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

LICENSING COMMITTEE REPORT
September 26, 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

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

Attachment 1

Pursuant to enactment of Assembly Bill 1812 (Statutes of 2018), the California Department of Corrections (CDCR) redefined its drug storage and delivery within correctional facilities. As the provisions of the measure became effective July 1, 2018, board staff is working on implementation.

At the committee meeting, CDCR's representatives Linda MacLachlan, Statewide Pharmacy Services Manager and Gregory B. Doe, PharmD, Chief of Pharmacy Services presented changes to the CDCR model, as well as an overview of the benefits of such changes. The changes impact state correctional institutions only and include authority for the board to issue clinic licenses to areas within the CDCR correctional institutions to store drugs in various locations providing for secure storage and accountability of medications. Further changes allow for the use of automated drug delivery systems. This new model will improve continuity of care for inmates and reduce the amount of medication waste.

It is anticipated that each correctional institution will have several licensed clinics in areas where inmates will receive their medication from nurses at a "pill line" as well as other areas within the prison where medical care is received, such as dental clinics, and treatment and triage areas.

The presentation included various challenges experienced by CDCR within the current system as the medication is packaged as patient specific in a "pill pack or punch card" and the amount of medication waste that occurs as a result of the current system. Representatives also noted that one of the most common medication challenges occurs when an inmate is transported to another correctional institution and the difficulties of ensuring the inmate has his or her medication at the time of arrival at the new prison. Under the current system medication may not always be available which can result in delays in therapy.

This new model allows for the inmate to receive his or her medication at a licensed clinic within

the CDCR institutions as medication is stocked as nonpatient specific which allows the nurses to administer the medication to the inmate from a common stock of medications. Representatives also provided information about the electronic system for maintaining medical records in a statewide healthcare system which allows for immediate access to medical records and improved ability to receive the required medication.

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. CDCR presented their roll out plan which included submission of correctional clinic applications for the first prison in August of 2018. It is anticipated that full implementation will be achieved by 2020.

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

Attachment 1 includes a copy of AB 1812.

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

Attachment 2

During the committee meeting, members heard a presentation on the current Moratorium in Los Angeles that relates to issuing new Medi-Cal numbers to licensed facilities from representatives of the DHCS. As part of the presentation, it was noted 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. As part of the presentation it was noted that changes to the moratorium are based upon data and recommendations from the Audits and Investigations Unit within DHCS.

In September 2016, based on their ongoing re-evaluation of the moratorium, the moratorium was changed to no longer exempt pharmacist owned pharmacies. In May 2018, the moratorium was revised again to allow for specific exemptions and is set to expire on October 28, 2018. The exemptions include:

1. The enrollment of chain pharmacy providers (20 or more service locations).
2. An application based on the purchase or a change of control interest of an existing Medi-Cal provider pharmacy in Los Angeles County, whether It constitutes a change of ownership or not. This exception is only available when the applicant has assumed or retained all debts, obligations, and liabilities to which the existing provider was subject prior to the transfer or sale and the Department confirms that an access to care issue exists.
3. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.55, Requirements for Continued Enrollment.
4. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.30(a), by an existing Medi-Cal enrolled pharmacy provider for the sole reason

of changing its location, provided that its previous business address was located in Los Angeles County.

5. Applicants that are the exclusive persons or entities in the United States to provide a specific product or service that is a Medi-Cal covered benefit.
6. The enrollment of a county, state or federally owned and operated pharmacy.
7. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.30(b)(6) with no change in the person(s) previously identified in the last complete application package that was approved for enrollment as having a control or ownership interest in the provider totaling five percent or greater.
8. Applicants who will be enrolled solely for reimbursement of Medicare cost sharing amounts.
9. Applications submitted by a provider to operate at the same business location as a Federally Qualified Health Clinic (FQHC). The pharmacy, in whole or in part, must be owned and operated by the same entity that owns the FQHC.
10. Applications submitted by an Academic Specialty Pharmacy. For purposes of this Moratorium, an Academic Specialty Pharmacy is defined as a specialty pharmacy that is owned or operated by a higher education institution that is currently a Medi-Cal pharmacy provider.

The presentation also included an overview of instances when a new Medi-Cal provider application is required including:

1. New enrollment
2. Continued enrollment
3. New, additional or change in location
4. Change of ownership
5. 50% plus assets are sold or transferred
6. Issuance of a new TIN issued by IRS
7. New license number issued by the Board of Pharmacy
8. Change in 50% or more in the ownership or controlling interest.

The DHCS has an online PAVE Portal system to report or submit information to DHCS.

<u>Committee Discussion and Action</u>
As part of the committee's discussion, members expressed concern about the change is exemption status for independent pharmacy owners.

In response to committee questions regarding exemption requests, members were advised that DHCS independently reviews each request to determine if there are other pharmacies in existence in the area that 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. If the explanation provided by the pharmacy is reasonable and the pharmacy meets the criteria, then the exemption is typically approved. 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.

Attachment 2 includes a copy of the current moratorium and the PowerPoint presentation provided by Merrold Young, Chief Policy and Quality and Control Section of California Department of Health Care Services.

c. Discussion to Amend 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

Attachment 3

Background

As of August 1, 2018, the Board's one-hour webinar was available on the Board's website for pharmacist to earn continuing education (CE) credit as a result of CCR 1732.5, which states that at least two of the 30 CE hours required for a pharmacist license renewal be completed by participating in a Board-certified CE course in Law and Ethics. As of September 12, 2018, 1,542 pharmacists have completed this online webinar.

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 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. Approximately 14 percent of the individuals that completed the webinar scored less than 80 percent on the quiz questions. The board's current regulation only requires pharmacists to complete the course but does not require pharmacists to pass the course.

Committee Discussion and Action

During the committee meeting, members discussed whether it may be appropriate for the committee to consider if, as currently written, the regulation is meeting its intended goal of or if further refinement to the language is necessary. The committee members expressed concern that the online webinar does not have restrictions in place to prevent a licensee from completing the webinar in what appears to be 10 minutes in some instances.

Committee Recommendation (Motion): Direct staff to work with counsel to develop suggested language for the board's consideration to address the inadequacies that currently exist regarding the amount of time it takes to complete the online webinar.

Recent Update

Subsequent to the committee meeting staff learned that this issue could be corrected through the use of technology. Specifically, the board could purchase software that will include prevent an individual from progressing in a webinar until the correct answer is given. As such staff is requesting as part of its discussion, the board consider this approach as an alternative to its original recommendation to amend the regulation language.

Based on discussion and the direction of the committee members, the following is provided as an alternative to the proposed draft language. Should members agree with this new direction, the following language could serve as a motion.

MOTION: Direct staff to work with DCA's SOLID Training Group and Office of Information Services to incorporate changes within the online webinar to prevent a person from completing the webinar if the licensee answers questions specific to the content of the webinar incorrectly.

Attachment 3 contains the proposed amendment to the regulation language as directed by the committee.

d. Discussion of Continuing Education Requirements for an Advanced Practice Pharmacist that Includes the Option for an Inactive Status of an Advanced Practice Pharmacist License

Attachment 4

Background

As of December 13, 2016, the board began accepting applications for advanced practice pharmacists and shortly thereafter in 2017 began issuing advanced practice pharmacist licenses to those that met the licensure requirements.

An advanced practice pharmacist is required to complete an additional 10 hours of continuing education each renewal cycle in addition to the 30 hours required for their pharmacist license renewal.

