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

**LICENSING COMMITTEE REPORT**
**September 25, 2019**

Debbie Veale, Licensee Member, Chairperson
Lavanza Butler, Licensee Member, Vice-Chairperson
Allen Schaad, Licensee Member
Albert Wong, Licensee Member

1. Call to Order and Establishment of Quorum

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

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

3. Discussion and Consideration of Proposal to Amend the Requirements in Business and Professions Code Section 4210 to Qualify for an Advanced Practice Pharmacist License

   Relevant Law
   Business and Professions Code (BPC) section 4210 establishes the requirements for an individual to qualify for recognition as an advanced practice pharmacist (APH).
   As identified in BPC 4210 to qualify for an APH license, an individual must hold an active license to practice pharmacy and satisfy two of the following criteria under subdivision (a)(2):
   A. Earned certification in a relevant area of practice.
   B. Completion of a post graduate residency.
   C. Clinical experience for at least one year under a collaborative practice agreement or protocol.

   Background
   At the July 2019 board meeting, the board directed the licensing committee to review and discuss the criteria under subsection (a)(2) of section 4210 of the BPC to reassess the requirements to qualify for an APH license. Specifically, when a pharmacist is applying to satisfy the criteria in subsection (A) the earned certification in a relevant area of practice and (B) completion of a postgraduate residency. When assessing applicant information, the board has identified several instances when a pharmacist seeking licensure as an APH is using completion of a single criterion (e.g. a residency program) that included as a condition of completion, a second criterion (e.g. completion of a certification program). Under current law this is considered “double-dipping” and is prohibited.

To remedy this situation, the applicant may seek to meet another criterion, such as completion of the collaborative practice experience pathway. In this instance, the board allows the applicant one year to satisfy one of the other criteria to complete their application, thus keeping the application in pending status.

For Committee Discussion and Consideration

During the meeting members may wish to discuss the underlying policy goal of the legislation and determine if changes would be appropriate to allow an individual to qualify based on a single pathway, if such a pathway includes as a condition of completion two of the requirements established in BPC 4210. Should the committee reach such a conclusion and the board agrees with the committee's recommendation, a statutory change would be necessary.

The draft proposal in **Attachment 1** can serve as a starting point for the committee's policy discussion to allow for a pharmacist to satisfy both criterions in subsection (a)(2)(A) and (B) where the earned postgraduate residency was applied to earn their certification.

4. Use of Automated Drug Delivery Systems

Relevant Law

BPC section 4427.2 specifies the licensure requirements for an automated drug delivery system (ADDS) installed, leased, owned, or operated in California shall be licensed by the board. As provided, an ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

BPC section 4427.3 establishes the authorized locations for an ADDS and specifies that an ADDS must be placed and operated inside an enclosed building, at a location approved by the board. Following are the authorized locations:

1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.
3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.
4) A correctional clinic licensed pursuant to Section 4187.1.
5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

BPC section 4186 authorizes an ADDS, as defined in Section 4017.3, to be located in any clinic licensed by the board pursuant to Section 4180 of the BPC.

BPC section 4187.5 authorizes an ADDS, as defined in subdivision (h), to be located in a correctional clinic licensed by the board.

BPC section 4119.11 authorizes an Automated Patient Dispensing System (APDS) to be located on the premises of a covered entity as specified or on the premises of medical professional

practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met in this section.

a. Post Implementation Review of Legislation

SB 1447 (Chapter 666, Statutes of 2018) established the board's ADDS provisions. The provisions for this licensure took effect July 1. Since July 1, the board has licensed 695 ADDS.

AB 2037 (Chapter 647, Statutes of 2018) established the authority for a pharmacy to operate an APDS in a 340B clinic as specified. This measure included an urgency provision and took effect on September 21, 2018. Since September 21, 2018, the board has issued one such APDS license.

As the board's implementation efforts continue staff has identified several policy areas that may be appropriate to discuss to determine if additional changes should be pursued. Additional information is provided below.

b. Proposal to Expand the Use to Other Locations

One area of possible discussion is expansion of the locations where a pharmacy may operate an ADDS. Current law provides for ADDS to be used in the following locations:

- Licensed acute care hospital facility operating an AUDS pursuant to BPC 4427.2(i)
- Licensed acute psychiatric hospital facility operating an AUDS pursuant to BPC 4427.2(i)
- Licensed pharmacy premise operating ADDS pursuant to BPC 4427.2(j)
- Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license pursuant to BPC 4427.3(b)(1).
- A health facility licensed pursuant to HSC 1250 that complies with HSC 1261.6 pursuant to BPC 4427.3(b)(2).
- A clinic licensed pursuant to HSC 1204 and 1204.1 or BPC 4180 and 4190 pursuant to BPC 4427.3(b)(3).
- A correctional clinic licensed pursuant to BPC 4187.1 pursuant to BPC 4427.3(b)(4).
- An APDS located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice pursuant to BPC 4427.6(j).
- Premises of a covered entity or on the premises of a medical professional practices under contract to provide medical services to covered entity patients pursuant to BPC 4119.11(a).

Provided below are additional locations that have been identified through the application process that may also be appropriate locations for a pharmacy to operate an ADDS.

A. **Mental Health Rehabilitation Center (MHRC):** An MHRC is a residential facility that is licensed by the State Department of Health Care Services and is a regional center vendor.
B. **Psychiatric Health Facility (PHF):** A PHF is considered a "health facility" as defined in HSC 1250 and is defined to mean a health facility, licensed by the State Department of Health Care Services, the provides 24-hour inpatient care for people with mental health disorders or other persons as specified. Care provided shall include, among other services, drug administration.
C. **Jails**. Many county jails currently obtain drugs from either a county hospital system or a pharmacy contracted with the jail. Drugs are transferred to the jail under the medical director's license, but the drugs are administered from a common stock of drugs and not solely used by the medical director.
D. **Juvenile Hall Clinic:** Such a clinic is part of a county's juvenile hall detention center under a probation department. Juveniles reside at the detention centers and attend school during the day on the premises.
E. **Correctional Treatment Center:** CTC is a health facility operated by the Department of Corrections and Rehabilitation, Division of Juvenile Facilities or a county, city or city and county law enforcement agency that, as determined by the department, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services. The health services provided by a CTC shall include, pharmacy services.
F. **Hospice Facility:** Such facilities are health facilities licensed by the Department of Public Health. Hospice services include, pharmacy services under the direction of a licensed pharmacist.

<u>For Committee Discussion and Consideration</u>
During the meeting the committee may wish to discuss the identified settings above to determine what, if any, amendments should be pursued to authorize the use of ADDS and provide direction when additional locations are identified by board staff. Should the committee believe expansion of the authorized settings is appropriate, the committee's recommendation could be considered during the November Board Meeting.

c. <u>Proposal to Align the Self-Assessment Requirement Frequency to be Consistent with other Laws</u>

Currently, Section 4427.7 and 4119.11 of the BPC requires a pharmacy holding an ADDS license to complete <u>an annual</u> self-assessment, pursuant to Section 1715 of Title 16 of the CCR.

However, Section 1715 of Title 16 of the CCR specifies the assessment shall be performed before July 1 of every odd-numbered year.

Additionally, to clarify BPC 4427.7 requires a "pharmacy holding an ADDS license" to complete the self-assessment. However, licensed acute care hospital facility and acute psychiatric hospital facilities are exempt from licensure if the ADDS is owned/leased by the licensed hospital pharmacy and the drugs are owned by the licensed hospital pharmacy. BPC 4427.2(i) also requires the licensed hospital pharmacy to comply with all other requirements for an ADDS in the article. Although the licensed hospital pharmacy's ADDS are not licensed, they should also complete the self-assessment if they are to comply with all other requirements for an ADDS.

For Committee Discussion and Consideration
During the meeting members may wish to discuss the variances in frequency for completing the self-assessment and determine if changes should be recommended to the full board for consideration. Should the committee believe amendments to either the statutes or regulation are appropriate, staff will work with legal counsel and the committee chair on proposed language. The committee's recommendation and proposed language could be considered during the November Board Meeting.

d. Other Next Steps

In addition to the policy areas identified above, the committee may wish to direct staff to explore other areas related to the use of ADDS.

**Attachment 2** contains the relevant law for the automated drug delivery systems.

5. Discussion and Consideration of Proposal to Amend Business and Professions Code section 4312 to Expand the Provisions to Apply to all Facility Licenses

Relevant Law
Currently, BPC 4312 authorizes the board to cancel the license of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility if the licensed premises remains closed. The statute does not include all facility licenses issued by the board. Therefore, the law as currently written prevents the board from applying this law to all facility licenses.

For Committee Discussion and Consideration
As the board's regulatory jurisdiction continues to grow, it is imperative that new and existing license types be included in this statute.

Board staff is recommending amendments to BPC 4312 to simplify the statute to consolidate all facility license types into this provision. This approach would allow for the incorporation of existing and new licenses that will be implemented in the future.

**Attachment 3** includes draft amendments intended to facilitate discussion. Should the committee agree, a committee recommendation could be considered by the board during is November meeting.

