New Issues identified by the Board in this Report

1. Nonresident Pharmacies:

Provisions of California pharmacy law provide that any pharmacy located outside of California, that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices, into California, is considered a nonresident pharmacy, and licensure by the Board is required.

Over the course of several public meetings, the Board discussed the requirements for nonresident pharmacies and noted that nonresident pharmacies must comply with California laws, but may not understand California requirements. Under current law, while the nonresident pharmacy is required to hold a nonresident pharmacy license issued by the Board, neither the pharmacist-in-charge or other pharmacists are required be licensed in California. This stands in contrast to many other states which require such licensure. In addition, the Board is concerned about actions taken in a few jurisdictions to waive examination requirements for pharmacists.

Through the Board's discussion members expressed concerns about the Board's current inability to perform inspections at nonresident pharmacies and the disparity this creates. Members also expressed concern that a pharmacist-in-charge of nonresident pharmacy has not established minimum competency with California law, yet is responsible for operational and legal compliance with California pharmacy law.

Following discussion, the Board determined that changes in pharmacy law are required to address several issues including:

a. Require the pharmacist-in-charge of a nonresident pharmacy to be licensed in California.
b. Require the Board to conduct inspections at nonresident pharmacies at least once every four years as a condition of renewal.
c. Require pharmacists providing services to California patients to meet minimum examination requirements.
d. Clarify that nonresident pharmacies are required to comply with California law.

The Board previously approved statutory language addressing items (a)-(c) above. Language to effectuate the policy is (d) is new and is reflected in the proposed changes to BPC section 4303. The statutory proposal is included in **Attachment 1**.

2. Pharmacist to Pharmacy Technician Ratio

Provisions of California pharmacy law generally provide that a pharmacy with only one pharmacist shall have no more than one pharmacy technician performing tasks and that the ratio of pharmacy technicians to pharmacists shall not exceed 2:1 for each additional pharmacist. The law further provides that this ratio does not apply to personnel performing clerical functions, nor does it apply to an inpatient setting (licensed health facility, home health agency, State Department of State hospitals, State Department of Developmental Services) to an inmate of a CDCR correctional facility, or a person receiving treatment in a facility operates by the Department of Veteran's Affairs.

The Board has the authority to enact regulations establishing the ratio of pharmacy technicians in in patient facilities, but does not have similar regulatory authority in the outpatient or community pharmacy setting.

Over the years there have been several legislative attempts to change the ratio requirements. Most recently, Senate Bill 1365 (Glazer, 2024) would have changed the ratio in California in the outpatient setting to establish a ratio of one pharmacist to four pharmacy technicians. The measure was held in Senate Appropriations Committee.

To solicit feedback on the current ratio requirements in both the outpatient and inpatient pharmacy settings, the Board developed a survey in partnership with the DCA Office of Professional Examination Services. The survey was released in March 2024 with the Board receiving responses from over 4, 510 pharmacists. Analysis of responses was provided for specific pharmacy settings (institutional and noninstitutional) where pharmacists were asked to respond to questions related to their belief about the current pharmacist to pharmacy technician ratio. This data was further broken down to include respondents that indicated they were in a management or administrative position for their employer.

Based on the survey results, the Board considered a number of different approaches offered by interested stakeholders during public discussion. Survey results were broken down based on the in-patient and outpatient pharmacy settings. Specifically related to the outpatient setting, survey results revealed consensus among pharmacists irrespective of their role within the pharmacy (e.g., pharmacist-in-charge, those not working in a position of management, etc.) that the current 1:1 ratio is not appropriate. Further review of the data reveals that in the outpatient setting, the majority of respondents believe that a ratio of one pharmacist to two pharmacy technicians (1:2) is appropriate.

In light of the survey results, and following considerable discussion and public comment, the Board believes a change to the current ratio in the outpatient setting is appropriate.

The Board has committed to scheduling additional discussion on the current ratio requirement in the inpatient setting and notes that should a change be determined appropriate, the Board will initiate a rulemaking, consistent with its authority to update the ratio.

The Board approved the statutory proposal is in **Attachment 2**.

3. Pharmacy Technicians Compounding Outside of a Pharmacy

As provided in California pharmacy law, a pharmacy technician is defined as an individual who assists a pharmacist **in a pharmacy** in the performance of their pharmacy related duties. The Board is aware of many instances in which an individual who possesses a pharmacy technician license is hired by a prescriber to perform compounding outside of a pharmacy. In some instances these pharmacy technicians are specifically recruited to perform compounding in a physician's office, an unlicensed infusion center, oncology clinic, IV hydration clinic or wellness spa. Although the Board does not generally license these locations, consistent with the Board's authority, inspector staff have inspected such practices and noted significant deviations from the national compounding standards established in the United States Pharmacopeia (USP), in a violation of federal law. The deviations from the USP standards, the potential for harm and documented harm cause grave concerns for the Board. Examples of deviations include using nonsterile ingredients and repacking the nonsterile ingredient, adding water, and then labeling the end product as a sterile injectable product. Another example of serious patient harm included a pharmacy technician license was working in a pain management clinic, compounding non-sterile to sterile compounded preparations for intrathecal injection in an unsafe environment and in an unsafe matter.

