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

LICENSING COMMITTEE REPORT
April 3, 2019

Debbie Veale, Licensee Member, Chairperson
Stan Weisser, Licensee Member, Vice-Chairperson
Lavanza Butler, Licensee Member
Amjad Khan, Public Member
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. Presentation on Medication-Assisted Treatment and Discussion and Consideration of Proposal to Establish Authority for Pharmacist to Provide Non-Opioid Medication-Assisted Treatment

   Attachment 1

   Background

   There is a huge nationwide opioid crisis. One of the recommended solutions to address the crisis is to provide medication-assisted treatment (MAT) to help wean patients from opioids. There are three main medications used for this -- methadone, buprenorphine and naltrexone. Methadone and buprenorphine are controlled substances that require a DATA 2000 waiver to prescribe. Regrettable, pharmacists are currently not eligible to receive such a waiver. Rather, such waiver authority is currently limited to physicians, nurse practitioners, and physician assistants.

   However, naltrexone 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.

Committee Discussion and Consideration

During the meeting, members will receive a presentation from two experts in the field. The presentation will include an overview of the larger issue and will identify current gaps in treatment access.

The committee will also have an opportunity to review a draft statutory proposal intended as the next step to allowing pharmacists to participate in MAT in California. This proposal is consistent with the policy statement approved by the board.

Attachment 1 includes the draft statutory proposal for the committee's consideration and Kentucky's Opioid Use Disorder Naltrexone Therapy Protocol.

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

Attachment 2

Relevant Law

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

Business and Professions Code (BPC) section 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.

A more detailed description of the provisions cited above is included in **Attachment 2.**

For 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 collaborative practice agreements 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.

The National Alliance of State Pharmacy Associations prepared a report; Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority. As part of its report, it notes that state laws, if too restrictive, can impede innovative team-based care models.

For the committee's consideration is a 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.

This draft proposal can serve as a starting point for the committee's policy discussion. In addition to the relevant legal provisions, **Attachment 2** also includes the report referenced earlier as well as the draft statutory language.

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

Attachment 3

Relevant Law

BPC 4210 establishes the requirements for an individual to qualify for recognition as an advanced practice pharmacist.

BPC 4052.6 identifies the privileges of an advanced practice pharmacist.

Title 16, California Code of Regulations (CCR) section 1730.1 defines the application requirements for advanced practice pharmacist licensure.

Background

Pursuant to BPC 4052.6, a pharmacist recognized by the board as an advanced practice pharmacist may do the following:

1) Perform patient assessments.
2) Order and interpret drug therapy-related tests.
3) Refer patients to other health care providers.
4) Participate in the evaluation and management of diseases and health conditions with other health care providers.
5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of BPC 4052.2.

On February 9, 2017, the board issued its first advanced practice pharmacist (APH) license. As of March 18, 2019, the board has issued a total of 488 APH licenses.

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):

- Earned certification in a relevant area of practice.
- Completion of a post graduate residency.
- Clinical experience for at least one year under a collaborative practice agreement or protocol.

At the staff level, changes have been made 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. Board staff continue to amend the instructions for clarity when a trend in deficiencies is identified.

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.

Further, staff has noted that some individuals are completing a certification program that does not satisfy the requirements established in regulation, specifically some programs that do not include a continuing education requirement. Regrettably, denial of the certification program results in the applicant having to qualify via another certification or another one of the qualifying criteria.

The board currently has received 173 advanced practice pharmacist applications this fiscal year and has 204 pending applications.

<u>For Committee Consideration and Discussion</u>
In addition to discussing the licensure requirements, the committee will receive a presentation from Dr. Joe Guglielmo, Dean of the University of California San Francisco College of Pharmacy.

Attachment 3 incudes a copy of the relevant laws.

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

Attachment 4

Relevant Law

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."

BPC 4201(f) specifies, "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".

Background

During the December 19, 2018 committee meeting, members discussed the impact the recent declared state of emergency disasters have had on pharmacies licensed by the board. During the most recent declared emergency resulting from the Camp Fire, five pharmacies were closed because the business either burned down or sustained significant fire damage and one wholesaler facility was destroyed. This resulted in facilities having to either secure a mobile pharmacy or relocate to another area to operate.

Currently, BPC 4062 only allows for a pharmacy or clinic to employ a mobile pharmacy in the impacted area. If the pharmacy or clinic relocates to another surrounding area or location in the impacted state of emergency area that is not a mobile pharmacy, this constitutes a license transfer.

Although state requirements vary, a survey was conducted to determine how other states handle this issue. It was determined that no states require issuance of a new license when a pharmacy must relocate because it has been destroyed.

