CFR 1301.76 & BPC 4104)).

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Yes No N/A

☐☐☐ 5.33. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies shall be reviewed annually:

Yes No N/A

☐☐☐ 5.34. Maintaining the security of the APDS and dangerous drug and devices within the APDS (BPC 4427.6 (a)(1)).

☐☐☐ 5.35. Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients (BPC 4427.6 (a)(2)).

☐☐☐ 5.36. Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS (BPC 4427.6 (a)(3)).

☐☐☐ 5.37. Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS (BPC 4427.6 (a)(4)).

☐☐☐ 5.38. Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices (BPC 4427.6 (a)(5)).

☐☐☐ 5.39. Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions (BPC 4427.6 (a)(6)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of Section 1250 that has and ADDS provided by a pharmacy (HSC 1261.6 (a)(2)).

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician (HSC 1261.6 (a)(3)).

Yes No N/A

☐☐☐ 6.1. The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices (BPC 4427.3 (c), HSC 1261.6 (d)(1)).

☐☐☐ 6.2. The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs (HSC 1261.6 (d)(1)).

☐☐☐ 6.3. All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used (HSC 1261.6 (d)(2), (BPC 4427.3 (c)).

☐☐☐ 6.4. The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS (HSC 1261.6 (h)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: (HSC 1261.6 (g).

☐☐☐ 6.6. The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist (HSC 1261.6 (g)(1)).

Yes No N/A

☐☐☐ 6.7. The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container (HSC 1261.6 (g)(2)).

☐☐☐ 6.8. The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS (HSC 1261.6 (g)(3)).

☐☐☐ 6.9. Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs (BPC 1261.6 (c)).

☐☐☐ 6.10. A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions (HSC 1261.6 (f)(2)).

☐☐☐ 6.11 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system (HSC 1261.6 (h)).

The Pharmacist-in-Charge of the offsite ADDS/APDS has ensured that (CCR 1715.65(h)):

☐☐☐ 6.12. All controlled substances added to the ADDS/APDS are accounted for:

☐☐☐ 6.13. Access to ADDS/APDS is limited to authorized facility personnel;

☐☐☐ 6.14. An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and

☐☐☐ 6.15. Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.16 The stocking and restocking of the ADDS is performed in compliance with Section 1261.6 of the Health and Safety Code (BPC 4427.4 (e)(1)).

☐☐☐ 6.17 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used,

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the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: (HSC 1261.6 (g)).

Yes No N/A

☐☐☐ 6.18 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist (HSC 1261.6 (g)(1)).

☐☐☐ 6.19 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container (HSC 1261.6 (g)(2)).

☐☐☐ 6.20. The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS (HSC 1261.6 (g)(3)).

☐☐☐ 6.21 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs (BPC 1261.6 (c)).

☐☐☐ 6.22. Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages (BPC 4427.4 (f)).

☐☐☐ 6.23 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years (HSC 1261.6 (b).

☐☐☐ 6.24. Information required by BPC Section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards (HSC 1261.6 (i)).

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following (HSC 1261.6 (e)):

Yes No N/A

☐☐☐ 6.25. A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions (HSC 1261.6 (e)(1)).

☐☐☐ 6.26. Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist (HSC 1261.6 (e)(2)).

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Yes No N/A

☐☐☐ 6.27. Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours (HSC 1261.6 (e)(3).

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements (HSC 1261.6 (f)):

Yes No N/A

☐☐☐ 6.28. Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages (HSC 1261.6 (f)(1)).

☐☐☐ 6.29. A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions (HSC 1261.6 (f)(2)).

☐☐☐ 6.30. The pharmacy controls access to the drugs stored in the ADDS (HSC 1261.6 (f)(3)).

☐☐☐ 6.31. Access to the ADDS is controlled and tracked using an identification or password system or biosensor (BPC 4427.4 (e)(2), (HSC 1261.6 (f)(4)).

☐☐☐ 6.32. The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system (BPC 4427.4(e)(3), (HSC 1261.6 (f)(5)).

☐☐☐ 6.33. After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient (HSC 1261.6 (f)(6)).

☐☐☐ 6.34. When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration (HSC 1261.6 (f)(6)).

☐☐☐ 6.35. If the ADDS system allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS system has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 6.36 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records (BPC 4427.7 (b)).

☐☐☐ 6.37 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years (HSC 1261.6 (b).

☐☐☐ 6.38 The pharmacy reports drug losses as required by law. (CCR 1715.6, 21 CFR 1301.76 & BPC 4104)).

☐☐☐ 6.39 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.40. The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices (BPC 4427.3 (c), HSC 1261.6 (d)(1)).

☐☐☐ 6.41 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs (HSC 1261.6 (d)(1)).

☐☐☐ 6.42. All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used (HSC 1261.6 (d)(2), (BPC 4427.3 (c)).

☐☐☐ 6.43. The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS (HSC 1261.6 (g)(3)).

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Yes No N/A

☐☐☐ 6.44. The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. (BPC 4427.2 (d)(3)).

☐☐☐ 6.45. The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. (BPC 4427.2 (d)(4), CCR 1715.6, 21CFR 1301.76, & BPC 4104)

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premise address, at a location approved by the Board (BPC 4427.3 (a)). The clinic has a current Board of Pharmacy Clinic permit pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1: (BPC 4427.3(b)3)

Permit number: _____Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. (BPC 4186(a))

☐☐☐ 7.3 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to this division. (BPC 4186(b))

☐☐☐ 7.4 The clinic has developed and implemented written policies and procedures that ensure the maintenance of the quality, potency and purity of the drugs. (BPC 4186(a)) **These policies shall be maintained at the location where the ADDS is being used. (BPC 4186(a))**

☐☐☐ 7.5 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to this division. (BPC 4186(b))

☐☐☐ 7.6 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. (BPC 4186 (d))

Yes No N/A

☐☐☐ 7.7 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), BPC 4426.7(h)]

☐☐☐ 7.8 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. (BPC 4180(2))

☐☐☐ 7.9 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals (BPC 4427.2(d)2)

☐☐☐ 7.10 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65(a))

☐☐☐ 7.11 The clinic shall compile an inventory reconciliation report of all **federal Schedule ll controlled substance** at least every three months. (CCR 1715.65(c)) The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule ll controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule ll controlled substances** since that last inventory reconciliation report: Date of last inventory_____
- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

☐☐☐ 7.12 The clinic shall report in writing identified losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances (CCR 1715.65(d))

☐☐☐ 7.13 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. (CCR 1715.65(e))

☐☐☐ 7.14 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i)]

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Yes No N/A

☐☐☐ 7.15 The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐☐☐ 7.16 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717)

☐☐☐ 7.17 Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐☐☐ 7.18 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 7.19 Medication guides are provided on required medications. (21 CFR 208.1)

☐☐☐ 7.20 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.21 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.22 The pharmacist performs the stocking of the ADDS. (BPC 4186(c))

☐☐☐ 7.23 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. (BPC 4186(b)).

