California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

LICENSING COMMITTEE REPORT
December 19, 2018

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

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

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

   *(Note: the committee may not discuss or take action on any matter raised during the public comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a).)

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

Attachment 1

Relevant Law

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

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

Background

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 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).

For Committee Consideration and Discussion

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

Board staff is aware of some challenges patients and/or pharmacies experienced during the Camp Fire emergency that may be appropriate for the committee to discuss.

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

Attachment 1 includes a copy of all three subscriber alerts released and the relevant law sections.

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

Background

The board referred this item to the Licensing Committee during the October 23-24, 2018, Board Meeting based on the recommendation from the Enforcement Committee. A sterile compounding license shall not be issued or renewed until the location has been inspected by the board and found in compliance with pharmacy law. A fee is assessed for the issuance or renewal of a sterile compounding license.

At times sterile compounding pharmacies require an inspection after a remodel has been completed. 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 preform 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.

For Committee Consideration and Discussion

During this meeting, the committee will have an opportunity to discuss whether the board should require the facility to a pay fee for inspecting the remodeled areas. Should the committee determine that assessing a fee is appropriate, board staff would suggest a fee similar to the renewal fee for a sterile compounding pharmacy, which is currently $1,325. Legislation would be necessary to make such a change.

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

Attachment 2

Earlier this year the Governor signed AB 2037 and SB 1447, both relating to the licensure and use of Automated Drug Delivery Systems. 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.

To facilitate implementation of this requirement, promulgation of regulations will 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. Should the board approve this

approach, staff will work with counsel to finalize the self-assessment form. Staff will initiate the rulemaking with the intent to have the regulation in place by May 1, 2020.

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

6. 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. 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 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 with opioid addiction and co-occurring conditions

This skill set well 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. Additionally, in California pharmacists with appropriate education and experience may secure an additional pharmacists 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. As a health care practitioner in California, expanding this authority to pharmacists would allow pharmacists to fully exercise their pharmaceutical education and experience in this area of health care services. Additionally, expanding this authority to pharmacists increases the number and availability of health care providers to Californians.

During the October 23-24, 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.

For Committee Consideration and Discussion
During the meeting, members will have an opportunity to discuss the draft policy statement and possible ways to advocate this policy. Board staff recommends working with a coalition of groups on this policy including: the American Pharmacist Association, the National Association of Boards of Pharmacy, the California Healthcare Foundation, the California Pharmacists Association, the California Society of Health-System Pharmacists, schools of pharmacy and other interested parties.

Attachment 3 contains a copy of the draft policy statement.

7. Licensing Statistics

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
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 leaves of absence.
- 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
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 draft meeting minutes from the September 26, 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.

Attachment 2

Title 16. Board of Pharmacy
DRAFT Proposed Regulation

Proposal to Add §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) 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.

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

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

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

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

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

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

(D) Hours of operation of the operating pharmacy and the ADDS; and

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the ADDS is, at the time of the self-assessment, operating in compliance with the identified laws and regulations.

(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. 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 pharmacy 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 ADDS'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 operating pharmacy for three years after it is performed.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment. Such corrections shall be verified and documented as completed by the pharmacist-in-charge.

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

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

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 1715 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 pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. 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 on "CORRECTIVE ACTION OR ACTION PLAN" 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 Inventory Date: _____
Last C2 Inventory Reconciliation Date (CCR 1715.65(c)):_____
Hours: M-F: _____**Saturday**_____ **Sunday**_____
PIC: _____**RPH#**_____

ADDS Permit: _____
ADDS Address: _____
City: _____

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

SECTION 1: DEFINITIONS/TYPE OF DEVICE USED

Yes No N/A

☐☐☐ 1.1 The pharmacy uses 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)]

☐☐☐ 1.2. 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)]

☐☐☐ 1.3 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)]

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:

_____

_____

_____
_____
_____
_____

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)]

Yes No N/A

☐☐☐ 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 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)]

☐☐☐ 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:

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.

- ☐ 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))

CORRECTIVE ACTION OR ACTION PLAN:

_____

_____

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. _____

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:

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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.

Yes No N/A

☐☐☐ 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)

☐☐☐ 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:

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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: _____

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

Yes No N/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)

☐☐☐ 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)

Yes No N/A

☐☐☐ 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:

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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 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:

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_____
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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: _____

CORRECTIVE ACTION OR ACTION PLAN:

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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. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN:

_____
_____
_____
_____

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:

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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)).

☐☐☐ 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:

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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)).

☐☐☐ 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:

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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:

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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:

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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)).

☐☐☐ 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:

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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, 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)).

☐☐☐ 6.18 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)).

☐☐☐ 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)).

Yes No N/A

☐☐☐ 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:

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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:

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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)).

☐☐☐ 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:

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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))

☐☐☐ 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))

Yes No N/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)]

☐☐☐ 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)

Yes No N/A

☐☐☐ 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:

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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))

☐☐☐ 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)]

☐☐☐ 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))

Yes No N/A

☐☐☐ 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:

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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.

☐☐☐ 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)]

Yes No N/A

☐☐☐ 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 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.