6. Discussion and Consideration of Amendments to Title 16 California Code of Regulations Section 1709, to Specify Required Reporting Requirements for Individuals Vested with Management and Control

Relevant Law

Section 4201 of the BPC defines the application requirements for a facility license. It specifies the application shall state the information as to each person beneficially interested therein or any person with management or control over the license.

Title 16 California Code of Regulation (CCR) section 1709 details when a licensed business entity shall notify the board when there has been change to the beneficial interest of the license either by submitting a change of permit or change of ownership application to the board.

Background

The board approved drafted language to amend CCR section 1709 to include provisions relating to trust ownership of pharmacies. The following is the timeline on the status of this regulation.

**Timeline:**

Approved by Board: October 26, 2016
Submitted to DCA for Pre-Notice Review: January 26, 2017
Returned to the Board on: March 28, 2017
Re-submitted to DCA for Pre-Notice Review: May 24, 2018
Returned to the board: August 6, 2018
Re-submitted to DCA for Pre-Notice Review: August 16, 2018

Subsequent to the above regulatory proposal, passage of SB 1193, effective January 1, 2017, amended BPC 4201 to include reporting information for any person with management or control over a licensed facility.

Given the changes in statute it may be appropriate to pursue additional changes to CCR section 1709.

For Committee Discussion and Consideration

During the meeting the committee may wish to discuss if reporting of changes in individuals exercising management and control is appropriate. Based on the discussion of the committee, staff can work with counsel to develop regulation language to fulfill the policy goal.

Should such a determination be made, a recommendation can be considered during the November meeting.

**Attachment 4** includes the proposed regulation language currently undergoing promulgation previous approved by the board as well as BPC 4201.

7. Discussion and Consideration of Proposal to Standardize the Requirements, including Qualifications, for all Designated Representatives Licenses (Business and Professions Code Sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, & 4053.2)

   Relevant Law
   BPC 4022.5, 4022.6 and 4022.7 provides for the definition of the various designated representative license categories.

   Section 4053, 4053.1 and 4053.2 specifies how an individual may qualify for one of the three designated representative license categories which consist of working in a wholesaler, third-party logistics provider, or a reverse distributor wholesaler business.

   Background
   Staff has identified areas within the three designated representative licenses that are inconsistent. As an example, under certain provisions, the law explicitly provides authority for a pharmacist to perform the same functions as a designated representative and serve as the designated representative-in-charge of a wholesaler provider facility. However, this similar provision is not explicitly included for the designated representative-3PL. Additionally, when an entity is located outside of California the law is unclear if a pharmacist needs to be licensed in the home state.

   Staff has developed a summary chart detailing the inconsistencies when comparing the three designated representative licensure definitions and qualifications.

   For Committee Discussion and Consideration
   During the meeting, the committee may wish to discuss the discrepancies identified by staff to determine if a policy change should be pursued to amend the statutes pertaining to the designated representative licenses.

   To assist in the policy discussion, the following questions may be appropriate to discuss:

   1. Should the board require a designated representative-in-charge of a nonresident wholesaler or a responsible manager of a third-party logistics provider to be licensed in California if the individual is a pharmacist licensed in another jurisdiction? Further, should such a pharmacist be required to be located in the same state as the nonresident facility and be required to be licensed in the nonresident state?

   2. The law explicitly states that a pharmacist can serve as the designated representative-in-charge of wholesaler and a nonresident wholesaler, but the same explicit authority is not provided for a pharmacist to serve as a responsible manager in a third-party logistics

provider and nonresident third-party logistics provider facility. Should the board seek to amend the law to explicitly state such is allowed?

3. Under the application requirement for all designated representative licenses, an individual must either be a graduate of a high school or possession of a general education development certificate equivalent. At times an applicant is able to provide the board with transcripts confirming graduation from a secondary educational institution but is unable to produce a high school diploma. Should the board secure a change to accept graduation from a secondary education as satisfactory proof of high school graduation or equivalent?

4. Under the training requirements for a designated representative, the board formally approved a training program for only the designated representative-reverse distributor but has not formally approved the training programs for the designated representative or designated representative-3PL. Should the board formally review and approve the training program(s) to qualify for licensure for a designated representative and designated representative-3PL?

5. The law explicitly provides that a wholesaler cannot operate without either a pharmacist or designated representative on its premises. There is no similar explicit provision for a third-party logistics provider. Should the board pursue change to amend to law to explicitly state such is required?

Should such a determination be made to secure changes to these sections of law, based on the discussion of the committee, staff can work with counsel to develop proposed amendments to pharmacy law to fulfill the policy goals.

**Attachment 5** includes the summary chart as well as a copy of the relevant laws for BPC sections 4022.5, 4022.6, 4022.7, 4053, 4053.2, and 4053.1.

8. Discussion and Consideration of Proposal to Develop Intern Conferences for Students Recently Enrolled in a California School of Pharmacy and for Students Ready to Graduate from a California School of Pharmacy

Board staff is recommending the committee consider a proposal to develop two intern conferences, one intended for first year students and the second intended for students preparing for graduation. The conference for first year students could serve as an introduction to the board and focus on intern licensing requirements, board expectations of licensees. The conference for graduating students could serve as a reminder of the board's expectations, provide information on pharmacist examination application process and requirements as well as pharmacy law.

The conferences may also provide the board with an opportunity to collaborate with the schools of pharmacy, should they so choose.

Should the committee agree with the basic concept board staff can refine the proposal.

9. Discussion and Consideration of Committee's Strategic Plan Goals

During the meeting discussion to include reviewing the licensing 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. The board issued two cease and desist orders for unlicensed activity in fiscal year 2018/2019.

**1.2** Implement online application, license renewal, and fee payment for applicants and licensees to improve licensing conveniences.
**Status:** The board implemented online license renewal payment to accept credit card payment for the individual licenses. The board is continuing to work with the department to establish online license renewal payment for facility licenses. Further, board staff has started the Business Modernization process, the process used to assess business processes and determine how best to meet the needs of the organization and stakeholders.

**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 ongoing
- Occupation Analysis has been completed for both the recognized pharmacy technician certification examinations and regulation changes are pending to update the training requirements. The committee will be reviewing the reported prepared by the DCA at the November Licensing Committee meeting.
- Review of hospital pharmacy practice was evaluated, and legislative changes secured to established satellite compounding pharmacies. The board is continuing to receive hospital satellite compounding applications for licensure.
- Post implementation review of the Automated Drug Delivery Systems is underway.

**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:**

- The passage of AB 2037 became effective on September 21, 2018 as well as SB 1447 became effective on July 1, 2019 to operate a licensed ADDS.
- AB 690 includes the requirements for the pharmacy technicians to work in a remote dispensing site pharmacy. This measure is currently awaiting action by the governor. Upon signature staff will work on implementation of this alternative work site.

**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.

**1.8** Implementing New Licensing Programs
**Status:** The board has implemented the following licenses within FY 2018/2019:

- Designated Representative-Reverse Distributor
- Designated Paramedic
- Correctional Clinics
- ADDS licensure

**1.9** Annual Benchmarking with National Practice Standards
**Status:** No action has been taken on this goal.

10. Approval of December 19, 2018, and April 3, 2019, Licensing Committee Meeting Minutes

The draft meeting minutes from the December 19, 2018 and April 3, 2019, committee meetings have been provided in **Attachment 6**.

11. Review of Licensing Statistics

Licensing statistics for July 1, 2019 through August 31, 2019, are provided in **Attachment 7**.

As of August 31, 2019, the board has received 3,024 initial applications, including:
1,062 intern pharmacists

- 528 pharmacist exam applications
- 47 advanced practice pharmacists
- 826 pharmacy technicians
- 69 community pharmacy license applications
- 23 sterile compounding pharmacy license applications
- 1 nonresident pharmacy license applications

- 6 hospital pharmacy license applications

As of August 31, 2019, the board has received 92 requests for temporary site license applications, including:

- 42 community pharmacy license applications
- 7 sterile compounding pharmacy license applications
- 12 nonresident pharmacy license applications
- 5 hospital pharmacy license applications

As of August 31, 2019, the board has issued 2,694 licenses, renewed 10,205 licenses and has 140,727 active licenses, including:

- 7,144 intern pharmacists
- 46,962 pharmacists
- 569 advanced practice pharmacists
- 70,014 pharmacy technicians
- 6,451 community pharmacies
- 385 hospital pharmacies

Processing Times

The general application and deficiency mail processing times by license type are provided below reflecting data current as of September 18, 2019. The data reflects the time from when an application or deficiency response is received by the board through to the time it is processed by licensing staff.