☐☐☐ 7.24 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. (BPC 4186(d))

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☐☐☐ 7.25 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

Yes No N/A

☐☐☐ 7.26 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 7.27 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.28 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.69g)]

☐☐☐ 7.29 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. (BPC 4186(e))

☐☐☐ 7.30 The pharmacist operating the ADDS shall be located in California (BPC 4186(f)).

☐☐☐ 7.31 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to

subdivision (b) of Section 4427.3, regarding maintenance and filing procedures for the APDS.

- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

☐☐☐ 7.33 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]

☐☐☐ 7.34 Does the APDS have a means of identifying each patient and only releases the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c)]

☐☐☐ 7.35 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]

☐☐☐ 7.36 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred in subdivision (b) of Section 1206 of the Health and Safety Conde, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

☐☐☐ 8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from

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another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: (BPC 4187.1(a)

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

Yes No N/A

☐☐☐ 8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.5 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.6 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of Section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 8.7 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. [BPC 4187.1(c)]

☐☐☐ 8.8 The records are available and maintained for a minimum of three years for inspection by all properly authorized personnel. {BPC 4187.1(c)]

☐☐☐ 8.9 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 8.10 A separate license was obtained for each correctional clinic location where a APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 8.11 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 8.12 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

☐☐☐ 8.13 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

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CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 8.14 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 8.15 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

☐☐☐ 8.16 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 8.17 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 8.18 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 8.19 Schedule II, III, IV or V controlled substances administered by a health care staff of the licensed correctional clinic is lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. (BPC 4187.3)

☐☐☐ 8.20 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 8.21 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

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CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 8.22 A correctional facility pharmacist inspects the clinic at least quarterly. {BPC 4187.2(c)]

☐☐☐ 8.23 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

☐☐☐ 8.24The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 8.25 Drugs removed from the automated drug delivery system is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 8.26 The review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

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Yes No N/A

☐☐☐ 8.27 The automated drug delivery system is operated by a licensed correctional pharmacy. Any drugs within the automated drug delivery system are considered owned by the licensed correctional pharmacy until they are dispensed from the automated drug delivery system. [BPC 4187.5(f)]

☐☐☐ 8.28 Drugs from the automated drug delivery system in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

☐☐☐ 8.29 Drugs from the automated drug delivery system in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 8.30 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

☐☐☐ 8.31All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

I, (please print)_____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

Attachment 3

DRAFT Policy Statement

California law declares pharmacist health care providers who have authority and ability to provide health care services. Today pharmacists have six to eight years of collegiate education with focused experience in performing medication management. Increasingly this also includes additional residency experience.

Under California law for a number of years and in conjunction with collaborative practice agreements with prescribers, pharmacists have the ability to:

1. Design treatment plans
2. Initiate adjust and discontinue medications
3. Monitor patient progress
4. Order and review necessary laboratory tests
5. Coordinate care with other medical providers
6. Serve as expert consultants to support prescribers in making medication decisions for patients.

This skill set serves a dual purpose of positioning pharmacists so they may provide direct care to patients with opioid addiction and assist other medical providers in caring for this population, thereby expanding access to treatment. In recognition of these factors, the California State Board of Pharmacy advocates for changes in the law that will permit pharmacists to provide medication assisted treatment as part of a collaborative health care team.

Attachment 4

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

APPLICATIONS

Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	31	29	37	29	41	23							190
Designated Representatives Vet (EXV)	0	3	0	0	1	0							4
Designated Representatives-3PL (DRL)	4	5	1	8	10	13							41
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	0							0
Designated Paramedic (DPM)	0	0	0	0	0	0							0
Intern Pharmacist (INT)	152	1038	210	177	51	53							1681
*Pharmacist (exam applications)	193	171	186	195	114	176							1035
Pharmacist (initial licensing applications)	34	179	764	368	49	207							1601
Advanced Practice Pharmacist (APH)	25	20	12	21	28	26							132
Pharmacy Technician (TCH)	504	522	413	479	381	340							2639
	* total includes retake exam applications												
Centralized Hospital Packaging (CHP)	0	0	1	0	0	0							1
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0	0							0
Clinics (CLN)	120	6	10	10	3	19							168
Clinics Exempt (CLE)	0	14	0	26	14	0							54
Drug Room (DRM)	0	0	0	0	0	0							0
Drug Room -Temp	0	0	0	0	0	0							0
Drug Room Exempt (DRE)	0	0	0	0	0	0							0
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0							0
Hospitals (HSP)	3	2	0	2	27	4							38
Hospitals - Temp	0	0	1	2	27	4							34
Hospitals Exempt (HPE)	0	1	0	0	0	2							3
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	1	0							1
Hospital Satellite Sterile Compounding - Temp	0	0	0	0	1	0							1
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes (HYP)	2	2	2	1	1	1							9
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0							0
Correctional Pharmacy (LCF)	0	0	0	0	0	1							1
Outsourcing Facility (OSF)	0	1	0	0	0	0							1
Outsourcing Facility - Temp	0	0	0	0	0	0							0
Outsourcing Facility Nonresident (NSF)	0	1	0	1	0	0							2
Outsourcing Facility Nonresident - Temp	0	0	0	0	0	0							0
Pharmacy (PHY)	36	27	54	33	44	37							231
Pharmacy - Temp	583	10	37	20	23	17							690
Pharmacy Exempt (PHE)	0	1	0	0	0	1							2
Pharmacy Nonresident (NRP)	8	15	35	10	10	10							88
Pharmacy Nonresident Temp	3	16	32	0	5	5							61
Sterile Compounding (LSC)	10	5	4	8	44	11							82
Sterile Compounding - Temp	4	0	1	7	37	10							59
Sterile Compounding Exempt (LSE)	0	0	2	0	0	4							6
Sterile Compounding Nonresident (NSC)	2	1	3	0	1	3							10
Sterile Compounding Nonresident Temp	1	0	3	0	1	2							7
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0							0
Third-Party Logistics Providers (TPL)	3	0	0	0	0	0							3
Third-Party Logistics Providers - Temp	3	0	0	0	0	0							3
Third-Party Logistics Providers Nonresident (NPL)	1	0	0	0	2	1							4
Third-Party Logistics Providers Nonresident Temp	1	0	0	0	0	0							1
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	0	0	0							3
Veterinary Food-Animal Drug Retailer - Temp	0	1	0	0	0	0							1
Wholesalers (WLS)	8	4	7	7	2	1							29
Wholesalers - Temp	1	3	4	6	0	1							15
Wholesalers Exempt (WLE)	0	0	0	0	0	0							0
Wholesalers Nonresident (OSD)	5	11	8	5	4	13							46
Wholesalers Nonresident - Temp	4	2	3	3	0	3							15
Total	1742	2091	1831	1418	922	988	0	0	0	0	0	0	8992

