California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

LICENSING COMMITTEE REPORT
November 5, 2019

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

1. Call to Order and Establishment of Quorum

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

3. Discussion and Consideration of Draft Collaborative Practice Agreement: Pharmacist Protocol for Management of Opioid Use Disorders

   Background

   As part of its May 2019 meeting, the committee received a presentation from Dr. James Gaspar and Dr. Talia Puzantian providing an overview of Medication Assisted Treatment (MAT) and current gaps in treatment access. As part of the presentation 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. Dr. Gaspar further described pharmacists' role in community pharmacies and emphasized that pharmacists can make or break someone's MAT. Following that meeting, the board identified a three-pronged solution intended to address this current treatment gap, including directing the Licensing Committee to develop a sample Collaborative Practice Agreement (CPA) pharmacist could use in collaboration with a practitioner that has received a DATA 200 waiver.

   For Committee Discussion

   During the meeting members will have the opportunity to review a draft CPA prepared by Dr. Gaspar and Dr. Puzantian. Dr. Gaspar will be present to discuss the CPA.

   Attachment 1 includes a copy of the draft CPA.

4. Approval of September 25, 2019, Licensing Committee Meeting Minutes

   The draft meeting minutes from the September 25, 2019, committee meetings have been provided in **Attachment 2**.

5. Review of Licensing Statistics

   Licensing statistics for July 1, 2019 through September 30, 2019, are provided in **Attachment 3**.

   As of September 30, 2019, the board has received 4,132 initial applications, including:
   - 1,425 intern pharmacists
   - 340 pharmacist exam applications
   - 60 advanced practice pharmacists
   - 1,277 pharmacy technicians
   - 110 community pharmacy license applications
   - 43 sterile compounding pharmacy license applications
   - 28 nonresident pharmacy license applications
   - 8 hospital pharmacy license applications
   - 148 automated drug delivery system applications

   As of September 30, 2019, the board has received 129 requests for temporary site license applications, including:
   - 63 community pharmacy license applications
   - 16 sterile compounding pharmacy license applications
   - 16 nonresident pharmacy license applications
   - 7 hospital pharmacy license applications

   As of September 30, 2019, the board has issued 4,168 licenses, renewed 16,336 licenses and has 140,727 active licenses, including:
   - 7,700 intern pharmacists
   - 47,023 pharmacists
   - 574 advanced practice pharmacists
   - 70,150 pharmacy technicians
   - 6,572 community pharmacies
   - 468 hospital pharmacies
   - 795 automated drug delivery systems

   Processing Times
   The general application and deficiency mail processing times by license type are provided below reflecting the data as of September 18, 2019 (as reported at the September 25 committee meeting) and a comparison to the data as of October 22, 2019.

To reduce processing times board staff worked overtime and others were redirected to assisted with some functions. As the data reflects the board is meeting or close to meeting the 30-day performance standards for processing an initial application and still slightly over the 10-day processing time for deficiency mail on some of the applications. The most notable reductions in process times include timeframes for processing deficiency mail as well as the initial application processing time for several license categories.

Premises Application Types	Application Processing Times as of 9/18/2019	Application Processing Times as of 10/22/2019	Deficiency Mail Processing Times as of 9/18/2019	Deficiency Mail Processing Times as of 10/22/2019
Pharmacy	30	29	107	25
Nonresident Pharmacy	30	33	103	15
Sterile Compounding	33	22	79	33
Nonresident Sterile Compounding	30	5	Current	14
Outsourcing	Current	Current	Current	Current
Nonresident Outsourcing	20	Current	Current	Current
Hospital Satellite Compounding Pharmacy	Current	Current	Current	Current
Hospital	28	6	30	20
Clinic	33	21	58	22
Wholesaler	37	Current	46	20
Nonresident Wholesaler	43	32	56	20
Third-Party Logistics Provider	10	Current	35	Current

