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

Seung Oh, PharmD, Licensee Member, Chairperson
Satinder Sandhu, PharmD, Licensee Member, Vice-Chairperson
Renee Barker, PharmD, Licensee Member
Jessica Crowley, PharmD, Licensee Member
Kartikeya Jha, Licensee Member
Claudia Mercado, Public Member

a. Summary of Discussion Regarding and Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1707, Related to Waiver Requirements for Off-Site Storage of Records

Relevant Law

California Civil Code, Division 1, Part 2.6 (sections 56-56.37), the Confidentiality of Medical Information Act (CMIA), establishes protections to safeguard the privacy, security, and integrity of a person's medical information and to strictly control who can access or disclose it. These provisions expand upon federal requirements under the Health Insurance Portability and Accountability Act (HIPAA). The CMIA covers entities licensed by the Board including pharmacies and wholesalers. The Act ensures that medical information remains confidential, whether it is stored on paper, electronically, or shared through a third-party service.

Business and Professions Code (BPC) section 4333 specifies that all prescriptions filled by a pharmacy and all other records required by section 4081 shall be maintained on the premises and available for inspection by authorized officers of the law for a period of at least three years. The section further provides that in cases where the pharmacy discontinues business, the records shall be maintained in a board-licensed facility for at least three years. Subdivision (c) of this section further establishes authority for the Board to grant a waiver of the requirement that records be maintained on the licensed premises or, in the event the pharmacy discontinues business, that the records be maintained in a board licensed facility.

Similarly, BPC section 4105 requires that all records or other documentation required to be maintained pursuant to Chapter 9 of Division 2 of the BPC by any entity licensed by the Board shall be retained on the licensed premises for a period of three years from the date of making. Section 4105 also specifies that the Board may grant to a licensee a waiver of the requirements that records be kept on the licensed premises.

California Code of Regulations, title 16, section 1707 clarifies the Board's waiver requirements related to the off-site storage of records including the conditions that must be met for the Board to grant such a waiver.

Background

The Board's current regulation specifies that a waiver permitting offsite storage of records may be granted to "any entity licensed by Board." As the regulation is currently worded, a pharmacy that has discontinued business (because of license cancellation, revocation, surrender of the pharmacy license, etc.) may not be eligible for a waiver.

Board staff recommend that the Committee consider if the regulation should be broadened to explicitly permit the Board to also grant waivers to entities formerly licensed by the Board.

Staff note that regrettably in the past there have been instances where a pharmacy owner has abandoned the pharmacy, including all of the records.

Board staff are also aware of challenges some pharmacy owners have encountered trying to identify another pharmacy to store records when the business closes.

Board staff believe that establishing provisions that expressly enable the Board to grant waivers to former licensees for off-site storage of records, with appropriate conditions and safeguards in place to protect against unlawful disclosure of records and ensure the Board will maintain access to the records if needed, may provide an appropriate solution.

Summary of Committee Discussion

During the meeting, members considered a draft regulation proposal that would establish authority to allow for a previously licensed entity to request a waiver to store records off-site.

Members noted agreement with the proposed regulation text. Members also received public comment in support of the policy goal underlying the proposed regulation text.

Should the Board agree, the following motion could be used to initiate the formal rulemaking process.

> **Recommended Motion**: Move to initiate a rulemaking to amend California Code of Regulations, title 16, section 1707 [either "as proposed" or "consistent with the Board's discussion"], direct staff to submit the text to the Director of the Department of Consumer Affairs, and Business, Consumer Services and Housing Agency for review, and authorize the executive officer to take all

steps necessary to initiate the rulemaking process, make any technical or nonsubstantive changes to the package, and set the matter for hearing, if requested. If, during the 45-day comment period, the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or the procedures followed by the Board in proposing or adopting the action, and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at section 1707.

Attachment 1 includes a copy of the proposed regulation text.

b. Summary of Discussion of Public Comment Suggesting the Board Establish Requirements for Outsourcing Facilities to Provide Advance Notification of Closure/Cessation of Business Operations in California, Including Possible Action to Initiate a Rulemaking to Amend California Code of Regulations, Title 16, Section 1708.2 Related to Discontinuance of Business

Relevant Law
BPC sections 4129-4129.9 establish the requirements for outsourcing facilities licensed by the Board. Included in these requirements is the authority for the Board to adopt regulations to establish policies, guidelines, and procedures to implement the provisions.[1]

California Code of Regulations, title 16, section 1708.2 generally requires permit holders to contact the Board prior to transferring or selling any dangerous drugs, devices, or hypodermics inventory as a result of termination of business or bankruptcy proceedings, and to follow official instructions given by the Board applicable to the transaction. This section further establishes additional requirements applicable to certain pharmacies that cease operations due to a closure, including a requirement that the pharmacy provide written notice to patients 45 days in advance of the closure.

