



**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
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.