Premises Application Types	Application Processing Times as of 9/18/2019	Application Processing Times as of 10/22/2019	Deficiency Mail Processing Times as of 9/18/2019	Deficiency Mail Processing Times as of 10/22/2019
Nonresident Third-Party Logistics Provider	29	19	35	12
Automated Drug Delivery System	N/A	Current	N/A	Current
Automated Patient Dispensing System	N/A	Current	N/A	Current
Emergency Medical Services Automated Drug Delivery System	N/A	Current	N/A	Current

Individual Application Type	Application Processing Times as of 9/18/2019	Application Processing Times as of 10/22/2019	Deficiency Mail Processing Times as of 9/18/2019	Deficiency Mail Processing Times as of 10/22/2019
Pharmacist Examination	25	34	45	11
Pharmacist Initial Licensure	9	4	Current	Current
Advanced Practice Pharmacist	50	28	15	22
Intern Pharmacist	46	8	30	Current

Individual Application Type	Application Processing Times as of 9/18/2019	Application Processing Times as of 10/22/2019	Deficiency Mail Processing Times as of 9/18/2019	Deficiency Mail Processing Times as of 10/22/2019
Pharmacy Technician	34	33	10	7
Designated Representative	44	33	58	20
Designated Represenative-3PL	42	33	Current	15
Designated Representative-Reverse Distributor	Current	Current	Current	Current

6. Future Committee Meeting Dates
   The committee will meet as part of the January 2020 and May 2020 Board Meetings.

7. Adjournment

Attachment 1

Collaborative Practice Agreement:

Pharmacist Protocol for Management of Opioid Use Disorders

I. Authority: California Business and Professions Code § 4050-4052

II. Purpose: To formally identify the role that pharmacists play in providing drug therapy management to patients with opioid use disorder (OUD).

III. Referral criteria
    a. Patients with a known or suspected opioid use disorder are referred by a patient care team member or by patient self-referral.

IV. Pharmacist is permitted to conduct the following authorized functions in accordance with this protocol and the standards of care for the treatment of opioid use disorder:
    a. Assessment of opioid use disorder including physical and laboratory examination for signs and symptoms of opioid use and opioid use disorder sequalae.
    b. Medication Management
        i. Initiate, modify, discontinue, and administer medications for the treatment of opioid withdrawal symptoms including but not limited to alpha-2 agonists, antiemetics, antihistamines, anticonvulsants, antidiarrheal agents, analgesics, and sedative-hypnotics.
        ii. Initiate, modify, discontinue, and administer formulations of buprenorphine indicated for OUD in collaboration with a DATA 2000 waivered prescriber.
        iii. Initiate, modify, discontinue, and administer naltrexone for opioid use disorder.

DRAFT

iv. Initiate, modify, discontinue, and administer naloxone for overdose prevention.
v. Initiate, modify, discontinue, and administer medications for the treatment of opioid induced side effects.

c. Develop a treatment plan for opioid use disorder including referral to case management, psychosocial services, substance use counseling, and residential treatment when indicated.

V. Documentation

a. The pharmacist's assessment, clinical findings, and plan of care will be documented in an electronic health record mutually accessible by the referring provider and/or primary care physician.

VI. References

a. Substance Abuse and Mental Health Services Administration. Medications for Opioid Use Disorder. Treatment Improvement Protocol (TIP) Series 63. HHS Publication No. (SMA) 18-5063EXSUMM. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2018.

VII. Signatures

Physician	Sign	Date

Pharmacist	Sign	Date

DRAFT

Attachment 2

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

LICENSING COMMITTEE
DRAFT MEETING MINUTES

DATE:	September 25, 2019
LOCATION:	California State Board of Pharmacy First Floor Hearing Room 2720 Gateway Oaks Drive, Suite 100 Sacramento, CA 95833
BOARD MEMBERS PRESENT:	Deborah Veale, Licensee Member, Chair Albert Wong, Licensee Member Allen Schaad, Licensee Member
BOARD MEMBERS NOT PRESENT:	Lavanza Butler, Licensee Member, Vice Chair
STAFF PRESENT:	Anne Sodergren, Interim Executive Officer Laura Freedman, DCA Staff Counsel Norine Marks, DCA Staff Counsel

1. Call to Order, Establishment of Quorum, and General Announcements

Chairperson Veale called the meeting to order at 10:03 a.m.