Background
During prior discussion on the Board's outsourcing program, members received public comment suggesting that the Board should establish mandatory notification requirements for an outsourcing facility that will be ceasing operations in California, as a means to ensure continuity of patient care. Members noted agreement with the recommendation to discuss the issue.

Summary of Committee Discussion
During the meeting, members considered a draft regulation proposal to establish the requirement for an outsourcing facility to provide advance notification of closure. Members noted agreement with the policy goal underlying the proposed regulation text and suggested that the draft regulation proposal be

[1] BPC section 4129(c).

modified to require 90 days advance notification in lieu of the 45-day timeframe included in the proposed text considered by the Committee.

Members also discussed the proposal as it relates to an outsourcing facility closure stemming from disciplinary actions.

Public comment spoke in support of the regulation proposal, including extending the advance notification timeframe. Public comment also suggested that the proposal should be modified to require mandatory notification by an outsourcing facility when it ceases to compound a specific product.

Recent Update: Following the meeting, staff considered the public comment suggesting expansion of the notification requirement to encompass notification when an outsourcing facility ceases to compound a specific product. Staff do not believe such notification requirement is appropriate and note that if a customer believes such notification is necessary, the customer could negotiate such a requirement directly through its business relationship. Such an approach could address any potential concern without establishing a legal requirement for all California-licensed outsourcing facilities to provide such notice. Note: The FDA provides a searchable outsourcing facility product report database, available here.

Further, staff have confirmed that the Board's Disciplinary Guidelines include model language to ensure continuity of care upon license revocation or surrender; however the model language appears to be directed specifically to pharmacy closures. It may be appropriate to consider updates to the Disciplinary Guidelines model language to expand the provisions to other business entity license types. Below is the current model disciplinary language for premises licenses, which appears in the revocation and surrender orders, as well as in standard condition of probation 9 (License Surrender While on Probation/Suspension):

> Respondent shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five (5) days of its provision to the pharmacy's ongoing patients, Respondent shall provide a copy of the written notice to the Board. For the purposes of this provision, "ongoing patients" means those patients for whom the pharmacy has on file a prescription with one or more refills outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60) days.

Should the Board agree with the consensus of the Committee, the following motion could be used to initiate the formal rulemaking process.

> **Recommended Motion**: Move to initiate a rulemaking to amend California Code of Regulations, title 16, section 1708.2 [either "as proposed" or "consistent with the Board's discussion"], direct staff to submit the text to the Director of the Department of Consumer Affairs, and Business, Consumer Services and Housing Agency for review, and authorize the executive officer to take all steps necessary to initiate the rulemaking process, make any technical or nonsubstantive changes to the package, and set the matter for hearing, if requested. If, during the 45-day comment period, the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or the procedures followed by the Board in proposing or adopting the action, and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at section 1708.2.

Attachment 2a includes a copy of the proposed regulation text consistent with the committee's direction. Attachment 2b illustrates the change in the text since the Committee's discussion.

c. Summary of Discussion Regarding and Possible Action to Approve Frequently Asked Questions Related to Continuing Education Requirements for Pharmacists

Relevant Law

BPC section 4231 establishes requirements for a pharmacist to complete 30 hours of continuing education (CE) during each two-year renewal cycle as specified. As provided in this section, the Board shall not renew the license and shall issue an inactive pharmacist license if the licensee has not completed CE as specified and in instances where, as part of an investigation or audit conducted by the Board, a pharmacist fails to provide documentation substantiating completion of required CE.

Article 4 of Division 17 of Title 16 of the California Code of Regulations further defines and makes more specific the continuing education requirements for Board licensees, including pharmacists.

Background

The Board uses a variety of means to assist licensees in maintaining compliance with legal requirements, including development of Frequently Asked Questions (FAQs).

Given recent changes stemming from the transition to a more robust standard of care practice model for pharmacists, it appears appropriate to consider FAQs related to CE requirements for pharmacists.

Summary of Committee Discussion
During the meeting, members considered the draft FAQs. Members provided feedback to staff on changes to incorporate, including: eliminating the footnotes and moving information originally included in footnotes into the body of the document, adding hyperlinks to improve usability of the FAQs, adding questions regarding cultural competency and specialized CE requirements that no longer apply based on Pharmacy Law changes effected by Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025), as well as reorganization of the questions. Member Crowley was delegated to work with staff on the reorganization.

The public was offered the opportunity to comment on the draft FAQs; however, no public comment was received.

Recent Update: Following the meeting, staff updated the draft FAQs and worked with Member Crowley on the reformatting and classification of the questions.

Should the Board believe the draft FAQs are ready for approval, the following motion could be used.

> **Recommended Motion**: Approve the frequently asked questions related to continuing education requirements for pharmacists.

Attachment 3 includes a copy of the updated FAQs for consideration by the Board.

d. Summary of Discussion of Changes in Pharmacy Law Included in Assembly Bill 1503 (Berman, Chapter 196, Statutes of 2025) Including Updates on Implementation Activities

Background
Assembly Bill (AB) 1503 is the Board's sunset measure. The measure extends the operations of the Board until January 1, 2030. The measure also includes several policy issues raised by the Board in its 2025 Sunset Oversight Review Report. The measure was approved by Governor Newsom on October 1, 2025.