☐☐☐ 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)]

Yes No N/A

☐☐☐ 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)]

CORRECTIVE ACTION OR ACTION PLAN:

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_____

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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)]

CORRECTIVE ACTION OR ACTION PLAN:

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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:

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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)]

Yes No N/A

☐☐☐ 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)]

☐☐☐ 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:

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E. RECORD KEEPING REQUIREMENTS

☐☐☐ 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:

_____
_____
_____

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 _____

Attachment 3

DRAFT Policy Statement

California law declares pharmacists 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								167
Designated Representatives Vet (EXV)	0	3	0	0	1								4
Designated Representatives-3PL (DRL)	4	5	1	8	10								28
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0								0
Designated Paramedic (DPM)	0	0	0	0	0								0
Intern Pharmacist (INT)	152	1038	210	177	51								1628
*Pharmacist (exam applications)	193	171	186	195	114								859
Pharmacist (initial licensing applications)	34	179	764	368	49								1394
Advanced Practice Pharmacist (APH)	25	20	12	21	28								106
Pharmacy Technician (TCH)	504	522	413	479	381								2299
	* total includes retake exam applications												
Centralized Hospital Packaging (CHP)	0	0	1	0	0								1
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0								0
Clinics (CLN)	120	6	10	10	3								149
Clinics Exempt (CLE)	0	14	0	26	14								54
Drug Room (DRM)	0	0	0	0	0								0
Drug Room -Temp	0	0	0	0	0								0
Drug Room Exempt (DRE)	0	0	0	0	0								0
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0								0
Hospitals (HSP)	3	2	0	2	27								34
Hospitals - Temp	0	0	1	2	27								30
Hospitals Exempt (HPE)	0	1	0	0	0								1
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	1								1
Hospital Satellite Sterile Compounding - Temp	0	0	0	0	1								1
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0								0
Hypodermic Needle and Syringes (HYP)	2	2	2	1	1								8
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0								0
Correctional Pharmacy (LCF)	0	0	0	0	0								0
Outsourcing Facility (OSF)	0	1	0	0	0								1
Outsourcing Facility - Temp	0	0	0	0	0								0
Outsourcing Facility Nonresident (NSF)	0	1	0	1	0								2
Outsourcing Facility Nonresident - Temp	0	0	0	0	0								0
Pharmacy (PHY)	36	27	54	33	44								194
Pharmacy - Temp	583	10	37	20	23								673
Pharmacy Exempt (PHE)	0	1	0	0	0								1
Pharmacy Nonresident (NRP)	8	15	35	10	10								78
Pharmacy Nonresident Temp	3	16	32	0	5								56
Sterile Compounding (LSC)	10	5	4	8	44								71
Sterile Compounding - Temp	4	0	1	7	37								49
Sterile Compounding Exempt (LSE)	0	0	2	0	0								2
Sterile Compounding Nonresident (NSC)	2	1	3	0	1								7
Sterile Compounding Nonresident Temp	1	0	3	0	1								5
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0								0
Third-Party Logistics Providers (TPL)	3	0	0	0	0								3
Third-Party Logistics Providers - Temp	3	0	0	0	0								3
Third-Party Logistics Providers Nonresident (NPL)	1	0	0	0	2								3
Third-Party Logistics Providers Nonresident Temp	1	0	0	0	0								1
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	0	0								3
Veterinary Food-Animal Drug Retailer - Temp	0	1	0	0	0								1
Wholesalers (WLS)	8	4	7	7	2								28
Wholesalers - Temp	1	3	4	6	0								14
Wholesalers Exempt (WLE)	0	0	0	0	0								0
Wholesalers Nonresident (OSD)	5	11	8	5	4								33
Wholesalers Nonresident - Temp	4	2	3	3	0								12
Total	1742	2091	1831	1418	922	0	0	0	0	0	0	0	8004

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								110
Designated Representatives Vet (EXV)	0	0	0	1	0								1
Designated Representatives-3PL (DRL)	8	6	2	3	2								21
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0								0
Designated Paramedic (DPM)	0	0	0	0	0								0
Intern Pharmacist (INT)	75	623	399	337	117								1551
Pharmacist (initial licensing applications)	42	183	670	405	85								1385
Advanced Practice Pharmacist (APH)	21	17	17	22	28								105
Pharmacy Technician (TCH)	506	570	200	722	393								2391
Centralized Hospital Packaging (CHP)	0	0	0	0	0								0
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0								0
Clinics (CLN)	2	7	2	17	12								40
Clinics Exempt (CLE)	0	0	0	14	1								15
Drug Room (DRM)	0	0	0	0	0								0
Drug Room-Temp	0	0	0	0	0								0
Drug Room Exempt (DRE)	0	1	0	0	0								1
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0								0
Hospitals (HSP)	1	0	0	0	0								1
Hospitals - Temp	1	1	0	2	0								4
Hospitals Exempt (HPE)	0	0	0	1	0								1
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	2								2
Hospital Satellite Sterile Compounding - Temp	0	0	0	0	0								0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0								0
Hypodermic Needle and Syringes (HYP)	0	8	1	1	0								10
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0								0
Correctional Pharmacy (LCF)	0	0	0	0	0								0
Outsourcing Facility (OSF)	0	0	0	0	3								3
Outsourcing Facility - Temp	0	0	0	0	0								0
Outsourcing Facility Nonresident (NSF)	1	1	0	1	0								3
Outsourcing Facility Nonresident - Temp	0	0	0	0	0								0
Pharmacy (PHY)	8	5	14	16	13								56
Pharmacy - Temp	6	11	12	31	14								74
Pharmacy Exempt (PHE)	0	0	0	0	0								0
Pharmacy Nonresident (NRP)	1	0	3	2	0								6
Pharmacy Nonresident Temp	3	3	4	5	3								18
Sterile Compounding (LSC)	4	3	0	5	3								15
Sterile Compounding - Temp	0	3	0	1	0								4
Sterile Compounding Exempt (LSE)	0	0	0	0	3								3
Sterile Compounding Nonresident (NSC)	1	0	0	2	0								3
Sterile Compounding Nonresident Temp	1	1	0	0	0								2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0								0
Third-Party Logistics Providers (TPL)	0	0	0	0	2								2
Third-Party Logistics Providers-Temp	0	2	0	0	0								2
Third-Party Logistics Providers Nonresident (NPL)	0	1	1	1	0								3
Third-Party Logistics Providers Nonresident Temp	0	1	1	1	0								3
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0								0
Veterinary Food-Animal Drug Retailer - Temp	0	0	1	0	0								1
Wholesalers (WLS)	0	5	1	0	4								10
Wholesalers - Temp	2	3	4	2	1								12
Wholesalers Exempt (WLE)	0	0	0	0	0								0
Wholesalers Nonresident (OSD)	2	2	3	10	0								17
Wholesalers Nonresident - Temp	5	2	2	4	0								13
Total	734	1477	1346	1622	709	0	0	0	0	0	0	0	5888