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

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

Aaron Bukofer, speaking on behalf of AlphaScript, expressed his frustration over the application delays his clients has experienced with the processing of their application. He further stated the current 107-day processing delay of deficiency mail, as reported in the licensing statistics, for this meeting is unacceptable and urges the board to process applications quicker.

Danny Martinez representing the California Pharmacist Association (CPhA) requested the committee to revisit discussing the advanced pharmacy technician requirements. He informed the members he has some new information to share on this topic.

Chairperson Veale responded this will be added as a future agenda item and asked that he share his new information with Anne Sodergren via email.

The committee agreed to discuss Agenda Item 8 to address the processing times.

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

Chairperson Veale provided relevant law and background. Business and Professions Code (BPC) section 4210 establishes the requirements for an individual to qualify for recognition as an advanced practice pharmacist (APH). As identified in BPC 4210 to qualify for an APH license, an individual must hold an active license to practice pharmacy and satisfy two of the following criteria under subdivision (a)(2):

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

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

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

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

Chairperson Veale discussed the proposed language adding paragraph (3) as an amendment to BPC 4210(a) to allow the certification to apply to the two criteria if the certification included either a postgraduate residency or 1,500 hours of collaborative practice experience. The members were in support of this policy.

Danny Martinez with CPhA was also in support of this policy. However, he did not see where the existing statute prohibits the double dipping described. He suggested that

removal of subdivision (b) from section 1730.1 of Title 16, California Code of Regulations (CCR) could remedy the issue.

DCA Legal Counsel Freedman responded that this has been extensively reviewed and because the statute specifically states that you have to meet two of the criteria, it is prohibited.

Mr. Martinez commented on the proposal describing how it would allow for the requirement to be satisfied with (A) and (B) which would be a certification that included a residency as well as with (A) and (C) which would be a certification that included collaborative practice but does not see how it allows (B) and (C) which would be a residency that included collaborative practice.

Chairperson Veale responded that originally when developing the language, completion of a residency that included collaborative practice was still viewed as one effort while completion of a certification that included a residency or collaborative practice was viewed as completing two separate efforts therefore would satisfy the intent of the law. Typically, residency requires working under collaborative practice agreement or protocol. If voted to be sent to the full board, Mr. Martinez offered to provide additional commentary at the full board meeting.

Dr. Steve Grey, pharmacist, commented on how he was very active in writing the original language of BPC 4210, but the end result did not relay the intent of the sponsors or authors. Interpretation of current language does lend to a problem of "double dipping". He says we missed the boat on this proposed amendment and states that a pharmacist when completing a residency would be getting both the experience and the collaborative practice which qualifies the pharmacist under BPC 4052.2 to initiate, adjust, modify and discontinue drug therapy under a protocol. Dr. Grey explained that residencies can also provide the experiential training and if the board is going to allow experiential training to be included with the certification then it needs to be allowed for the residency as well.

Additionally, Dr. Grey commented that not all residencies include the experiential training and it depends on how the residency was designed. This is why the board moved forward with a regulation defining what was required under the experiential training. He recommended that if the experiential training completed is part of (A) which is a certification or (B) which is a residency, the experiential training must meet the requirements of the regulation. Documentation could be required to verify this.

Chairperson Veale responded that while the experience that is required for a certification can be easily verified, she is concerned with the ability to measure the experiential training included with a residency. Dr. Grey responded that there are many different types of residencies which is why the regulation could be used to ensure the minimum experiential training is met.

Chairperson Veale further suggested adding language to further define the experiential component of the residency.

As part of the discussion it was noted that two-thirds of a residency has to be done in direct patient care and questioned whether this was different from the collaborative practice experience requirement. The committee request that staff review the American Society of Health-System Pharmacists (ASHP) for accreditation of the residency programs to understand the minimum requirements to determine if there is overlap in the two requirements.