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

APPLICATIONS (continued)

Issued	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	44	18	9	16	23	18							128
Designated Representatives Vet (EXV)	0	0	0	1	0	0							1
Designated Representatives-3PL (DRL)	8	6	2	3	2	0							21
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	0							0
Designated Paramedic (DPM)	0	0	0	0	0	0							0
Intern Pharmacist (INT)	75	623	399	337	117	49							1600
Pharmacist (initial licensing applications)	42	183	670	405	85	170							1555
Advanced Practice Pharmacist (APH)	21	17	17	22	28	6							111
Pharmacy Technician (TCH)	506	570	200	722	393	383							2774
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0							0
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0	0							0
Clinics (CLN)	2	7	2	17	12	4							44
Clinics Exempt (CLE)	0	0	0	14	1	1							16
Drug Room (DRM)	0	0	0	0	0	0							0
Drug Room-Temp	0	0	0	0	0	0							0
Drug Room Exempt (DRE)	0	1	0	0	0	0							1
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0							0
Hospitals (HSP)	1	0	0	0	0	0							1
Hospitals - Temp	1	1	0	2	0	1							5
Hospitals Exempt (HPE)	0	0	0	1	0	0							1
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	2	0							2
Hospital Satellite Sterile Compounding - Temp	0	0	0	0	0	0							0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes (HYP)	0	8	1	1	0	1							11
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0							0
Correctional Pharmacy (LCF)	0	0	0	0	0	0							0
Outsourcing Facility (OSF)	0	0	0	0	3	0							3
Outsourcing Facility - Temp	0	0	0	0	0	0							0
Outsourcing Facility Nonresident (NSF)	1	1	0	1	0	0							3
Outsourcing Facility Nonresident - Temp	0	0	0	0	0	0							0
Pharmacy (PHY)	8	5	14	16	13	11							67
Pharmacy - Temp	6	11	12	31	14	11							85
Pharmacy Exempt (PHE)	0	0	0	0	0	0							0
Pharmacy Nonresident (NRP)	1	0	3	2	0	7							13
Pharmacy Nonresident Temp	3	3	4	5	3	36							54
Sterile Compounding (LSC)	4	3	0	5	3	1							16
Sterile Compounding - Temp	0	3	0	1	0	4							8
Sterile Compounding Exempt (LSE)	0	0	0	0	3	0							3
Sterile Compounding Nonresident (NSC)	1	0	0	2	0	1							4
Sterile Compounding Nonresident Temp	1	1	0	0	0	5							7
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0							0
Third-Party Logistics Providers (TPL)	0	0	0	0	2	0							2
Third-Party Logistics Providers-Temp	0	2	0	0	0	0							2
Third-Party Logistics Providers Nonresident (NPL)	0	1	1	1	0	2							5
Third-Party Logistics Providers Nonresident Temp	0	1	1	1	0	0							3
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0							0
Veterinary Food-Animal Drug Retailer - Temp	0	0	1	0	0	0							1
Wholesalers (WLS)	0	5	1	0	4	3							13
Wholesalers - Temp	2	3	4	2	1	0							12
Wholesalers Exempt (WLE)	0	0	0	0	0	0							0
Wholesalers Nonresident (OSD)	2	2	3	10	0	4							21
Wholesalers Nonresident - Temp	5	2	2	4	0	2							15
Total	734	1477	1346	1622	709	720	0	0	0	0	0	0	6608

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

APPLICATIONS (continued)

Pending	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
Designated Representatives (EXC)	293	298	321	333	346	346						
Designated Representatives Vet (EXV)	0	3	3	2	3	3						
Designated Representatives-3PL (DRL)	93	91	89	92	100	110						
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	1						
Designated Paramedic (DPM)	0	0	0	0	0	0						
Intern Pharmacist (INT)	296	420	498	308	237	227						
Pharmacist (exam applications)	1122	1034	1085	957	932	921						
Pharmacist (eligible exam(Status A))	2698	2654	1957	1498	1470	1294						
Advanced Practice Pharmacist (APH)	178	177	175	174	173	191						
Pharmacy Technician (TCH)	1150	1095	1287	1046	1002	934						
Centralized Hospital Packaging (CHP)	2	2	3	3	3	2						
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0	0						
Clinics (CLN)	188	194	203	196	183	196						
Clinics Exempt (CLE)	8	22	22	33	46	46						
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0						
Drug Room (DRM)	0	0	0	0	0	1						
Drug Room Exempt (DRE)	1	0	0	0	0	0						
Hospitals (HSP)	10	7	8	6	33	36						
Hospitals Exempt (HPE)	0	1	1	0	0	2						
Hospital Satellite Sterile Compounding (SCP)	5	6	5	3	3	3						
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0						
Hypodermic Needle and Syringes (HYP)	25	19	20	20	21	23						
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0						
Correctional Pharmacy (LCF)	1	1	1	1	1	2						
Outsourcing Facility (OSF)	3	4	4	4	3	2						
Outsourcing Facility Nonresident (NSF)	11	11	10	9	8	8						
Pharmacy (PHY)	713	152	178	161	174	184						
Pharmacy Exempt (PHE)	3	4	4	4	4	5						
Pharmacy Nonresident (NRP)	95	106	134	136	142	107						
Sterile Compounding (LSC)	77	64	64	65	106	113						
Sterile Compounding - Exempt (LSE)	7	6	8	8	5	9						
Sterile Compounding Nonresident (NSC)	21	21	23	20	20	18						
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0						
Third-Party Logistics Providers (TPL)	12	9	7	7	5	5						
Third-Party Logistics Providers Nonresident (NPL)	50	48	46	45	46	44						
Veterinary Food-Animal Drug Retailer (VET)	1	1	2	2	2	2						
Wholesalers (WLS)	51	44	46	50	45	42						
Wholesalers Exempt (WLE)	1	1	1	1	1	1						
Wholesalers Nonresident (OSD)	113	120	122	106	110	117						
Total	7228	6615	6327	5290	5224	4995	0	0	0	0	0	0

The number of temporary applications are included in the primary license type.

