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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
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LICENSING COMMITTEE REPORT

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Lavanza Butler, Licensee Member
Amjad Khan, Public Member
Allen Schaad, Licensee Member
Albert Wong, Licensee Member

The Licensing Committee met on April 3, 2019.

a) 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. Regrettably, 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 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.

At the April 2019 committee meeting, 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 presenters provided background and relevant statistics on the three medications used in the treatment of opioid use disorder. Dr. Puzantian described a study in which 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 presenters highlighted that one of the current gaps in treatment is a result of a lack of access to the medications as well as the stigma of opioid use disorder can be a barrier to treatment. It was emphasized that pharmacists have a responsibility to take a role in the treatment of opioid use disorder and are in a unique position to do so.

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 a licensed healthcare professional under a collaborative practice agreement (CPA). One issue 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 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. Gasper described pharmacists' role in administration of methadone in licensed opioid treatment programs (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.There are only two licensed pharmacies in California that have been licensed as OTPs.

Dr. Gasper described how DATA 2000 waivers for prescribers has expanded access to treatment outside of OTPs by enabling qualified practitioners to provide buprenorphine. The waiver is very underutilized as many professionals that have the authority to use the waiver are not either using their waiver or using the waiver far below its capacity. He further described pharmacists' role in community pharmacies and emphasized that pharmacists can make or break someone's MAT.

Dr. Puzantian and Dr. Gasper will present to the board a condensed version of their presentation provided at the April 2019 committee meeting.

<u>Committee Discussion and Action</u>
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.

Based on the information provided in the presentation, the committee suggested the board work toward a protocol for naltrexone similar to the example from Kentucky as well as take additional steps

to expand pharmacist's ability to provide MAT services. In addition to the proposal to amend BPC 4052 which only addresses non-opioid medication (naltrexone) the committee suggested the board should consider addressing the lack of pharmacies licensed as OTP to provide methadone treatment as well as develop a statewide CPA for pharmacists to provide buprenorphine as a way to further expand access to treatment.

Committee Recommendation (Motion): 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.

Should members agree with this new direction, the following language could serve as a motion.

Motion: Approve the proposed statutory language to amend BPC 4052 to add subdivision (a)(14), to direct staff to secure an author to sponsor the statutory change, and direct the licensing committee to move forward with parts two and three of the committee's recommendation.

Attachment 1 contains the proposed statutory language for BPC 4052(a)(14) that would be used to facilitate the statewide protocol for administering naltrexone as well as Kentucky's Opioid Use Disorder Naltrexone Therapy Protocol.

b) <u>Discussion and Consideration of Pharmacy Law Related to Collaborative Practice Agreements</u>
Attachment 2

<u>Relevant Law</u>
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 Action

The committee noted that as health care models evolve, and patient access points increase, it is appropriate to evaluate the current collaborative practice agreements to determine if pharmacy law has remained current with national trends and patient care needs.

Pharmacy law declares the practice of pharmacy as a profession to be a 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 committee reviewed 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 considered the draft statutory language proposed to recognize the continued evolution of team-based care approaches. 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". The committee agreed using a broader term instead of "prescriber or medical group" so as not to provide limitations in the future as well as not limit the authority of the CPA to the prescriber level.

Committee Recommendation (Motion): 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" in the proposed language.

Recent Update

Following the meeting counsel drafted language based on the committee's recommendation for the board's consideration. The draft language for BPC section 4052(a)(13) is provided in **Attachment 2.** Should members agree with this new direction, the following language could serve as a motion.

Motion: Approve the proposed statutory language to amend BPC 4052 to add subdivision (a)(13) and to direct staff to secure an author to sponsor the statutory change.

Attachment 2 includes a copy of the proposed language for BPC 4052(a)(13), relevant law sections, and the National Alliance of State Pharmacy Associations (NASPA) report.

c) 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 (APH) 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.

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. As of March 2019, there were 57 applications pending in which an experience conflict was a deficiency with the application.

Further, staff notes that some individuals are completing a certification program that does not satisfy the requirements established in regulation, specifically some programs 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.

On February 9, 2017, the board issued its first APH license. As of March 31, 2019, the board has issued a total of 515 APH licenses.

The board currently has received 190 APH applications this fiscal year and has 179 pending applications.

Committee Discussion and Action

During the April 2019 committee meeting, Dr. Joe Guglielmo, Dean of the University of California San Francisco College of Pharmacy, shared with the members that he supports the committee in their efforts in reviewing the criteria of the APH license and the collaborative practice agreements.

The committee discussed the authority of an advance practice pharmacist as defined in BPC 4052.6 and possible ways to expand the authority beyond that of a licensed pharmacist as well as the proposed changes to the language.

The committee discussed the licensing requirements under BPC 4210(a)(2) which requires a person to satisfy two of the three criteria to qualify for an APH license. The committee agreed based on public comment this section of the law needs to be revisited by the licensing committee to ensure that the requirements align with the scope of practice of an APH.

Committee Recommendation (Motion): Recommend 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.

Committee Recommendation (Motion): Recommend the board 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.

Recent Update

Following the meeting, based on the committee's recommendation counsel drafted language to amend BPC 4052.6(a)(5) for the board's consideration which is included in **Attachment 3.** Should members agree with this new direction, the following language could serve as a motion.

Attachment 3 includes the proposed statutory language for BPC 4052.6(a)(5) as well as the relevant law sections.

d) 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 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 location in the impacted state of emergency area or surrounding area that is not a mobile pharmacy, this constitutes a license transfer pursuant to BPC 4201.

Committee Discussion and Action

During the April 2019 committee meeting, members 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.

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 a 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.