Committee Recommendation: Direct staff to work with counsel to draft statutory proposal that would define if completion of one requirement as identified in BPC 4210(a)(2) is subsumed within completion of another requirement specified, such completion would satisfy the requirement of the law in BPC 4210(a)(2). Further, to accept if certification is earned as part of the requirements for completion of a residency or completion of 1,500 hours of collaborative practice experience or a residency is completed that included the 1,500 hours of collaborative practice experience.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

Dr. Steve Grey cautioned against only looking at ASHP, as the criteria was developed prior to collaborative practice in California and the residencies now may incorporate more than what ASHP requires.

4. Use of Automated Drug Delivery Systems

Chairperson Veale provided an overview of the relevant statutes and regulations relating to automated drug delivery systems (ADDS).

a. <u>Post Implementation Review of Legislation</u>

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

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

Chairperson Veale stated as the board's implementation efforts continue staff has identified several policy areas that may be appropriate to discuss to determine if additional changes should be pursued.

b. Proposal to Expand the Use to Other Locations

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

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

Chairperson Veale explained that additional locations that have been identified through the application process that may also be appropriate locations for a pharmacy to operate an ADDS including:

A. **Mental Health Rehabilitation Center (MHRC):** An MHRC is a residential facility that is licensed by the State Department of Health Care Services and is a Regional Center vendor.
B. **Psychiatric Health Facility (PHF):** A PHF is considered a "health facility" as defined in HSC 1250 and is defined to mean a health facility, licensed by the State Department of Health Care Services, the provides 24-hour inpatient care for people with mental health disorders or other persons, as specified. Care provided shall include, among other services, drug administration.

C. **Jails**. Many county jails currently obtain drugs from either a county hospital system or a pharmacy contracted with the jail. Drugs are transferred to the jail under the medical director's license, but the drugs are administered from a common stock of drugs and not solely used by the medical director.
D. **Juvenile Hall Clinic:** Such a clinic is part of a county's juvenile hall detention center under a probation department. Juveniles reside at the detention centers and attend school during the day on the premises.
E. **Correctional Treatment Center (CTC):** CTC is a health facility operated by the Department of Corrections and Rehabilitation, Division of Juvenile Facilities or a county, city or city and county law enforcement agency that, as determined by the department, provides inpatient health services to that portion of the inmate population who do not require a general acute care level of basic services. The health services provided by a CTC shall include, pharmacy services.
F. **Hospice Facility:** Such facilities are health facilities licensed by the Department of Public Health. Hospice services include, pharmacy services under the direction of a licensed pharmacist.

The committee discussed the identified settings above to determine what amendments should be pursued to authorize the use of ADDS and provided direction when additional locations are identified by board staff.

Chairperson Veale suggested including any facility listed in HSC 1250 but believed that still does not include all the locations. She asked if there were any suggestions that would be more encompassing.

The committee indicated there may be locations regulated under Department of Social Services where as a function of their license they are involved with medication administration. Further the committee noted used of devices in jail may also be appropriate.

The committee provided policy guidance to staff noting that members were in support of ensuring there is control over the ADDS to include these other locations and future locations that are identified as well. The members noted that the board does not want to allow ADDS in locations that are not already handling medications.

Paige Talley with the California Council for the Advancement of Pharmacy (CCAP) was in support of including HSC 1250 to include all the location categories. She explained that the psychiatric health care facilities (PHF) are regulated by Department of Healthcare Services (DHCS) and recommended the board check will this agency as well. Limiting to Department of Social Services, would not include PHF locations. It was recommended to expand the language to include other organizations licensed by the state to be more general.

Mark Johnston with CVS Health was also in support of including HSC 1250. He also commented on another facility licensed under Department of Healthcare Services which are detox facilities with 24-hour nursing services. He recommended including all locations licensed by the state of California with statutory authority to administer drugs. He offered another complex example with Program of All-Inclusive Care for the Elderly (PACE) facilities. If the facility is for profit it does not qualify for licensure under HSC 1204 and as law is currently written this prevent the facility from using ADDS. Mr. Johnston will send information on this type of location to Ms. Sodergren to review and consider when drafting proposed language.

Dr. Wong commented that this all requires regulation and we have to all work together and be mindful not to over regulate.