For Committee Consideration and Discussion

During this meeting, members will have an opportunity to hear from a pharmacist whose business was impacted by the Camp Fire. Further, the committee may wish to consider the proposed language in **Attachment 4** which would allow for a licensed business that is damaged or destroyed to change locations without it being deemed transferred under specified conditions.

Note: According to the Department of Health Care Services, any change in location will require submission of an application to DHCS to apply for enrollment at the new location.

Attachment 4 incudes a copy of the proposed language.

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

Attachment 5

Relevant Law

BPC 4127.1(c) establishes the authority to inspect a 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".

BPC 4127.2 (b) establishes similar authority for nonresident pharmacies.

Background

During the December 19, 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 considered whether to assess a new inspection fee if the inspection occurs outside the parameters of the mandated renewal inspection.

The board is mandated to ensure sterile compounding pharmacies are in compliance with pharmacy law. 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 as a result 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.

As discussed during the December 19, 2018 meeting, 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.

Additional discussion included establishing 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.

For Committee Consideration and Discussion

During this meeting, the committee will have an opportunity to consider the proposed language in **Attachment 5** establishing a notification requirement, establishment of an inspection fee and the parameters for assessing an inspection fee.

8. Licensing Statistics

Licensing statistics for July 1, 2018 through February 28, 2019, are provided in **Attachment 6**.

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

Processing Times

The general application and deficiency mail processing times by license type are provided below reflecting data current as of March 19, 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.

Currently, the board is 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

9. Future Committee Meeting Dates

The 2019 Licensing Committee dates are as follows:

- June 26, 2019
- October 2, 2019

The draft meeting minutes from the December 19, 2018, committee meeting have been provided in **Attachment 7**.

ATTACHMENT 1

Proposal to Amend Business and Professions Code section 4052 as follows:

Furnishing to Prescriber; Permitted Procedures by Pharmacist

(a) Notwithstanding any other law, a pharmacist may:
(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber…

(14) Provide non-opioid medication-assisted treatment pursuant to a state protocol.

Attachment 1

OPIOID USE DISORDER
NALTREXONE THERAPY PROTOCOL v2
Approved 12/12/18

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

ATTACHMENT 2

Proposal to Amend Business and Professions Code section 4052 as follows:

Furnishing to Prescriber; Permitted Procedures by Pharmacist

(a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber…

(13) Initiate, adjust, or discontinue drug therapy for a patient, whose diagnosis is known to the pharmacist, under a collaborative practice agreement with a prescriber or medical group.

Relevant Laws

4052.1. Permitted Pharmacist Procedures in Licensed Health Care Facility

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.
(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

4052.2. Permitted Pharmacist Procedures in Health Care Facility; Home Health Agency or Clinic with Physician Oversight

(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional center, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.
(2) Ordering drug therapy-related laboratory tests.
(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.
(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.
(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.
(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:
(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.
(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.
(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.
(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:
(1) Successfully completed clinical residency training.
(2) Demonstrated clinical experience in direct patient care delivery.

4052.6. Advanced Practice Pharmacist; Permitted Procedures

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
(1) Perform patient assessments.
(2) Order and interpret drug therapy-related tests.
(3) Refer patients to other health care providers.
(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.
(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.
(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.
(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.
(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

Attachment 2

PHARMACIST COLLABORATIVE PRACTICE AGREEMENTS:
KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY

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

ATTACHMENT 3

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) 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) 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).

4052.6. Advanced Practice Pharmacist; Permitted Procedures

(a) A pharmacist recognized by the board as an advanced practice pharmacist may do all of the following:
(1) Perform patient assessments.
(2) Order and interpret drug therapy-related tests.
(3) Refer patients to other health care providers.
(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.
(5) Initiate, adjust, or discontinue drug therapy in the manner specified in paragraph (4) of subdivision (a) of Section 4052.2.
(b) A pharmacist who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist who initiates drug therapy shall promptly transmit written notification to, or enter the appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.
(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.
(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.
(e) A pharmacist who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

1730.1. Application Requirements for Advanced Practice Pharmacist Licensure

(a) For purposes of Business and Professions Code section 4210, an applicant for advanced practice pharmacist licensure must satisfy two of the following subsections.

(1) Demonstrate possession of a current certification as specified in Business and Professions Code section 4210, subdivision (a)(2)(A), by providing either:

(A) A copy of the certification award that includes the name of the applicant pharmacist, the area of specialty and date of completion, or

(B) A letter from the certification program confirming the award of the certification that includes the name of the applicant pharmacist, the area of specialty and the date of completion.