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

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

APPLICATIONS (continued)

Withdrawn	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	21	4	1	2	2								30
Designated Representatives Vet (EXV)	1	0	0	0	0								1
Designated Representatives-3PL (DRL)	3	0	1	2	0								6
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0								0
Designated Paramedic (DPM)	0	0	0	0	0								0
Intern Pharmacist (INT)	0	1	0	9	1								11
Pharmacist (exam applications)	2	0	1	2	2								7
Advanced Practice Pharmacist (APH)	0	0	0	0	0								0
Pharmacy Technician (TCH)	1	6	5	5	18								35
Centralized Hospital Packaging (CHP)	0	0	0	0	0								0
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0								0
Clinics (CLN)	1	1	0	0	4								6
Clinics Exempt (CLE)	0	0	0	0	0								0
Drug Room (DRM)	0	0	0	0	0								0
Drug Room Exempt (DRE)	0	0	0	0	0								0
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0								0
Hospitals (HSP)	0	0	0	0	0								0
Hospitals Exempt (HPE)	0	0	0	0	0								0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0								0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0								0
Hypodermic Needle and Syringes (HYP)	1	0	0	0	0								1
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0								0
Correctional Pharmacy (LCF)	0	0	0	0	0								0
Outsourcing Facility (OSF)	0	0	0	0	0								0
Outsourcing Facility Nonresident (NSF)	0	1	0	0	1								2
Pharmacy (PHY)	1	566	3	2	2								574
Pharmacy Exempt (PHE)	0	0	0	0	0								0
Pharmacy Nonresident (NRP)	0	1	0	0	2								3
Sterile Compounding (LSC)	0	1	0	1	1								3
Sterile Compounding Exempt (LSE)	0	1	0	0	0								1
Sterile Compounding Nonresident (NSC)	1	0	0	0	1								2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0								0
Third-Party Logistics Providers (TPL)	0	1	2	0	0								3
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	1	0								1
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0								0
Wholesalers (WLS)	0	0	0	0	1								1
Wholesalers Exempt (WLE)	0	0	0	0	0								0
Wholesalers Nonresident (OSD)	2	0	1	5	1								9
Total	34	583	14	29	36	0	0	0	0	0	0	0	696

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.

APPLICATIONS (continued)

Designated Representatives (EXC)	0	0	0	0	0								0
Designated Representatives Vet (EXV)	0	0	0	0	0								0
Designated Representatives-3PL (DRL)	0	0	0	0	0								0
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0								0
Designated Paramedic (DPM)	0	0	0	0	0								0
Intern Pharmacist (INT)	0	1	1	0	0								2
Pharmacist (exam applications)	0	0	0	0	3								3
Pharmacist (eligible)	0	0	1	0	0								1
Advanced Practice Pharmacist (APH)	0	0	0	0	0								0
Pharmacy Technician (TCH)	3	3	1	4	4								15
Centralized Hospital Packaging (CHP)	0	0	0	0	0								0
Centralized Hospital Packaging Exempt (CHE)	0	0	0	0	0								0
Clinics (CLN)	1	0	0	0	0								1
Clinics Exempt (CLE)	0	0	0	0	0								0
Drug Room (DRM)	0	0	0	0	0								0
Drug Room Exempt (DRE)	0	0	0	0	0								0
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0								0
Hospitals (HSP)	0	0	0	0	0								0
Hospitals Exempt (HPE)	0	0	0	0	0								0
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0								0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0								0
Hypodermic Needle and Syringes (HYP)	0	0	0	0	0								0
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0								0
Correctional Pharmacy (LCF)	0	0	0	0	0								0
Outsourcing Facility (OSF)	0	0	0	0	0								0
Outsourcing Facility Nonresident (NSF)	0	0	1	0	0								1
Pharmacy (PHY)	0	2	0	0	1								3
Pharmacy Exempt (PHE)	0	0	0	0	0								0
Pharmacy Nonresident (NRP)	0	0	0	0	0								0
Sterile Compounding (LSC)	0	0	0	0	0								0
Sterile Compounding Exempt (LSE)	0	0	0	0	0								0
Sterile Compounding Nonresident (NSC)	0	0	0	0	0								0
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	0								0
Third-Party Logistics Providers (TPL)	0	0	0	0	0								0
Third-Party Logistics Providers Nonresident (NPL)	0	0	0	0	0								0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0	0	0								0
Wholesalers (WLS)	0	0	0	0	1								1
Wholesalers Exempt (WLE)	0	0	0	0	0								0
Wholesalers Nonresident (OSD)	1	0	0	1	0								2
Total	5	6	4	5	9	0	0	0	0	0	0	0	29