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' renewal requirements. As part of the discussion it was noted that while the board has the authority to issue an inactive pharmacist license under specified condition, the board does not similar authority for an advanced practice pharmacist license renewal.

At the conclusion of the board's discussion, staff was asked to further review the continuing education requirements and bring recommendations to the board to create renewal requirements for an advanced practice pharmacist that mirror the requirements for pharmacists.

Committee Discussion and Action

During the committee meeting, members discussed the following concerns identified below that are not included in the renewal requirements for advanced practice pharmacists.

1. Pharmacists are exempt from earning CE hours during their first renewal cycle. A similar provision does not exist for advanced practice pharmacists. Staff noted 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.
2. The board has the authority to issue an inactive a pharmacist license to an individual that has not satisfied the CE requirements. Staff noted 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.

3. Provisions exist to establish the process to reactivate a pharmacist license, however there is no similar process to reactivate an advanced practice pharmacist license.
4. Pharmacists are required to retain their CE certificates for four years, but there is no similar requirement for advanced practice pharmacists.

Committee Recommendation (Motion): Direct staff to in concert with counsel, develop language for the board's consideration to align the advanced practice pharmacist renewal requirements with the renewal requirements for the pharmacists.

Attachment 4 contains the proposed as directed by the committee.

e. Discussion of Amending Business and Professions Code Section 4400, subdivisions (n) and (o), to Regarding the Fees for a Duplicate License or for Updating Licensing Record Information

Attachment 5

Background

BPC section 4400(n) establishes the fee for the board to reissue a license certificate at the request of the licensee when a license has been lost or destroyed or due to a name change. The current fee to reissue a license is $45.

BPC section 4400(o) establishes the fee for the board to reissue a license when there has been any change to the license information. The current fee to reissue for such a change is $100.

BPC 4307 establishes the board's authority to prohibit someone from serving as a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management and control under specified conditions.

BPC section 4101 establishes requirements for notification of changes in a pharmacist-in-charge or designated representative-in-charge.

CCR Section 1709 establishes the reporting requirement for an entity to notify the board of specified changes including changes in owners, officers and pharmacist-in-charge.

Similar reporting requirements exist throughout Pharmacy Law of entities licensed by the board.

Committee Discussion and Action

The committee considered a proposal from staff that would amend BPC 4400 to provide clarity and transparency regarding the fees collected and the purpose for which the fee is collected. Under the current construct with BPC 4400(o), all reported changes are processed and either approved or denied under the board's authority. In all such instances, when such a change is approved, the entity receives a new license.

The committee noted the confusion with the current statutory language and considered questions from the public about events that would trigger a new printed license to be issued.

Committee Recommendation (Motion): Direct staff to work with legal counsel to develop language for the board's consideration to update the law to provide more clarity on the fee to update the license record and the reissuance of the printed license certificate.

Attachment 5 contains the proposed as recommended by the committee.

Staff notes that given the number of questions during the committee meeting regarding the reporting requirements, staff will develop an FAQ to include in a future issue of *The Script.*

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

Attachment 6

Relevant Law

BPC section 4115.5 establishes the provisions that allows an individual to work as a pharmacy technician trainee is specified conditions are met. Under the conditions of this section, a pharmacy technician trainee is limited in the number of hours experience can be earned. Such limitations include a maximum of 120 hours of experience in a work site as well as a total maximum of 320 hours.

BPC section 4202 establishes the general requirements for licensure as a pharmacy technician. Further, (a)(2) of this section provides as one of the pathways to licensure, completion of a course of training specified by the board.

CCR section 1793.6(a) expands upon such training courses and designates a pharmacy technician training program accredited by the American Society of Health Systems Pharmacies (ASHP) as one such training course approved by the board.

Background

ASHP accredited pharmacy technician training programs require a total of 130 pharmacy technician trainee hours at each location, which exceeds the 120 hours limit established in BPC 4115.5. This is results in a conflict for the ASHP accredited pharmacy technician training programs to comply with Pharmacy Law as well meet the accreditation standards with ASHP. Further, the current limitation on the maximum number of hours a pharmacy technician trainee can gain, 320 hours, prevents an individual from meeting the elements for advanced level training under ASHP guidelines. Advanced level training must include at least 340 hours experiential hours.

Committee Discussion and Action

During the committee meeting, members discussed the conflict in the number of trainee hours allowed currently in BPC section 4115.5 and the conflict it creates for individuals seeking licensure as a pharmacy technician through completion of an ASHP pharmacy technician

training.

Committee Recommendation (Motion): Direct staff to work with counsel to develop language for the board's consideration to modify section 4115.5©(1) to amend the language to read no less than 120 and no more than 140 hours as wells as to amend 4115.5©(2) to increase 320 hours to 340 hours and remove the last sentence in this subdivision.

Attachment 6 contains the proposed language as directed by the committee.

g. Discussion of Establishing Authority to Allow for an Advanced Practice Pharmacist to Provide Medically Assisted Treatment

Attachment 7

Issue

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

Attachment 7 contains information on medication assisted treatment from the *Substance Abuse and Mental Health Services Administration* (SAMHSA).

Overview

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 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.

Barriers

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. Having this authority would allow them to fully exercise their pharmaceutical expertise in this area and expand the pool of providers for medication assisted treatment.

Committee Discussion and Action

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

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

Members of the public spoke in support of adding pharmacists to the group of health care providers who can perform collaborative therapy using buprenorphine. It was also recommended that when drafting the policy statement, the committee focus on seeking approval for pharmacist to provide MAT rather than listing specific medications that a pharmacist can provide. This approach would ensure that if new medications become available to use for MAT a pharmacist could provide 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.

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

Attachment 8

During the meeting members reviewed the committee's goals currently included in the board's strategic plan as well as the status of each goal as detailed below.

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 of the 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 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.

Committee Discussion and Action

During the committee meeting, members discussed the licensing strategic goals and the consensus was to continue with the current goals and add two more goals that would include: 1) Implementing New Licensing Programs and 2) Annual Benchmarking with National Practice Standards.

Committee Recommendation (Motion): Direct staff to continue with the current goals and recommend to the board two additional goals:

1) Implementing New Licensing Programs
2) Annual Benchmarking with National Practice Standards.

Attachment 8 includes the relevant portion of the board's strategic plan.

i. Licensing Statistics

Licensing statistics for July 1-September 30, 2018, are provided in **Attachment 9**.

As of September 30, 2018, the board has received 5,664 initial applications, including:

- 1,400 intern pharmacists.
- 550 pharmacist exam applications.
- 57 advanced practice pharmacists.
- 1,439 pharmacy technicians.
- 1 outsourcing facility.
- 1 nonresident outsourcing facilities.

As of September 30, 2018, the board has issued 3,557 licenses, renewed 16,580 licenses and has 140,558 active licenses, including:

- 7,104 intern pharmacists.
- 46,741 pharmacists.
- 389 advanced practice pharmacists.
- 71,316 pharmacy technicians.
- 6,476 pharmacies.
- 468 hospitals and exempt hospitals.
- 21 nonresident outsourcing facilities.
- 2 outsourcing facilities

Information on application processing times is also provided in **Attachment 9**.

j. Future Committee Meeting Dates

The 2018 and 2019 Licensing Committee dates are as follows:

- December 19, 2018
- 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 10**.