Given the comprehensive nature of the measure, significant implementation activities are required and will be ongoing.

Since AB 1503 was signed in October 2025, members have discussed activities necessary to implement the various provisions of the measure at both Board and Committee meetings.

Summary of Committee Discussion

During the June meeting, members reviewed progress made to implement the various changes to Pharmacy Law that are included in AB 1503, including recent updates. The activities described below are in addition to the Board's traditional implementation activities such as updates to the Board's mandatory online pharmacy law course, the Board's newsletter, reflected in updated versions of the relevant self-assessment form, and displayed on the Board's website.

The public was offered the opportunity to comment on the AB 1503 implementation activities; however, no public comment was received.

Recent Update: At the March 2026 Board meeting, the Board approved a recommendation to award 1 hour of CE to complete the Board's online webinar on AB 1503. Since that time, the webinar has been added to the Board's PharmEd learning management system, and 392 pharmacists have completed the training.

New BPC Section 4001.5, Related to the Pharmacy Technician Advisory Committee (PTAC)

Summary: This new section requires the Board to establish an advisory committee to advise and make recommendations to the Board on matters related to pharmacy technicians. The committee shall consist of four licensed pharmacy technicians representing a range of practice settings; two licensed pharmacists, one of whom shall be a member of the Board; and one public member.

Implementation Activities: At the November 2025 Board meeting, members finalized the appointment process, duration of appointment, and minimum qualifications for individuals interested in serving on the PTAC.

Implementation Status: Since the November Board meeting, several implementation activities have been initiated, including draft updates to the Board Member Procedure Manual to reflect the addition of the PTAC. Members were also surveyed for interest in serving on the PTAC, and Satinder Sandhu was appointed by President Oh to serve as the Board member on the PTAC.

Recent Update: Board staff have submitted the required service ticket to the Department to create the online application portal. It is anticipated the portal will be live by the beginning of July.

Amended BPC Sections 4016.5, 4210, and 4233, Related to Advanced Pharmacist Practitioners (Formerly Known as Advanced Practice Pharmacists)

Summary: Renames the title "Advanced Practice Pharmacist" to "Advanced Pharmacist Practitioner."

Implementation Activities: Pursue a Section 100 change to affected regulations to reflect the new license title. Changes will be required in the following sections

of title 16, California Code of Regulations (CCR): 1702, 1702.1, 1706.6, 1730, 1730.1, 1730.2, and 1749.

Reminder: The Board voted to initiate a rulemaking to amend title 16, CCR, section 1730.1 related to Application Requirements for Advanced Pharmacist Practitioner Licensure that includes more substantive changes.

Implementation Status: Since the November 2025 Board meeting, Board staff prepared the Section 100 regulation changes. Updates to the Application and Instructions for Advanced Pharmacist Practitioner Licensure, the Duplicate/Replacement License Request, and the online PDF renewal application have also been made. In addition, staff have submitted the appropriate service requests to update impacted IT systems.

Recent Update: Technical changes to the Board's IT systems have been completed. The prepared rulemaking documents are undergoing pre-notice review by the Department of Consumer Affairs.

Amended BPC Section 4036, Pharmacist Defined
Summary: Updates the definition of "pharmacist" to provide that the holder of an unexpired and active pharmacist license issued by the Board is entitled to practice pharmacy as defined by Chapter 9 of Division 2 of the BPC, within or outside of a licensed pharmacy.

Implementation Activities: Pursue regulations to define provisions for remote processing of prescriptions.

Implementation Status: Since the Board approved the initiation of a rulemaking to add section 1717.11, Remote Processing of Prescriptions, to title 16 of the CCR at the November 2025 Board meeting, Board staff prepared the rulemaking materials. Proposed regulatory text was released for a 45-day comment period on January 9, 2026.

Recent Update: During the March 18, 2026 Board meeting, members considered comments received during the 45-day comment period and voted to further modify the proposed regulation text based on the comments received. The revised text went out for a 15-day comment period which ended on April 3. During the April 29-30, 2026 Board meeting, following consideration of comments received, the Board adopted the proposed regulation text. Staff prepared the post-adoption regulation materials, which are currently under review by the Department.

New BPC Sections 4040.6 and 4102, Related to Self-Assessment Process
Summary: Establishes the self-assessment process in statute.

Implementation Activities: Maintain the process of annual updates to the self-assessment forms for review by the appropriate committee and Board prior to finalizing and updating the form. Pursue a Section 100 change to remove regulations establishing the self-assessment process. Changes will be required in the following sections of title 16 of the CCR: 1715, 1715.1, 1735.1, 1736.1, and 1784.

