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

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

The Licensing Committee met on September 25, 2019 and will be convening a second meeting on November 5 in advance of the board meeting. During the meetings the following items were discussed.

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

Relevant Law

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

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

Background

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

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

Committee Discussion and Action
The committee discussed the underlying policy goal of the legislation and determined changes would be appropriate and if the board agrees a statutory change would be necessary. Additionally, the committee discussed researching the minimum requirements of residency programs established by ASHP to determine if minimum requirements of collaborative practice are met. The committee agreed ASHP will not be the benchmark but a method of gaining foundational information.

Committee Recommendation (Motion): 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.

Recent Update
Staff and counsel are working on statutory language that will be provided during the meeting.

Should members agree with the proposal, the following language could serve as a motion.

Motion: Approve the proposed statutory language to amend BPC 4210 as drafted and to direct staff to secure an author to sponsor the statutory change.

Attachment 1 contains the existing statutory language for BPC 4210.

b) Discussion and Consideration of Legislative Proposal Regarding the Use of Automated Drug Delivery Systems

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

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

1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.
2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.
3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

4) A correctional clinic licensed pursuant to Section 4187.1.
5) If the ADDS is an APDS, in a location as provided in Section 4427.6.

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

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

BPC section 4119.11 authorizes an Automated Patient Dispensing System (APDS) to be located on the premises of a covered entity as specified or on the premises of medical professional practices under contract to provide medical services to covered entity patients, which need not be the same location as the pharmacy, if all of the following conditions are met in this section.

1. Post Implementation Review of Legislation

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

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

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

2. Proposal to Expand the Use to Other Locations

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

- Licensed acute care hospital facility operating an AUDS pursuant to BPC 4427.2(i)
- Licensed acute psychiatric hospital facility operating an AUDS pursuant to BPC 4427.2(i)
- Licensed pharmacy premise operating ADDS pursuant to BPC 4427.2(j)
- Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license pursuant to BPC 4427.3(b)(1).
- A health facility licensed pursuant to HSC 1250 that complies with HSC 1261.6 pursuant to BPC 4427.3(b)(2).
- A clinic licensed pursuant to HSC 1204 and 1204.1 or BPC 4180 and 4190 pursuant to BPC 4427.3(b)(3).
- A correctional clinic licensed pursuant to BPC 4187.1 pursuant to BPC 4427.3(b)(4).

- An APDS located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice pursuant to BPC 4427.6(j).
- Premises of a covered entity or on the premises of a medical professional practices under contract to provide medical services to covered entity patients pursuant to BPC 4119.11(a).

Provided below are additional locations that were identified through the application process that were also discussed as appropriate locations for a pharmacy to operate an ADDS.

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

Committee Discussion and Action The committee discussed the identified settings above as well as including any facility listed in HSC 1250. The committee agreed they cannot limit the expansion to only HSC 1250 as other locations such as PHF and jails would not be included. The language would need to be broad enough to encompass locations that have authority to administer drugs and would require the ADDS to be licensed with the board.

The committee noted the board does not want to allow ADDS in locations that are not already handling medications. Further, 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.

Committee Recommendation (Motion): 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.

Recent Update
Staff and counsel are working on statutory language that will be provided during the meeting.

Should members agree with the proposal, the following language could serve as a motion.

Motion: Approve the proposed statutory language to amend BPC 4427.3 as drafted, to direct staff to secure an author to sponsor the statutory change.

Attachment 2 contains the existing statutory language for BPC 4427.3.

3. Proposal to Align the Self-Assessment Requirement Frequency to be Consistent with other Laws

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

Committee Discussion and Action
The committee discussed the variances in frequency for completing the self-assessment and the conflict between the ADDS self-assessment and the pharmacy self-assessment frequency and directed staff to provide amended language to align the requirements to the full board for consideration.

Should members agree with the proposed statutory language, the following language could serve as a motion.

Motion: Approve the proposed statutory language to amend BPC 4427.7 and 4119.11 to align the ADDS self-assessment requirements with the pharmacy self-assessment requirement in Title 16 CCR 1715 as drafted, to direct staff to secure an author to sponsor the statutory change.

Attachment 2 contains the proposed statutory language for BPC 4427.7 and 4119.11.

c) Discussion and Consideration of Legislative Proposal to Amend Business and Professions Code section 4312 to Expand the Provisions to Apply to All Facility Licenses

Relevant Law

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

Committee Discussion and Action

The committee discussed as the board's regulatory jurisdiction continues to grow, it is imperative that the law is written to allow new and existing license types to be included in this statute.

Committee Recommendation (Motion): Approve the proposed statutory language to amend BPC 4312 as drafted, to direct staff to secure an author to sponsor the statutory change.