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								1870
Designated Representative Responded	984	215	0	0	1								1200
Pharmacist/Intern Received	314	158	767	656	431								2326
Pharmacist/Intern Responded	49	44	158	200	74								525
Pharmacy Technician Received	421	466	355	405	342								1989
Pharmacy Technician Responded	454	294	322	355	286								1711
Pharmacy Received	510	537	491	662	483								2683
Pharmacy Responded	519	560	475	735	529								2818
Sterile Compounding/Outsourcing Received	514	638	354	354	344								2204
Sterile Compounding/Outsourcing Responded	205	398	275	354	258								1490
Wholesale/Clinic/Hypodermic/3PL Received	321	319	253	367	282								1542
Wholesale/Clinic/Hypodermic/3PL Responded	256	289	272	431	139								1387
Pharmacist-in-Charge Received	142	180	161	227	105								815
Pharmacist-in-Charge Responded	99	133	155	205	20								612
Change of Permit Received	343	530	890	569	482								2814
Change of Permit Responded	352	424	395	319	331								1821
Renewals Received	516	580	544	519	476								2635
Renewals Responded	418	466	439	447	348								2118

B. Telephone Calls Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Represenative	5	2	9	11	0								27
Pharmacist/Intern	7	6	8	19	3								43
Pharmacy	90	66	45	116	57								374
Sterile Compounding/Outsourcing	13	12	15	23	32								95
Wholesale/Clinic/Hypodermic/3PL *	44	38	36	24	0								142
Pharmacist-in-Charge	4	78	34	74	4								194
Change of Permit	88	38	82	103	56								367
Renewals	602	641	548	548	473								2812

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								985
Processed	124	375	251	285	12								1047
Approved	122	347	235	276	50								1030
Pending	515	337	275	241	366								366

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								51
Processed	4	29	14	8	0								55
Approved	3	21	14	10	1								49
Pending	60	46	44	44	51								51

C. Change of Responsible Manager	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	2	0	0	2	3								7
Processed	3	5	0	1	0								9
Approved	3	9	0	1	0								13
Pending	11	2	2	3	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								693
Processed	107	148	233	0	67								555
Approved	103	182	170	34	13								502
Pending	953	873	866	986	1142								1142

E. Automated Drug Delivery Systems	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	61	36	68	23	7								195
Processed	0	0	0	0	0								0
Approved	0	0	0	0	0								0
Pending	94	134	202	191	198								198

F. Clinic Co-Location	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Received	0	0	0	0	0								0
Processed	0	1	0	0	0								1
Approved	0	1	0	0	0								1
Pending	1	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								212
Processed	72	20	98	24	0								214
Approved	42	30	64	29	0								165
Pending	179	198	181	191	229								229

H. Requests Approved	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Address/Name Changes	1127	1310	1393	1048	836								5714
Off-site Storage	26	0	27	12	3								68
Transfer of Intern Hours	4	2	1	4	0								11
License Verification	187	223	141	338	182								1071

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								1,050
Designated Representatives Vet (EXV)	9	4	5	2	3								23
Designated Representatives-3PL (DRL)	15	27	31	16	13								102
Designated Representatives-Reverse Distributor (DRR)	0	0	0	0	0								0
Designated Paramedic (DPM)	0	0	0	0	0								0
Pharmacist (RPH)	1534	2091	1743	1910	1466								8,744
Advanced Practice Pharmacist (APH)	9	14	18	18	15								74
Pharmacy Technician (TCH)	2442	3102	2392	3094	2220								13,250
Centralized Hospital Packaging (CHP)	3	0	0	1	0								4
Centralized Hospital Packaging Exempt (CHE)	1	0	0	0	0								1
Clinics (CLN)	73	87	64	108	55								387
Clinics Exempt (CLE)	2	0	69	124	13								208
Drug Room (DRM)	2	0	2	3	1								8
Drug Room Exempt (DRE)	0	0	5	4	0								9
Emergency Medical Services Automated Drug Delivery System	0	0	0	0	0								0
Hospitals (HSP)	16	18	43	52	22								151
Hospitals Exempt (HPE)	16	2	31	4	3								56
Hospital Satellite Sterile Compounding (SCP)	0	0	0	0	0								0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0	0	0								0
Hypodermic Needle and Syringes (HYP)	12	22	19	27	21								101
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0	0	0								0
Correctional Pharmacy (LCF)	0	1	33	18	2								54
Outsourcing Facility (OSF)	1	3	1	0	0								5
Outsourcing Facility Nonresident (NSF)	0	0	0	1	2								3
Pharmacy (PHY)	232	377	712	1031	560								2,912
Pharmacy Exempt (PHE)	3	0	71	29	3								106
Pharmacy Nonresident (NRP)	24	35	23	42	38								162
Sterile Compounding (LSC)	55	42	42	140	51								330
Sterile Compounding Exempt (LSE)	28	8	24	0	0								60
Sterile Compounding Nonresident (NSC)	4	1	2	7	4								18
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0	0	1								1
Third-Party Logistics Providers (TPL)	1	1	3	2	0								7
Third-Party Logistics Providers Nonresident (NPL)	1	0	8	3	9								21
Veterinary Food-Animal Drug Retailer (VET)	1	1	1	3	1								7
Wholesalers (WLS)	22	63	25	36	20								166
Wholesalers Exempt (WLE)	0	0	6	3	0								9
Wholesalers Nonresident (OSD)	54	51	57	43	45								250
Total	4777	6195	5608	6940	4759	0	0	0	0	0	0	0	28279