Implementation Status: Since the November 2025 Board meeting, staff have been developing updated draft self-assessment forms for consideration by the Enforcement and Compounding Committee and the Board. Further, Board staff prepared the Section 100 regulation changes.

Recent Update: The updated Community Pharmacy Self-Assessment/Hospital Outpatient Self-Assessment was approved by the Board in January 2026, and has been posted on the Board's website. During the April 29-30, 2026 Board meeting, the Board approved the updated self-assessment forms for Wholesaler/Third Party Logistics Providers, Surgical Clinics, and Hospital Pharmacies, and those updated forms have been posted on the Board's website as well.

Further, as part of the April 29-30, 2026 Board meeting, as the Board was advised by the Office of Administrative Law (OAL) that it could not pursue the streamlined Section 100 process to repeal the self-assessment regulations, the Board voted to initiate a regular rulemaking to repeal regulations that are no longer required given the statutory changes made in AB 1503.

Amended BPC Sections 4051 and 4052, Related to Standard of Care

Summary: Defines "accepted standard of care" and transitions some provisions for pharmacist-provided health care services to a standard of care practice model, including in the following areas:

1. Furnish epinephrine
2. Furnish FDA-approved or authorized medications as part of preventative health care services that do not require a diagnosis, including the following:
    a. Emergency contraception
    b. Contraception
    c. Smoking cessation
    d. Travel medications
    e. Anti-viral or anti-infective medications
3. Order and interpret tests
4. Furnish medication used to reverse opioid overdose and medication used to treat substance use disorder (e.g. Naloxone)
5. Complete missing information on a prescription for a noncontrolled medication if there is evidence to support the change
6. Initiate and administer immunizations for persons three years of age and older

The law also provides that a pharmacist should not provide a service or function if the pharmacist has made a professional determination that (1) they lack sufficient education, training, or expertise, or access to sufficient patient medical information, to perform the service or function properly or safely; (2) performing or providing the service or function would place a patient at risk; or (3) pharmacist staffing at the pharmacy is insufficient to facilitate comprehensive patient care. Provisions also establish a notification requirement to a patient's primary care provider, as specified.

As part of the transition to a standard of care practice model for certain pharmacist-provided health care services, some provisions of law that established prescriptive requirements and/or required pharmacists to follow standardized procedures and protocols have been repealed, for example, former BPC sections 4052.01, 4052.02, 4052.03, 4052.3, 4052.8, and 4052.9.

Implementation Activities: Pursue a Section 100 change to repeal several regulations that establish protocols and other prescriptive requirements that are deemed moot by the transition to a standard of care practice model, including the following sections of title 16 of the CCR: 1732.5, 1746, 1746.1, 1746.2, 1746.3, 1746.4, 1746.5, and 1747. Further, remove the current online training regarding HIV PEP and PrEP. Release a policy statement related to standard of care practice model.

Implementation Status: Since the November 2025 Board meeting, Board staff prepared the Section 100 regulation changes. The Board's policy statement was posted on the Board's website and updates to the Board Member Procedure Manual to reflect the addition of the policy statement have been made.

Recent Update: As part of April 29-30, 2026 Board meeting, given the direction from OAL that the Board could not pursue the streamlined Section 100 process to repeal regulations affected by the standard of care transition, the Board voted to initiate a regular rulemaking to repeal regulations that are no longer required given the statutory changes made in AB 1503.

Amended BPC Sections 4081 and 4105, Related to Pharmacy Records
Summary: Updates pharmacy records requirements to specify that policies and procedures related to pharmacy personnel and pharmacy operations must also be maintained. Allows all records to be maintained in digitized format subject to specified conditions.

Implementation Activity: Develop FAQs regarding digitizing records.

Implementation Status: As part of April 29-30, 2026 Board meeting, the Board approved FAQs regarding digitizing records.

Amended BPC Section 4111, Related to Ownership Prohibitions
Summary: Updates ownership prohibition to allow for ownership of a pharmacy by a person with whom the person shares a community or other financial interest under specified conditions.

Implementation Activity: Update the pharmacy license application and instructions.

Implementation Status: Since the November 2025 Board meeting, staff have updated the pharmacy license application and instructions.

Amended BPC Sections 4112, 4113, and 4113.1, Related to Nonresident Pharmacies
Summary: Effective July 1, 2026, updates the requirements for a nonresident pharmacy to include authority for the Board to inspect a nonresident pharmacy and assess a reasonable fee to cover the Board's costs. Further, effective July 1, 2026, requires a nonresident pharmacy to designate a California-licensed pharmacist to serve as the pharmacist-in-charge. In addition, updates the medication error reporting requirements for nonresident pharmacies to clarify that only medication errors related to prescriptions dispensed to California residents must be reported.

Implementation Activities: Update the nonresident pharmacy license application and instructions, and the Change of PIC application form and instructions. Update the FAQs related to medication error reporting.