Dr. Steve Grey, pharmacist, commented on his experience with assisted living facilities licensed by Department of Social Services which are not allowed to administer medications; however, they are allowed to distribute. The prescriptions are sent to the location for the individual patients and the ADDS machines are needed for security to control the medications. He pointed out that the requirement for licensure only applies if the pharmacy operates the machine. However, there are facilities that own the ADDS to operate them for storage purposes only. These should not require a license.

Committee Recommendation: Direct staff to work with counsel and the chair to develop a statutory proposal to expand the locations in which ADDS can be licensed to include all facilities listed in HSC 1250 as well as other locations licensed by the state that as a function of the underlying license are authorized to offer medication services.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

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

Chairperson Veale reported that currently, Section 4427.7 and 4119.11 of the BPC requires a pharmacy holding an ADDS license to complete an annual self-assessment, pursuant to Section 1715 of Title 16 of the CCR. However, Section 1715 of Title 16 of the CCR specifies the assessment shall be performed before July 1 of every odd-numbered year.

Additionally, Chairperson Veale clarified BPC 4427.7 requires a "pharmacy holding an ADDS license" to complete the self-assessment. However, licensed acute care hospital facility and acute psychiatric hospital facilities are exempt from licensure if the ADDS is owned/leased by the licensed hospital pharmacy and the drugs are owned by the licensed hospital pharmacy. BPC 4427.2(i) also requires the licensed hospital pharmacy to comply with all other requirements for an ADDS in the article. Although the licensed hospital pharmacy's ADDS are

not licensed, they should also complete the self-assessment if they are to comply with all other requirements for an ADDS.

The committee discussed the variances in frequency for completing the self-assessment and determined if changes should be recommended to the full board for consideration.

Chairperson Veale recommended to the members to align the self-assessment requirements with the pharmacy self-assessment requirement.

Committee Recommendation: Direct staff to work with counsel and the chair to draft proposed language to align the ADDS self-assessment requirements to align with the pharmacy self-assessment requirement and to bring to the November board meeting.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

d. Other Next Steps

In addition to the policy areas identified above, the committee explored other areas related to the use of ADDS and heard comments from the public.

Paige Talley asked how to respond to her members regarding the requirements for posting the ADDS license. Ms. Sodergren responded that when the ADDS license is issued the license verification is provided in the issuance email. This is to be posted on the ADDS machine and replaced with the original wall license once received. Ms. Sodergren offered to post instructions on the board's website for posting the license verification on the ADDS machine.

Dr. Steve Grey recommended the board look into the relationship between the various types of ADDS and the Drug Enforcement Agency (DEA). He stated, some DEA districts are saying each machine has to have a DEA registration for each location that stores controlled substances. Dr. Grey recommends reaching out to determine DEA policy at the local level. The national policy is that each location where controlled substances are stored needs a DEA registration. Additionally, it needs to be identified where the distribution records need be kept. Chairperson Veale responded with concerns for the impact that this would have on the resources of board staff.

Paige Talley stated that her understanding was since the drugs in the ADDS are owned by the pharmacy that is controlling the drugs that DEA license should be with the pharmacy. Ms. Talley recommended leaving it to the DEA because the pharmacy's license extends to the ADDS.

Mark Johnston commented on the problem when the DEA issues clarification letters and it is issued to the person who asked the questions specifically and not posted their website.

Mr. Johnston referenced a letter from the DEA dated November 30, 2016 to the American Society of Consultant Pharmacists referring to a 1980 policy clarifying that emergency kits do not require DEA registration unless used for continuous dosing.

Brian Sullivan with UC Davis commented on similar questions they had when looking into the DEA requirements for their ADDS. He asked that the board provide guidance, possibly in The Script, to help licensees understand the new state license and how it overlays with the registration with the DEA.

Chairperson Veale suggested that someone from DEA could be invited to a future meeting to address this. The committee noted that interpretation of DEA regulations are sometimes at the regional level. It was suggested that the board encourage licensees to reach out to the DEA for their policy to ensure compliance with their requirements and indicated that the information should in The Script.