Attachment 1

recognized as training facilities by the California Board of Registered Nursing.

SEC. 5. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

SEC. 6. Article 13.5 (commencing with Section 4187) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 13.5. Correctional Clinics

4187. For purposes of this article the following terms shall have the following meanings:

(a) “Correctional clinic” means a primary care clinic, as referred to in subdivision (b) of Section 1206 of the Health and Safety Code, conducted, maintained, or operated by the state to provide health care to eligible patients of the Department of Corrections and Rehabilitation.

(b) “Chief executive officer” means the highest ranking health care administrator at a correctional institution.

(c) “Chief medical executive” means a physician and surgeon acting in the capacity of medical director within the correctional institution.

(d) “Chief nurse executive” means the highest ranking nurse within the correctional institution.

(e) “Licensed correctional clinic” means a correctional clinic that is licensed pursuant to this article.

(f) “Supervising dentist” means the highest ranking dentist within the correctional institution.

4187.1. (a) Notwithstanding any other provision of this chapter, a correctional clinic licensed by the board under this article may obtain 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 under this article 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:

(1) The direction of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.

(2) An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

(b) The dispensing or administering of drugs in a correctional clinic may be performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. The dispensing of drugs in a correctional clinic shall only be performed by a physician and surgeon, a dentist, a pharmacist, or other person lawfully authorized to dispense drugs. Medications dispensed to patients that are to be kept on the patient’s person for use shall meet the labeling requirements of Section 4076 and all recordkeeping requirements of this chapter.

(c) A correctional clinic shall keep records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(d) (1) A correctional clinic shall not be entitled to the benefits of this section until it has obtained a license from the board.

(2) A separate license shall be required for each correctional clinic location and shall not be transferrable.

(3) A correctional clinic’s location and address shall be identified by correctional institution and building within that correctional institution.

(4) A clinic shall notify the board in advance of any change in the clinic’s address on a form furnished by the board.

4187.2. (a) The policies and procedures to implement the laws and regulations of this article within a correctional clinic shall be developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. Prior to the

issuance of a correctional clinic license by the board, an acknowledgment shall be signed by the correctional facility pharmacist-in-charge servicing that 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.

(b) (1) The chief executive officer shall be responsible for the safe, orderly, and lawful provision of pharmacy services. 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 5024.2 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.

(2) A licensed correctional clinic shall notify the board within 30 days of any change in the chief executive officer on a form furnished by the board.

(c) A correctional facility pharmacist shall be required to inspect the clinic at least quarterly.

4187.3. A Schedule II, III, IV, or V controlled substance may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

4187.4. The board shall have the authority to inspect a correctional clinic at any time in order to determine whether a correctional clinic is, or is not, operating in compliance with this article.

4187.5. (a) An automated drug delivery system, as defined in subdivision (h), may be located in a correctional clinic licensed by the board under this article. If an automated drug delivery system is located in a correctional clinic, the correctional clinic shall implement 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. All policies and procedures shall be maintained either in electronic form or paper form at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system 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, in the prescriber's professional judgment, delay in therapy may cause patient harm, a medication may be removed from the automated drug delivery system and administered or furnished to a 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 medication from an automated drug delivery system shall be documented and provided to the correctional pharmacy when it reopens.

(c) Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division who is lawfully authorized to perform that task.

(d) The stocking of an automated drug delivery system shall be performed by either:

(1) A pharmacist.

(2) An intern pharmacist or pharmacy technician, acting under the supervision of a pharmacist.

(e) 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. The review shall be 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.

(f) The automated drug delivery system shall be operated by a licensed correctional pharmacy. Any drugs within an automated drug delivery system are considered owned by the licensed correctional pharmacy until they are dispensed from the automated drug delivery system.

(g) Drugs from the automated drug delivery system in a correctional clinic shall only be removed by a person lawfully authorized to administer or dispense the drugs.

(h) For purposes of this section, an "automated drug delivery system" means 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.

SEC. 7. Section 4203.6 is added to the Business and Professions Code, to read:

4203.6. (a) Each application for a license as a correctional clinic under Article 13.5 (commencing with Section 4187) shall be made on a form furnished by the board. The application form shall contain the name and address of the applicant, the name of its chief executive officer, as defined in Section 4187, and the name of the pharmacist-in-charge of the correctional pharmacy that provides drugs to the clinic.

(b) Upon the filing of the application and payment of the fee prescribed in Section 4400, where applicable, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for licensure. The board shall also

determine whether this article has been complied with and shall investigate all matters directly related to the issuance of the license. The board shall not, however, investigate any matters connected with the operation of a premises, including, but not limited to, operating hours, parking availability, or operating noise, except those matters relating to the furnishing or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made does not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under this article, the executive officer of the board shall issue a license authorizing the correctional clinic to which it is issued to obtain drugs pursuant to Article 13.5 (commencing with Section 4187). The license shall be renewed annually on or before December 31 of each year upon payment of the renewal fee prescribed in Section 4400, if applicable. A license shall not be transferable.

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board,

necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360).

SEC. 9. Section 12838.1 of the Government Code is amended to read:

recognized as training facilities by the California Board of Registered Nursing.

SEC. 5. Section 4081 of the Business and Professions Code is amended to read:

4081. (a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

SEC. 6. Article 13.5 (commencing with Section 4187) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 13.5. Correctional Clinics

4187. For purposes of this article the following terms shall have the following meanings:

(a) “Correctional clinic” means a primary care clinic, as referred to in subdivision (b) of Section 1206 of the Health and Safety Code, conducted, maintained, or operated by the state to provide health care to eligible patients of the Department of Corrections and Rehabilitation.

(b) “Chief executive officer” means the highest ranking health care administrator at a correctional institution.

(c) “Chief medical executive” means a physician and surgeon acting in the capacity of medical director within the correctional institution.

(d) “Chief nurse executive” means the highest ranking nurse within the correctional institution.

(e) “Licensed correctional clinic” means a correctional clinic that is licensed pursuant to this article.

(f) “Supervising dentist” means the highest ranking dentist within the correctional institution.

4187.1. (a) Notwithstanding any other provision of this chapter, a correctional clinic licensed by the board under this article may obtain 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 under this article 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:

(1) The direction of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.

(2) An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

(b) The dispensing or administering of drugs in a correctional clinic may be performed pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. The dispensing of drugs in a correctional clinic shall only be performed by a physician and surgeon, a dentist, a pharmacist, or other person lawfully authorized to dispense drugs. Medications dispensed to patients that are to be kept on the patient’s person for use shall meet the labeling requirements of Section 4076 and all recordkeeping requirements of this chapter.

(c) A correctional clinic shall keep records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(d) (1) A correctional clinic shall not be entitled to the benefits of this section until it has obtained a license from the board.

(2) A separate license shall be required for each correctional clinic location and shall not be transferrable.

(3) A correctional clinic’s location and address shall be identified by correctional institution and building within that correctional institution.

(4) A clinic shall notify the board in advance of any change in the clinic’s address on a form furnished by the board.

4187.2. (a) The policies and procedures to implement the laws and regulations of this article within a correctional clinic shall be developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code. Prior to the

issuance of a correctional clinic license by the board, an acknowledgment shall be signed by the correctional facility pharmacist-in-charge servicing that 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.

(b) (1) The chief executive officer shall be responsible for the safe, orderly, and lawful provision of pharmacy services. 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 5024.2 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.