Attachment 3 contains the proposed statutory language for BPC 4312.

d) Discussion and Consideration of Amendments to Title 16 CCR Section 1709, to Specify Required Reporting Requirements for Individuals vested with Management and Control

Relevant Law

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

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

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

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

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

Given the changes in statute the committee agreed it is appropriate to pursue additional changes to CCR section 1709.

Committee Discussion and Action
The committee discussed the importance of reporting changes in individuals exercising management and control over a facility license. Members agreed to move forward with incorporating the change to add any person with management and control over the license.

Committee Recommendation (Motion): Direct staff to work with counsel and the chair to incorporate changes into the regulation to require reporting of any person with management and control into Title 16, CCR section 1709 and to incorporate this change into the current regulatory package.

Recent Update
Staff and counsel are working on the regulatory language that will be provided during the meeting.

Should members agree with the proposal, the following language could serve as a motion.

Motion: Approve the proposed regulatory language to amend Title 16, CCR section 1709 to include any person with management in subdivision (b) and (c) and to incorporate this change into the current regulatory package.

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

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

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

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

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

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

Committee Discussion and Action
During the meeting, 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.

To assist in the policy discussion, the following questions were provided to the committee for 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 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 committee agreed the language should be 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 committee agreed the requirement should be expanded 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 committee agreed the board should be consistent in approving the 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 committee agreed this requirement should be consistent for both wholesalers and third-party logistics providers.

Committee Recommendation (Motion): 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.

<u>Recent Update</u>
Staff and counsel are working on statutory language that will be provided during the meeting.

Should members agree with the proposal, the following language could serve as a motion.

Motion: Approve the proposed statutory language to amend BPC 4022.5, 4022.7, 4053, 4053.1, and 4053.2 as drafted, to direct staff to secure an author to sponsor the statutory change.

Attachment 5 contains the existing statutory language for BPC sections 4022.5, 4022.6, 4022.7, 4053, 4053.1, and 4053.2.

f) 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

The committee discussed and recommends the board to consider a proposal to develop two intern conferences, one intended for first year students and the second intended for students preparing for graduation. The conference for first year students could serve as an introduction to the board and focus on intern licensing requirements, board expectations of licensees. The conference for graduating students could serve as a reminder of the board's expectations, provide information on pharmacist examination application process and requirements as well as pharmacy law. The conferences can 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 conferences may also provide the board with an opportunity to collaborate with the schools of pharmacy, should they so choose.

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

<u>Recent Update</u>
Regrettably staff has been unable to further refine this proposal. Staff notes that the concept was discussed with several of the deans of the pharmacy schools. Some of the deans expressed concern with the general concept while others suggested, should the board move forward, the conference should be available through a webinar or coordinated with other meetings, e.g. the annual meetings convened by the associations.

g) Discussion and Consideration of Committee's Strategic Plan Goals

During the meeting the committee reviewed and discussed 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.

h) 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 6 includes a copy of the draft CPA.

i) Review of Licensing Statistics

Licensing statistics for July 1, 2019 through September 30, 2019, are provided in **Attachment 7**.

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

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
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
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
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

Attachment 1

Current Statutory Language – Advanced Practice Pharmacist

Business and Profession Code 4210.

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

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

(2) Satisfy any two of the following criteria:

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

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

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

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

(4) Pay the applicable fee to the board.

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

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

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

Attachment 2

Current - Business and Professions Code section 4427.3

4427.3. Automated Drug Delivery System Location Requirements

(a)An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b)An ADDS shall be placed and operated in one of the following locations:

(1)Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2)A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3)A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4)A correctional clinic licensed pursuant to Section 4187.1.

(5)If the ADDS is an APDS, in a location as provided in Section 4427.6.

(c)Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

Proposed Amendments to Business and Professions Code Section 4427.7(a) and 4119.11(i).

4427.7. Self-Assessment and Recordkeeping Requirements

(a)A pharmacy holding an ADDS license shall complete a ~~an annual~~ self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b)The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

4119.11. Automated Patient Dispensing Systems

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

(1)The pharmacy obtains a license from the board to operate the automated patient dispensing system at the covered entity or affiliated site. As part of the application, the pharmacy shall provide the address at which the automated patient dispensing system shall be placed and identify the covered entity. A separate license shall be required for each location and shall be renewed annually concurrent with the pharmacy license. The application and renewal fee shall be three hundred dollars ($300) and may be increased to five hundred dollars ($500). The board is authorized to lower the renewal fee to not less than two hundred dollars ($200) if a lower fee level will provide sufficient resources to support the regulatory activities.

(2)The pharmacy providing the pharmacy services to the patients of the covered entity, including, unless otherwise prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with that covered entity as described in Section 4126 to provide those pharmacy services through the use of the automated patient dispensing system.