Regrettably the board is outside of the 30-day performance standards for processing an initial application as well as the 10-day processing time for deficiency mail for several of its types of applications. There are several factors including vacancies, implementation of new programs and increased workload. Management staff are working with staff to reprioritize workload and where possible redirecting staff from other areas of operations to assist.

| Premises Application Types | Application Processing Times As of 9/18/2019 | Deficiency Mail Processing Times As of 9/18/2019 |
|---|---|---|
| Pharmacy | 30 | 107 |
| Nonresident Pharmacy | 30 | 103 |
| Sterile Compounding | 33 | 79 |

| | | |
|---|---|---|
| Nonresident Sterile Compounding | 30 | 0 |
| Outsourcing | 0 | 0 |
| Nonresident Outsourcing | 20 | 0 |
| Hospital Satellite Compounding Pharmacy | 0 | 0 |
| Hospital | 28 | 30 |
| Clinic | 33 | 58 |
| Wholesaler | 37 | 46 |
| Nonresident Wholesaler | 43 | 56 |
| Third-Party Logistics Provider | 10 | 35 |
| Nonresident Third-Party Logistics Provider | 29 | 35 |

| **Individual Application Type** | **Application Processing Times As of 9/18/2019** | **Deficiency Mail Processing Times As of 9/18/2019** |
|---|---|---|
| Pharmacist Examination | 25 | 45 |
| Pharmacist Initial Licensure | 9 | 0 |
| Advanced Practice Pharmacist | 50 | 15 |
| Intern Pharmacist | 46 | 30 |
| Pharmacy Technician | 34 | 10 |
| Designated Representative | 44 | 58 |
| Designated Represenative-3PL | 42 | 0 |

12. Future Committee Meeting Dates
    - November 5, 2019

13. Adjournment

# Attachment 1

**Proposal to Amend BPC Section 4210. Advanced Practice Pharmacist License**

(a) A person who seeks recognition as an advanced practice pharmacist shall meet all of the following requirements:

(1) Hold an active license to practice pharmacy issued pursuant to this chapter that is in good standing.

(2) Except as otherwise specified in this section, ~~S~~satisfy any two of the following criteria:

(A) Earn certification in a relevant area of practice, including, but not limited to, ambulatory care, critical care, geriatric pharmacy, nuclear pharmacy, nutrition support pharmacy, oncology pharmacy, pediatric pharmacy, pharmacotherapy, or psychiatric pharmacy, from an organization recognized by the Accreditation Council for Pharmacy Education or another entity recognized by the board.

(B) Complete a postgraduate residency through an accredited postgraduate institution where at least 50 percent of the experience includes the provision of direct patient care services with interdisciplinary teams.

(C) Have provided clinical services to patients for at least one year under a collaborative practice agreement or protocol with a physician, advanced practice pharmacist, pharmacist practicing collaborative drug therapy management, or health system.

(3) For purposes of this section, where (1) completion of a certification as provided in (2)(A) includes at least one year of experience working under a collaborative practice agreement as provided (2)(C) or completion of a postgraduate residency as provided in (2)(B), or (2) where completion of a residence program as provided in (2)(B) includes completion of a certification program as provided in (2)(A), such completion shall be deemed to satisfy the experience requirements of this section.

(3) File an application with the board for recognition as an advanced practice pharmacist.

(4) Pay the applicable fee to the board.

(b) An advanced practice pharmacist recognition issued pursuant to this section shall be valid for two years, coterminous with the certificate holder's license to practice pharmacy.

(c) The board shall adopt regulations establishing the means of documenting completion of the requirements in this section.

(d) The board shall, by regulation, set the fee for the issuance and renewal of advanced practice pharmacist recognition at the reasonable cost of regulating advanced practice pharmacists pursuant to this chapter. The fee shall not exceed three hundred dollars ($300).

# Attachment 2

## Relevant Law - Automated Drug Delivery Systems

**4427.2. Licensing Requirements**

(a)An ADDS installed, leased, owned, or operated in California shall be licensed by the board.

(b)An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California.

(c)A separate application and license shall be required for each ADDS.

(d)An ADDS license shall only be issued when the following conditions are met:

(1)Use of the ADDS is consistent with legal requirements.

(2)The proposed location for installation of the ADDS meets the requirements of Section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

(3)The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(4) The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

(e)Prior to issuance of the license, the board shall conduct a prelicensure inspection, within 30 days of a completed application for an ADDS license, at the proposed location of the ADDS. Relocation of the ADDS shall require a new application for licensure. Replacement of an ADDS shall require notification to the board within 30 days.

(f)The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license may be submitted to the board.

(g)The holder of an ADDS license shall advise the board in writing within 30 days if use of the ADDS is discontinued.

(h)The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.

(i)An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to

patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of Section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in this article. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request.
(j)An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices.

**4427.3. Location Requirements**
(a)An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.
(b)An ADDS shall be placed and operated in one of the following locations:
(1)Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
(2)A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.
(3)A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.
(4)A correctional clinic licensed pursuant to Section 4187.1.
(5)If the ADDS is an APDS, in a location as provided in Section 4427.6.
(c)Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices.

These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

**4186. Automated Drug Delivery Systems**

(a)Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written 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 at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c)The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d)Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the 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.

(e)The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f)The pharmacist operating the automated drug delivery system shall be located in California.

(g)Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076 and

with Section 1707.5 of Title 16 of the California Code of Regulations.
(h)This section shall become operative on July 1, 2019.

**4187.5 Correctional Clinics: Automated Drug Delivery Systems**
(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.

**4119.11. Automated Patient Dispensing Systems**

(a)A pharmacy located in the state may provide pharmacy services to the patients of a "covered entity," as defined in Section 256b of Title 42 of the United States Code, through the use of an automated patient dispensing system located on the premises of the covered entity or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met:
(1)The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated

site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.
(2)The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.
(3)Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.
(4)The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.
(5)The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.
(6)The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.
(7)The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.
(8)Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.
(9)The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated

patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.
(10)The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.
(11)A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.
(b)For purposes of this section, the following definitions shall apply:
(1)An “automated drug delivery system” (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2)An “automated patient dispensing system” (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.
(3)An “automated unit dose system” (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.
(c)(1) An automated patient dispensing 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.
(2)Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.
(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:
(1)The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:

(A)Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.
(B)Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.
(C)Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.
(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.
(E)Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.
(F)Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.
(2)The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).
(3)The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.
(4)A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.
(5)Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.
(7)The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.
(8)The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.
(9)Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.
(10)The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.
(11)The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.
(e)Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.
(f)The automated patient dispensing system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.
(g)The stocking of an automated patient dispensing system shall be performed by a pharmacist. If the automated patient dispensing system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopeia, the stocking system may be done outside of the facility

and be delivered to the facility if all of the following conditions are met:
(1) The task of placing drugs into the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
(2)The removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
(3)The pharmacy, in conjunction with the covered entity, has developed policies and procedures to ensure that the removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the automated patient dispensing system.
(h)Review of the drugs contained within, and the operation and maintenance of, the automated patient dispensing system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated patient dispensing system, an inspection of the automated patient dispensing system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.
(i) A pharmacy holding an automated patient dispensing system license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the automated patient dispensing system. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the automated patient dispensing system shall be included in the self-assessment.
(j) The pharmacy shall comply with all recordkeeping and quality assurance requirements pursuant to this chapter, and shall maintain those records within the pharmacy holding the automated patient dispensing system license and separately from other pharmacy records. *(Added by Stats. 2018, Ch. 647, Sec. 1. (AB 2037) Effective September 21, 2018.)*

# Attachment 3

**Proposal to Amend BPC Section 4312 - Voiding License of Entity Remaining Closed: Notice; Disposition of Stock; Distribution of Proceeds Where Board Sells Stock**

(a) The board may cancel ~~the license of~~ a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ license of a facility which is licensed by the board if the licensed premises remain closed, as defined in subdivision (e), other than by order of the board. For good cause shown, the board may cancel a license after a shorter period of closure. To cancel a license pursuant to this subdivision, the board shall make a diligent, good faith effort to give notice by personal service on the licensee. If a written objection is not received within 10 days after personal service is made or a diligent, good faith effort to give notice by personal service on the licensee has failed, the board may cancel the license without the necessity of a hearing. If the licensee files a written objection, the board shall file an accusation based on the licensee remaining closed. Proceedings shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code, and the board shall have all the powers granted in that chapter.

(b) If ~~the~~ a facility license issued by the board ~~of a wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing facility~~ is canceled pursuant to subdivision (a) or revoked pursuant to Article 19 (commencing with Section 4300), or a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility notifies the board of its intent to remain closed or to discontinue business, the licensee shall, within 10 days thereafter, arrange for the transfer of all dangerous drugs and controlled substances or dangerous devices to another licensee authorized to possess the dangerous drugs and controlled substances or dangerous devices. The licensee transferring the dangerous drugs and controlled substances or dangerous devices shall immediately confirm in writing to the board that the transfer has taken place.

(c) If a ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility fails to comply with subdivision (b), the board may seek and obtain an order from the superior court in the county in which the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ facility licensed by the board is located, authorizing the board to enter the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility and inventory and store, transfer, sell, or arrange for the sale of, all dangerous drugs and controlled substances and dangerous devices found in the ~~wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, or outsourcing~~ licensed facility.

(d) If the board sells or arranges for the sale of any dangerous drugs, controlled substances, or dangerous devices pursuant to subdivision (c), the board may retain from the proceeds of the sale an amount equal to the cost to the board of obtaining and enforcing an order issued pursuant to subdivision (c), including the cost of disposing of the dangerous drugs, controlled substances, or dangerous devices. The remaining proceeds, if any, shall be returned to the licensee from whose premises the dangerous drugs or controlled substances or dangerous devices were removed.