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

APPLICATIONS (continued)

Withdrawn	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	21	4	1	2	2	1							31
Designated Representatives Vet (EXV)	1	0	0	0	0	0							1
Designated Representatives-3PL (DRL)	3	0	1	2	0	0							6
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	0							0
Designated Paramedic (DPM)	0	0	0	0	0	0							0
Intern Pharmacist (INT)	0	1	0	9	1	0							11
Pharmacist (exam applications)	2	0	1	2	2	0							7
Advanced Practice Pharmacist (APH)	0	0	0	0	0	0							0
Pharmacy Technician (TCH)	1	6	5	5	18	6							41
Centralized Hospital Packaging (CHP)	0	0	0	0	0	1							1
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0	0							0
Clinics (CLN)	1	1	0	0	4	1							7
Clinics Exempt (CLE)	0	0	0	0	0	0							0
Drug Room (DRM)	0	0	0	0	0	0							0
Drug Room Exempt (DRE)	0	0	0	0	0	0							0
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0							0
Hospitals (HSP)	0	0	0	0	0	0							0
Hospitals Exempt (HPE)	0	0	0	0	0	0							0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0	0							0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes (HYP)	1	0	0	0	0	0							1
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0							0
Correctional Pharmacy (LCF)	0	0	0	0	0	0							0
Outsourcing Facility (OSF)	0	0	0	0	0	0							0
Outsourcing Facility Nonresident (NSF)	0	1	0	0	1	0							2
Pharmacy (PHY)	1	566	3	2	2	4							578
Pharmacy Exempt (PHE)	0	0	0	0	0	0							0
Pharmacy Nonresident (NRP)	0	1	0	0	2	1							4
Sterile Compounding (LSC)	0	1	0	1	1	0							3
Sterile Compounding Exempt (LSE)	0	1	0	0	0	0							1
Sterile Compounding Nonresident (NSC)	1	0	0	0	1	0							2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0							0
Third-Party Logistics Providers (TPL)	0	1	2	0	0	0							3
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	1	0	0							1
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0							0
Wholesalers (WLS)	0	0	0	0	1	1							2
Wholesalers Exempt (WLE)	0	0	0	0	0	0							0
Wholesalers Nonresident (OSD)	2	0	1	5	1	0							9
Total	34	583	14	29	36	15	0	0	0	0	0	0	711

FY 18/19 There were 564 Pharmacy applications withdrawn as a result of a large chain purchase being cancelled. The number of temporary applications withdrawn is reflected in the primary license type.

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

APPLICATIONS (continued)

Denied	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	0	0	0	0	0	0							0
Designated Representatives Vet (EXV)	0	0	0	0	0	0							0
Designated Representatives-3PL (DRL)	0	0	0	0	0	0							0
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	0							0
Designated Paramedic (DPM)	0	0	0	0	0	0							0
Intern Pharmacist (INT)	0	1	1	0	0	3							5
Pharmacist (exam applications)	0	0	0	0	3	1							4
Pharmacist (eligible)	0	0	1	0	0	0							1
Advanced Practice Pharmacist (APH)	0	0	0	0	0	0							0
Pharmacy Technician (TCH)	3	3	1	4	4	5							20
Centralized Hospital Packaging (CHP)	0	0	0	0	0	0							0
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0	0							0
Clinics (CLN)	1	0	0	0	0	0							1
Clinics Exempt (CLE)	0	0	0	0	0	0							0
Drug Room (DRM)	0	0	0	0	0	0							0
Drug Room Exempt (DRE)	0	0	0	0	0	0							0
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0							0
Hospitals (HSP)	0	0	0	0	0	0							0
Hospitals Exempt (HPE)	0	0	0	0	0	0							0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0	0							0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0							0
Correctional Pharmacy (LCF)	0	0	0	0	0	0							0
Outsourcing Facility (OSF)	0	0	0	0	0	0							0
Outsourcing Facility Nonresident (NSF)	0	0	1	0	0	0							1
Pharmacy (PHY)	0	2	0	0	1	0							3
Pharmacy Exempt (PHE)	0	0	0	0	0	0							0
Pharmacy Nonresident (NRP)	0	0	0	0	0	0							0
Sterile Compounding (LSC)	0	0	0	0	0	0							0
Sterile Compounding Exempt (LSE)	0	0	0	0	0	0							0
Sterile Compounding Nonresident (NSC)	0	0	0	0	0	0							0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0	0							0
Third-Party Logistics Providers (TPL)	0	0	0	0	0	0							0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0	0							0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0	0							0
Wholesalers (WLS)	0	0	0	0	1	0							1
Wholesalers Exempt (WLE)	0	0	0	0	0	0							0
Wholesalers Nonresident (OSD)	1	0	0	1	0	0							2
Total	5	6	4	5	9	9	0	0	0	0	0	0	38

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

RESPOND TO STATUS REQUESTS

A. **Email Inquiries**	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representative Received	867	637	104	133	129	209							2079
Designated Representative Responded	984	215	0	0	1	8							1208
Pharmacist/Intern Received	314	158	767	656	431	398							2724
Pharmacist/Intern Responded	49	44	158	200	74	148							673
Pharmacy Technician Received	421	466	355	405	342	368							2357
Pharmacy Technician Responded	454	294	322	355	286	427							2138
Pharmacy Received	510	537	491	662	483	456							3139
Pharmacy Responded	519	560	475	735	529	491							3309
Sterile Compounding/Outsourcing Received	514	638	354	354	344	402							2606
Sterile Compounding/Outsourcing Responded	205	398	275	354	258	259							1749
Wholesale/Clinic/Hypodermic/3PL Received	321	319	253	367	282	123							1665
Wholesale/Clinic/Hypodermic/3PL Responded	256	289	272	431	139	124							1511
Pharmacist-in-Charge Received	142	180	161	227	105	235							1050
Pharmacist-in-Charge Responded	99	133	155	205	20	132							744
Change of Permit Received	343	530	890	569	482	373							3187
Change of Permit Responded	352	424	395	319	331	213							2034
Renewals Received	516	580	544	519	476	538							3173
Renewals Responded	418	466	439	447	348	407							2525