Implementation Status: Since the November 2025 Board meeting, the updated FAQs related to medication error reporting have been posted on the Board's website. Staff have also updated the nonresident pharmacy application and instructions. Further, the Board released subscriber alerts describing all of the relevant changes impacting nonresident pharmacies; added two additional CPJE test administration dates to provide more opportunities for pharmacists seeking California licensure in order to serve as the PIC of a nonresident pharmacy; and provided email notification to nonresident pharmacies describing relevant changes. In addition, the Board's policy statement on the role of the PIC, which highlighted relevant changes related to PICs of nonresident pharmacies, was posted on the Board's website.

Recent Update: As part of April 29-30, 2026 Board meeting, the Board voted to approve a policy statement related to nonresident pharmacies. In addition to subscriber alerts and emails, Board staff have released correspondence to all nonresident pharmacies that have not yet taken steps to comply with the new PIC requirements.

Amended BPC Section 4113, Related to Pharmacist-in-charge, Staffing

Summary: Provides that the Pharmacist-in-Charge (PIC) shall (instead of may) make staffing decisions at the pharmacy. Requires the PIC to determine appropriate pharmacist to technician ratio, which may not exceed 1 pharmacist to 3 pharmacy technicians (1:3).

Implementation Activities: Update the FAQs related to PIC staffing authority. Update the Board provided PIC education. Release a policy statement related to the role of a PIC.

Implementation Status: The Board's policy statement was posted on the Board's website and updates to the Board Member Procedure Manual to reflect the addition of the policy statement have been made. Further, the updated FAQs related to PIC staffing authority have been posted on the Board's website.

Recent Update: The Board's Pharmacist-in-Charge: Overview and Responsibilities Training webinar was updated and made available in the Board's learning management system.

Amended BPC Section 4113.6, Related to Chain Community Pharmacy
Summary: Requires a chain community pharmacy to post, in a prominent place for pharmacy personnel, a notice that provides information on how to file a complaint with the Board.

Implementation Activity: Develop a sample notice.

Implementation Status: The Communication and Public Education Committee developed a sample notice. Following review by the Board, the sample notice was posted on the website.

Amended BPC Section 4115, Related to Pharmacy Technicians
Summary: Clarifies the authorized duties of a certified pharmacy technician, increases the pharmacist to pharmacy technician ratio, and establishes authority for pharmacy technicians to perform specified duties outside of a licensed pharmacy.

Implementation Activity: Update the FAQs related pharmacy technician authorizations.

Implementation Status: The updated FAQs have been posted on the Board's website.

Amended BPC Section 4200.5, Related to Retired Pharmacist License
Summary: Establishes provisions for an individual to restore their retired pharmacist license under specified conditions.

Implementation Activity: Develop a standardized request form that can be used to facilitate collection of information and fees.

Implementation Status: Since the November 2025 Board meeting, staff have updated the retired pharmacist form to include provisions for restoration of a license.

New BPC Section 4317.6, Related to Mail Order Pharmacy
Summary: Establishes provisions to allow the Board to issue fines for up to $100,000 under specified conditions.

Implementation Activity: Include as part of the annual citation and fine presentation, citations issued under the new authority.

Implementation Status: Following implementation, it is anticipated that the annual citation and fine presentation will incorporate data documenting citations issued under this new authority.

Amended BPC Section 4400, Related to Fees
Summary: Establishes authority for the Board to waive the application and renewal fee for a pharmacy providing in-person patient care services in a medically underserved area, as defined.

Implementation Status: Board staff processes have been updated. Board staff identified one currently licensed pharmacy that meets the eligibility requirements for a fee waiver.

e. Summary of Discussion Regarding Requirements Related to the Use of Automated Patient Dispensing Systems, Including Provisions in Business and Professions Code Sections 4427.3 and 4427.6 and California Code of Regulations, Title 16, Section 1713, Including Possible Action to Initiate a Rulemaking to Add Section 1713.1, Related to Automated Patient Dispensing System Location, to Title 16 of the California Code of Regulations

Relevant Law
BPC section 4017.3 defines an "automated drug delivery system" (ADDS) to mean a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. The section further provides that 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. Finally, the section defines "automated patient dispensing system" (APDS) as an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

Article 25 of the Pharmacy Law (BPC sections 4427-4427.8) establishes the provisions for use of ADDS, including licensure and operational requirements. Subdivision (a) of BPC section 4427.3(a) states that an ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the Board. Subdivision (b)(5) of BPC section 4427.3 further provides that if the ADDS is an APDS, it shall be placed and operated in a location as provided in BPC section 4427.6.

BPC section 4427.6 establishes additional requirements applicable to APDS units. Subdivision (j) of section 4427.6 states: "An APDS may be 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." The section further prohibits the Board from issuing a pharmacy more than 15 ADDS licenses for APDS units and specifically provides that the Board may, by regulation, reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

California Code of Regulations, title 16, section 1713 also sets forth specific requirements applicable to the use and operation of an APDS. Such requirements are consistent with the requirements of the statute including provisions for policies and procedures, patient consultation, inclusion criteria for patients, and quality assurance requirements.