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

Current Licensees

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

Attachment 5

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
DRAFT MINUTES

DATE:	September 26, 2018
LOCATION:	Department of Consumer Affairs – **Building Two** 1747 North Market Blvd., Room 186 Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Debbie Veale, Licensee Member, Chairperson Stan Weisser, Licensee Member, Vice-Chairperson Lavanza Butler, Licensee Member Albert Wong, Licensee Member
COMMITTEE MEMBERS NOT PRESENT:	Allen Schaad, Licensee Member Amjad Khan, Public Member
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Kelsey Pruden, DCA Staff Counsel Debi Mitchell, Staff Services Manager II

1. Call to Order and Establishment of Quorum

Chairperson Veale called the meeting to order at 10:41 a.m. Roll call was taken and Debbie Veale, Stan Weisser, Lavanza Butler, and Albert Wong were present.

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

No public comments were offered.

3. Presentation by the California Department of Corrections to Provide an Overview of the Correctional Clinic Model as a Result of AB 1812.

Chairperson Veale provided an overview of Assembly Bill 1812, which establishes licensure of correctional clinics by the board and authorizes a clinic licensed by the board to obtain drugs from a correctional pharmacy. The bill will authorize the administration or dispensing of drugs in a correctional clinic or by a correctional pharmacy, as specified, and will

authorize the health care staff of a clinic to administer Schedule II through V controlled substances, as specified. The bill will require a correctional clinic to apply to the board for a license and will require the board to make a thorough investigation of whether the premises qualifies for licensure. As the provisions of the measure became effective July 1, 2018, board staff is working on implementation.

Chairperson Veale introduced Linda MacLachlan, Statewide Pharmacy Services Manager and Gregory B. Doe, PharmD, Chief of Pharmacy Services at the California Department of Corrections (CDCR) to present the changes to the CDCR model and provide an overview of the benefits of such changes.

Ms. MacLachlan explained that the changes impact the state correctional institutions only and will give the board the authority to issue clinic licenses to areas within the CDCR correctional institutions. This will allow each prison to store drugs in various locations and ensure there is secure storage and accountability for the medications by using automated drug delivery systems for certain types of medications. This new model will improve continuity of care for inmates as well as reduce the amount of medication waste.

Ms. MacLachlan stated that each correctional institution will have several licensed clinics in areas where inmates will receive their medication from nurses at a "pill line" or another area within the prison where medical care is received (such as dental clinic and treatment and triage areas).

Mr. Doe reported on the various challenges CDCR experiences in the current system and the amount of medication waste that occurs because of the current system. One of the most common challenges is transporting an inmate to another correctional institution and the logistical difficulties of ensuring the inmate has his or her medication at the time of arrival at the new prison. Mr. Doe stated that this new model allows for most inmates to receive his or her medication at a licensed clinic within the CDCR institutions in the form of non-patient specific pill packs, which allows the nurses to administer the medication to the inmate.

The committee asked how the nurse will ensure that the correct medication is dispensed. Mr. Doe explained the inmates medical record and history is maintained in the CDCR's electronic statewide healthcare system which is available statewide at any of the state correctional institutions. He added that this allows for immediate medical care and the ability to dispense the required medication.

Ms. MacLachlan reported that CDCR is anticipating applying for 20 clinic licenses at each of their state correctional institutions as well as installing 450-700 automated drug delivery systems statewide. Mr. Doe provided an overview of CDCR's roll out plan and stated that they anticipate applying for all their clinic licenses and automated drug delivery systems by 2020.

As part of the committee discussion, it was noted that board staff will be implementing this new licensing program with existing resources.

The committee thanked CDCR for their presentation and stated it was very informative.

4. Presentation by California Department of Health Care Services on the Los Angeles Moratorium relating to New Medi-Cal Numbers.

Chairperson Veale introduced Merrold Young, Chief of the Policy and Quality and Control Section of California Department of Health Care Services (DHCS) to present on the current moratorium in Los Angeles that relates to issuing new Medi-Cal numbers to licensed facilities.

Mr. Young explained that the pharmacy moratorium was implemented in June 2002 to safeguard public funds and maintain the fiscal integrity of the Medi-Cal program. The DHCS re-evaluates the moratorium every 180 days to assess its effectiveness and necessity pursuant to their statute.

Mr. Young stated that over the years DHCS has implemented several exemptions to the moratorium. In September 2016, based on their ongoing re-evaluation, the moratorium was changed to no longer exempt pharmacist owned pharmacies.

On May 1, 2018, the moratorium was revised again to allow for specific exemptions and the expiration was extended to October 28, 2018. There were 10 exemptions listed in the revised May 1, 2018 moratorium (reference attachment 2 of the meeting materials).