B. **Telephone Calls Received**	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Represenative	5	2	9	11	0	2							29
Pharmacist/Intern	7	6	8	19	3	18							61
Pharmacy	90	66	45	116	57	100							474
Sterile Compounding/Outsourcing	13	12	15	23	32	23							118
Wholesale/Clinic/Hypodermic/3PL *	44	38	36	24	0	0							142
Pharmacist-in-Charge	4	78	34	74	4	52							246
Change of Permit	88	38	82	103	56	60							427
Renewals	602	641	548	548	473	493							3305

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

UPDATE LICENSING RECORDS

A. Change of Pharmacist-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	198	188	184	240	175	171							1156
Processed	124	375	251	285	12	131							1178
Approved	122	347	235	276	50	87							1117
Pending	515	337	275	241	366	449							449

B. Change of Desig. Representative-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	14	7	11	11	8	12							63
Processed	4	29	14	8	0	22							77
Approved	3	21	14	10	1	13							62
Pending	60	46	44	44	51	52							52

C. Change of Responsible Manager	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	2	0	0	2	3	1							8
Processed	3	5	0	1	0	5							14
Approved	3	9	0	1	0	1							14
Pending	11	2	2	3	6	6							6

D. Change of Permits	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	118	100	152	153	170	85							778
Processed	107	148	233	0	67	3							558
Approved	103	182	170	34	13	3							505
Pending	953	873	866	986	1142	1230							1230

E. Automated Drug Delivery Systems	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	61	36	68	23	7	4							199
Processed	0	0	0	0	0	0							0
Approved	0	0	0	0	0	0							0
Pending	94	134	202	191	198	202							202

F. Clinic Co-Location	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	0	0	0	0	0	0							0
Processed	0	1	0	0	0	0							1
Approved	0	1	0	0	0	0							1
Pending	1	0	0	0	0	0							0

G. Discontinuance of Business	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	37	47	51	39	38	38							250
Processed	72	20	98	24	0	24							238
Approved	42	30	64	29	0	42							207
Pending	179	198	181	191	229	225							225

H. Requests Approved	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Address/Name Changes	1127	1310	1393	1048	836	845							6559
Off-site Storage	26	0	27	12	3	9							77
Transfer of Intern Hours	4	2	1	4	0	9							20
License Verification	187	223	141	338	182	274							1345

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

Licenses Renewed

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	217	245	178	219	191	197							1,247
Designated Representatives Vet (EXV)	9	4	5	2	3	1							24
Designated Representatives-3PL (DRL)	15	27	31	16	13	23							125
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	0							0
Designated Paramedic (DPM)	0	0	0	0	0	0							0
Pharmacist (RPH)	1534	2091	1743	1910	1466	1671							10,415
Advanced Practice Pharmacist (APH)	9	14	18	18	15	11							85
Pharmacy Technician (TCH)	2442	3102	2392	3094	2220	2437							15,687
Centralized Hospital Packaging (CHP)	3	0	0	1	0	0							4
Centralized Hospital Packaging Exempt (CHE)	1	0	0	0	0	0							1
Clinics (CLN)	73	87	64	108	55	63							450
Clinics Exempt (CLE)	2	0	69	124	13	7							215
Drug Room (DRM)	2	0	2	3	1	2							10
Drug Room Exempt (DRE)	0	0	5	4	0	0							9
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0							0
Hospitals (HSP)	16	18	43	52	22	25							176
Hospitals Exempt (HPE)	16	2	31	4	3	1							57
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0	0							0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes (HYP)	12	22	19	27	21	17							118
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0							0
Correctional Pharmacy (LCF)	0	1	33	18	2	0							54
Outsourcing Facility (OSF)	1	3	1	0	0	0							5
Outsourcing Facility Nonresident (NSF)	0	0	0	1	2	1							4
Pharmacy (PHY)	232	377	712	1031	560	293							3,205
Pharmacy Exempt (PHE)	3	0	71	29	3	0							106
Pharmacy Nonresident (NRP)	24	35	23	42	38	41							203
Sterile Compounding (LSC)	55	42	42	140	51	39							369
Sterile Compounding Exempt (LSE)	28	8	24	0	0	2							62
Sterile Compounding Nonresident (NSC)	4	1	2	7	4	5							23
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	1	0							1
Third-Party Logistics Providers (TPL)	1	1	3	2	0	0							7
Third-Party Logistics Providers Nonresident (NPL)	1	0	8	3	9	3							24
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	3	1	2							9
Wholesalers (WLS)	22	63	25	36	20	30							196
Wholesalers Exempt (WLE)	0	0	6	3	0	0							9
Wholesalers Nonresident (OSD)	54	51	57	43	45	43							293
Total	4777	6195	5608	6940	4759	4914	0	0	0	0	0	0	33193