BPC section 2290.5 sets forth provisions relating to telehealth. Subdivision (a)(6) defines "telehealth" to mean the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment, education, care management, and self-management of a patient's health care. Subdivision (a)(2) defines "distant site" to mean a site where a health care provider who provides health care services is located while providing these services via a telecommunications system. Subdivision (a)(4) defines "originating site" to mean a site where a patient is located at the time health care services are provided via a telecommunications system or where the asynchronous store and forward service originates.[2]

Background

Senate Bill 1447 (Hernandez, Chapter 666, Statutes of 2018) established the current statutory provisions related to automated drug delivery systems, including BPC section 4427.6. The Legislative Counsel's Digest of the bill states:

> This bill, beginning on July 1, 2019, would repeal the general ADDS provisions and the additional conditions for an ADDS located in a health facility. The bill instead would require an ADDS, as defined, to meet specified requirements in order to be installed, leased, owned, or operated in the state, including a

[2] BPC section 2290.5(a) also defines the terms "asynchronous store and forward" and "health care provider."

license for the ADDS issued by the board to the holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in the state. The bill would limit the placement and operation of an ADDS to specified locations, including the licensed pharmacy holding that ADDS license, a licensed health facility, a licensed clinic, or a specified medical office if the ADDS is an automated patient dispensing system (APDS), as defined.

The bill stemmed from a 2015 pilot project that placed an ADDS at Sharp Memorial Hospital in San Diego. The ADDS delivered new and refilled prescriptions and over-the-counter medications to patients 24 hours a day, seven days a week. Consultation was provided via telephone before medication could be dispensed to a patient for first time fills. The study results concluded that the ADDS was a convenient and safe extension of the outpatient pharmacy affiliated with the hospital, with similar prescription pick up and consultation patterns as the regular pharmacy counter. Staff note that the type of ADDS used for this study was akin to a pharmacy locker, where the medication was filled at a pharmacy and placed in the pharmacy locker for pick-up. The subsequent legislation referred to this type of ADDS as an APDS.

The legislative history of the bill indicates that the bill contemplated that ADDS units would be located in health care settings. (See, *e.g.*, Senate Floor Analyses dated August 30, 2018, stating: "An ADDS is a machine that dispenses prescription drugs outside of a pharmacy. Designs vary by need, but an ADDS is essentially an exceptionally sophisticated drug vending machine with the security and patient safety controls of a pharmacy. These machines enable healthcare settings to have access to limited pharmacy services without bearing the cost and responsibility of housing an entire pharmacy.")

Section 2290.5 was added to the BPC as part of the Telehealth Advancement Act of 2011, Assembly Bill 415 (Logue, Chapter 547, Statutes of 2011). Section 2290.5 is part of the Medical Practice Act (BPC sections 2000-2529.8.1), but the statute expressly provides that the definitions set forth in subdivision (a) thereof apply for purposes of Division 2 (Healing Arts) of the BPC, which includes the Pharmacy Law.

Since the enactment of SB 1447 in 2018, advances in ADDS technology have occurred. In addition, the health care system generally has experienced more widespread adoption and use of telehealth as a means of providing health care services. Specifically related to APDS technology, in addition to APDS that function like a prescription locker, APDS technology also exists that functions more akin to a "kiosk," where the machine holds prefilled prescription vials and upon receipt of a prescription, the machine will select the appropriate prefilled prescription vial, label the prescription vial, and release the medication to the patient.

As noted in the Committee's April 2026 discussion of this issue, the Board has received inquiries regarding the placement and use of APDS in light of rapid increases in use of telehealth and advancements in APDS technology.

Some inquiries have suggested that any place where a physician and patient interact (including the patient's location when receiving health care services via telehealth) meets the requirements of a "medical office or other location where patients are regularly seen for purposes of diagnosis and treatment." Board staff disagree and note that such an interpretation appears overly broad and oversimplified.

Board staff also note that if SB 1447 had contemplated that an APDS would be placed at a location where a patient was receiving health care services via telehealth, it would have incorporated the defined terms set forth in BPC section 2290.5, given that BPC 2290.5 was existing law when SB 1447 was passed. Accordingly, it is perhaps inconsistent with the legislative intent of SB 1447 to interpret the phrase "medical office or other location where patients are regularly seen for purposes of diagnosis and treatment" to mean anything other than a traditional, in-person health care setting.

The Board has also received requests for clarification about the conditions for use of an APDS when a patient is receiving medical care via telehealth and if such patients can receive their prescriptions from an APDS as opposed to at a pharmacy.

During the April 2026 Committee meeting, the Committee considered the issue and determined it appropriate to develop regulations to more precisely define the phrase "medical office or other location where patients are regularly seen for purposes of diagnosis and treatment." Further, in response to requests for clarification about the conditions for use of an APDS when a patient is receiving medical care via telehealth, during the April 29-30, 2026 Board meeting, the Board clarified that if a patient is prescribed a medication as part of a telehealth appointment they can receive their medication via an APDS operated by a pharmacy as part of a medical practice.