(2) A licensed correctional clinic shall notify the board within 30 days of any change in the chief executive officer on a form furnished by the board.

(c) A correctional facility pharmacist shall be required to inspect the clinic at least quarterly.

4187.3. A Schedule II, III, IV, or V controlled substance may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in Section 4019, a valid prescription consistent with this chapter, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

4187.4. The board shall have the authority to inspect a correctional clinic at any time in order to determine whether a correctional clinic is, or is not, operating in compliance with this article.

4187.5. (a) An automated drug delivery system, as defined in subdivision (h), may be located in a correctional clinic licensed by the board under this article. If an automated drug delivery system is located in a correctional clinic, the correctional clinic shall implement 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. All policies and procedures shall be maintained either in electronic form or paper form at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system 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, in the prescriber's professional judgment, delay in therapy may cause patient harm, a medication may be removed from the automated drug delivery system and administered or furnished to a 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 medication from an automated drug delivery system shall be documented and provided to the correctional pharmacy when it reopens.

(c) Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division who is lawfully authorized to perform that task.

(d) The stocking of an automated drug delivery system shall be performed by either:

(1) A pharmacist.

(2) An intern pharmacist or pharmacy technician, acting under the supervision of a pharmacist.

(e) 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. The review shall be 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.

(f) The automated drug delivery system shall be operated by a licensed correctional pharmacy. Any drugs within an automated drug delivery system are considered owned by the licensed correctional pharmacy until they are dispensed from the automated drug delivery system.

(g) Drugs from the automated drug delivery system in a correctional clinic shall only be removed by a person lawfully authorized to administer or dispense the drugs.

(h) For purposes of this section, an "automated drug delivery system" means 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.

SEC. 7. Section 4203.6 is added to the Business and Professions Code, to read:

4203.6. (a) Each application for a license as a correctional clinic under Article 13.5 (commencing with Section 4187) shall be made on a form furnished by the board. The application form shall contain the name and address of the applicant, the name of its chief executive officer, as defined in Section 4187, and the name of the pharmacist-in-charge of the correctional pharmacy that provides drugs to the clinic.

(b) Upon the filing of the application and payment of the fee prescribed in Section 4400, where applicable, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for licensure. The board shall also

determine whether this article has been complied with and shall investigate all matters directly related to the issuance of the license. The board shall not, however, investigate any matters connected with the operation of a premises, including, but not limited to, operating hours, parking availability, or operating noise, except those matters relating to the furnishing or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made does not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under this article, the executive officer of the board shall issue a license authorizing the correctional clinic to which it is issued to obtain drugs pursuant to Article 13.5 (commencing with Section 4187). The license shall be renewed annually on or before December 31 of each year upon payment of the renewal fee prescribed in Section 4400, if applicable. A license shall not be transferable.

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board,

necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360).

SEC. 9. Section 12838.1 of the Government Code is amended to read:

Attachment 2

LOS ANGELES COUNTY
PHARMACY MORATORIUM

May 1, 2018

In accordance with Section 14043.55 of the *California Welfare and Institutions Code*, I, Jennifer Kent, Director of the Department of Health Care Services, Health and Human Services Agency, State of California, will implement for 180 days, a moratorium on the enrollment of Pharmacy providers located in Los Angeles County. Upon approval of this moratorium, the Los Angeles County Pharmacy Moratorium dated November 1, 2017, will expire and be superseded by this moratorium. This new moratorium will expire on October 28, 2018. This moratorium exempts any of the following applications for provider enrollment:

1. The enrollment of Chain Pharmacy providers. For the purposes of this moratorium, a Chain Pharmacy is defined as an entity with 20 or more service locations.

2. An application based on the purchase or a change of control interest of an existing Medi-Cal provider pharmacy in Los Angeles County, whether it constitutes a change of ownership or not. This exception is only available when the applicant has assumed or retained all debts, obligations, and liabilities to which the existing provider was subject prior to the transfer or sale and the Department confirms that an access to care issue exists.

3. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.55, Requirements for Continued Enrollment.

4. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.30(a), by an existing Medi-Cal enrolled pharmacy provider for the sole reason of changing its location, provided that its previous business address was located in Los Angeles County.

5. Applicants that are the exclusive persons or entities in the United States to provide a specific product or service that is a Medi-Cal covered benefit.

6. The enrollment of a County, State, or Federally owned and operated pharmacy.

7. Applications submitted pursuant to California Code of Regulations, Title 22, Section 51000.30(b)(6) with no change in the person(s) previously identified in the last complete application package that was approved for enrollment as having a control or ownership interest in the provider totaling five percent or greater.

8. Applicants who will be enrolled solely for reimbursement of Medicare cost sharing amounts.

9. Applications submitted by a provider to operate at the same business location as a Federally Qualified Health Clinic (FQHC). The pharmacy, in whole or in part, must be owned and operated by the same entity that owns the FQHC.

10. Applications submitted by an Academic Specialty Pharmacy. For purposes of this Moratorium, an Academic Specialty Pharmacy is defined as a specialty pharmacy that is owned or operated by a higher education institution that is currently a Medi-Cal pharmacy provider.

This action is necessary to safeguard public funds and to maintain the fiscal integrity of the Medi-Cal program.

Original Signed by Jennifer Kent

Jennifer Kent
Director
Department of Health Care Services
Health and Human Services Agency
State of California

APR 2 0 2018

Date

Los Angeles County Pharmacy Moratorium

Merrold Young
Chief, Policy and Quality Control Section
Provider Enrollment Division
Department of Health Care Services

Background

- DHCS implemented the moratorium in June 2002 to safeguard public funds and maintain the fiscal integrity of the Medi-Cal program
- Every 180 days PED consults with other divisions to re-evaluate its effectiveness and necessity
- PED works with Audits and Investigations re: program integrity concerns and consults with Pharmacy Benefits to ensure the moratorium is not causing access to care issues
- Exceptions have been added to allow for: continued enrollment, sole source, FQHCs, reorganizations of ownership, and most recently academic specialty pharmacies

When is a new Medi-Cal provider application needed?

- New enrollment
- Continued enrollment
- New, additional, or change in location
- Change of ownership
- 50%+ assets are sold or transferred
- New TIN issued by IRS
- New site permit number is issued by the Board of Pharmacy
- Change of 50%+ in the person(s) with ownership or control interest

What changes can be reported without a complete application package?

- All changes to a previous application should be reported to DHCS within 35 days

- The following changes can be reported either via the PAVE Portal or by submitting a paper Medi-Cal Supplemental Changes Form (DHCS 6209):
  - Pay-to address
  - Mailing address
  - Business telephone number
  - Managing employee
  - Pharmacist-in-charge
  - Business activities
  - DBA name
  - Deactivation of a provider number
  - Change of < 50% in person(s) with an ownership/control interest

Attachment 3

Proposal to Amend Section 1732.5 of Title 16 California Code of Regulation as follows:

§ 1732.5. Renewal Requirements for Pharmacists

(a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.

(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. For an online course, the course shall be considered completed when the pharmacist correctly answers eighty percent of the questions posed, which questions are based directly on the course materials. with a score of eighty percent or higher. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.

(c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4232, Business and Professions Code.