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

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

Ms. Veale stated as the board's regulatory jurisdiction continues to grow, it is imperative that new and existing license types be included in this statute.

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

The committee supported this policy change.

There were no public comments.

Committee Recommendation: Recommend to the board to approve the proposed change to BPC 4312 at the November board meeting.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

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

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

Additionally, Ms. Veale reported Title 16 CCR section 1709 details when a licensed business entity shall notify the board when there has been change to the beneficial interest of the license either by submitting a change of permit or change of ownership application to the board.

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

Timeline:

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

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

Ms. Veale stated that given the changes in statute it may be appropriate to pursue additional changes to CCR section 1709.

The committee discussed if reporting of changes of individuals exercising management and control is appropriate. The members agreed to move forward with incorporating the change to add management and control.

Ms. Freedman recommended that the board carry forward with the existing language that has been approved and to consider waiting to add management and control.

It was suggested that staff could work with legal and the chair to include the changes into the language in line with the policy decision and to work with DCA Legal in incorporating this into the existing regulatory package.

Committee Recommendation: Direct staff to work with counsel and the chair to include the policy of any person with management and control into Title 16, CCR section 1709 and to incorporate this change into the current regulatory package.

M/S: Schaad/Wong

Support:3 Oppose: 0 Abstain:0

Dr. Steve Grey recommended that the board would need to define control including what control means and who has control as it can become complex with large corporations.

Ms. Sodergren provided an example with a Limited Liability Company (LLC). The board is currently notified of the owning members of the LLC but may not be notified with a managing director changes. She believes that it is important for the board to be notified of such a change.

Danny Martinez presented a letter sent to board from CPhA on July 25, 2017 discussing his concerns with the regulation overall.

Ms. Veale responded the committee is not addressing the language that has been approved by the board to add the trust. Ms. Veale explained the discussion today is only speaking on behalf of any person with management and control due to the change in BPC 4201. Ms. Sodergren reminded Mr. Martinez that these concerns can be submitted once the rulemaking has been noticed for public comment

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

Chairperson Veale provided an overview of the relevant statutes and regulations relating to designated representative licenses.

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

Chairperson Veale noted that staff has developed a summary chart detailing the inconsistencies when comparing the three designated representative licensure definitions and qualifications.

The committee discussed the discrepancies identified by staff to determine if a policy change should be pursued to amend the statutes pertaining to the designated representative licenses.

The committee discussed the following questions for policy consideration:

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

   The members indicated it is appropriate for a Designated Representative-in-Charge (DRIC) and Responsible Manager to be licensed in the home state as a pharmacist if not licensed in California as a designated representative.

   The committee discussed that if an individual was not licensed in California, the board would still be able to discipline that facility which would be license by the board.

2. The law explicitly states that a pharmacist can serve as the designated representative-in-charge of wholesaler and a nonresident wholesaler, but the same explicit authority is not provided for a pharmacist to serve as a responsible manager in a third-party logistics provider and nonresident third-party logistics provider facility. Should the board seek to amend the law to explicitly state such is allowed?

   The members agreed to move forward with making this requirement consistent.

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

   The members agreed to expand this requirement to include a post-secondary education.

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

The members agreed the board shall review and approve all the designated representative training programs.

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

   The members agreed to move forward with making this requirement consistent for both wholesalers and third-party logistics providers.

Dr. Steve Grey pointed out that there are some individuals in the United States that do not graduate from high school but go straight into college and supports this change.

Committee Recommendation: Direct staff to work with counsel and the chair to develop proposed amendments to pharmacy law based on the discussion of the committee to bring to the November board meeting.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

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

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

Chairperson Veale explained the conferences may also provide the board with an opportunity to collaborate with the schools of pharmacy, should they so choose. As proposed, the conferences will be available in Northern and Southern California as well as available via webcast. It is not mandatory for students to attend but is being offered as education and outreach to the students.

The members agreed with moving forward with this.

Committee Recommendation: Direct staff to develop this proposal and have check points with the chair to bring to the November board meeting.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

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

Chairperson Veale reviewed the licensing goals currently included in the board's strategic plan as well as the status of each goal as detailed below.