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

Current Licensees

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	3017	2997	2919	3025	3043	3060							3060
Designated Representatives Vet (EXV)	68	67	69	68	68	68							68
Designated Representatives-3PL (DRL)	291	291	295	298	298	298							298
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0	0							0
Designated Paramedic (DPM)	0	0	0	0	0	0							0
Intern Pharmacist (INT)	6854	7248	7104	7028	7061	7005							7005
Pharmacist (RPH)	45967	46049	46741	46978	46989	47053							47053
Advanced Practice Pharmacist (APH)	355	372	389	415	439	456							456
Pharmacy Technician (TCH)	71473	71432	71316	71401	71267	71138							71138
Centralized Hospital Packaging (CHP)	8	8	8	8	8	8							8
Centralized Hospital Packaging Exempt (CHE)	2	2	2	2	2	2							2
Clinics (CLN)	1108	1114	1105	1119	1125	1125							1125
Clinics Exempt (CLE)	242	241	241	254	255	254							254
Drug Room (DRM)	23	23	23	23	23	22							22
Drug Room Exempt (DRE)	9	10	10	10	10	10							10
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0	0							0
Hospitals (HSP)	385	383	383	385	385	386							386
Hospitals Exempt (HPE)	84	84	85	85	85	84							84
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	2	2							2
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0	0							0
Hypodermic Needle and Syringes (HYP)	293	301	300	299	299	296							296
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0	0							0
Correctional Pharmacy (LCF)	58	58	58	57	57	57							57
Outsourcing Facility (OSF)	2	2	2	3	5	5							5
Outsourcing Facility Nonresident (NSF)	19	20	21	21	21	21							21
Pharmacy (PHY)	6500	6488	6476	6446	6450	6437							6437
Pharmacy Exempt (PHE)	126	126	126	126	126	126							126
Pharmacy Nonresident (NRP)	546	544	538	539	542	545							545
Sterile Compounding (LSC)	755	759	755	756	756	754							754
Sterile Compounding Exempt (LSE)	117	116	113	113	116	115							115
Sterile Compounding Nonresident (NSC)	76	76	74	76	75	73							73
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1	1	1	1							1
Third-Party Logistics Providers (TPL)	23	23	23	23	24	24							24
Third-Party Logistics Providers Nonresident (NPL)	65	64	66	66	66	68							68
Veterinary Food-Animal Drug Retailer (VET)	20	20	21	21	21	21							21
Wholesalers (WLS)	538	538	534	533	537	533							533
Wholesalers Exempt (WLE)	16	16	16	16	16	15							15
Wholesalers Nonresident (OSD)	750	748	744	756	756	758							758
Total	139791	140221	140558	140951	140928	140820	0	0	0	0	0	0	140820

Attachment 5

California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Governor Edmund G. Brown Jr.

LICENSING COMMITTEE
DRAFT MEETING MINUTES

DATE: December 19, 2018

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS PRESENT: Deborah Veale, Licensee Member, Chair
Stanley Weisser, Licensee Member, Vice Chair
Albert Wong, Licensee Member
Lavanza Butler, Licensee Member
Allen Schaad, Licensee Member

BOARD MEMBERS NOT PRESENT: Amjad Khan, Public Member

STAFF PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Staff Counsel
Kelsey Pruden, DCA Staff Counsel
Debi Mitchell, Senior Licensing Manager

1. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Veale called the meeting to order at 10:05 a.m.

Committee members present: Albert Wong, Stanley Weisser, Deborah Veale, Lavanza Butler, and Allen Schaad.

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

Steve Grey, pharmacist, requested information regarding the new designated paramedic license accessing drugs.

Chairperson Veale responded the Licensing Committee will add to the next agenda information and discussion regarding the new legislation that was enacted last year to allows pharmacies,

manufactures, and wholesalers to sell naloxone to first responders.

3. <u>Presentation by the California Department of Public Health Regarding Provisions for Pharmacy Services During a Declared State of Emergency and Possible Next Steps</u>

Chairperson Veale provided Business and Professions Code (BPC) 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 explained that BPC 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 in recent years the number of declared state of emergencies in California has 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 (CDPH) on the provision of pharmacy services during a declared state of emergency.

Chairperson Veale explained 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 Department of Healthcare Services (DHCS) solved this.

2. A pharmacy in an evacuation area that had not been destroyed was being watched for possible drug theft opportunities.
3. Early on in the emergency, patients could not get their medications because they had no money to cover copays.

Tom Ahrens, a pharmacist contracted to CDPH and currently working for UC Davis, and Mark Chew, a pharmacist with Orange County Emergency Services and also one of the respondents from the California Medical Assistance Team, provided a presentation on the emergency response to the Camp and Woolsey Fires.

Dr. Ahrens stated the 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. The committee was advised about the different entities that may establish shelters (e.g., The Red Cross, Salvation Army, local government, and religious organizations). However, the presenters stated that problems exist in some shelters where medical care is not included (more commonly community shelters). The presenters clarified different problems exist in the different types of shelters.

The presenters explained some shelters provided medical care with some over-the-counter medications and limited prescriptions being provided to evacuees. In other cases, patients receive a written prescription and then need 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 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.

Vice Chairperson 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 continuing education (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 volunteered to provide information on performing eligibility checks to be included 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 commented 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 communications 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 valid throughout the state and 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 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 issues related to prescribing controlled substances during the recent declared state of emergency.

M/S: Weisser/Butler

Support: 5 Oppose: 0 Abstain: 0

4. Discussion and Consideration of Inspections of Sterile Compounding Pharmacies Required as a Result of Remodeling of the Facility

Chairperson Veale reported this item was referred to the Licensing Committee from the October 2018 Board Meeting based on the recommendation from the Enforcement Committee for the committee to discuss whether the board should require the facility to pay for inspection of a remodeled sterile compounding pharmacy.

Chairperson Veale explained the board shall not issue or renew a sterile compounding license until the location has been inspected by the board and found in compliance with pharmacy law. The facility is assessed a fee for the issuance or renewal of a sterile compounding license.

Chairperson Veale reported that the board conducts inspections of sterile compounding pharmacies after a remodel has been completed, regardless if the remodel coincides with the renewal of the pharmacy. While there is no requirement in pharmacy law for the board to conduct an inspection of the sterile compounding pharmacy after a remodel, the board is mandated by law to ensure that sterile compounding pharmacies are in compliance with pharmacy law, and as such a remodel inspection is conducted to confirm compliance. Such reinspection is necessary to reassess the compounding conditions and compliance with pharmacy law and to ensure that changes do not pose a safety threat to consumers. This process is similar to CETA guidelines that establish recertification of equipment when changes are made to certain types of equipment used. Under current law, however, the board does not have the authority to assess a fee for such an inspection. The board must immediately respond to perform such remodel inspections because a delay could impact patient care.

Since July 1, 2015, the board has completed approximately 65 sterile compounding remodel inspections. This number is expected to increase as sterile compounding pharmacies remodel for compliance with the new USP chapters.

The scope of a remodel ranges from simple projects to a full remodel or an expansion. There are several reasons that a remodel may trigger an inspection such as:

- unforeseen damage (e.g., flood, fire);
- planned upgrades (e.g., replacement of a PEC, addition of a PEC, repairing walls, floors, ceilings); and
- expansion of a facility.

Currently when board staff is notified of a pending remodel to a sterile compounding pharmacy, the board attempts to conduct an inspection as soon as possible after receiving the notification. Most remodel inspection requests are planned projects that the facility is aware of months in advance. Travel costs and inspector time for remodel inspections are currently being absorbed by the board.