(1) The licensee shall be notified of his or her right to the remaining proceeds by personal service or by certified mail, postage prepaid.

(2) If a statute or regulation requires the licensee to file with the board his or her address, and any change of address, the notice required by this subdivision may be sent by certified mail,

postage prepaid, to the latest address on file with the board and service of notice in this manner shall be deemed completed on the 10th day after the mailing.
(3) If the licensee is notified as provided in this subdivision, and the licensee fails to contact the board for the remaining proceeds within 30 calendar days after personal service has been made or service by certified mail, postage prepaid, is deemed completed, the remaining proceeds shall be deposited by the board into the Pharmacy Board Contingent Fund. These deposits shall be deemed to have been received pursuant to Chapter 7 (commencing with Section 1500) of Title 10 of Part 3 of the Code of Civil Procedure and shall be subject to claim or other disposition as provided in that chapter.
(e) For the purposes of this section, “closed” means not engaged in the ordinary activity for which a license has been issued for at least one day each calendar week during any 120 day period.
(f) Nothing in this section shall be construed as requiring a pharmacy to be open seven days a week.

# Attachment 4

**Title 16. Board of Pharmacy**
**Proposed Text**

**To Amend Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:**

§1709. ~~Names of Owners and Pharmacist In Charge~~ Ownership, Management, and Control of Pharmacies and Other Business Entities.

(a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership ~~(individual, partnership or corporation)~~ and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership ~~transfer of permit~~ and shall require a new application for ~~a change of ownership~~ licensure:

(1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. The new owner shall apply to the board for licensure in advance of the proposed transaction taking place.

(d) If any beneficial interest of a business entity licensed by the board is held in trust, the applicant, licensee, or any person with management or control of the business entity, shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and renewal, report the name of any other person in any position with management or control of the business entity.

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and

any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the renewal, the name, address, phone number and any email address for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and renewal shall also include the name, address, phone number and any email address for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the business entity.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked, based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307, or 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4101, 4110, 4111, 4112, 4113, 4120, ~~4124,~~ 4130, 4131, ~~4133,~~ ~~4141, 4149, 4160, 4161, 4196,~~ 4201, 4207, 4302, ~~4304,~~ 4305, 4307, 4308, and 4330, Business and Professions Code.

**Relevant Law**

**4201. Application Form: Required Information; Authority Granted by License; Reporting Changes in Beneficial Ownership**

(a) Each application to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility shall be made on a form furnished by the board and shall state the name, address, usual occupation, and professional qualifications, if any, of the applicant. If the applicant is other than a natural person, the application shall state the information as to each person beneficially interested therein or any person with management or control over the license.

(b) As used in this section, and subject to subdivision (c), the term "person beneficially interested" means and includes:

(1) If the applicant is a partnership or other unincorporated association, each partner or member.

(2) If the applicant is a corporation, each of its officers, directors, and stockholders, provided that a natural person shall not be deemed to be beneficially interested in a nonprofit corporation.

(3) If the applicant is a limited liability company, each officer, manager, or member.

(c) If the applicant is a partnership or other unincorporated association, a limited liability company, or a corporation, and the number of partners, members, or stockholders, as the case may be, exceeds five, the application shall so state, and shall further state the information required by subdivision (a) as to each of the five partners, members, or stockholders who own the five largest interests in the applicant entity. Upon request by the executive officer, the applicant shall furnish the board with the information required by subdivision (a) as to partners, members, or stockholders not named in the application, or shall refer the board to an appropriate source of that information.

(d) The application shall contain a statement to the effect that the applicant has not been convicted of a felony and has not violated any of the provisions of this chapter. If the applicant cannot make this statement, the application shall contain a statement of the violation, if any, or reasons which will prevent the applicant from being able to comply with the requirements with respect to the statement.

(e) Upon the approval of the application by the board and payment of the fee required by this chapter for each pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer, the executive officer of the board shall issue a license to conduct a pharmacy, wholesaler, third-party logistics provider, veterinary food-animal drug retailer, or outsourcing facility if all of the provisions of this chapter have been complied with.

(f) Notwithstanding any other law, the pharmacy license shall authorize the holder to conduct a pharmacy. The license shall be renewed annually and shall not be transferable.

(g) Notwithstanding any other law, the wholesaler license shall authorize the holder to wholesale dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.

(h) Notwithstanding any other law, the third-party logistics provider license shall authorize the holder to provide or coordinate warehousing, distribution, or other similar services of

dangerous drugs and dangerous devices. The license shall be renewed annually and shall not be transferable.
(i) Notwithstanding any other law, the veterinary food-animal drug retailer license shall authorize the holder to conduct a veterinary food-animal drug retailer and to sell and dispense veterinary food-animal drugs as defined in Section 4042.
(j) For licenses referred to in subdivisions (f), (g), (h), and (i), any change in the proposed beneficial ownership interest shall be reported to the board within 30 days thereafter upon a form to be furnished by the board. *(Amended by Stats. 2015, Ch. 303, Sec. 7. Effective January 1, 2016.)*

# Attachment 5

**Designated Representative Comparison Summary**

A hardcopy of this document will be made available at the meeting or upon request. Requests may be emailed to Debbie.Damoth@dca.ca.gov.

**Relevant Law**

**4022.5. Designated Representative; Designated Representative-in-Charge**

(a) "Designated representative" means an individual to whom a license has been granted pursuant to Section 4053. A pharmacist fulfilling the duties of Section 4053 shall not be required to obtain a license as a designated representative.

(b) "Designated representative-in-charge" means a designated representative or designated representative-reverse distributor, or a pharmacist proposed by a wholesaler or veterinary food-animal drug retailer and approved by the board as the supervisor or manager responsible for ensuring the wholesaler's or veterinary food-animal drug retailer's compliance with all state and federal laws and regulations pertaining to practice in the applicable license category.

**4022.6. Designated Representative-Reverse Distributor**

"Designated representative-reverse distributor" means an individual to whom a license has been granted pursuant to Section 4053.2, who is responsible for supervision over a licensed wholesaler that only acts as a reverse distributor. A pharmacist fulfilling the duties of Section 4053.2 shall not be required to obtain a license as a designated representative-reverse distributor.

**4022.7. Designated Representative-3PL; Responsible Manager**

(a) "Designated representative-3PL" means an individual to whom a license has been granted pursuant to Section 4053.1.

(b) "Responsible manager" means a designated representative-3PL selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

**Relevant Law**

**4053. Designated Representative to Supervise Wholesaler or Veterinary Food-Animal Drug Retailer**

(a) Notwithstanding Section 4051, the board may issue a license as a designated representative to provide sufficient and qualified supervision in a wholesaler or veterinary food-animal drug retailer. The designated representative shall protect the public health and safety in the handling, storage, and shipment of dangerous drugs and dangerous devices in the wholesaler or veterinary food-animal drug retailer.

(b) An individual who is at least 18 years of age may apply for a designated representative license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.

(2) He or she shall have a minimum of one year of paid work experience in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, in the past three years, related to the distribution or dispensing of dangerous drugs or dangerous devices or meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.

(3) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:

(A) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.

(C) Knowledge and understanding of quality control systems.

(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.

(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.

(4) The board may, by regulation, require training programs to include additional material.
(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

**4053.1. Designated Representative 3-PL to Supervise Third-Party Logistics Provider**

(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.
(b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.
(2) He or she shall meet one of the following requirements:
(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.
(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.

(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii) Knowledge and understanding of quality control systems.
(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B) The board may, by regulation, require the training program required under this paragraph to include additional material.
(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.
(c) A third-party logistics provider shall not operate without at least one designated representative-3PL present at each of its licensed places of business as required under Section 4160.

**4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements**

(a)Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.
(b)An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:

(1)He or she shall be a high school graduate or possess a general education development certificate equivalent.
(2)He or she shall meet one of the following requirements:
(A)Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the
distribution, dispensing, or destruction of dangerous drugs or dangerous devices.
(B)Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.
(C)Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3)(A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i)Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii)Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii)Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.
(iv)Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B)The board may, by regulation, require the training program required under this paragraph to include additional material.
(C)The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.
(c)A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

# Attachment 6

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

**LICENSING COMMITTEE**
**DRAFT MEETING MINUTES**

**DATE:** December 19, 2018

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

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

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

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

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

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

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

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

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

**3. 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 working of the waiver notice to make it clear that the waivers are valid throughout the state and not limited to the disaster area itself. Dr. Gray also recommended that the board work with neighboring states as well so that patients who leave the state when they are evacuated can still receive care.

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

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

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

M/S: Weisser/Butler

Support: 5 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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.