1.1 Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.
Status: The Executive Officer serves on the NABP's Pharmacy task force and provides updates on the national efforts to address unlicensed internet pharmacy sales. The board issued two cease and desist orders for unlicensed activity in fiscal year 2018/2019.

The committee agreed that the board has completed its work on this goal and the Enforcement Committee now monitors this data.

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

1.3 Complete a comprehensive review of at least five licensure categories and update requirements to ensure relevancy and keep licensing requirements current with professional practices.
Status:

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

The committee agreed with moving forward with implementation of the advanced pharmacy technician license.

1.4 Explore, and possibly implement, opportunities to use contracted organizations to administer the board's California Practice Standards and Jurisprudence Examination to increase access to the examination.
Status: No action has been taken on this goal.

The committee agreed that this goal is not a priority at this time.

1.5 Improve the application process for new licensees, including providing informational resources directed toward applicants to offer more guidance about the application process.
Status: Applications are in various stages of being streamlined and standardized.

The committee agreed that this goal is a high priority focusing first on pharmacy licenses.

1.6 Establish requirements to form a licensing process for alternate work sites and vendors in the pharmacy marketplace to advance patient safety and health.
Status:

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

The committee suggested looking at call centers in the future.

1.7 Identify opportunities to expand electronic interfaces with licensees to allow for online application and renewal.
Status: The board is currently working with the department on Business Modernization.

The committee discussed how the board has several licenses that already offer online renewal.

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

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

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

After the discussion, the committee decided to remove two of the current committee goals. The committee did not believe that there were any additional goals to add but did emphasize that its priorities are business modernization and application review.

Committee Recommendation: To remove 1.1 and 1.4 from the strategic licensing goals as identified below.

1.1 Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.

1.4 Explore, and possibly implement, opportunities to use contracted organizations to administer the board's California Practice Standards and Jurisprudence Examination to increase access to the examination.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

Dr. Steve Grey commented with all the new California schools graduating, he is concerned the vendor for the CPJE could not accommodate the number of students to sit for the exam. Additionally, he commented the board needs to include a post implementation of the remote dispensing site pharmacy. Ms. Sodergren responded AB 690 have not been signed by the Governor and therefore, this has not been implemented.

Dr. Grey also commented the residency applicants are impacted when the applications are not processed quickly.

Dr. Wong commented on whether the board has the authority to limit the number of California pharmacy schools and was advised that ACPE accredits schools of pharmacy.

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

Committee Recommendation: Approve the December 19, 2018 licensing committee meeting minutes with the correction on page 4 last paragraph to change the word "working" to "wording" and approve the April 3, 2019 licensing meeting minutes as written.

M/S: Schaad/Wong

Support: 3 Oppose: 0 Abstain: 0

Dr. Steve Grey commented that the word on page 4 should be changed.

11. Review of Licensing Statistics

Chairperson Veale reported on the Licensing statistics for July 1, 2019 through August 31, 2019.

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

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

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

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

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

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

Ms. Sodergren reported the board completed a substantial amount of work during this reporting period.

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

Regrettably the board is outside of the 30-day performance standards for processing an initial application as well as the 10-day processing time for deficiency mail for several of its types of applications. There are several factors including vacancies, implementation of new programs

and increased workload. Management staff are working with staff to reprioritize workload and where possible redirecting staff from other areas of operations to assist. In addition, staff is working overtime in order to improve the processing times.

Premises Application Types	Application Processing Times as of 9/18/2019	Deficiency Mail Processing Times as of 9/18/2019
Pharmacy	30	107
Nonresident Pharmacy	30	103
Sterile Compounding	33	79
Nonresident Sterile Compounding	30	0
Outsourcing	0	0
Nonresident Outsourcing	20	0
Hospital Satellite Compounding Pharmacy	0	0
Hospital	28	30
Clinic	33	58
Wholesaler	37	46
Nonresident Wholesaler	43	56
Third-Party Logistics Provider	10	35
Nonresident Third-Party Logistics Provider	29	35

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

Ms. Sodergren responded on behalf of the outstanding processing times. One of the factors that has impacted the board's processing times is when the board changed the conditions of expanding the criteria of when a facility could request a temporary license. The board issues temporary licenses with minimal information; however, the full license is not issued until the applicant has demonstrated they met all the licensure requirements. Board staff have found that as a result of the temporary licenses, staff is having to focus on the temporary license applications because the board only has authority to issue a temporary license for up to 180 days. If the applicant fails to fulfill their application within the 180 days, the license expires, and the facility is required to close.

