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

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

# LICENSING COMMITTEE
# MEETING MINUTES

**DATE:** December 19, 2018

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

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

**BOARD MEMBERS NOT PRESENT:** Amjad Khan, Public Member

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

1. **Call to Order, Establishment of Quorum, and General Announcements**
   Chairperson Veale called the meeting to order at 10:05 a.m.

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

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

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

   Chairperson Veale responded the Licensing Committee will add to the next agenda information and discussion regarding the new legislation that was enacted last year to allows pharmacies, manufactures, and wholesalers to sell naloxone to first responders.

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

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

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

Chairperson Veale stated in recent years the number of declared state of emergencies in California has grown both in frequency and scope. The board has relied upon both its strong policy and legislative authority during such emergencies to guide pharmacists in helping displaced patients.

Chairperson Veale reported that when such an event occurs, the board uses its subscriber alert system to remind pharmacists about authorities provided in the law. Further, the board's duty inspector provides real time guidance. During the most recent declared emergency resulting from the Camp Fire, in addition to mandatory evacuations and loss of homes, five pharmacies were closed because the business either burned down or sustained significant fire damage. An additional six pharmacies closed for limited time due to air quality concerns.

Chairperson Veale noted that in addition to working with licensees, board staff also collaborates with other state agencies involved in disaster response, most notably the California Department of Public Health and the Office of Emergency Services. During this most recent emergency, the board disseminated information on a pharmacist's ability to care for patients under emergency conditions via the subscriber alert system. For the first time the board also shared reimbursement procedures for pharmacies providing emergency dispensing through the Emergency Prescription Assistance Program (EPAP).

Chairperson Veale stated that during this meeting, the committee will have an opportunity to hear a presentation from the California Department of Public Health (CDPH) on the provision of pharmacy services during a declared state of emergency.

Chairperson Veale explained board staff has reported some challenges that patients and/or pharmacies experienced during the Camp Fire emergency that may be appropriate for the committee to discuss.

Methadone patients were in some cases unable to get their prescribed doses of methadone. A call to Department of Healthcare Services (DHCS) solved this.
A pharmacy in an evacuation area that had not been destroyed was being watched for possible drug theft opportunities.

Early on in the emergency, patients could not get their medications because they had no money to cover copays.

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

Dr. Ahrens stated the Camp Fire required a larger response than past fires due to the large number of individuals displaced and the significant damage to infrastructure and health care facilities including pharmacies. The committee was advised about the different entities that may establish shelters (e.g., The Red Cross, Salvation Army, local government, and religious organizations). However, the presenters stated that problems exist in some shelters where medical care is not included (more commonly community shelters). The presenters clarified different problems exist in the different types of shelters.

The presenters explained some shelters provided medical care with some over-the-counter medications and limited prescriptions being provided to evacuees. In other cases, patients receive a written prescription and then need to find a pharmacy. If transportation was not available, filling the prescription was a problem. It was noted that this problem was aggravated because shelter managers are typically not healthcare providers. It was also noted that even if a patient could find transportation to a pharmacy, many lacked the ability to cover copays and did not have insurance information.

The presenters stated that there is a need for more healthcare providers in shelters as well as more dispensing options available to patients in need of medications. The presenters also highlighted that challenges exist in transporting prescription drugs to shelters, especially for controlled substances.

Dr. Chew reported that he performed dispensing functions during the recent disaster. He noted that one of the most frustrating issues is that pharmacists don't read the statements issued by the board or are hesitant to follow the directions provided by the board.

Note: The presenters provided a handout to the committee and the public which highlighted the issues faced by shelters and the recommendations from CDPH to the board. The document has been provided following these minutes.

Vice Chairperson Stanley Weisser expressed concerns with the challenges pharmacies face when seeking reimbursement from PBMs for a patient who was unable to provide insurance information during an emergency.

Chairperson Veale noted during emergencies PBMs provide information to pharmacies in the affected areas on how to use over-ride codes for patients who need medications. Ms. Veale noted that pharmacists can also do an eligibility check of a patient through SureScripts to attempt to gather the information needed for reimbursement.

Committee member Dr. Albert Wong suggested that the state should consider guaranteeing payments to pharmacies who provide medications to patients during a declared state of emergency.

The committee discussed the Emergency Prescription Assistance Program, or EPAP, which helps people in a federally-identified disaster area who do not have health insurance get the prescription drugs, vaccinations, medical supplies, and equipment that they need. Dr. Chew stated that this program is helpful, but it only is available if a federal disaster is declared and if the patient has **ZERO** insurance. Dr. Chew noted that only six patients were able to use the program during the wildfires. Board staff offered to research options regarding co-pays and reimbursements.

Committee member Lavanza Butler asked if there were any problems with the board communicating with pharmacies. Ms. Herold stated that she took phone calls as well as the duty inspector. She added that there is always room to improve the board's outreach and education. Dr. Wong suggested that the board's inspectors proactively reach out to pharmacies in the disaster area to see if they need assistance.