Members of the committee expressed concern that independent pharmacies are being treated unfairly and will not be granted exemptions. Mr. Young stated that when evaluating the exemption requests, DHCS independently reviews each request to determine if other pharmacies are in the area that may offer the same services or if the pharmacy applying for an exemption is a specialized pharmacy. The exemptions are evaluated to ensure patient care is provided in all areas within Los Angeles county. Mr. Young stated that if the exemption request provided by the pharmacy adequately justifies why their pharmacy provides specialized care that cannot be provided at other area pharmacies then the exemption will typically be approved.

A member of the public asked if the pharmacy can continue to bill using the current Medi-Cal number while their exemption request is being reviewed. Mr. Young stated that during the review process, the pharmacy can continue to bill using their current Medi-Cal number until such request is denied or a new Medi-Cal number is issued.

At the request of the committee, Mr. Young provided an overview of when a new Medi-Cal provider application is required to be submitted which includes:

- New enrollment
- Continued enrollment
- New, additional or change in location
- Change of ownership

- 50% plus assets are sold or transferred
- Issuance of a new TIN issued by IRS
- New license number issued by the Board of Pharmacy
- Change in 50% or more in the ownership or controlling interest.

Mr. Young reported that the DHCS has an online portal system called "PAVE" which pharmacies can use to report or submit information to DHCS. He added that pharmacies that use the PAVE portal have significantly less deficiencies in their applications.

The committee thanked DHCS for their presentation and will continue to watch the status of the moratorium as of October 28, 2018.

5. Discussion and Consideration of Amending section 1732.5(b) of Title 16 California Code of Regulations to Require a Pharmacist to Pass the Continuing Education Course Relating to Pharmacy Law.

Chairperson Veale explained that board staff developed a one-hour webinar which covers new 2018 pharmacy laws. The webinar was posted on the board's website August 1, 2018. As of September 12, 2018, 1,542 pharmacists have completed this online webinar.

Chairperson Veale stated that while reviewing completion data gathered from this course, staff has found that some individuals have completed the training in less than 10 minutes and in many such instances, the individuals are not answering the questions correctly. It appears that some individuals are fast-forwarding through the course and may be missing out on the content. She added that approximately 14 percent of the individuals that completed the webinar scored less than 80 percent on the quiz questions. Ms. Veale stated that the board's current regulation only requires pharmacists to complete the course -- but does not require pharmacists to pass the course.

Chairperson Veale noted that the committee should consider if, as currently written, the regulation is meeting the intended goal of the regulation or if further refinement to the language is necessary. She added that if the committee determines that it would be appropriate to clarify that a pharmacist must pass the course, staff believes the current regulation would need to be amended.

The members expressed concern that the online webinar does not have restrictions in place to prevent a person from completing the webinar in a specific time. They stated that the intent of the webinar is to provide important information to pharmacists, and if they are not watching the webinar and accurately answering the questions, then the webinar is not effective.

Member of the public stated that many online C.E. programs have the same difficulty with their programs and come C.E. vendors are considering not offering online webinars anymore.

MOTION: Direct staff to work with counsel to develop language for the board's consideration to address the inadequacies of the online webinar.

M/S: Weisser/Butler

Support: 4 Oppose: 0 Abstain: 0

6. Discussion and Consideration of Continuing Education Requirements for an Advanced Practice Pharmacist that Includes the Option for an Inactive Status for an Advanced Practice Pharmacist license.

Chairperson Veale provided an overview of the relevant statutes and regulations relating to advanced practice pharmacists.

Chairperson Veale reminded the committee the board began accepting applications for advanced practice pharmacists in December 2016 and began issuing the advanced practice pharmacist licenses shortly thereafter in February 2017. She added that to date the board has issued 372 advanced practice pharmacists licenses.

Chairperson Veale explained that during the April 2018 committee meeting and the May 2018 board Meeting, members discussed the current continuing education requirements for pharmacists and advanced practice pharmacists. As part of the discussion it was noted that while the board has the authority to issue an inactive pharmacist license under specified conditions, the board does not have similar authority for an advanced practice pharmacist. At the end of the board's discussion, staff was requested to further review the continuing education requirements and bring recommendations to create renewal requirements for an advanced practice pharmacist that mirror the requirements for pharmacists.

The committee reviewed the following policy considerations.

- Pharmacists are exempt from earning continuing education hours during their first renewal cycle. A similar provision does not exist for advanced practice pharmacists. Staff further notes that the advanced practice pharmacist expiration date is issued coterminous with their primary pharmacist license and as such, the licensee may not receive the full two years during the first renewal cycle.
- The board has the authority to issue an inactive pharmacist license to an individual that has not satisfied the CE requirements. Staff notes that this ability applies when either the pharmacist fails to provide satisfactory proof as part of a renewal or in response to an audit. A similar provision does not exist of advanced practice pharmacists.
- Provisions exist to establish the process to reactivate a pharmacist license however there is no similar process to reactivate an advanced practice pharmacist license.
- Pharmacists are required to retain their CE certificates for four years, but there is no similar requirement for advanced practice pharmacists.

After reviewing the policy considerations, the committee agreed that the renewal

requirements for advanced practice pharmacists should mirror the renewal requirements for pharmacists.

There were no comments from the public.

MOTION: Direct staff to work with counsel to develop language for the board's consideration to align the advanced practice pharmacist renewal requirements with the renewal requirements for the pharmacists.