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

**LICENSING COMMITTEE**
**DRAFT MEETING MINUTES**

| | |
|---|---|
| **DATE:** | April 3, 2019 |
| **LOCATION:** | Department of Consumer Affairs<br>First Floor Hearing Room<br>1625 North Market Blvd.<br>Sacramento, CA 95834 |
| **BOARD MEMBERS PRESENT:** | Deborah Veale, Licensee Member, Chair<br>Albert Wong, Licensee Member<br>Lavanza Butler, Licensee Member<br>Allen Schaad, Licensee Member |
| **BOARD MEMBERS NOT PRESENT:** | Stanley Weisser, Licensee Member, Vice Chair<br>Amjad Khan, Public Member |
| **STAFF PRESENT:** | Anne Sodergren, Interim Executive Officer<br>Laura Freedman, DCA Staff Counsel<br>Kelsey Pruden, DCA Staff Counsel<br>Debi Mitchell, Senior Licensing Manager |

1. **Call to Order, Establishment of Quorum, and General Announcements**
   Chairperson Veale called the meeting to order at 10:08 a.m.

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

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

   Paige Talley with the California Council for the Advancement of Pharmacy (CCAP) inquired on the implementation of the Automated Drug Delivery System (ADDS) license. Anne Sodergren notified Ms. Talley the new licensing application for ADDS will be available on the board's website in May.

   Chairperson Veale indicated that the status of the ADDS implementation will be added to the June 26, 2019 licensing committee meeting agenda.

   Public comment requested inclusion on the June 26, 2019 agenda an item related to pharmacist getting paid for the services that are being added to their professional scope of practice.

**3. Presentation on Medication-Assisted Treatment and Discussion and Consideration of Proposal to Establish Authority for Pharmacist to Provide Non-Opioid 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. She further explained methadone and buprenorphine are controlled substances that require a DATA 2000 waiver to prescribe and regrettably, pharmacists are currently not eligible to receive such a waiver. The waiver authority is currently limited to physicians, nurse practitioners, and physician assistants.

Chairperson Veale reported the committee is moving forward with discussion on naltrexone which is a non-opioid medication that is also used in MAT. In Kentucky, pharmacists are allowed to provide naltrexone pursuant to a statewide protocol. The protocol specifies the criteria and procedures for pharmacists to initiate the dispensing and administration of naltrexone for MAT to individuals as part of the patient's recovery.

During the board's January 2019 Board Meeting, the board approved a policy statement that supports the role of pharmacists providing direct care to patients with opioid addiction and to assist medical providers in caring for such patients, thereby expanding access to treatment. As such the board's policy advocates for changes in the law that will permit pharmacists to provide MAT as part of a collaborative health care team.

The committee heard from two experts in the field, Talia Puzantian, PharmD, BCPP Associate Professor with Keck Graduate Institute School of Pharmacy and Health Sciences (KGI) and James J. Gasper, PharmD, BCPP Psychiatric and Substance Use Disorder Pharmacist with Pharmacy Benefits Division, California Department of Health Care Services (DCHCS) who presented an overview of the larger issue and identified current gaps in the treatment access.

In the presentation, Dr. Puzantian reported overdose deaths are now the leading cause of mortality for Americans under 50. There are millions of Americans in pain, misusing opioids, and dealing with opioid use disorder. The treatment of opioid use disorder with MAT uses three different types of medication; naltrexone, methadone, and buprenorphine. Only 19% of the Americans affected by opioid use disorder are receiving treatment at specialized facilities leaving over 80% untreated, much of this has to do with access, reimbursement and stigma.

Dr. Puzantian described a study conducted in Massachusetts of survivors of opioid overdose and the effectiveness of the three medications with respect to the duration of treatment and the reduction in all-cause mortality. The use of methadone and buprenorphine in MAT was shown to have a greater duration of time in treatment and approximately 50 percent reduction in mortality rate. The use of naltrexone was shown to have a much shorter duration in treatment and no reduction in mortality rate. The study also showed there is a greater percentage of patients receiving treatment in Massachusetts in comparison with California which has to do with Massachusetts having a higher prevalence of insurance coverage translating to more access to treatment.

Dr. Puzantian described the use of naltrexone in MAT and provided the pros and cons of using this opioid antagonist. Unlike methadone and buprenorphine, naltrexone does not have regulatory restrictions on

prescribing and can be prescribed by any licensed healthcare professional including pharmacists under a collaborative practice agreement. One limitation with naltrexone is that a person cannot begin using naltrexone until they have been opioid free for 7-10 days. Due to this waiting period before the starting naltrexone, solely utilizing naltrexone in MAT has shown to have a high relapse rate because patients are less likely to stay opioid free for those 7-10 days. Methadone and buprenorphine can be taken at the first sign of withdrawals within 1-2 days of last use of opioids thus resulting is more successful treatment.

Dr. Puzantian described that pharmacists are currently able to administer doses of naltrexone and follow-up on patient treatment. Collaborative practice agreements (CPA) enable pharmacists to initiate, adjust, discontinue the medication and order lab tests as appropriate. She further clarified that pharmacists can administer naloxone to treat a potential opioid overdose while naltrexone is administered as a weekly dose for the duration of the MAT.

Dr. Gasper presented on methadone and buprenorphine use in MAT. Methadone is an opioid agonist and is effective in reducing overdose deaths and opioid use. One of the limitations with methadone is that it must be administered in highly supervised clinic. These clinics or opioid treatment programs (OTP) are highly under-utilized and are often not located in areas were opioid use disorder is most prevalent; especially in rural areas, thus limiting access to treatment. There have been two remote dispensaries that have opened in California; however, the process is slow and costly. Individuals end up using buprenorphine during treatment when they do not have access to methadone. By allowing pharmacists to administer methadone under a CPA, this would allow individuals to have more access to receive methadone treatment.

Dr. Gasper described pharmacists' role in administration of methadone in licensed OTP including clinical management of methadone dosing and monitoring within scope of practice. Community pharmacies can become licensed as OTPs in collaboration with a community physician that is licensed as an OTP to enable pharmacists to become involved with the monitoring and the dosing of methadone and help fill the need for access to treatment. Dr. Gasper described that there are currently two pharmacies in San Francisco that are licensed as OTPs and his involvement in the establishment of the locations.

Dr. Gasper further described that when methadone is used to control pain it can have a high rate of overdose when not supervised properly. Further showing the importance of having pharmacists involved in supervising the dosing of methadone.

Dr. Gasper explained differences between methadone and buprenorphine. Buprenorphine is a partial opioid agonist with a lower abuse potential and is safer from overdose. Similar to methadone, buprenorphine is effective in reducing opioid deaths and opioid use. The effectiveness of the each of the medications can have much to do with the patient.

Dr. Gasper described how DATA 2000 waivers for prescribers has expanded access to treatment outside of OTPs by enabling qualified practitioners to provide buprenorphine in other types of settings. The waiver is very underutilized and many professionals that have the authority to use the waiver are either not using their waiver or using the waiver far below its capacity. While there is not a limit of the number of waivers that can be issued, there is a limit to the number of people that can be treated under the waiver. Initially, prescribers were limited to less than 30 patients and could apply for expanded capacity after one year. The Comprehensive Addiction and Recovery Act (CARA) in 2017 further expanded

treatment to allow for nurse practitioners and physician assistants to be waivered and increased the maximum number treated from 100 to 275. He described how the waiver is an underutilized resource in many ways including lack of support by the clinic and suggested that clinics need mentoring to start treating for opioid addiction as well as support along the way. Dr. Gasper provided statistics to the show how California is underperforming compared to the national rate regarding to the number waivers issued. He described that there is only a short training class required to the get waivered and the training is free in most cases.

Dr. Gasper stated removing the waiver requirement is one option to allow other practitioners to prescribe these medications which would allow more patients to receive treatment. France removed the waiver requirement and over dose deaths have reduced 80%. He suggested another option of amending the waiver to include pharmacists which would also expand treatment access. Other states including Rhode Island, North Carolina and Maryland have expanded access by allowing pharmacists to provide buprenorphine under a CPA.

Dr. Gasper described pharmacists' role in community pharmacies. As pharmacists are exposed to patients requesting clean needles and can recognize if someone is being over prescribed opioids, this should allow pharmacist to intercede and discuss addiction to opioids with the patient. He emphasized that pharmacists can make or break someone's MAT. If they do not have on stock buprenorphine at all times this could be life threating to a patient. Because a patient is picking up their prescription for these drugs every 5-7 days, this allows pharmacists to really become part of the patient's care.

Dr. Gasper discussed how stigma is the biggest barrier to people who have an opioid addiction. He recommends making clear tangible roles that pharmacists and pharmacies can do to provide care for these patients. He further suggested the board put together a sample CPA that pharmacist can use to provide buprenorphine to expand access points. He provided an example of the CPA created in Maryland and suggested that it could be implemented in California with very few modifications.

Dr. Puzantian stated that she believes that pharmacists are hungry to participate in meeting the needs of the patients and providing them this level of care. This is substantiated by the number of pharmacists that have taken the webinar for naloxone. She encourages the board to take action to guide and support pharmacists.

The committee discussed the draft statutory proposal to amend Business and Professions Code (BPC) section 4052 to allow pharmacist to provide non-opioid medication-assisted treatment pursuant to a state protocol in California.

During the discussion, Chairperson Veale had questions regarding the example given of the CPA in Maryland. The presenters clarified that the CPA is statewide policy that signed off by both the Board of Pharmacy and the Medical Board and involves the treating physician and the pharmacist. The CPA includes a requirement for the pharmacist to meet a minimum competency standard to be eligible to participate.

