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

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

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

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

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

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

Committee Discussion and Consideration

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Wong/Butler

Support: 4 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Wong/Butler

Support: 4 Oppose: 0 Abstain: 0

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

M/S: Butler/Wong

Support: 4 Oppose: 0 Abstain: 0

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

M/S: Schaad/Butler

Support: 4 Oppose: 0 Abstain: 0

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

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

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

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

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

Remodels vary in scope ranging from simple projects to full remodels or expansions. There are several reasons that a remodel may trigger an inspection such as:

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

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

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

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

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

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

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

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

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

inspection fee due to the inspection will be limited to the area of the remodel and not the entire pharmacy, which may not impact the policy and procedures.

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

M/S: Butler/Schaad

Support: 4 Oppose: 0 Abstain: 0

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

M/S: Butler/Wong

Support: 4 Oppose: 0 Abstain: 0

8. Licensing Statistics

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

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

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

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

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

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

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

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

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

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

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

9. Future Committee Meeting Dates

The 2019 Licensing Committee dates are as follows:

- June 26, 2019
- October 2, 2019