The committee discussed the development of a free, voluntary continuing education (CE) program regarding disaster response as well as a contact list for chain pharmacies so that the board can use it to provide information quickly during a disaster. The committee also discussed the development of a fact sheet for pharmacies. Ms. Veale volunteered to provide information on performing eligibility checks to be included on the fact sheet for pharmacies. The committee noted that these items would be best handled by the Communication and Public Education Committee.

Dr. Wong suggested that the board create a specific blank prescription form to be used during emergencies. Ms. Sodergren explained that there is currently an exemption in pharmacy law for terminally ill patients and suggested that the board could use a similar exemption during declared emergencies.

Dr. Chew explained another difficulty they faced was that wholesalers refused to delivery to remote unlicensed locations. Ms. Herold stated that the board will reach out to the wholesalers to discuss operations during a declared state of emergency.

Dr. Chew again stated that a major problem during disasters is the lack of health care professionals available to assist evacuees. He explained that there is a disaster healthcare volunteer system and encouraged pharmacists to join (including the board's inspectors).

A representative from Walgreens commented that the board has a good communication plan in place for emergencies. She indicated that Walgreens is able to provide information to stores quickly after receiving a subscriber alert sent by the board. It was also noted that Walgreens felt the board's communications were clear and did not have any problems interpreting the board's laws during declared emergencies.

Pharmacist Steve Gray noted that other states have not had to deal with disaster responses and commended the board for their efforts in the area. Dr. Gray stated that when people are evacuated they often travel to other areas of the state. He recommended changing the wording of the waiver notice to make it clear that the waivers are valid throughout the state and not limited to the disaster area itself. Dr. Gray also recommended that the board work with neighboring states as well so that patients who leave the state when they are evacuated can still receive care.

Paige Tally explained the difficulties skilled nursing facilities faced when they had to evacuate their patients. She asked if CDPH assists with evacuations. Dr. Chew stated that CDPH does help track where patients are evacuated so they can continue to receive medical care.

Chairperson Veale asked if Dr. Chew and Dr. Ahrens would provide their presentation to the Communication and Public Education Committee. Dr. Chew and Dr. Ahrens agreed to present at the January 8th committee meeting.

**Committee Recommendation:** Authorize the Chair to work with staff to develop a statutory proposal for the board to consider regarding issues related to prescribing controlled substances during the recent declared state of emergency.

M/S: Weisser/Butler

Support: 5 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

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

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

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

Ms. Sodergren provided risk factors if a remodel inspection exceeds a time period close to the renewal inspections. The board is mandated to inspect the sterile compounding pharmacy prior to the expiration of the license and to approve the license for renewal. Therefore, the board could not hold off on conducting an inspection after the expiration date of the license if the remodel completed shortly after the expiration date of the license. Additionally, a sterile compounding pharmacy license renewal period runs congruent with the underlying primary pharmacy or hospital pharmacy license and as such the expiration date for the sterile compounding pharmacy cannot be altered. She suggested placing parameters in law to possibly state, if the remodel inspection is within 90 days of the renewal of the license, then the inspection would also serve as the renewal inspection.

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

Ms. Sodergren shared Danny Martinez's comments that opposes assessing a remodel inspection fee he sent to the board via email on behalf of CPHA.

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

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

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

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

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

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

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

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

(a) A pharmacy holding an automated drug delivery system (ADDS) license as defined under section 4119.11, 4187.5 or section 4427.2 of the Business and Professions Code shall complete a self-assessment

of compliance with federal and state pharmacy law for each location where an ADDS license is granted. The assessment shall be performed by the pharmacist-in-charge annually before July 1 of every year.
(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:

(1) A new ADDS license has been issued, or
(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge, or
(3) There is a change in the licensed location of an ADDS to a new address.

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

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

M/S: Weisser/Butler

Support: 5 Oppose: 0 Abstain: 0

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

**Draft Automated Drug Delivery System Self-Assessment form**

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

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

M/S: Butler/ Weisser

Support: 5 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Veale/Weisser

Support: 5 Oppose: 0 Abstain: 0

**7. Licensing Statistics**

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

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

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

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

- 7,061 intern pharmacists.
- 46,989 pharmacists.

- 439 advanced practice pharmacists.
- 71,267 pharmacy technicians.
- 6,450 community pharmacies.
- 408 hospital pharmacies

Processing Times

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

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

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

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

| **Premises Application Types** | **Application Processing Times As of 11/30/2018** | **Deficiency Mail Processing Times As of 11/30/2018** |
|---|---|---|
| Pharmacy | 38 | 56 |
| Nonresident Pharmacy | 43 | 74 |
| Sterile Compounding | 35 | 24 |
| Nonresident Sterile Compounding | 14 | 32 |
| Outsourcing | 0 | 0 |
| Nonresident Outsourcing | 0 | 0 |
| Hospital | 24 | Included w/PHY |
| Clinic | 17 | 10 |
| Wholesaler | 25 | 43 |
| Nonresident Wholesaler | 28 | 43 |
| Third-Party Logistics Provider | 0 | 32 |
| Nonresident Third-Party Logistics Provider | 17 | 46 |

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

**8. Future Committee Meeting Dates**

The 2019 Licensing Committee dates are as follows:

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

The licensing committee meeting adjourned at 1:00pm.