(2) Demonstrate completion of a postgraduate residency earned in the United States through an accredited postgraduate institution as specified in Business and Professions Code section 4210, subdivision (a)(2)(B), by providing either:

(A) A copy of the residency certificate awarded by the postgraduate institution that includes the name of the applicant pharmacist, the area of specialty, and dates of participation and completion, or

(B) A letter of completion of a postgraduate residency, signed by the dean or residency program director of the postgraduate institution and sent directly to the board from the postgraduate institution, that lists the name of the applicant pharmacist, the area of specialty, and the dates of participation and completion. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(3) Demonstrate that experience earned under a collaborative practice agreement or protocol, as required by Business and Professions Code section 4210, subdivision (a)(2)(C), has been earned within 10 years of the time of application for advanced practice pharmacist licensure. Additionally, the one year of experience must include no fewer than 1,500 hours of experience providing clinical services to patients. The experience earned under a collaborative practice agreement or protocol must include initiating, adjusting, modifying or discontinuing drug therapy of patients as authorized by law. An applicant shall demonstrate possession of experience by providing both of the following:

(A) A written statement from the applicant attesting under penalty of perjury that he or she has:

(i) Earned the clinical experience within the required time frame; and

(ii) Completed the required number of hours of experience providing clinical services to patients, as specified in subsection (a)(3).

(I)The applicant shall provide a copy of the collaborative practice agreement or protocol.

(II)If a copy of the collaborative practice agreement or protocol is not available, the applicant shall provide a description of the collaborative practice agreement or protocol, including examples of the clinical services the applicant provided to patients.

(B) A written statement from the supervising practitioner, program director or health facility administrator attesting under penalty of perjury that the applicant has completed at least 1,500 hours of experience providing clinical services to patients. For an applicant who cannot satisfy this documentation requirement, the board may, for good cause shown, grant a waiver for this subsection.

(b) The experience an applicant offers to demonstrate compliance with one of the three criteria in subsection (a) above may not also be used to satisfy another of the criteria.

Note: Authority cited: Sections 4005 and 4210, Business and Professions Code. Reference: Sections 4052.1, 4052.2 and 4210, Business and Professions Code

Attachment 3

Articles

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

ATTACHMENT 4

Proposal to Amend Business and Professions Code 4062 as follows:

4062. Furnishing Dangerous Drugs during Emergency; Mobile Pharmacy

(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy or clinic.

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board’s opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

(e) A pharmacy destroyed or damaged either as part of a state, federal or local disaster, or otherwise destroy may be relocated. Such a relocation shall not be considered transferred if no changes are made to the management and control, or ownership of the pharmacy. Notification of such relocation must be made to the board immediately upon identifying the new location.

ATTACHMENT 5

Proposal to Add Business and Professions Code section 4127.XX

A pharmacy licensed pursuant to 4127.1 or 4127.2 must notify the board of its intentions to remodel a facility within 30 days of initiation of the remodel. As part of the notification the licensee must provide the anticipated date of completion and the provisions for patient care during the remodel. For any remodel that results in recertification of an ISO classified area under USP 797 the board must perform an inspection to confirm compliance with this article and regulations approved by the board prior to resumption of sterile compounding within the facility. When possible, the board will conduct the inspection within the preceding 90 days of renewal of the license. In such instances a fee shall not be required.

Proposal to Amend Business and Professions Code section 4400. Fees

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

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

…

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855). <u>The fee for the inspection of a remodeled facility shall be $780 dollars.</u>

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant. <u>The fee for inspection of a remodeled facility shall be $780 dollars. In addition to paying the remodel inspection fee, the nonresident sterile compounding pharmacy shall deposit, when requested by the board following receipt of a remodel notification, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.xx. If the required deposit is not submitted, the remodel notification will be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount. Any remaining outstanding balance will be added to renewal costs.</u>

…

ATTACHMENT 6

Licensing Statistics

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

ATTACHMENT 7

California State Board of Pharmacy
1625 N. Market Blvd, N219
Sacramento, CA 95834
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www.pharmacy.ca.gov

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. <u>Presentation by the California Department of Public Health Regarding Provisions for Pharmacy Services During a Declared State of Emergency and Possible Next Steps</u>

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.

1. Methadone patients were in some cases unable to get their prescribed doses of methadone. A call to Department of Healthcare Services (DHCS) solved this.

2. A pharmacy in an evacuation area that had not been destroyed was being watched for possible drug theft opportunities.
3. 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. Note: Mr. Martinez's comments have been provided following these minutes.

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. <u>Licensing Statistics</u>

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

Premises Application Types	Application Processing Times As of 11/30/2018	Deficiency Mail Processing Times As of 11/30/2018
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.