M/S: Butler/Wong

Support: 4 Oppose: 0 Abstain: 0

7. Discussion and Consideration of Amending Business and Professions Code (BPC) section 4400, Subdivisions (n) and (o), to Specify the Reissuance Fees for a Duplicate License or for Updating License Record Information.

Chairperson Veale explained that under BPC section 4400(n) a licensee can request that the board issue them a new license if theirs has been lost or destroyed or if they have changed their name. The current fee to reissue a license is $45. If a licensee notifies the board of an address and/or name change but does not wish to order a new printed license, there is no fee associated to update the individual license record. The $45 fee is to cover the cost to print the license and mail it to the licensee. As BPC section 4400(n) is currently written, it does not allow the board to reissue a license when there is any other type of change licensee information (i.e. address change).

Chairperson Veale reported that the fee to change the information on a premises license because of a change in the pharmacist-in-charge, change of designated representative-in-charge, change in responsible manager, change in professional director, or change in ownership information is $100. The $100 fee includes updating the premises license record, a thorough investigation on the change being requested, and printing a new license certificate.

Ms. Veale explained that not all changes to a premise license affect the information that is on the printed license (i.e. change in ownership percentages). Currently under BPC section 4400(o) when there has been *any* change to the license information the board will reissue a printed license, regardless if the change impacts information on the printed license.

Ms. Veale stated that board staff is proposing to update the language in BPC 4400(o) to clarify that the fee to change the information on a premises license is $100 and includes the re-issuance of a printed license if the change results in a change to what is printed on the license. However, if there is no change to the information printed on the license, the board will not reissue a printed license.

Members of the public asked why a pharmacy should have to pay $100 to change license information if they will not be getting a new printed license. Ms. Sodergren explained that the $100 is to cover the cost of labor to update the license information. She explained that

updating the records for a premise license is not just simple data entry -- staff conducts a detailed assessment of the requested changes prior to making any updates.

Ms. Veale again stated that proposed changes to 4400(n) and (o) will clarify that the $100 is the fee to cover the cost of updating the license information, not the fee to print a new license.

The committee agreed that the language in 4400(n) and (o) should be updated and noted that in other industries it is common to have to pay a fee to update information.

MOTION: Direct staff to work with legal counsel to develop language for the board's consideration which would update the law to provide clarity regarding the fee to update the license record and reissue a printed license certificate.

M/S: Weisser/Butler

Support: 4 Oppose: 0 Abstain: 0

8. Discussion and Consideration of Amending Business and Professions Code Section 4115.5, Regarding Pharmacy Technician Trainee Externship Hour Requirements.

Chairperson Veale provided an overview of BPC section 4115.5 which requires a pharmacy technician trainee to complete an externship for the purpose of obtaining practical training to become licensed as a pharmacy technician. Subdivision (c)(1) and (2) specifies the number of trainee externship hours required in a community pharmacy and a hospital pharmacy.

Chairperson Veale explained that individuals applying for a pharmacy technician license may qualify under BPC section 4202(a)(2) and CCR section 1793.6(a) which requires the completion of a training program accredited by the American Society of Health-System Pharmacists (ASHP). ASHP accredited pharmacy technician training programs require a total of 130 pharmacy technician trainee hours, ten more than the 120-hour limit established in BPC 4115.5(c)(1) and (2). This makes it difficult for ASHP-accredited pharmacy technician training programs to comply with California Pharmacy Law while also meeting the ASHP accreditation standards.

The members discussed the conflict between current California law and the ASHP accreditation standards and agreed work to align the requirements of each.

MOTION: Direct staff to work with counsel to develop language for the board's consideration to modify:

1. Business and Professions Code section 4115.5(c)(1) to amend the 120-hour limit for pharmacy technician training programs to "No less than 120 hours and no more than 140 hours."
2. Business and Professions Code section 4115.5(c)(2) to amend the 320-hour limit for externships rotating between community and hospital pharmacies to "340 hours."
3. Business and Professions Code section 4115.5(c)(2) to delete the last sentence.

M/S: Weisser/Wong

Support: 3 Oppose: 0 Abstain: 1 (Butler)

9. Discussion and Consideration of Establishing Authority to Allow for an Advance Practice Pharmacist to Provide Medication-Assisted Treatment (MAT).

Chairperson Veale stated that in the midst of 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.

Chairperson Veale stated that staff has asked the committee to consider whether pharmacists should be added to the group of health care providers who can perform collaborative therapy using buprenorphine.

Chairperson Veale stated that 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. Chairperson Veale added that under California law for several years and in conjunction with collaborative practice agreements with prescribers, pharmacists have the ability to:

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

Chairperson Veale stated that 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. Additionally, California pharmacists with appropriate education and experience may secure an Advanced Practice Pharmacist license, which authorizes collaborative practice with primary care providers.

Chairperson Veale explained that although pharmacists in many states can prescribe controlled substances under collaborative drug therapy management agreements, they are not eligible to obtain a federal DATA 2000 waiver to prescribe buprenorphine for opioid addiction. Under federal regulations only physicians, nurse practitioners, and physician assistants can obtain this authority. Giving pharmacists this authority would allow them to fully exercise their pharmaceutical expertise in this area and expand the

pool of providers for medication-assisted treatment.

The committee spoke in support of adding pharmacists to the group of health care providers who can perform collaborative therapy using buprenorphine

A representative from the California Pharmacists Association also spoke in support of adding pharmacists to the group of health care providers who can perform collaborative therapy using buprenorphine.