Chairperson Veale discussed the implementation of a CPA in California similar to that of Maryland. Ms. Veale noted the need for additional training and asked how many hours should be included in the training and what training resources are available. Ms. Sodergren suggested referencing the types of

training or completion of training from an organization in a specific area while keeping the number of hours of training more fluid to avoid barriers that could arise in the future.

During the discussion, Laura Freedman asked about pharmacy education and the incorporation of addiction and substance abuse into the curriculum of pharmacy schools. Currently pharmacy students are exposed to the topic, but it is not a component of the accredited curriculum.

Committee member Butler discussed the proposal applying to all pharmacists; not limited only to advanced practice pharmacists.

Based on the information in the presentation, Chairperson Veale suggested that the proposal before the committee may be too limited based on the information from the presenters. to only address naltrexone may be insufficient. The presenters reinforced that pharmacists should be able to provide all three medications.

Committee member Schaad discussed treatment coverage and reimbursement and emphasized the importance in reimbursement as an aspect in promoting treatment. Ms. Sodergren stated that she was aware of pending legislation to address some the current challenges with reimbursement.

Committee member Wong questioned the cause of overdose. The presenters responded that the highest risk of overdose is with opioids taken by injection and noted the risk of overdose when people transition to heroin when they can no longer get their opioids as frequently. Additionally, people that relapse after being abstinent for a period have a higher rate of overdose death. It was noted that pharmacists are in a position to identify those that are abusing other drugs.

Dr. Steve Grey, pharmacist, offered clarification as the background of the issues discussed in the presentation. He described the problems methadone clinics have been experiencing for years. He described the mindset of “not in my backyard” where the establishment of methadone clinics was objected by communities. It wasn’t until the realization that opioid abuse affects everyday people that more clinics opened. He also described the advent of buprenorphine in allowing for office-based treatment centers.

Dr. Grey emphasized the importance of helping address the stigma as a barrier to treatment and pharmacists’ responsibility to take a role in treatment. He compared the map shown in the presentation depicting the prominence of opioid overdose related deaths found in Northern California in the rural areas and compared to the Medi-Cal population in the same area. He described that the current administration wants to expand Medi-Cal and recommended that now is the time to include pharmacists in providing this type of treatment.

Additionally, Dr. Grey clarified his role helping to establish a CPA with other states in which state law required that the protocols be approved by the Board of Pharmacy and the Medical Board. The boards experienced lack of resources to accommodate the approval process. Dr. Grey recommended the board to move towards a statewide protocol until the federal law is changed including patient specific authorization by the physician to initiate the treatment and management of treatment be performed by the pharmacist.

April Grant speaking on behalf of Alkermes Inc, supported of the use of all three medications in MAT and agrees that all three medications should be available at all times in a pharmacy. She further stated that MAT should also be available for people that are receiving treatment in residential and rural settings as well as those released from incarceration. Ms. Grant agreed with all comments made today and the discussion to move forward with the proposal.

Pharmacist Dr. Steve Grey emphasized a recent case of a patient receiving treatment while being incarcerated. After being released, the patient could not find access to medication and ended up returning to the original prescribing pharmacy refilled a prescription for opioids and overdosed on the prescribed opioids. He described how the pharmacy should have been aware of the risk and recommended that pharmacists need to be educated to identify those at risk.

Chairperson Veale suggested the board work toward a protocol similar to example from Kentucky. Ms. Butler agreed with the idea and recommended having continuing education to open avenues for interested pharmacists.

**Committee Recommendation:** Move forward with a three-pronged approach including (1) to recommend approving the proposed statutory language as written to amend BPC 4052 to add subdivision (a)(14) and move forward with developing a state protocol for administering naltrexone that could be implemented immediately, (2) encourage pharmacies to become licensed as OTPs for methadone dosing, and (3) to direct the licensing committee to develop a sample CPA for pharmacists to provide MAT in collaboration with a practitioner that has obtained a DATA 2000 waiver. If approved by the board, the committee will continue to discuss this item and will bring forward their recommendations to the board once finalized.

M/S: Butler/Wong

Support: 4 Oppose: 0 Abstain: 0

**4. Discussion and Consideration of Pharmacy Law Related to Collaborative Practice Agreements**

Chairperson Veale reported there are several provisions of pharmacy law that establish authorities for pharmacists and advanced practice pharmacists to perform functions under a collaborative practice agreement.

BPC 4052.1 in general provides the authority for a pharmacist to order and perform routine drug therapy-patient related patient assessment procedures, order drug therapy based on related lab results, administer drugs and biologics by injection, and initiate or adjust drug regimen pursuant to policies, procedures or protocols as specified in a licensed health care facility.

BPC 4052.2 in general provides similar authorities for pharmacists included in the prior section but allows for the procedures to be performed in other health care settings including licensed clinics and other licensed facilities owned or operated by a health care service plan.

BPC 4052.6 in general provides the authority for an advanced practice pharmacist to participate in and evaluate diseases and health conditions in collaboration with other health care providers.

BPC 4052(a)(9), BPC 4052(a)(11) & BPC 4052(a)(12) provide general authorities for pharmacists, in any setting to participate in interdisciplinary review of patient progress, administer vaccinations, and order and interpret tests.

Committee Discussion and Consideration

As health care models evolve and patient access points increase, it is appropriate to evaluate the current provisions that establish authorities for pharmacist to work under CPAs to determine if pharmacy law has remained current with national trends and patient care needs.

BPC 4040 declares the practice of pharmacy as a profession which is dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of appropriate drug use, drug-related therapy, and communication for clinical and consultative purposes, and further provides that pharmacy practice is continually evolving to include more sophisticated and comprehensive patient care activities.

Chairperson Veale provided an overview of The National Alliance of State Pharmacy Associations (NASPA) report; Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority. As part of its report, NASPA notes that state laws, if too restrictive, can impede innovative team-based care models.

The committee discussed the draft statutory proposal that will recognize the continued evolution of team-based care approaches and position pharmacist involvement and provide flexibility as patient care access points evolve. Specifically, under the proposal pharmacists would have the authority to initiate, adjust or discontinue drug therapy for a patient under the following conditions:

1. The pharmacist is performing the functions under a collaborative practice agreement with either a prescriber or medical group.
2. The pharmacist is aware of the underlying medical condition(s) for which the patient is being treated.

The committee members discussed removing the phrase “whose diagnosis is known to the pharmacist” from the proposed language and discussed the term in the proposed language “a prescriber or medical group”.

Dr. Steve Grey, pharmacist, commented on the intent of the proposal. He summarized the intent of the authorities defined in BPC 4052, 4052.1, and 4052.2. The current provisions identify requirements for training or credentials for a pharmacist to provide clinical services under a CPA. He expressed concerns with the proposal in that it would allow for all pharmacists to provide clinical services under a CPA without establishing required training.

Danny Martinez, California Pharmacist Association (CPhA), discussed CPhA’s role in the development of the discussed NASPA report and recommended the proposed language change to include reference to an “health care entity” instead of a “medical group” to align with the concept identified in the report.

Mark Johnson speaking behalf of CVS stands in support of the comments regarding the proposal and the direction the board is moving with CPAs. He discussed the issue nationally to offer insight to the

continuum of where pharmacy practice is going. He gave an example of Idaho where pharmacists will have full prescriptive authority with parameters effective July 1, 2019. He also cited Ohio where pharmacists have independent prescriptive authority. In other states, pharmacists have the authority to prescribe under statewide protocols. There are currently 11 states that allow population-based CPAs where the physician oversees what the pharmacist can do with the patient but does not actually see the patient. He cited a study showing that under 50 percent of patients that present with a condition do not have a primary care physician and that symptoms often present themselves after hours, thus further demonstrating the need for pharmacists to be able to treat patients under a CPA. Mr. Johnson discussed the proposed language and suggested keeping the language broad so there are not impediments to pharmacists' ability to provide care.

Lorri Walmsley speaking on behalf of Walgreens was also in support the direction of the proposal. She described a business item for the House of Delegates with policy similar to the NASPA report discussed that she coauthored with American Pharmacist Association (APhA) in conjunction with Idaho looking at expanding the meaning of CPA and the APhA policy manual. She summarized how the committee's discussion is in line with national policy.

Dr. Steve Grey also commented on the proposed language and offered clarifying suggestions to the proposal and terminology and suggested to use "prescriber group" in the proposed language.

Laura Freedman, legal counsel, responded that the term "prescriber group" sounds unique and does not recommend using that term. She would need to further research this term as well as review the pharmacy law to ensure the appropriate term is used.

In response to public comment, Ms. Sodergren suggested making the specific requirements of who is participating in the collaborative practice agreement as a function of the collaborative practice agreement and not a function of the law. The committee and counsel discussed the terminology that would align with the intention of the policy.

**Committee Recommendation:** To recommend to the board to approve the proposed language in BPC 4052 to add subdivision (a)(13) "Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with a prescriber or medical group". (The committee removed the following language from the proposal "whose diagnosis is known to the pharmacist.")