The committee discussed the barriers that Dr. Hohenthaner experienced as well as others who were impacted during this type of emergency and agreed that the law needs to be amended to allow for businesses that are impacted to quickly return to pharmacy practice and provide patient care during a declared emergency.

Committee Recommendation (Motion): 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.

Recent Update

Following the meeting, based on the committee's recommendation counsel made non-substantive changes to the proposed language to amend BPC 4062 in **Attachment 4.**

e) 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 sterile compounding pharmacies.

Background

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 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 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.

Committee Discussion and Action

The committee discussed the board's mandate to inspect the facility to ensure compliance after the conclusion of a remodel as well as addressed the concerns received by public comment regarding charging a fee for the inspection outside of the renewal period. After receiving additional public comment, the committee proposed moving forward with accepting the proposed language as written, which includes charging a fee if the facility is unable to coordinate the completion of the construction within the renewal inspection. Additionally, the committee also agreed that nonresident sterile compounding facilities will need to continue to pay for the cost of the travel for board inspectors to conduct the inspection.

Committee Recommendation (Motion): Approve 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.

Committee Recommendation (Motion): Approve the language as proposed and seek legislation to add BPC 4127.5. Direct staff to work with counsel on finalizing the language to bring to the board.

Recent Update
Following the meeting, based on the committee's recommendation counsel made non-substantive changes to the proposed language to amend BPC 4400 and to add BPC 4127.5 and the updated language is included in **Attachment 5.**

f) Licensing Statistics

Licensing statistics for July 1, 2018 through March 31, 2019, are provided in **Attachment 6**. The licensing statistics have been updated to include the number of facilities that notified the board of a discontinuance of business by date of closure as requested by Dr. Albert Wong.

As of March 31, 2019, the board has received 10,671 initial applications, including:

- 1,904 intern pharmacists
- 1,489 pharmacist exam applications
- 190 advanced practice pharmacists
- 3,793 pharmacy technicians
- 363 community pharmacy license applications
- 111 sterile compounding pharmacy license applications
- 122 nonresident pharmacy license applications
- 48 hospital pharmacy license applications

As of March 31, 2019, the board has received 1,038 requests for temporary site license applications, including:

- 782 community pharmacy license applications
- 69 sterile compounding pharmacy license applications
- 83 nonresident pharmacy license applications
- 38 hospital pharmacy license applications

As of March 31, 2019, the board has issued 8,835 licenses, renewed 49,353 licenses and has 140,382 active licenses, including:

- 6,938 intern pharmacists
- 47,093 pharmacists
- 515 advanced practice pharmacists
- 70,726 pharmacy technicians
- 6,441 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 April 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 majority of initial applications are being processed within the board's 30-day performance standards. The board is currently outside of the 10-day processing time for

deficiency mail for a number of its application types. It is anticipated the two vacant positions will be filled on or about July 1, 2019 which should assist in further improvements in process times.

Premises Application Types	Application Processing Times As of 4/19/2019	Deficiency Mail Processing Times As of 4/19/2019
Pharmacy	32	30
Nonresident Pharmacy	36	37
Sterile Compounding	28	9
Nonresident Sterile Compounding	14	18
Outsourcing	7	0
Nonresident Outsourcing	25	0
Hospital Satellite Compounding Pharmacy	31	0
Hospital	25	0
Clinic	22	1
Wholesaler	23	4
Nonresident Wholesaler	21	4
Third-Party Logistics Provider	23	0
Nonresident Third-Party Logistics Provider	0	0

Individual Application Type	Application Processing Times As of 4/19/2019	Deficiency Mail Processing Times As of 4/19/2019
Pharmacist Examination	15	4
Pharmacist Initial Licensure	4	N/A
Advanced Practice Pharmacist	23	14
Intern Pharmacist	25	7
Pharmacy Technician	24	2
Designated Representative	23	15
Designated Represenative-3PL	17	15

g) <u>Future Committee Meeting Dates</u>

The 2019 Licensing Committee dates are as follows:

- October 2, 2019

The draft meeting minutes from the December 19, 2018 and April 3, 2019, 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 under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

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

Proposal to Amend Business and Professions Code section 4052.6 as follows:

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.

Current Law

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).

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 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 a result of a declared state, federal or local emergency, or otherwise destroyed by natural disaster 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 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 4127.5. 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>

…

Proposal to Add Business and Professions Code section 4127.5

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 remodel inspection fee shall not be required.

ATTACHMENT 6

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
Phone: (916) 574-7900 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

LICENSING COMMITTEE
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.

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. <u>Discussion and Consideration of a Policy Statement and Strategic Steps to Authorize a Pharmacist to Provide Medication-Assisted Treatment</u>

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
Hospital	24	Included w/PHY
Clinic	17	10
Wholesaler	25	43
Nonresident Wholesaler	28	43

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

California State Board of Pharmacy
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Sacramento, CA 95834
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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
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, CA 95834

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

BOARD MEMBERS NOT PRESENT: Stanley Weisser, Licensee Member, Vice Chair
Amjad Khan, Public Member

STAFF PRESENT: Anne Sodergren, Interim 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 10:08 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. <u>Discussion and Consideration of Pharmacy Law Related to Collaborative Practice Agreements</u>

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. <u>Post Implementation Review of the Advanced Practice Pharmacist Licensing Program including Licensing Requirements and Functions Authorized</u>

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. <u>Discussion and Consideration of Proposed Language Establishing Parameters and Fees for Inspections of Sterile Compounding Pharmacies as a Result of Remodeling of the Facility</u>

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

Individual Application Type	Application Processing Times As of 3/19/2019	Deficiency Mail Processing Times As of 3/19/2019
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. <u>Future Committee Meeting Dates</u>

The 2019 Licensing Committee dates are as follows:

- June 26, 2019
- October 2, 2019