Attachment 4

§ 4233. Advanced Practice Pharmacist; Continuing Education Requirement
(a)A pharmacist who is recognized as an advanced practice pharmacist shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

Proposal to Add section 1732.55 an Advanced Practice Pharmacist Renewal Requirements as follows:

§ 1732.55 Renewal Requirements for an Advanced Practice Pharmacist
(a) An applicant for renewal of an advanced practice pharmacist license shall maintain a current and active pharmacist license and shall submit all of the follow as part of the renewal:
(1) Application and payment of the renewal fee.
(2) Submit proof satisfactory to the board that the licensee has completed 10 hours of continuing education. This is in addition to continuing education requirements necessary for pharmacist license renewal.
(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an advanced practice pharmacist license.
(c) The board may issue an inactive advanced practice pharmacist license under any of the following conditions:
(1) The pharmacist license becomes inactive.
(2) The licensee fails to provide documentation of the completion of the required continuing education.
(3) As part of an investigation or audit conducted by the board, an advanced practice pharmacist fails to provide documentation substantiating the completion of continuing education as required.
(d) An inactive advanced practice pharmacist license may only be reactivated by paying the renewal fees due, submitting satisfactory proof to the board that the licensee has completed 10 hours of continuing education, and is confirmed have met all licensure renewal requirements.
(f) An advanced practice pharmacist shall retain documentation of completion of continuing education for four (4) years following completion.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231 and 4233 Business and Professions Code.

Attachment 5

Proposal to Amend Section 4400 subdivisions (n) and (o) of the Business and Professions Code as follows:

4400. Fees

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

…..

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for processing of an application to change information on a premises license record ~~reissuance of any license, or renewal thereof, that must be reissued because of a change in the information,~~ shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

Attachment 6

Proposal to Amend Section 4115.5 subdivision (c)(2) of the Business and Professions Code as follows:

4115.5. Pharmacy Technician Trainee; Placement; Supervision; Requirements

(a) Notwithstanding any other provision of law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no ~~more~~ less than 120 and no more than 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to ~~320~~ 340 hours. ~~No more than 120~~ ~~130 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy~~

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates his or her trainee status.

Attachment 7

Medication and Counseling Treatment

Medication-Assisted Treatment (MAT) is the use of medications, in combination with counseling and behavioral therapies, to provide a “whole-patient” approach to the treatment of substance use disorders. Research shows that a combination of medication and therapy can successfully treat these disorders, and for some people struggling with addiction, MAT can help sustain recovery. Learn about many of the substance use disorders that MAT is designed to address.

MAT is primarily used for the treatment of addiction to opioids such as heroin and prescription pain relievers that contain opiates. The prescribed medication operates to normalize brain chemistry, block the euphoric effects of alcohol and opioids, relieve physiological cravings, and normalize body functions without the negative effects of the abused drug. Medications used in MAT are approved by the Food and Drug Administration (FDA), and MAT programs are clinically driven and tailored to meet each patient’s needs. Combining medications used in MAT with anxiety treatment medications can be fatal. Types of anxiety treatment medications include derivatives of Benzodiazepine, such as Xanax or valium.

Opioid Treatment Programs (OTPs)

Opioid treatment programs (OTPs) provide MAT for individuals diagnosed with an opioid use disorder. OTPs also provide a range of services to reduce, eliminate, or prevent the use of illicit drugs, potential criminal activity, and/or the spread of infectious disease. OTPs focus on improving the quality of life of those receiving treatment.

OTPs must be accredited by a SAMHSA-approved accrediting body and certified by SAMHSA. The Division of Pharmacologic Therapies (DPT), part of the SAMHSA Center for Substance Abuse Treatment (CSAT), oversees accreditation standards and certification processes for OTPs. Learn more about the certification of OTPs and SAMHSA’s oversight of OTP Accreditation Bodies.

Federal law requires patients who receive treatment in an OTP to receive medical, counseling, vocational, educational, and other assessment and treatment services, in addition to prescribed medication. The law allows MAT professionals to provide treatment and services in a range of settings, including hospitals, correctional facilities, offices, and remote clinics. Learn more about the legislation, regulations, and guidelines that govern OTPs.

As of 2015, OTPs were located in every U.S. state except North Dakota and Wyoming. The District of Columbia and the territories of Puerto Rico and the Virgin Islands also had OTPs in operation.

Counseling and Behavioral Therapies

Under federal law, MAT patients must receive counseling, which could include different forms of behavioral therapy. These services are required along with medical, vocational, educational, and other assessment and treatment services. Learn more about these treatments for substance use disorders.

MAT Effectiveness

In 2013, an estimated 1.8 million people had an opioid use disorder related to prescription pain relievers, and about 517,000 had an opioid use disorder related to heroin use. MAT has proved to be clinically effective and to significantly reduce the need for inpatient detoxification services for these individuals. MAT provides a more comprehensive, individually tailored program of medication and behavioral therapy. MAT also includes support services that address the needs of most patients.

The ultimate goal of MAT is full recovery, including the ability to live a self-directed life. This treatment approach has been shown to:

- Improve patient survival
- Increase retention in treatment
- Decrease illicit opiate use and other criminal activity among people with substance use disorders
- Increase patients' ability to gain and maintain employment
- Improve birth outcomes among women who have substance use disorders and are pregnant

Research also shows that these medications and therapies can contribute to lowering a person's risk of contracting HIV or hepatitis C by reducing the potential for relapse. Learn more about substance misuse and how it relates to HIV, AIDS, and Viral Hepatitis. Learn more about common comorbidities that occur with substance use disorders.

Unfortunately, MAT is greatly underused. For instance, according to SAMHSA's Treatment Episode Data Set (TEDS) 2002-2010, the proportion of heroin admissions with treatment plans that included receiving medication-assisted opioid therapy fell from 35% in 2002 to 28% in 2010. The slow adoption of these evidence-based treatment options for alcohol and opioid dependence is partly due to misconceptions about substituting one drug for another. Discrimination against MAT patients is also a factor, despite state and federal laws clearly prohibiting it. Other factors include lack of training for physicians and negative opinions toward MAT in communities and among health care professionals.

MAT and Patient Rights

SAMHSA's Partners for Recovery Initiative produced a brochure designed to assist MAT patients and to educate and inform others. This Medication-Assisted Treatment Know Your Rights Brochure – 2009 presents and explains the federal laws that prohibit discrimination against individuals with disabilities and how they protect people receiving MAT for opioid addiction.

Under the Confidentiality Regulation, 42 Code of Federal Regulations (CFR) 2, personally identifiable health information relating to substance use and alcohol treatment must be handled with a higher degree of confidentiality than other medical information.

Medications Used in MAT

FDA has approved several different medications to treat opioid addiction and alcohol dependence.

A common misconception associated with MAT is that it substitutes one drug for another. Instead, these medications relieve the withdrawal symptoms and psychological cravings that cause chemical imbalances in the body. MAT programs provide a safe and controlled level of medication to overcome the use of an abused opioid. And research has shown that when provided at the proper dose, medications used in MAT have no adverse effects on a person's intelligence, mental capability, physical functioning, or employability.

Medications used in MAT for opioid treatment can only be dispensed through a SAMHSA-certified OTP. Some of the medications used in MAT are controlled substances due to their potential for misuse. Drugs, substances, and certain chemicals used to make drugs are classified by the Drug Enforcement Administration (DEA) into five distinct categories, or schedules, depending upon a drug's acceptable medical use and potential for misuse. Learn more about DEA drug schedules.