The committee discussed establishing parameters for sterile compounding facilities to notify the board when a remodel is planned.

Chairperson Veale supports inspecting a sterile compounding pharmacy after a remodel to confirm the facility is in compliance with pharmacy law and to establish parameters in law on when to assess the inspection fee. She further stated the board is mandated to ensure sterile compounding pharmacies are in compliance with pharmacy law and as such it is expected the board confirms compliance if the remodel falls outside the required inspection to renew the license. Additionally, conducting an inspection is costly to the board and when an inspection occurs outside the parameters of the renewal and there is not a fee assessed this could continue to impact the board's budget.

Vice Chairperson Stanley Weisser strongly supports leveraging the renewal inspection for the sterile compounding pharmacy not to incur additional costs.

Dr. Wong stated the sterile compounding pharmacies already know their facility will be inspected at the time of renewal. He recommended the facilities plan their remodel to align with the renewal in order to prevent having to pay for an additional inspection fee. Otherwise, the facility will need to pay for an additional inspection.

Committee discussion included leveraging the renewal inspection either prior to the renewal or shortly after the renewal to prevent the sterile compounding pharmacy from having to incur additional inspection costs.

Ms. Sodergren provided risk factors if a remodel inspection exceeds a time period close to the renewal inspections. The board is mandated to inspect the sterile compounding pharmacy prior to the expiration of the license and to approve the license for renewal. Therefore, the board could not hold off on conducting an inspection after the expiration date of the license if the remodel completed shortly after the expiration date of the license. Additionally, a sterile compounding pharmacy license renewal period runs congruent with the underlying primary pharmacy or hospital pharmacy license and as such the

expiration date for the sterile compounding pharmacy cannot be altered. She suggested placing parameters in law to possibly state, if the remodel inspection is within 90 days of the renewal of the license, then the inspection would also serve as the renewal inspection.

Ms. Herold further provided that staff already work with the pharmacy to schedule the remodel in alignment with the renewal inspection if this can be achieved. This issue is specific for those times when the remodel does not occur in alignment with the renewal.

Ms. Sodergren shared Danny Martinez's comments that opposes assessing a remodel inspection fee he sent to the board via email on behalf of CPHA. Note: Mr. Martinez's comments have been provided following these minutes.

Ms. Sodergren clarified only remodels that alter and have impact to the sterile compounding pharmacy result in an inspection. Assessing a remodel inspection fee is not a mechanism for the board to earn additional fees. Conducting inspections is costly to the board and a remodel inspection fee will only be assessed when it is determined by the board that inspecting the pharmacy is crucial to ensure the facility is in compliance and if the inspection falls outside of the parameters of the renewal inspection. She further suggested the committee consider developing a form for pharmacies to submit that describes their remodel.

Steve Grey, pharmacist, recommends developing regulations to require the sterile compounding pharmacy to notify the board of the remodel in advance for approval and to consider using already established guides if one exits for example in a hospital. He also suggested considering requiring a remodel application. His concern that assessing an additional inspection fee may cause people to hold off on remodeling their sterile compounding pharmacy. By requiring an application for approval to remodel, this will allow the board to determine if an inspection is required at the conclusion of the remodel.

The committee requested staff to develop language with legal to establish remodel inspection parameters and fees for the committee to review at the next committee meeting.

5. **Discussion and Consideration of Proposed Regulation Regarding the Self-Assessment Requirement for Automated Drug Delivery Systems**

Chairperson Veale reported earlier this year the Governor Brown signed AB 2037 and SB 1447, both relating to the licensure and use of Automated Drug Delivery Systems (ADDS). Both measures also require the operating pharmacy to complete an annual self-assessment to ensure compliance with pharmacy law as it relates to the use of the ADDS.

Chairperson Veale explained to facilitate implementation of this requirement, promulgation of regulations will be necessary as the intent is to initiate the rulemaking to have the regulations in place by May 1, 2020. Similar to the approach the board is taking with the pharmacy self-assessment process, board staff recommends detailing the specific reporting elements in the regulation language while also incorporating a self-assessment form by reference.

The committee discussed and reviewed the proposed draft self-assessment of an ADDS by a pharmacist-in-charge regulation. The committee added a comma and the word "or" at the end of paragraph (2) of subdivision (b).

Draft Regulation to read as follows: § 17##. Self-Assessment of an Automated Drug Delivery System by Pharmacist-in-Charge.

(a) A pharmacy holding an automated drug delivery system (ADDS) license as defined under section 4119.11, 4187.5 or section 4427.2 of the Business and Professions Code shall complete a self-assessment of compliance with federal and state pharmacy law for each location where an ADDS license is granted. The assessment shall be performed by the pharmacist-in-charge annually before July 1 of every year.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new ADDS license has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge, or

(3) There is a change in the licensed location of an ADDS to a new address.

Chairperson Veale requested clarification on when an ADDS requires a new license due to a change. Executive Officer Herold responded that the law requires that if the facility changes the type of machine a new license is not required; however, if the location of the ADDS machine changes a new license is required.

Committee Recommendation: Recommend to the full board to approve the draft language with the addition of the ", or" after (b)(2) and to direct staff to initiate the rulemaking with the intent to have the regulation in place by May 1, 2020.

M/S: Weisser/Butler

Support: 5 Oppose: 0 Abstain: 0

The committee discussed and reviewed the proposed draft ADDS self-assessment and made the following changes to the assessment.

Draft Automated Drug Delivery System Self-Assessment form

- Include in the assessment form the hours of the ADDS as required in the draft regulation in (c)(1)(D) and add if the hours of the ADDS are different than the pharmacy, what are they and why?
- Need to reference to sign the certification on page 34 for the ADDS listed under sections 4, 5, 6, 7, and 8 after completing the assessment.
- Correct if the ADDS is either an AUDS and/or an APDS in Section 1 and to provide instruction that there are two different types of ADDS.

Committee Recommendation: Direct staff to make the necessary changes as discussed in the draft regulation and draft assessment for ADDS to bring forward to the full board.

M/S: Butler/ Weisser

Support: 5 Oppose: 0 Abstain: 0

Chairperson Veale thanked staff for developing the draft regulatory language and the draft self-assessment for their review.

6. Discussion and Consideration of a Policy Statement and Strategic Steps to Authorize a Pharmacist to Provide Medication-Assisted Treatment

Chairperson Veale reported there is a huge nationwide opioid crisis. One of the recommended solutions to address the crisis is to provide medication-assisted treatment (MAT) to help wean patients from opioids. There are three main medications used for this -- methadone, buprenorphine and naltrexone.