The committee directed staff to work with legal counsel to further refine defining the correct term for "a prescriber or medical group".

M/S: Wong/Butler

Support: 4 Oppose: 0 Abstain: 0

**5. Post Implementation Review of the Advanced Practice Pharmacist Licensing Program including Licensing Requirements and Functions Authorized**

Chairperson Veale reported on the provisions that establish the requirements for an individual to qualify for recognition as an advanced practice pharmacist as well as the privileges of an advanced practice pharmacist (APH).

As part of qualifying for an APH license an individual must hold an active license to practice pharmacy and satisfy two out of three of the following criteria: earned certification in a relevant area of practice; completion of a post graduate residency; and clinical experience for at least one year under a collaborative practice agreement or protocol.

Chairperson Veale reported changes have been made at the staff level to the application process to minimize deficiencies. For example, one of the most common deficiencies initially encountered was the required documentation to satisfy the qualifying criteria of experience under collaborative practice agreement or protocol. In response to this common deficiency, the board developed an affidavit that could be completed and signed by both the applicant and the supervising practitioner, program director or health facility administrator to satisfy these required statements. The affidavit resolved the deficiencies pertaining to the specific language attesting under penalty of perjury. This change has reduced the deficiency rate but regrettably, some applicants continue to submit affidavits that lack the required signature from one of the required individuals listed in this section who must be either the supervising physician, program director, or health facility administrator.

Another implementation challenge noted by board staff relates to applicants using a single pathway to licensure to fulfill two separate requirements. For example, this experience conflict or "double dipping" is encountered when an applicant wishes to apply the residency requirement to fulfill both that pathway as well as the certification pathway. In such cases the applicant must complete a second criterion which is typically the collaborative practice experience pathway. In this instance, the board allows the applicant one year to satisfy one of the other criteria to complete their application, thus keeping the application in pending status. There are currently 57 applications pending in which an experience conflict was a deficiency with the application.

Chairperson Veale reported a pharmacist recognized by the board as an APH may do the following: perform patient assessments; order and interpret drug therapy-related tests; refer patients to other health care providers; participate in the evaluation and management of diseases and health conditions with other health care providers; and initiate, adjust, or discontinue drug therapy in the manner specified in pharmacy law.

Chairperson Veale reported the board issued its first APH license on February 9, 2017 and as of March 18, 2019, the board has issued a total of 488 APH licenses.

The board currently has received 173 APH applications this fiscal year and has 204 pending applications.

Dr. Joe Guglielmo, Dean of the University of California San Francisco College of Pharmacy supports the committee in their efforts in reviewing the criteria of the APH and the collaborative practice agreements. He discussed the current gap in healthcare in which patients lack up-to-date medication lists and providers are not reviewing the medication list. He noted that every patient deserves the right to be on the safest, most cost-effective medication and recommended that pharmacists may be in a position to uniquely provide this care.

Dr. Guglielmo offered a review comparing how California and Washington have handled pharmacist provider status and the issues faced with implementation. He suggested there needs to be more done to advance safe effective medication treatment and make it easier for pharmacists to practice at the top of their profession; emphasizing the need for policy change to move law forward.

The committee discussed the authorities of an APH as defined in BPC 4052.6 and possible ways to expand the authorities beyond that of a licensed pharmacist. Ms. Sodergren suggested removing reference to BPC 4052.2 from subdivision (a)(5) of BPC 4052.6 thus authorizing an advanced practice pharmacist to initiate, adjust, or discontinue drug therapy without a CPA.

The current chair of the CPC speaking on behalf of the deans of the California Schools of Pharmacy supports changing the practice, so pharmacists will be more successful at changing the trajectory of care. He discussed two things that would need to happen; 1) develop standard of care as model of practice and regulation of practice and 2) help get pharmacist paid for these services. He suggested that the latter will make the most difference and believes the law which currently states that "may be paid" should be changed to "shall be paid". He and others are going to take on the other regulatory agencies to pursue such change to stimulate the payment for pharmacists providing these services.

Mark Johnston with CVS supported the discussion to expand authorities of the APH offering Idaho as an example where pharmacists are allowed to prescribe in certain circumstances and disease states.

Dr. Steve Grey, pharmacist, offered insight on the original intent of the APH license to offer an avenue to enable pharmacists to initiate, adjust, and discontinue drug therapy and to the get the pharmacist paid for the services. The APH license is utilized as a designation to differentiate pharmacists providing these services.

Victor Law, representing himself, described when he was approached by a physician to handle transition of patient care for discharged patients which included reconciling and organizing the patient medications. The result was 96 patients successfully treated with zero readmissions to the hospital. He forecasted that the next step is to have the pharmacists initiate and change the medications to promote treatment.

Danny Martinez, CPhA, supported the suggestion made to amend the language of BPC 4052.6. He also suggested that reducing the number of qualifying criteria defined BPC 4210 will help reduce barriers to licensure.

Dr. James Gasper, pharmacist, commented on the early barriers to licensure that had delayed some of his colleges for obtaining APH licensure. He described the deficiency with an experience conflict that could arise when an individual is attempting to qualify for licensure with a residency and a certification. He described his own reasons for applying for an APH license.

During the discussion, the committee considered looking at reducing the number of criteria needed to qualify for APH licensure from two of the three qualifying criteria to only one of the three and possible removal of the provision that prevents "double dipping" of qualify criteria to reduce barriers for licensure.

Dr. Gasper also suggested the need for clarification of the term “assessments” for in BPC 4052.6(a)(1) and application of this term in his practice as a psychiatric pharmacist in treating patients.

Dr. Steve Grey recommended the board be strategic in how they move forward with this issue.

**Committee Recommendation:** To recommend to the board to amend BPC 4052.6(a)(5) to remove the following language “in the manner specified in paragraph (4) of subdivision (a) of BPC 4052.2” after “initiate, adjust, or discontinue drug therapy”.

The committee directed staff to work with counsel to make the necessary changes to BPC 4052.6(a)(5) in accordance with the policy discussed to present at the board meeting.

M/S: Wong/Butler

Support: 4 Oppose: 0 Abstain: 0

**Committee Recommendation:** To recommend to the board to consider directing the licensing committee to reassess the requirements in BPC 4210 to qualify for an APH license to bring in the scope of practice.

M/S: Butler/Wong

Support: 4 Oppose: 0 Abstain: 0

**6. Discussion and Consideration of the Current Provisions of Pharmacy Law Governing Board Licensed Facilities either Impacted by Declared Disasters or Otherwise Destroyed**

Chairperson Veale provided BPC 4062(c) specifies “during a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care.”

Chairperson Veale explained that BPC 4201(f) specifies that a license shall not be transferable, which can impact a pharmacy during a declared federal, state, or local emergency when a pharmacy is no longer able to operate out of their licensed location due to damage sustained during the emergency.

Chairperson Veale further provided that during the December 2018 committee meeting, members discussed the impact the recent declared state of emergency disasters have had on pharmacies licensed by the board, especially the Camp Fire where five pharmacies were closed because the business either burned down or sustained significant fire damage and one wholesaler facility was destroyed. This resulted in these facilities having to either secure a mobile pharmacy or relocate to another area to operate. If the facility was not able to employ the use of a mobile pharmacy as specified in BPC 4062, this would constitute a license transfer.

Chairperson Veale reported staff surveyed other states and it was found that other states do not issue a new license when a pharmacy relocates because it had been destroyed.

The committee heard from pharmacist Lisa Hohenthaner, owner of two pharmacies impacted by the Camp Fire. Dr. Hohenthaner advised the committee that one of her pharmacies was completely destroyed, and second pharmacy was severely damaged. Dr. Hohenthaner described the challenges that resulted from the inability to transfer their pharmacy license to the new location and how it negatively impacted their ability to provide service to the residents of Paradise during this emergency.

Dr. Hohenthaner emotionally reported to the committee they could not open another pharmacy in the same location as the fire completely destroyed the community. Paradise is a small rural area that is mostly retired and low-income seniors with a huge need of a pharmacy that did more than just dispensing medications. Their pharmacy was the first fully medication synchronized pharmacy in the area. Both pharmacies serve high risk senior patients providing medication synchronized services which involves the pharmacy working with the physicians to synchronize the refills of patient's medications to allow patients to pick up their medications on the same day every month. This helps with medication compliance because the average senior patient is taking eight or more medications. This has improved patients' prognosis and improved compliance which has reduced patients from being readmitted into the hospital.

During the emergency, patients reached out to her pharmacy through Facebook, through her personal cell phone and by the Internet. She reported it was very emotional to hear the devastation that the patients were experiencing because they could not get their medications filled, which in some cases resulted in the patients being hospitalized.

She explained the barriers they experienced and continue to experience trying to get reestablished. She described the difficulty of a mobile pharmacy and noted that wholesalers are reluctant to deliver medications to the mobile pharmacies. Dr. Hohenthaner further noted that a mobile pharmacy is only temporary solution because the authority for its use expires when the declared emergency is lifted. The difficulty in having to apply for a new license as a result of moving into a new location involves reapplying to all the third-party payors in order to bill for the services provided. When they initially opened their pharmacy, they experienced up to nine months delay when applying to third-party payors. Ms. Hohenthaner detailed the need to have an exception to allow for a license to be transferrable so that businesses during this type of emergency are not negatively impacted by delays that prevent them from helping their patients. The patients themselves require immediate assistance during this type of emergency and delaying their ability to provide care ultimately impacts the welfare of the community that is affected.