The committee was advised that staff is doing a more robust screening of on new pharmacy applications seeking a temporary license. Board staff have found that there are several applications being submitted that do not meet this criterion.

Additionally, the majority of the site applications received are deficient which extends the processing time of being issued a license. Board staff are finding that many applicants do not provide the board with complete ownership information for example, information that is required. Often, when an applicant provides deficient items requested by the board, the subsequent review poses new questions because the information received is often inconsistent with what was first reported. If an applicant submits the required items, as outlined in the application instructions, at the beginning when submitting the application, that reduction in the number of application deficiencies would simplify the application review process.

The committee noted that a presentation of application requirement would be an appropriate agenda item for a future meeting.

The committee members commented on the importance of reducing the processing times for the pharmacy applications. Additionally, responding to phone calls and emails needs to be a priority with staff.

Ms. Sodergren reported the board is currently going through the Business Modernization process that requires staff to map out the current process and identify opportunities where the board can streamline the process. The board is hopeful through this process that there may be opportunities of getting a new computer system to improve the board's processing of applications.

Dr. Wong commented it would be helpful to educate the pharmacy community on the application requirements and identify what are the frequent mistakes when submitting an application to encourage applicants to submit more complete applications.

Chairperson Veale suggested involving the Communication and Public Education Committee in the process of educating applicants about the application requirements.

Danny Martinez with CPhA supports the idea of educating its members and offered to participate in offering education on licensing procedures if needed.

Ms. Sodergren asked if it would be helpful to see the number of applications received complete versus applications received deficient by license type. The members agreed this would be extremely helpful and directed staff to provide this information at the next full quarterly licensing committee meeting. Ms. Sodergren stated that staff will work on gathering this information for the next quarterly licensing committee meeting.

Ms. Talley additionally commented on the delay in receiving the hard copy of the license for the ADDS once the license is approved. Pharmacy law requires that the hard copy license be posted on the ADDS machine. Ms. Sodergren responded that the hard copy license is printed and mailed from another state agency therefore the board does not have control over this timeframe and which is why license verification is proof of licensure.

Ms. Sodergren also commented that the ADDS licenses are not on the website as the license is being used for a different purpose. The board implemented ADDS licensure outside of its system and has developed a work around for the ADDS license. Licensees should be aware when the license has been issued as proof of licensure is sent to the pharmacy via email.

Danny Martinez of CPhA commented that other facilities have experienced delays in receiving the hard copy license which impacts facilities' ability to contract with other

agencies offering an example of a PBM that would not contract with a pharmacy without a copy of the physical license. Ms. Sodergren responded that in certain circumstances the board can provide official license verification to assist.

Dr. Steve Grey, pharmacist, commented that the problem is not only with the PBMs but if a pharmacy does not have the actual license then this impacts them being able to operate. The pharmacy cannot get the business license and it also impacts insurance certification coverage. He also added that the problem with delays it that the longer the delay the more likely something will change in the process. Dr. Grey applauded the board for not posting the ADDS and APDS on the board's website due to the security problem it poses.

Mr. Schaad asked if the website can have a comment or notice that states the license verification on the board's website can be used as license verification.

Ms. Freedman responded that she has worked with boards and can work with this board to ensure that this language is on this board's website.

12. Future Committee Meeting Dates

- The next Licensing Committee meetings is scheduled for November 5, 2019 first day of the board meeting. This will be a limited meeting to review items that were not prepared today to go to the full meeting.

13. Adjournment

Chairperson Veale adjourned the meeting at 1:08 p.m.

Attachment 3

Licensing Statistics

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