(3)Drugs stored in an automated patient dispensing system shall be part of the inventory of the pharmacy providing pharmacy services to the patients of the covered entity and drugs dispensed from the automated patient dispensing system shall be considered to have been dispensed by that pharmacy.

(4)The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs stored in the automated patient dispensing system separate from other pharmacy records.

(5)The pharmacy shall be solely responsible for the security, operation, and maintenance of the automated patient dispensing system.

(6)The pharmacy shall provide training regarding the operation and use of the automated patient dispensing system to both pharmacy and covered entity personnel using the system.

(7)The operation of the automated patient dispensing system shall be under the supervision of a licensed pharmacist acting on behalf of the pharmacy providing services to the patients of the covered

entity. The pharmacist need not be physically present at the site of the automated patient dispensing system and may supervise the system electronically.
(8)Notwithstanding Section 4107, the board may issue a license for the operation of an automated patient dispensing system at an address for which it has issued another site license.
(9)The board, within 30 days after receipt of an application for an automated patient dispensing system license, shall conduct a prelicensure inspection at the proposed location of the automated patient dispensing system. Relocation of the automated patient dispensing system shall require a new application for licensure. Replacement of an automated patient dispensing system shall require notice to the board within 30 days.
(10)The automated patient dispensing system license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an automated patient dispensing system license may be submitted to the board.
(11)A pharmacy that holds an automated patient dispensing system license shall advise the board in writing within 30 days if use of the automated patient dispensing system is discontinued.
(b)For purposes of this section, the following definitions shall apply:
(1)An “automated drug delivery system” (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2)An “automated patient dispensing system” (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.
(3)An “automated unit dose system” (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.
(c)(1) An automated patient dispensing system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.
(2)Transaction information shall be made readily available in a downloadable format for review and inspection by individuals authorized by law. These records shall be maintained by the pharmacy for a minimum of three years.
(d) Drugs from the automated patient dispensing system may be dispensed directly to the patient if all of the following requirements are met:
(1)The pharmacy shall develop, implement, and annually review written policies and procedures with respect to all of the following:
(A)Maintaining the security of the automated patient dispensing system and the dangerous drugs and devices within that automated patient dispensing system.
(B)Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the automated patient dispensing system and for which patients.
(C)Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via the automated patient dispensing system.
(D) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the automated patient dispensing system at the location where the automated patient

dispensing system is placed, regarding maintenance and filing procedures for the automated patient dispensing system.
(E)Orienting participating patients on the use of the automated patient dispensing system, notifying patients when expected prescription medications are not available in the automated patient dispensing system, and ensuring that patient use of the automated patient dispensing system does not interfere with delivery of drugs and devices.
(F)Ensuring delivery of drugs and devices to patients expecting to receive them from the automated patient dispensing system in the event the automated patient dispensing system is disabled or malfunctions.
(2)The automated patient dispensing system shall only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from an automated patient dispensing system and whose use of the automated patient dispensing system meet the criteria pursuant to paragraph (1).
(3)The automated patient dispensing system shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.
(4)A pharmacist shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.
(5)Drugs shall be dispensed from the automated patient dispensing system only upon authorization from a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.
(6) All prescribed drugs and devices dispensed from the automated patient dispensing system for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way audio and video.
(7)The automated patient dispensing system shall include a notice, prominently posted on the automated patient dispensing system, that provides the name, address, and telephone number of the pharmacy that holds the automated patient dispensing system license for that automated patient dispensing system.
(8)The labels on all drugs dispensed by the automated patient dispensing system shall comply with Section 4076 of this code and with Section 1707.5 of Title 16 of the California Code of Regulations.
(9)Any complaint, error, or omission involving the automated patient dispensing system shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.
(10)The board shall not issue a pharmacy more than 15 licenses for automated patient dispensing system units under this section. Consistent with Section 4001.1, the board may adopt regulations to reduce the number of automated patient dispensing system licenses that may be issued to a pharmacy.
(11)The pharmacy holding the license for the automated patient dispensing system shall maintain the policies and procedures developed pursuant to paragraph (1) for three years after the last date of use of that automated patient dispensing system.
(e)Access to the automated patient dispensing system shall be controlled and tracked using an identification or password system or biosensor. A system that is accessed via a password system shall include a camera that records a picture of the individual accessing the machine. Picture records shall be maintained for a minimum of 180 days.

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

Attachment 3

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

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

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

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

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

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

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

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

Attachment 4

Title 16. Board of Pharmacy
Proposed Text

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) The revocation of the trust.

(D) The dissolution of the trust.