Opioid Dependency Medications

Methadone, buprenorphine, and naltrexone are used to treat opioid dependence and addiction to short-acting opioids such as heroin, morphine, and codeine, as well as semi-synthetic opioids like oxycodone and hydrocodone. People may safely take medications used in MAT for months, years, several years, or even a lifetime. Plans to stop a medication must always be discussed with a doctor.

Methadone

Methadone tricks the brain into thinking it's still getting the abused drug. In fact, the person is not getting high from it and feels normal, so withdrawal doesn't occur. Learn more about methadone.

Pregnant or breastfeeding women must inform their treatment provider before taking methadone. It is the only drug used in MAT approved for women who are pregnant or breastfeeding. Learn more about pregnant or breastfeeding women and methadone.

Buprenorphine

Like methadone, buprenorphine suppresses and reduces cravings for the abused drug. It can come in a pill form or sublingual tablet that is placed under the tongue. Learn more about buprenorphine.

Naltrexone

Naltrexone works differently than methadone and buprenorphine in the treatment of opioid dependency. If a person using naltrexone relapses and uses the abused drug, naltrexone blocks the euphoric and sedative effects of the abused drug and prevents feelings of euphoria. Learn more about naltrexone.

Opioid Overdose Prevention Medication

FDA approved naloxone, an injectable drug used to prevent an opioid overdose. According to the World Health Organization (WHO), naloxone is one of a number of medications considered essential to a functioning health care system (link is external).

Alcohol Use Disorder Medications

Disulfiram, acamprosate, and naltrexone are the most common drugs used to treat alcohol use disorder. None of these drugs provide a cure for the disorder, but they are most effective in people who participate in a MAT program. Learn more about the impact of alcohol misuse.

Disulfiram

Disulfiram is a medication that treats chronic alcoholism. It is most effective in people who have already gone through detoxification or are in the initial stage of abstinence. This drug is offered in a tablet form and is taken once a day. Disulfiram should never be taken while intoxicated and it should not be taken for at least 12 hours after drinking alcohol. Unpleasant side effects (nausea, headache, vomiting, chest pains, difficulty breathing) can occur as soon as ten minutes after drinking even a small amount of alcohol and can last for an hour or more.

Acamprosate

Acamprosate is a medication for people in recovery who have already stopped drinking alcohol and want to avoid drinking. It works to prevent people from drinking alcohol, but it does not prevent withdrawal symptoms after people drink alcohol. It has not been shown to work in people who continue drinking alcohol, consume illicit drugs, and/or engage in prescription drug misuse and abuse. The use of acamprosate typically begins on the fifth day of abstinence, reaching full effectiveness in five to eight days. It is offered in tablet form and taken three times a day, preferably at the same time every day. The medication's side effects may include diarrhea, upset stomach, appetite loss, anxiety, dizziness, and difficulty sleeping.

Naltrexone

When used as a treatment for alcohol dependency, naltrexone blocks the euphoric effects and

feelings of intoxication. This allows people with alcohol addiction to reduce their drinking behaviors enough to remain motivated to stay in treatment, avoid relapses, and take medications. Learn more about how naltrexone is used to treat alcohol dependency.

Access Medication for the Treatment of Alcohol Use Disorder: A Brief Guide – 2015 to learn more about MAT for alcohol use disorder.

MAT Medications and Child Safety

It's important to remember that if medications are allowed to be kept at home, they must be locked in a safe place away from children. Methadone in its liquid form is colored and is sometimes mistaken for a soft drink. Children who take medications used in MAT may overdose and die.

Find Treatment

Additional Resources

Access information about SAMHSA's federal partners, associations, and other support organizations that offer MAT-related resources for consumers and substance use treatment professionals.

Attachment 8

CALIFORNIA STATE BOARD OF PHARMACY

STRATEGIC PLAN

2017-2021

GOAL 1

LICENSING

The board promotes licensing standards to protect consumers and allow reasonable access to the profession.

1.1 Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.

1.2 Implement online application, license renewal, and fee payment for applicants and licensees to improve licensing conveniences.

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.

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.

1.5 Improve the application process for new licensees, including providing informational resources directed toward applicants to offer more guidance about the application process.

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.

1.7 Identify opportunities to expand electronic interfaces with licensees to allow for online application and renewal.

Attachment 9

Premises Application Types	Application Processing Times As of 9/26/18	Application Processing Times As of 10/11/2018	Deficiency Mail Processing Times As of 9/26/18	Deficiency Mail Processing Times As of 10/11/2018
Pharmacy	50	27	40	67
Nonresident Pharmacy	58	23	40	67
Sterile Compounding	17	Current	4	21
Nonresident Sterile Compounding	Current	Current	3	15
Outsourcing	16	Current	Current	Current
Nonresident Outsourcing	17	Current	Current	9
Hospital	50	Current	Included in Pharmacy	Included in Pharmacy
Clinic	25	25	24	21
Wholesaler	4	28	29	Current
Nonresident Wholesaler	23	27	25	Current
Third-Party Logistics Provider	Current	Current	24	Current
Nonresident Third-Party Logistics Provider	Current	10	Current	Current

Individual Application Type	Application Processing Times As of 9/26/18	Application Processing Times As of 10/11/2018	Deficiency Mail Processing Times As of 9/26/18	Deficiency Mail Processing Times As of 10/11/2018
Pharmacist Examination	78	79	14	10
Pharmacist Initial Licensure	8	3	n/a	n/a
Advanced Practice Pharmacist	15	Current	7	8
Intern Pharmacist	38	29	21	10
Pharmacy Technician	44	30	22	7
Designated Representative	13	36	28	10
Designated Represenative-3PL	39	14	30	10

The board issued 1075 licenses between 9/26/2018 and 10/11/2018 including 375 Pharmacist licenses, 393 Pharmacy Technician licenses, 232 Intern Pharmacist licenses, and 27 Pharmacy licenses.

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										97
Designated Representatives Vet (EXV)	0	3	0										3
Designated Representatives-3PL (DRL)	4	5	1										10
Designated Representatives-Reverse Distributor (DRR)	0	0	0										0
Designated Paramedic (DPM)	0	0	0										0
Intern Pharmacist (INT)	152	1038	210										1400
*Pharmacist (exam applications)	193	171	186										550
Pharmacist (initial licensing applications)	34	179	764										977
Advanced Practice Pharmacist (APH)	25	20	12										57
Pharmacy Technician (TCH)	504	522	413										1439
	* total includes retake exam applications												
Centralized Hospital Packaging (CHP)	0	0	1										1
Centralized Hospital Packaging Exempt (CHE)	0	0	0										0
Clinics (CLN)	120	6	10										136
Clinics Exempt (CLE)	0	14	0										14
Drug Room (DRM)	0	0	0										0
Drug Room -Temp	0	0	0										0
Drug Room Exempt (DRE)	0	0	0										0
Emergency Medical Services Automated Drug Delivery System	0	0	0										0
Hospitals (HSP)	3	2	0										5
Hospitals - Temp	0	0	1										1
Hospitals Exempt (HPE)	0	1	0										1
Hospital Satellite Sterile Compounding (SCP)	0	0	0										0
Hospital Satellite Sterile Compounding - Temp	0	0	0										0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0										0
Hypodermic Needle and Syringes (HYP)	2	2	2										6
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0										0
Correctional Pharmacy (LCF)	0	0	0										0
Outsourcing Facility (OSF)	0	1	0										1
Outsourcing Facility - Temp	0	0	0										0
Outsourcing Facility Nonresident (NSF)	0	1	0										1
Outsourcing Facility Nonresident - Temp	0	0	0										0
Pharmacy (PHY)	36	27	54										117
Pharmacy - Temp	583	10	37										630
Pharmacy Exempt (PHE)	0	1	0										1
Pharmacy Nonresident (NRP)	8	15	35										58
Pharmacy Nonresident Temp	3	16	32										51
Sterile Compounding (LSC)	10	5	4										19
Sterile Compounding - Temp	4	0	1										5
Sterile Compounding Exempt (LSE)	0	0	2										2
Sterile Compounding Nonresident (NSC)	2	1	3										6
Sterile Compounding Nonresident Temp	1	0	3										4
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0										0
Third-Party Logistics Providers (TPL)	3	0	0										3
Third-Party Logistics Providers - Temp	3	0	0										3
Third-Party Logistics Providers Nonresident (NPL)	1	0	0										1
Third-Party Logistics Providers Nonresident Temp	1	0	0										1
Veterinary Food-Animal Drug Retailer (VET)	1	1	1										3
Veterinary Food-Animal Drug Retailer - Temp	0	1	0										1
Wholesalers (WLS)	8	4	7										19
Wholesalers - Temp	1	3	4										8
Wholesalers Exempt (WLE)	0	0	0										0
Wholesalers Nonresident (OSD)	5	11	8										24
Wholesalers Nonresident - Temp	4	2	3										9
Total	1742	2091	1831	0	0	0	0	0	0	0	0	0	5664