The Board notes that pharmacy technicians play an integral role in assisting pharmacists with performing their duties, but only do so under the direct supervision and control of a pharmacist. In the Board's review and assessment of the various locations where a pharmacy technician is working outside of a pharmacy, it appears that no such direct supervision and control of the pharmacy technician's practice occurs.

In response to these troubling practices, the Board believes an amendment to pharmacy law is appropriate to provide authority for a pharmacy technician to

work outside of a pharmacy, providing that such practice can only be undertaken under the direct supervision and control of a pharmacist.

The Board approved the statutory proposal is in **Attachment 3**.

4. Mail Order Pharmacies

Mail order pharmacies offer insurers and patients a different option to provide pharmacy care. Although there are benefits to this pharmacy model, it also creates unique challenges in meeting patient care issues. The Board notes a significant number of investigations involving mail order pharmacies, where patients are required to use such services in lieu of the pharmacy of their choice at the direction of their health insurer or face higher costs. Faced with this, many patients accept the payor-driven pharmacy model and use the services of a mail order pharmacy to receive their prescription medications.

The Board has some regulations governing mail order pharmacies which seek to ensure patients have ready access to a pharmacist and which impose threshold requirements for patients to receive patient consultations. Regrettably the Board has received a significant number of complaints specifically related to mail order pharmacies including delays in therapy and concerns about storage of medications throughout the shipping and delivery process. Mail order pharmacies create unique challenges for patients attempting to resolve issues in part because of difficulties speaking with a pharmacist. Under the Board's current authority, the maximum fine the Board can assess is $5,000 per investigation. The Board believes the current $5,000 maximum fine amount has not been sufficient to bring about changes in the practice to align with legal requirements.

The Board believes where it can demonstrate a pattern of similar violations over a period of time, the Board's fine authority should be increased. The Board suggests a model similar to that developed for chain community pharmacies may be appropriate.

The Board has not previously considered the proposed statutory change in **Attachment 4**.

5. Artificial Intelligence

The use of artificial intelligence in pharmacy practice has the potential to improve patient care and treatment, but also creates new risks to patients that must be carefully considered. If not implemented correctly, bias in the AI system can cause harm. The US Department of Health and Human Services Office of

Minority Health notes, "Healthcare algorithms and AI bias can contribute to existing health disparities for certain populations based on race, ethnicity, gender, age, or other demographic factors." Where pharmacies elect to provide AI as a tool for pharmacists, both the pharmacy and the pharmacists must remain vigilant and focus on the needs of the specific patient before them.

Regrettably, the Board has witnessed a trend in some community pharmacies where the independent clinical judgment of a pharmacist has been supplanted with use of an algorithm or AI, resulting in denial of treatment for a patient. In some investigations conducted by the Board, pharmacists have indicated that using their professional judgment, they would have dispensed a medication to a patient, but pharmacy systems prevented them from doing so. Such a system appears to be the equivalent to the corporate practice of pharmacy. Unlike in medicine where there is a prohibition on the corporate practice of medicine, such a prohibition does not exist for the practice of pharmacy. This has long been a challenge for the Board, pharmacists, and patients. Recently the Board sought changes to its unprofessional conduct code as an attempt to prevent the corporate practice of pharmacy. Regrettably, through both investigations, and public comments received, this dynamic continues to exist. It appears that with the advent of AI and its use in pharmacy, this current trend will continue, to the detriment of patient care.

As a national leader, California recently enacted legislation to establish protections against the use of AI in some industries. While the Board does not believe a total prohibition on the use of AI in pharmacy practice is either necessary or in the best interest of patients, and while the Board believes that AI is a tool to assist a pharmacist in making clinical judgment, the Board stands firm that AI cannot and should not supplant such clinical judgment.

The Board believes it is necessary to make this explicit in its regulations while the implementation and integration of AI is beginning.

The Board has not previously considered the proposed statutory change in **Attachment 5**.

6. IV Hydration Clinics:

Federal law establishes the authority for specified individuals to compound human drug productions under provisions specified in section 503A of the federal Food, Drug, and Cosmetic Act (FD&C Act) (21USC Section 353a). Drug

products compounded under these provisions are exempted from some of the requirements for drug manufacturing and the drug approval process.

In recent years, the U.S. Food and Drug Administration (FDA) has released warnings about instances of drug products being compounded under insanitary conditions. Many of these warnings stem from compounding occurring in sites that are not regulated by the Board or other regulatory agencies, including IV hydration clinics. Although business models vary, such clinics have been identified as operating in a variety of locations, including mobile vans, med spas, beauty salons, and gymnasiums. These locations generally do not have the appropriate equipment, storage, or classified areas, nor do they have authorized health care professionals performing the sterile compounding. Board staff are frequently contacted by various agencies to assist in assessing compounding operations and practices at such facilities by providing subject matter expertise, but the Board generally lacks jurisdiction over the practice and is unable to provide meaningful consumer protection.