<u>Summary of Committee Discussion</u>
During the June meeting, members considered draft regulation text to clarify and make more specific the phrases "a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment" and "patients of the practice." Members discussed the significance of including the words "diagnosis and treatment," noting the phrase is consistent with the statutory language, and determined that the language was appropriate.

Public comment noted agreement with the structure and suggested that it may be appropriate to include naturopathic doctors.

Should the Board agree with the consensus of the Committee, the following motion could be used to initiate the formal rulemaking process.

> **Recommended Motion**: Initiate a rulemaking to add California Code of Regulations, title 16, section 1713.1 [either "as proposed" or "consistent with the Board's discussion"], direct staff to submit the text to the Director of the Department of Consumer Affairs, and Business, Consumer Services and Housing Agency for review, and authorize the executive officer to take all steps necessary to initiate the rulemaking process, make any technical or nonsubstantive changes to the package, and set the matter for hearing, if requested. If, during the 45-day comment period, the Board does not receive any comments providing objections or adverse recommendations specifically directed at the proposed action or the procedures followed by the Board in proposing or adopting the action, and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking and adopt the proposed regulations at section 1713.1.

Attachment 4 includes the draft regulatory proposal.

f. Summary of Discussion Regarding Proposal to Establish Definitions for Outpatient Pharmacies Based on Business Model

Relevant Law
BPC section 4037 defines a "pharmacy" as an area, place, or premises licensed by the Board in which the profession of pharmacist is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in the license issued by the Board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail. The definition also exempts some facilities and drug storage areas.

Background
Generally, the requirements for pharmacies apply equally among a variety of business models, unless otherwise specified. This approach allows for broad regulation and requirements yet can become challenging when business models vary yet requirements many times do not.

Within existing law there are several instances where a more specific definition is referenced, but only when applying to a specific provision of the law. As an example, Pharmacy Law does not currently include a general definition of "chain community pharmacy." Rather, in specified sections of statute and regulation, the law refers to BPC section 4001 (which defines the composition of the Board

and sets forth the appointment process and qualifications for Board membership) for the definition. (**Note**: BPC section 4001 provides, "For the purposes of this subdivision, a 'chain community pharmacy' means a chain of 75 or more stores in California under the same ownership, and an 'independent community pharmacy' means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.")

As another example, Pharmacy Law sometimes refers to applicability of a requirement to "outpatient pharmacies" (see, *e.g.*, BPC section 4076(a)(11)(B)). In this context, the Board interprets this to mean pharmacies that provide medications to consumers outside of an inpatient setting, including mail order pharmacies, infusion center pharmacies, and specialty pharmacies. However, such references may cause confusion as Pharmacy Law and regulations continue to change.

Different jurisdictions nationally have taken varying approaches, with some jurisdictions (such as Texas) issuing separate licenses for different classes of pharmacy licenses. Nevada issues a single pharmacy license that covers a variety of different types of business models, but requires disclosure of the types of services to the Nevada Board.

The Committee first considered this issue during its October 2025 meeting. During this discussion, members noted that development of definitions could allow for more precise regulation and provide better transparency to patients regarding the types of services a pharmacy provides. Members noted that while consideration of definitions may be appropriate, separate license types do not appear appropriate.

Over the course of several meetings, members have continued their discussion and consideration of possible definitions of the various business models.

<u>Summary of Committee Discussion</u>
During the June meeting, members discussed proposed regulation text that includes definitions for pharmacy business models previously discussed by the Committee. Members reviewed the clarifying changes to proposed definitions incorporated in the draft regulations. In addition, the proposed regulation text also includes definitions for 'Federally Qualified Healthcare Pharmacy" and "Health System Pharmacy."

The Committee noted that following finalization of definitions, it will be appropriate for the Committee to consider if exemptions from certain regulatory requirements are appropriate for different pharmacy business models. It is recommended that the Committee consider developing the exemptions for inclusion in the rulemaking.

As an example, depending on the final proposed definition of an infusion center pharmacy, the Board could identify some regulation requirements that would not be required for an outpatient pharmacy that solely acts as an infusion center pharmacy such as:

1. Patient consultation requirement as defined in CCR 1707.2
2. Confidential space for consultation as defined in CCR 1714(a)
3. Notice to consumer poster as provided in CCR 1707.6

Members expressed concern about the PIC being responsible for making a determination that a pharmacy meets the definition of chain community pharmacy. Members also considered if definitions are needed for non-chain, "medium size" pharmacy as well as if the definition for specialty pharmacy requires additional changes.

Members also noted the need to evaluate if additional language is needed to ensure the Board's proposed definitions do not create any unintended consequences.