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										71
Designated Representatives Vet (EXV)	0	0	0										0
Designated Representatives-3PL (DRL)	8	6	2										16
Designated Representatives-Reverse Distributor (DRR)	0	0	0										0
Designated Paramedic (DPM)	0	0	0										0
Intern Pharmacist (INT)	75	623	399										1097
Pharmacist (initial licensing applications)	42	183	670										895
Advanced Practice Pharmacist (APH)	21	17	17										55
Pharmacy Technician (TCH)	506	570	200										1276
Centralized Hospital Packaging (CHP)	0	0	0										0
Centralized Hospital Packaging Exempt (CHE)	0	0	0										0
Clinics (CLN)	2	7	2										11
Clinics Exempt (CLE)	0	0	0										0
Drug Room (DRM)	0	0	0										0
Drug Room-Temp	0	0	0										0
Drug Room Exempt (DRE)	0	1	0										1
Emergency Medical Services Automated Drug Delivery System	0	0	0										0
Hospitals (HSP)	1	0	0										1
Hospitals - Temp	1	1	0										2
Hospitals Exempt (HPE)	0	0	0										0
Hospital Satellite Sterile Compounding (SCP)	0	0	0										0
Hospital Satellite Sterile Compounding - Temp	0	0	0										0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0										0
Hypodermic Needle and Syringes (HYP)	0	8	1										9
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0										0
Correctional Pharmacy (LCF)	0	0	0										0
Outsourcing Facility (OSF)	0	0	0										0
Outsourcing Facility - Temp	0	0	0										0
Outsourcing Facility Nonresident (NSF)	1	1	0										2
Outsourcing Facility Nonresident - Temp	0	0	0										0
Pharmacy (PHY)	8	5	14										27
Pharmacy - Temp	6	11	12										29
Pharmacy Exempt (PHE)	0	0	0										0
Pharmacy Nonresident (NRP)	1	0	3										4
Pharmacy Nonresident Temp	3	3	4										10
Sterile Compounding (LSC)	4	3	0										7
Sterile Compounding - Temp	0	3	0										3
Sterile Compounding Exempt (LSE)	0	0	0										0
Sterile Compounding Nonresident (NSC)	1	0	0										1
Sterile Compounding Nonresident Temp	1	1	0										2
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0										0
Third-Party Logistics Providers (TPL)	0	0	0										0
Third-Party Logistics Providers-Temp	0	2	0										2
Third-Party Logistics Providers Nonresident (NPL)	0	1	1										2
Third-Party Logistics Providers Nonresident Temp	0	1	1										2
Veterinary Food-Animal Drug Retailer (VET)	0	0	0										0
Veterinary Food-Animal Drug Retailer - Temp	0	0	1										1
Wholesalers (WLS)	0	5	1										6
Wholesalers - Temp	2	3	4										9
Wholesalers Exempt (WLE)	0	0	0										0
Wholesalers Nonresident (OSD)	2	2	3										7
Wholesalers Nonresident - Temp	5	2	2										9
Total	734	1477	1346	0	0	0	0	0	0	0	0	0	3557

APPLICATIONS (continued)

Pending	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN
Designated Representatives (EXC)	293	298	321									
Designated Representatives Vet (EXV)	0	3	3									
Designated Representatives-3PL (DRL)	93	91	89									
Designated Representatives-Reverse Distributor (DRR)	0	0	0									
Designated Paramedic (DPM)	0	0	0									
Intern Pharmacist (INT)	296	420	498									
Pharmacist (exam applications)	1122	1034	1085									
Pharmacist (eligible exam(Status A))	2698	2654	1957									
Advanced Practice Pharmacist (APH)	178	177	175									
Pharmacy Technician (TCH)	1150	1095	1287									
Centralized Hospital Packaging (CHP)	2	2	3									
Centralized Hospital Packaging Exempt (CHE)	0	0	0									
Clinics (CLN)	188	194	203									
Clinics Exempt (CLE)	8	22	22									
Emergency Medical Services Automated Drug Delivery System	0	0	0									
Drug Room (DRM)	0	0	0									
Drug Room Exempt (DRE)	1	0	0									
Hospitals (HSP)	10	7	8									
Hospitals Exempt (HPE)	0	1	1									
Hospital Satellite Sterile Compounding (SCP)	5	6	5									
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0									
Hypodermic Needle and Syringes (HYP)	25	19	20									
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0									
Correctional Pharmacy (LCF)	1	1	1									
Outsourcing Facility (OSF)	3	4	4									
Outsourcing Facility Nonresident (NSF)	11	11	10									
Pharmacy (PHY)	713	152	178									
Pharmacy Exempt (PHE)	3	4	4									
Pharmacy Nonresident (NRP)	95	106	134									
Sterile Compounding (LSC)	77	64	64									
Sterile Compounding - Exempt (LSE)	7	6	8									
Sterile Compounding Nonresident (NSC)	21	21	23									
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0									
Third-Party Logistics Providers (TPL)	12	9	7									
Third-Party Logistics Providers Nonresident (NPL)	50	48	46									
Veterinary Food-Animal Drug Retailer (VET)	1	1	2									
Wholesalers (WLS)	51	44	46									
Wholesalers Exempt (WLE)	1	1	1									
Wholesalers Nonresident (OSD)	113	120	122									
Total	7228	6615	6327	0	0	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										26
Designated Representatives Vet (EXV)	1	0	0										1
Designated Representatives-3PL (DRL)	3	0	1										4
Designated Representatives-Reverse Distributor (DRR)	0	0	0										0
Designated Paramedic (DPM)	0	0	0										0
Intern Pharmacist (INT)	0	1	0										1
Pharmacist (exam applications)	2	0	1										3
Advanced Practice Pharmacist (APH)	0	0	0										0
Pharmacy Technician (TCH)	1	6	5										12
Centralized Hospital Packaging (CHP)	0	0	0										0
Centralized Hospital Packaging Exempt (CHE)	0	0	0										0
Clinics (CLN)	1	1	0										2
Clinics Exempt (CLE)	0	0	0										0
Drug Room (DRM)	0	0	0										0
Drug Room Exempt (DRE)	0	0	0										0
Emergency Medical Services Automated Drug Delivery System	0	0	0										0
Hospitals (HSP)	0	0	0										0
Hospitals Exempt (HPE)	0	0	0										0
Hospital Satellite Sterile Compounding (SCP)	0	0	0										0
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0										0
Hypodermic Needle and Syringes (HYP)	1	0	0										1
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0										0
Correctional Pharmacy (LCF)	0	0	0										0
Outsourcing Facility (OSF)	0	0	0										0
Outsourcing Facility Nonresident (NSF)	0	1	0										1
Pharmacy (PHY)	1	566	3										570
Pharmacy Exempt (PHE)	0	0	0										0
Pharmacy Nonresident (NRP)	0	1	0										1
Sterile Compounding (LSC)	0	1	0										1
Sterile Compounding Exempt (LSE)	0	1	0										1
Sterile Compounding Nonresident (NSC)	1	0	0										1
Surplus Medication Collection Distribution Intermediary (SME)	0	0	0										0
Third-Party Logistics Providers (TPL)	0	1	2										3
Third-Party Logistics Providers Nonresident (NPL)	0	0	0										0
Veterinary Food-Animal Drug Retailer (VET)	0	0	0										0
Wholesalers (WLS)	0	0	0										0
Wholesalers Exempt (WLE)	0	0	0										0
Wholesalers Nonresident (OSD)	2	0	1										3
Total	34	583	14	0	0	0	0	0	0	0	0	0	631