Chairperson Veale thanked Ms. Hohenthaner for coming to the committee meeting to share her tragic experience during the Camp Fire and reported that the committee will be discussing the proposed changes to the law to hopefully make the necessary changes so that others will not have to experience this type of difficulty in future.

Danny Martinez, CPhA, thanked her for her services and reported the CDPH is doing their best to support her in her situation. He fully supports the board moving forward with this change and identified areas for the committee to consider such as addressing what immediate would mean and given the fact of Ms. Hohenthaner's testimony today and the impact this has had on her pharmacy and the community, can the board insert an urgency clause to seek an author for this bill this year to make the change immediately.

Ms. Sodergren reported the committee's recommendation will be discussed by the full board at the May 7 and 8, 2019 meeting. However, this type of change does not have to come from the board and that anyone is welcome to seek an author independently in order to move the process faster.

Dr. Steve Grey, pharmacist, recommends working with all parties involved to ensure that facilities are not having to reapply to all the different agencies for licensure with during an emergency.

Danny Martinez, CPhA, is working with some of the other agencies but in the interest of consumer protection he recommends the board fix this component first.

**Committee Recommendation:** Recommend to the board to approve the proposed language; pursue an urgency clause; and direct staff to work with counsel to make the necessary changes in accordance with the policy discussed today.

M/S: Schaad/Butler

Support: 4 Oppose: 0 Abstain: 0

**7. Discussion and Consideration of Proposed Language Establishing Parameters and Fees for Inspections of Sterile Compounding Pharmacies as a Result of Remodeling of the Facility**

Chairperson Veale provided that pharmacy law establishes the authority to inspect a California and nonresident sterile compounding pharmacy and specifies, "a license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance".

She further reported during the December 2018 committee meeting, members discussed the requirements of inspecting a sterile compounding pharmacy at the time of issuance and renewal as well as the need to perform inspections of sterile compounding pharmacies due to a remodel of the pharmacy. The committee further considered whether to assess a new inspection fee if the inspection occurs outside the parameters of the mandated renewal inspection.

Chairperson Veale reminded the committee that the board is mandated to ensure sterile compounding pharmacies are in compliance with pharmacy law and as such an inspection at the conclusion of a remodel is necessary to ensure that changes to the sterile compounding pharmacy as a result of a remodel do not pose a safety concern to consumers.

Currently, the board does not have the authority to require notification of, nor assess a fee for an inspection because of a remodel. Currently when the board is notified of a remodel, the board makes every effort to conduct the inspection as part of the mandated renewal inspection. However, if the remodel concludes outside of the typical timeframe for renewal inspection the board currently absorbs the cost, which impacts the board's budget. The board must immediately respond to perform such remodel inspections because a delay could impact patient care.

Remodels vary in scope ranging from simple projects to full remodels or expansions. 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.

Additionally, the committee discussed at the December 2018 meeting to establish the following parameters to determine if the remodel of the sterile compounding pharmacy requires an inspection and to assess if an inspection fee is required.

1. Require a remodel notification application prior to the conclusion of a remodel to collect the anticipated completion date and identify what is impacted by the remodel for the board to determine if an inspection is required.
2. The board to notify the sterile compounding pharmacy if the remodel impacts patient care in a manner that will result in an inspection of the pharmacy.
3. Assess an inspection fee if the remodel concludes more than 90 days prior to the expiration date of the license.
4. If the remodel concludes within the 90 days prior to the expiration date of the license, then the inspection would also serve as the renewal inspection.

Further, as part of the proposed revisions to USP 797, the standards provide that recertification of a classified area must occur if there are changes to the area such as redesign, construction, or replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality. Alignment with such requirements appears appropriate.

Chairperson Veale reported the committee agreed that an inspection is mandated after the conclusion of a remodel; however, the area of concern from the last meeting was charging a fee for the inspection outside of the renewal.

Committee member Butler proposed the committee move forward with accepting the proposed language as written, which includes charging a fee if the facility does not coordinate the completion of the construction within the renewal inspection.

Danny Martinez, CPhA, opposed the board charging a fee to conduct an in-state inspection if it is outside the renewal inspection as he believes the board can absorb the cost when the new fee increase become effective. He stated his belief that the fee is unnecessary.

Paige Talley, CCHP, expressed concern that pharmacies are now going to have to pay for the automated drug delivery systems and pay for a remodel inspection fee if remodel concludes outside the renewal inspection. These fees could end up costing pharmacies a lot money.

Victor Law, representing himself, shared that with all the remodeling of the sterile compounding pharmacies and the amount of money the pharmacies spend to become compliant in every aspect, the cost of remodeling is over thousands of dollars and the fee the board is proposing to charge is minimal for the inspection. The board puts a lot of effort in educating pharmacist to reduce citation and fines. The board needs to be able to charge for services that are being provided, especially when the cost is being incurred outside of the renewal fee. Dr. Law noted that the fee is not the full cost of a renewal inspection fee due to the inspection will be limited to the area of the remodel and not the entire pharmacy, which may not impact the policy and procedures.

**Committee Recommendation:** Recommend to the board approval of the proposed language in BPC 4400 to assess a remodel inspection fee for in-state sterile compounding pharmacies and to assess the remodel inspection fee and travel costs for out-of-state sterile compounding pharmacies. Direct staff to work with counsel on finalizing the language to bring to the board.

M/S: Butler/Schaad

Support: 4 Oppose: 0 Abstain: 0

**Committee Recommendation:** To recommend to the board to approve the language as proposed and seek legislation to add BPC 4127.XX. Direct staff to work with counsel on finalizing the language to bring to the board.

M/S: Butler/Wong

Support: 4 Oppose: 0 Abstain: 0

**8. Licensing Statistics**

Chairperson Veale reported on the licensing statistics for July 1, 2018 through February 28, 2019.

As of February 28, 2019, the board has received 9,761 initial applications, including:

- 1,836 intern pharmacists
- 1,350 pharmacist exam applications
- 173 advanced practice pharmacists
- 3,351 pharmacy technicians
- 303 community pharmacy license applications
- 104 sterile compounding pharmacy license applications
- 109 nonresident pharmacy license applications
- 47 hospital pharmacy license applications

As of February 28, 2019, the board has received 975 requests for temporary site license applications, including:

- 729 community pharmacy license applications
- 66 sterile compounding pharmacy license applications
- 75 nonresident pharmacy license applications
- 37 hospital pharmacy license applications

As of February 28, 2019, the board has issued 8,187 licenses, renewed 43,304 licenses and has 140,468 active licenses, including:

- 6,971 intern pharmacists
- 47,114 pharmacists
- 473 advanced practice pharmacists
- 70,877 pharmacy technicians
- 6,421 community pharmacies

- 409 hospital pharmacies

Chairperson Veale reported the board is currently within its 30-day performance standards for processing an initial application. However, it is outside of the 10-day processing time for deficiency mail for some of its types of applications. It is anticipated that vacant positions will be filled on or about July 1, 2019.

| Premises Application Types | Application Processing Times As of 3/19/2019 | Deficiency Mail Processing Times As of 3/19/2019 |
|---|---|---|
| Pharmacy | 13 | 28 |
| Nonresident Pharmacy | 27 | 15 |
| Sterile Compounding | 15 | 14 |
| Nonresident Sterile Compounding | 18 | 15 |
| Outsourcing | 0 | 0 |
| Nonresident Outsourcing | 0 | 0 |
| Hospital Satellite Compounding Pharmacy | 0 | 0 |
| Hospital | 0 | 0 |
| Clinic | 15 | 4 |
| Wholesaler | 13 | 8 |
| Nonresident Wholesaler | 25 | 5 |
| Third-Party Logistics Provider | 0 | 0 |
| Nonresident Third-Party Logistics Provider | 15 | 0 |

| Individual Application Type | Application Processing Times As of 3/19/2019 | Deficiency Mail Processing Times As of 3/19/2019 |
|---|---|---|
| Pharmacist Examination | 25 | 4 |
| Pharmacist Initial Licensure | 0 | n/a |
| Advanced Practice Pharmacist | 27 | 11 |
| Intern Pharmacist | 27 | 11 |
| Pharmacy Technician | 15 | 8 |
| Designated Representative | 28 | 11 |
| Designated Represenative-3PL | 22 | 11 |

Committee member Dr. Albert Wong requested the licensing stats be augmented to include the number of in-state pharmacies that notified the board of a discontinuance of business by date of closure.

**9. Future Committee Meeting Dates**

The 2019 Licensing Committee dates are as follows:

- June 26, 2019
- October 2, 2019

# Attachment 7

**Licensing Statistics**

A hardcopy of this document will be made available at the meeting or upon request. Requests may be emailed to Debbie.Damoth@dca.ca.gov.