Public comment noted that a health system pharmacy may also meet the definition of chain community pharmacy and suggested the Board should consider where that is the case, should both definitions apply, Public comment suggested the Board create some flexibility in such an instance, especially where the pharmacy is part of a nonprofit health system. Public comment also suggested that the overall policy goal is not clear, sought clarification about how the definitions would be enforced during an inspection, expressed concern with the proposed definition of mail order pharmacy, and suggested that the Board's definitions should focus on pharmacies that provide public access versus nonpublic access. Public comment also suggested that a definition for "rural pharmacy" be added to identify pharmacies located in pharmacy deserts/medically underserved areas.

Recent Update: Following the Committee meeting, further discussions between the Chair, staff and counsel made clear that the proposed regulation text requires additional consideration by the Committee before presentation to the Board. As such, no discussion will occur on this topic during the Board meeting.

g. Discussion of Licensing Statistics

Licensing statistics for the first 10 months of FY 2025/26 (July 1, 2025 – May 31, 2026) are provided in **Attachment 5**.

During the timeframe, the Board has received 12,916 initial applications, including:

- 1,272 intern pharmacists

- 3,708, pharmacist exam applications (2,279 new, 1,429 retake)
- 188 advanced pharmacist practitioner
- 5,806 pharmacy technicians
- 304 community pharmacy license applications (16 chain, 288 nonchain)
- 68 sterile compounding pharmacy license applications (44 LSC, LSE 4, 15 NSC, 3 SCP, 2 SCE)
- 110 nonresident pharmacy license applications
- 17 hospital pharmacy license applications

During the timeframe, the Board has received 9 requests for temporary individual applications (Military Spouses/Partners), including:
- 8 temporary pharmacy technicians
- 1 temporary pharmacist

During the timeframe, the Board has received 466 requests for temporary site license applications, including:
- 223 community pharmacy license applications
- 45 sterile compounding pharmacy license applications
- 75 nonresident pharmacy license applications
- 16 hospital pharmacy license applications

During the timeframe, the Board has issued 8,103 individual licenses, including:
- 1,225 intern pharmacists
- 1,342 pharmacists
- 136 advanced practice pharmacists
- 4,960 pharmacy technicians

During the timeframe, the Board has issued 12 temporary individual applications (Military Spouses/Partners), including:
- 11 temporary pharmacy technicians
- 1 temporary pharmacist

During the timeframe, the Board has issued 657 site licenses without temporary license requests, including:
- 241 automated drug delivery systems (137 AUD, 104 APD)
- 112 community pharmacies
- 1 hospital pharmacy

During the timeframe, the Board has issued 859 temporary site licenses, including:
- 677 community pharmacies
- 15 hospital pharmacies

***Processing times are reported by calendar days.**

Site Application Type	Application Processing Times as of 6/1/2026*	Application Processing Times as of 6/12/2026*	Deficiency Mail Processing Times as of 6/1/2026*	Deficiency Mail Processing Times as of 6/12/2026*
Pharmacy	32	30	18	25
Nonresident Pharmacy	14	25	41	16
Sterile Compounding	32	23	31	25
Nonresident Sterile Compounding	12	23	31	28
Outsourcing	Current	Current	28	4
Nonresident Outsourcing	Current	Current	21	32
Hospital Satellite Compounding Pharmacy	Current	Current	Current	Current
Hospital	Current	Current	18	Current
Clinic	46	46	28	39
Wholesaler	56	39	42	46
Nonresident Wholesaler	53	46	48	49
Third-Party Logistics Provider	56	11	25	36
Nonresident Third-Party Logistics Provider	Current	Current	39	50
Automated Drug Delivery System	31	25	Current	Current
Automated Patient Dispensing System	Current	Current	Current Combined with ADD	Current Combined with ADD
Emergency Medical Services Automated Drug Delivery System	Current	Current	Current Combined with ADD	Current Combined with ADD

Individual Application Type	Application Processing Times as of 6/1/2026*	Application Processing Times as of 6/12/2026*	Deficiency Mail Processing Times as of 6/1/2026*	Deficiency Mail Processing Times as of 6/12/2026*
Exam Pharmacist	21	17	Current	Current
Pharmacist Initial Licensure	10	2	Current	Current
Advanced Practice Pharmacist	70	29	62	Current
Intern Pharmacist	14	3	Current	Current
Pharmacy Technician	70	74	25	32
Designated Representative	52	36	24	25
Designated Represenatives-3PL	46	52	Combined with Designated Representative	Combined with Designated Representative
Designated Representatives-Reverse Distributor	Current	Current	Combined with Designated Representative	Combined with Designated Representative
Designated Paramedic	Current	8	Current	Current

***Processing times are reported by calendar days.**

Summary of Committee Discussion

Members expressed concern that the number of licensed pharmacies (including nonresident pharmacies and sterile compounding pharmacies) appears to be declining. Members also noted that the Board should focus on improving pharmacy technician application processing times.

Public comment expressed concern about the shortage of pharmacy technicians and suggested that a graph showing trends in the data be presented.