Ms. Sodergren explained that the committee could develop a policy statement outlining the committee's support of allowing pharmacists to prescribe buprenorphine for opioid addiction. She added that the committee could also direct staff to work to change the federal law to allow pharmacists to obtain a DATA 2000 waiver.

Pharmacist Steve Gray recommended that when drafting the policy statement, the committee focus on seeking approval for pharmacists to provide medication-assisted treatment rather than listing what medications a pharmacist can provide. This would ensure that if new medications become available to use for MAT a pharmacist could use them.

The committee directed staff to work on development of a draft policy statement supporting the role of pharmacists in providing MAT services. Further, the committee requested staff to develop options for advocating changes in federal law to allow such services to occur. Both items will be brought to the committee at its next meeting.

10. Discussion and Consideration of Licensing Committee Strategic Goals for Fiscal Year 2018/19 and Thereafter

Chairperson Veale reminded the committee that the board finalized its current strategic plan in 2016. She recommended that the committee discuss its strategic goals for the coming fiscal year as well as the remainder of the plan.

Chairperson Veale reviewed the committee's current strategic goals (below) and reported on the implementation status.

1.1 Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.
Status: The Executive Officer serves on the NABP's .PHARMACY task force and provides updates on the national efforts to address unlicensed internet pharmacy sales.

1.2 Implement online application, license renewal, and fee payment for applicants and licensees to improve licensing conveniences.
Status: The board is currently working with the department to secure the ability to accept credit card payments for renewal payments. Further, the board is in the initial stages of Business Modernization, the process used to evaluate legacy computer systems.

1.3 Complete a comprehensive review of at least five licensure categories and update requirements to ensure relevancy and keep licensing requirements current with professional practices.
Status:

- Post implementation review of the Advanced Practice Pharmacist is underway.
- Occupation Analysis is underway for both currently recognized pharmacy technician certification examinations and regulation changes are pending to update the training requirements.
- Review of hospital pharmacy practice was evaluated, and legislative changes secured to established satellite compounding pharmacies. The board has started to receive hospital satellite compounding applications for licensure.

1.4 Explore, and possibly implement, opportunities to use contracted organizations to administer the board's California Practice Standards and Jurisprudence Examination to increase access to the examination.
Status: No action has been taken on this goal.

1.5 Improve the application process for new licensees, including providing informational resources directed toward applicants to offer more guidance about the application process.
Status: Applications are in various stages of being streamlined and standardized.

1.6 Establish requirements to form a licensing process for alternate work sites and vendors in the pharmacy marketplace to advance patient safety and health.
Status: Statutory changes to allow for the use of Automated Drug Delivery Systems (ADDS) is awaiting signature by the Governor.

1.7 Identify opportunities to expand electronic interfaces with licensees to allow for online application and renewal.
Status: The board is currently working with the department on Business Modernization.

After discussion the committee decided not to remove any of the current committee goals. The committee added the two following strategic goals:

1) Implement new licensing programs.
2) Perform annual benchmarking with national practice standards.

There were no comments from the public.

MOTION: Continue with the current goals and add two additional goals:

1) Implement new licensing programs.
2) Perform annual benchmarking with national practice standards.

M/S: Weisser/Veale

Support: 4 Oppose: 0 Abstain: 0

11. Licensing Statistics for July 1, 2018 – August 31, 2018

Chairperson Veale reported the board's licensing statistics as of August 31, 2018.

The board has received 3,833 initial applications, including:

- 1,190 intern pharmacists.
- 364 pharmacist exam applications.
- 45 advanced practice pharmacists.
- 1,026 pharmacy technicians.
- 1 outsourcing facility.
- 1 nonresident outsourcing facilities.

The board has issued 2,211 licenses, renewed 10,972 licenses and has 140,221 active licenses, including:

- 7,248 intern pharmacists.
- 46,049 pharmacists.
- 372 advanced practice pharmacists.
- 71,432 pharmacy technicians.
- 6,488 pharmacies.
- 467 hospitals and exempt hospitals.
- 20 nonresident outsourcing facilities.
- 2 outsourcing facilities

Chairperson Veale reported the board is currently experiencing an increase in processing times because of the implementation of new license types that became effective on January 1, 2018. She added that there are several other contributing factors to the increased processing times including: six vacancies in the licensing unit; 379 temporary site license requests received in the past two months (due to of a change of ownership of the site license); 1,220 pharmacist examination applications received from California pharmacy schools; and 1,160 intern pharmacist applications received since August from new students enrolling in the California pharmacy schools.

Chairperson Veale stated that management has been actively recruiting to fill the six vacant positions and recently filled the position that processes the pharmacist examination applications on September 17, 2018, which had been vacant since June. The remaining five vacancies continue to impact the application processing times and the issuance of individual licenses, examination score processing, review and issuance of pharmacy applications, and the processing of temporary site license requests for pharmacy applications. It is anticipated that the vacancies will be filled within the next couple of months and once the onboarding of the new employees has been completed the processing times will decrease.

12. Future Committee Meeting Dates

The committee reviewed the proposed 2018 and 2019 Licensing Committee dates and accepted them as follows:

- December 19, 2018
- April 3, 2019
- June 26, 2019
- October 2, 2019

Chairperson Veale adjourned the meeting at 3:14 p.m.