The California Legislature declares pharmacists to be health care providers who have the authority to provide health care services. Pharmacists are medication specialists who are skilled in the assessment and management of substance related disorders such as opioid addiction. Chairperson Veale stated under California law and in conjunction with collaborative practice agreements with prescribers, pharmacists have the ability to:

1. Design treatment plans;
2. Initiate medications;
3. Monitor patient progress;
4. Order and review necessary laboratory tests;
5. Coordinate care with other medical providers; and
6. Serve as expert consultants to support prescribers in making medication decisions for patients with opioid addiction and co-occurring conditions.

Pharmacists with this skill set are well positioned to provide direct care to patients with opioid addiction and assist other medical providers in caring for this population, thereby expanding access to treatment for consumers. Additionally, in California, pharmacists with appropriate education and experience may secure an additional pharmacist's license, that of Advanced Practice Pharmacist, which authorizes collaborative practice with primary care providers.

Chairperson Veale explained currently, federal law prevents a pharmacist from prescribing MAT for opioid addiction. A pharmacist is not eligible to obtain a federal DATA 2000 waiver to prescribe buprenorphine. Pursuant to federal regulation, the only health care providers who can obtain this authority currently are physicians, nurse practitioners, and physician assistants. Expanding this authority to pharmacists would allow pharmacists to fully exercise their pharmaceutical education and experience in this area of health care services as a health care practitioner in California. Additionally, expanding this authority to pharmacists increases the number and availability of health care providers for Californians.

During the October 2018 Board Meeting, the board directed staff to draft a policy statement supporting the role of pharmacists in providing MAT services as well as develop options for advocating changes in federal law to allow such services to occur.

Chairperson Veale indicated that staff recommends working with a coalition of groups on this policy including: the American Pharmacist Association (APHA), the National Association of Boards of Pharmacy (NABP), the California Healthcare Foundation, the California Pharmacists Association (CPHA), the California Society of Health-System Pharmacists (CSHP), schools of pharmacy and other interested parties.

Chairperson Veale restated it will take changes at the federal level to allow a pharmacist the ability to prescribe MAT for opioid addiction.

Vice Chairperson Weisser and Executive Officer Herold further stated that the board is not in a position to lobby federally but agree that the board needs to encourage all the associations including APHA and CPHA and that the NABP should be advocating this on a national level.

The committee agreed to encourage the NABP to adopt this policy as they are the national organization and should be advocating for pharmacists to be a part of the list of providers federally.

Steve Grey, pharmacist, supports the draft policy and stated this was proposed to APHA several years ago but deliberately did not to move as they thought it would be confusing due to the Federal Part B providership and the designated provider. He reported that APHA is starting to move forward with this and more importantly he is optimistic that with the change in the national political scene that pharmacists will be successful with incorporating this into federal law in early 2019 as this is a national epidemic. He recommends adopting the draft policy statement as proposed, to request the NABP to adopt this policy as a model law for all the states, and the committee recommend to the full board to pursue legislation this year in California, if counsel says that legislation is needed in California to prevent any possible challenges the board may encounter when federal law is changed.

Committee Recommendation: Recommend to the board to adopt this policy statement; encourage the NABP establish this policy language as a model law for all states nationwide; and work with APHA, CPHA and other national organizations to implement this in federal law. The committee directed staff to work with legal counsel to determine if a change in statute is necessary at the state level.

M/S: Veale/Weisser

Support: 5 Oppose: 0 Abstain: 0

7. <u>Licensing Statistics</u>

Chairperson Veale reported the Licensing statistics for July 1-November 30, 2018, are provided in **Attachment 4**.

As of November 30, 2018, the board has received 8,004 initial applications, including:

- 1,628 intern pharmacists.
- 859 pharmacist exam applications.
- 106 advanced practice pharmacists.
- 2,299 pharmacy technicians.

As of November 30, 2018, the board has issued 5,888 licenses, renewed 28,279 licenses and has 140,928 active licenses, including:

- 7,061 intern pharmacists.
- 46,989 pharmacists.
- 439 advanced practice pharmacists.
- 71,267 pharmacy technicians.
- 6,450 community pharmacies.
- 408 hospital pharmacies

Processing Times

Chairperson Veale reported the general application and deficiency mail processing times by license type are provided below reflecting data current as of November 30, 2018. The data reflects the time from when an application or deficiency response is received by the board through to the time it is processed by licensing staff.

The processing times for certain license types is currently outside the standard 30-day processing performance standards for applications and 10-day processing times for deficiency mail. Several contributing factors continue to impact the licensing processing times:

- Staff vacancies and leave of absences.
- A total of 122 requests for temporary applications where received in the past two months.
- A major hospital chain of more than 80 pharmacies with 41 sterile compounding pharmacies is changing ownership before the end of the year.

Until processing times are reduced below the performance standard, management will continue to prioritize the workload to ensure that mission critical site applications are being processed and issued in a timely manner. It is anticipated that once the onboarding of the new employees has been completed, the processing times will decrease.

Premises Application Types	**Application Processing Times As of 11/30/2018**	**Deficiency Mail Processing Times As of 11/30/2018**
Pharmacy	38	56
Nonresident Pharmacy	43	74
Sterile Compounding	35	24
Nonresident Sterile Compounding	14	32
Outsourcing	0	0
Nonresident Outsourcing	0	0

Premises Application Types	Application Processing Times As of 11/30/2018	Deficiency Mail Processing Times As of 11/30/2018
Hospital	24	Included w/PHY
Clinic	17	10
Wholesaler	25	43
Nonresident Wholesaler	28	43
Third-Party Logistics Provider	0	32
Nonresident Third-Party Logistics Provider	17	46

Individual Application Type	Application Processing Times As of 11/30/2018	Deficiency Mail Processing Times As of 11/30/2018
Pharmacist Examination	39	15
Pharmacist Initial Licensure	11	N/A
Advanced Practice Pharmacist	36	17
Intern Pharmacist	43	14
Pharmacy Technician	31	16
Designated Representative	24	25
Designated Represenative-3PL	25	37

8. Future Committee Meeting Dates

The 2019 Licensing Committee dates are as follows:

- April 3, 2019
- June 26, 2019
- October 2, 2019

The licensing committee meeting adjourned at 1:00pm.