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)

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

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
	867	637	104										1608
	984	215	0										1199
	314	158	767										1239
Pharmacist/Intern Responded	49	44	158										251
Pharmacy Technician Received	421	466	355										1242
Pharmacy Technician Responded	454	294	322										1070
Pharmacy Received	510	537	491										1538
Pharmacy Responded	519	560	475										1554
Sterile Compounding/Outsourcing Received	514	638	354										1506
Sterile Compounding/Outsourcing Responded	205	398	275										878
Wholesale/Clinic/Hypodermic/3PL Received	321	319	253										893
Wholesale/Clinic/Hypodermic/3PL Responded	256	289	272										817
Pharmacist-in-Charge Received	142	180	161										483
Pharmacist-in-Charge Responded	99	133	155										387
Change of Permit Received	343	530	890										1763
Change of Permit Responded	352	424	395										1171
	516	580	544										1640
	418	466	439										1323
	5	2	9										16
	7	6	8										21
	90	66	45										201
	13	12	15										40
	44	38	36										118
	4	78	34										116
	88	38	82										208
	602	641	548										1791

UPDATE LICENSING RECORDS

A. Change of Pharmacist-in-Charge	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
	198	188	184										570
	124	375	251										750
	122	347	235										704
	515	337	275										275
	14	7	11										32
	4	29	14										47
	3	21	14										38
	60	46	44										44
	2	0	0										2
	3	5	0										8
	3	9	0										12
	11	2	2										2
	118	100	152										370
	107	148	233										488
	103	182	170										455
	953	873	866										866

E. Automated Drug Delivery Systems	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
	61	36	68										165
	0	0	0										0
	0	0	0										0
	94	134	202										202
	0	0	0										0
	0	1	0										1
	0	1	0										1
	1	0	0										0
	37	47	51										135
	72	20	98										190
	42	30	64										136
	179	198	181										181
			1393										3830
	26	0	27										53
	4	2	1										7
	187	223	141										551

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

Designated Representatives (EXC)	217	245	178										640
Designated Representatives Vet (EXV)	9	4	5										18
Designated Representatives-3PL (DRL)	15	27	31										73
Designated Representatives-Reverse Distributor (DRR)	0	0	0										0
Designated Paramedic (DPM)	0	0	0										0
Pharmacist (RPH)	1534	2091	1743										5,368
Advanced Practice Pharmacist (APH)	9	14	18										41
Pharmacy Technician (TCH)	2442	3102	2392										7,936
Centralized Hospital Packaging (CHP)		0	0										3
Centralized Hospital Packaging Exempt (CHE)		0	0										1
Clinics (CLN)		87	64										224
Clinics Exempt (CLE)		0	69										71
Drug Room (DRM)		0	2										4
Drug Room Exempt (DRE)		0	5										5
	0	0	0										0
		18	43										77
		2	31										49
													0
													0
		22	19										53
		0	0										0
		1	33										34
													5
													0
		377	712										1,321
		0	71										74
		35	23										82
													139
		8	24										60
	4	1	2										7
	0	0	0										0
		1	3										5
		0	8										9
	1	1	1										3
		63	25										110
		0	6										6
		51	57										162
	4777	6195	5608	0	0	0	0	0	0	0	0	0	16580

Board of Pharmacy Licensing Statistics - Fiscal Year 2018/19

Current Licensees

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Designated Representatives (EXC)	3017	2997	2919										
Designated Representatives Vet (EXV)	68	67	69										
Designated Representatives-3PL (DRL)	291	291	295										
Designated Representatives-Reverse Distributor (DRR)	0	0	0										
Designated Paramedic (DPM)	0	0	0										
Intern Pharmacist (INT)	6854	7248	7104										
Pharmacist (RPH)	45967	46049	46741										
Advanced Practice Pharmacist (APH)	355	372	389										
Pharmacy Technician (TCH)	71473	71432	71316										
Centralized Hospital Packaging (CHP)	8	8	8										
Centralized Hospital Packaging Exempt (CHE)	2	2	2										
Clinics (CLN)	1108	1114	1105										
Clinics Exempt (CLE)	242	241	241										
Drug Room (DRM)	23	23	23										
Drug Room Exempt (DRE)	9	10	10										
Emergency Medical Services Automated Drug Delivery System	0	0	0										
Hospitals (HSP)	385	383	383										
Hospitals Exempt (HPE)	84	84	85										
Hospital Satellite Sterile Compounding (SCP)	0	0	0										
Hospital Satellite Sterile Compounding Exempt (SCE)	0	0	0										
Hypodermic Needle and Syringes (HYP)	293	301	300										
Hypodermic Needle and Syringes Exempt (HYE)	0	0	0										
Correctional Pharmacy (LCF)	58	58	58										
Outsourcing Facility (OSF)	2	2	2										
Outsourcing Facility Nonresident (NSF)	19	20	21										
Pharmacy (PHY)	6500	6488	6476										
Pharmacy Exempt (PHE)	126	126	126										
Pharmacy Nonresident (NRP)	546	544	538										
Sterile Compounding (LSC)	755	759	755										
Sterile Compounding Exempt (LSE)	117	116	113										
Sterile Compounding Nonresident (NSC)	76	76	74										
Surplus Medication Collection Distribution Intermediary (SME)	1	1	1										
Third-Party Logistics Providers (TPL)	23	23	23										
Third-Party Logistics Providers Nonresident (NPL)	65	64	66										
Veterinary Food-Animal Drug Retailer (VET)	20	20	21										
Wholesalers (WLS)	538	538	534										
Wholesalers Exempt (WLE)	16	16	16										
Wholesalers Nonresident (OSD)	750	748	744										
Total	139791	140221	140558	0	0	0	0	0	0	0	0	0	0

Attachment 10

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.