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

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

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

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

Relevant Law

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

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

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

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

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

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

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

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

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

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

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

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

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

Attachment 5

Current Statutory Language – Designated Representative Licenses

4022.5. Designated Representative; Designated Representative-in-Charge

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

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

4022.6. Designated Representative-Reverse Distributor

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

4022.7. Designated Representative-3PL; Responsible Manager

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

(b) "Responsible manager" means a designated representative3PL selected by a third-party logistics provider and approved by the board as responsible for ensuring compliance of the licensed place of business with state and federal laws with respect to dangerous drugs and dangerous devices received by, stored in, or shipped from the licensed place of business of the third-party logistics provider.

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

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

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

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

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

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

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

(B) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(C) Knowledge and understanding of quality control systems.
(D) Knowledge and understanding of the United States Pharmacopoeia standards relating to the safe storage and handling of drugs.
(E) Knowledge and understanding of prescription terminology, abbreviations, dosages, and format.
(4) The board may, by regulation, require training programs to include additional material.
(5) The board may not issue a license as a designated representative until the applicant provides proof of completion of the required training to the board.
(c) The veterinary food-animal drug retailer or wholesaler shall not operate without a pharmacist or a designated representative on its premises.
(d) Only a pharmacist or a designated representative shall prepare and affix the label to veterinary food-animal drugs.
(e) Section 4051 shall not apply to any laboratory licensed under Section 351 of Title III of the Public Health Service Act (Public Law 78-410).

4053.1. Designated Representative 3-PL to Supervise Third-Party Logistics Provider
(a) Notwithstanding Section 4051, the board may issue a license to a qualified individual as a designated representative-3PL to provide sufficient and qualified supervision of a third-party logistics provider's place of business. The designated representative-3PL shall protect the public health and safety in the handling, storage, warehousing, distribution, and shipment of dangerous drugs and dangerous devices in the third-party logistics provider's place of business.
(b) An individual who is at least 18 years of age may apply for a designated representative-3PL license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1) He or she shall be a high school graduate or possess a general education development certificate equivalent.
(2) He or she shall meet one of the following requirements:
(A) Have a minimum of one year of paid work experience in the past three years with a third-party logistics provider.
(B) Have a minimum of one year of paid work experience in the past three years in a licensed pharmacy, or with a drug wholesaler, drug distributor, or drug manufacturer, performing duties related to the distribution or dispensing of dangerous drugs or dangerous devices.
(C) Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3) (A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i) Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii) Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii) Knowledge and understanding of quality control systems.
(iv) Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.

(B) The board may, by regulation, require the training program required under this paragraph to include additional material.
(C) The board shall not issue a license as a designated representative-3PL until the applicant provides proof of completion of the training required by this paragraph to the board.
(c) A third-party logistics provider shall not operate without at least one designated representative-3PL present at each of its licensed places of business as required under Section 4160.

4053.2. Designated Representative-Reverse Distributor – Licensing; Requirements
(a)Notwithstanding Sections 4051 and 4053, the board may issue a designated representative-reverse distributor license to a qualified individual who shall provide sufficient and qualified supervision over a licensed wholesaler that only acts as a reverse distributor. The designated representative-reverse distributor shall protect the public health and safety in the handling, storage, warehousing, and destruction of outdated or nonsaleable dangerous drugs and dangerous devices.
(b)An individual who is at least 18 years of age may apply for a designated representative-reverse distributor license. In order to obtain and maintain that license, the individual shall meet all of the following requirements:
(1)He or she shall be a high school graduate or possess a general education development certificate equivalent.
(2)He or she shall meet one of the following requirements:
(A)Have a minimum of one year of paid work experience in the past three years with a licensed wholesaler, third-party logistics provider, or pharmacy performing duties related to the distribution, dispensing, or destruction of dangerous drugs or dangerous devices.
(B)Have a minimum of one year of paid work experience in the destruction of outdated or nonsaleable dangerous drugs or dangerous devices pharmaceutical waste.
(C)Meet all of the prerequisites to take the examination required for licensure as a pharmacist by the board.
(3)(A) He or she shall complete a training program approved by the board that, at a minimum, addresses each of the following subjects:
(i)Knowledge and understanding of California law and federal law relating to the distribution of dangerous drugs and dangerous devices.
(ii)Knowledge and understanding of California law and federal law relating to the distribution of controlled substances.
(iii)Knowledge and understanding of California law and federal law relating to the removal and destruction of dangerous drugs, dangerous devices, and pharmaceutical waste.
(iv)Knowledge and understanding of the United States Pharmacopoeia or federal Food and Drug Administration standards relating to the safe storage, handling, and transport of dangerous drugs and dangerous devices.
(B)The board may, by regulation, require the training program required under this paragraph to include additional material.
(C)The board shall not issue a license as a designated representative-reverse distributor until the applicant provides proof of completion of the training required by this paragraph to the board.
(c)A reverse distributor shall not operate without at least one designated representative or designated representative-reverse distributor present at each of its licensed places of business as required under Section 4160.

Attachment 6

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.

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

Attachment 7

Licensing Statistics

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