The FDA warnings include an example of an investigation initiated after a California patient was hospitalized and treated for suspected septic shock with multi-organ failure, after having received an IV vitamin infusion in her home. The FDA reported that it is aware of sterile compounding activities, such as adding vitamins to IV infusion bags, being performed by businesses such as IV hydration clinics that are not licensed by the Board of Pharmacy, the California Department of Public Health, or any other similar agency, and notes that it is unknown and undocumented if the drug products are prepared, packed, or held under insanitary conditions by such entities. Additionally, it is unknown whether a licensed practitioner is on site to evaluate patients and write prescriptions for the drug products being administered. The FDA notes that the number of these entities and the compounding practices occurring at these entities are not fully understood given that compounders who compound drugs under section 503A of the FD&C Act generally do not register with the FDA.

Consistent with the Board's authority, Board staff have assisted in inspections and conducted independent inspections at some IV hydration clinics and have witnessed alarming practices that place consumers at risk. Board staff have identified challenges conducting inspections to evaluate for compliance with federal requirements for a variety of reasons including lack of basic patient information and administration information which is either not maintained or is not adequately, recorded. Inspector staff have also identified products in these clinics that are purchased from unlicensed sources, including in some instances sources with licenses that have been revoked in California. Additional, where products have been purchased from licensed sterile compounding pharmacies,

it is suspected that many times the products are not provided consistent with the requirements of section 503A of the FD&C Act and Board regulations. Further, in many instances there is no authorized prescriber on site evaluating the compounding practice.

An internet search of "IV Hydration Clinics in California" reveals that such businesses are extremely prevalent in our state. The Board is extremely concerned about these practices and the negative impacts to patients, who may not be aware of the safety concerns. To address this, the Board developed a consumer education policy statement to highlight some of the patient safety concerns and questions a patient should ask. In addition, the Board developed education for compounders. The educational materials are cobranded with several other DCA programs.

While education may address some of the patient safety challenges, it is apparent that many of these clinics are operating outside of the federal law and national standards and that no state entity is responsible for oversight of these facilities. The Board strongly believes that action is necessary to ensure compounding practices align with federal law and national standards. The Board believes it has the appropriate expertise to regulate these facilities where on site physician oversight is not in place.

The Board has not previously considered the proposed statutory change in **Attachment 6**.

7. Pharmacy Deserts

Pharmacists are one of the most accessible health care providers. Regrettably market forces have closed both independent and community chain pharmacies across the state. Over the last three years the Board has observed over a 117% increase in community chain pharmacy closures. The overall licensee population of pharmacies has also been reduced by seven percent over the past three years.

Such closures impact communities across California, most notable rural areas. Further, review of data from the Department of Health Care Services, Medi-Cal reveals that provider enrollment is significantly down, leaving gaps in care.

The Board has received public comment that certain payor practices (discussed elsewhere in this document) increase costs to patients and result in an unsustainable business model for many pharmacies.

The Board proposes to assist with the opening of new pharmacies in pharmacy deserts through the waiving of application and renewal fees for a pharmacy

that establishes a brick and mortar pharmacy in a pharmacy desert. Further the Board proposes to use dedicated staff to serve as an ombudsmen to assist the pharmacy owner with pharmacy application requirements. The pharmacies established in the pharmacy deserts will be eligible to operate without paying fees to the Board until such time as more than two pharmacies conduct business in the underserved area.

The Board estimates there are over 100 pharmacy deserts across California.

The Board has not previously considered the proposed statutory change in **Attachment 7.**

8. Online Health Platforms Directing Patients to Specific Pharmacies

As new practice trends emerge it is important for the Board to evaluate such practices to confirm compliance with pharmacy law and patient safety. Although telehealth platforms have existed for some time, during the COVID pandemic they appear to have grown in popularity. While these platforms may provide ease of access to a medical provider, they also create new patient safety concerns, especially when a patient is directed by the telehealth platform to a specific pharmacy.

The Board is aware of telehealth platforms that steer patients to a pharmacy owned and operated by the telehealth platform. Such a scheme appears to violate at a minimum the intent of the anti-kickback statute prohibiting offering or receiving any remuneration to induce referrals for services.

Patient safety is also of concern given that the telehealth platforms may not have full visibility into the patient's history, including underlying medical conditions, medication use including over-the-counter and prescription medications. This can lead to contraindications and duplication in therapies being overlooked, placing patients at risk.

The Board believes that at a minimum patient protections must be addressed to avoid potential patient steering, or other violations of anti-kickback provisions. The Board recognizes that many of these issues are outside the scope and jurisdiction of the Board and suggests that it may be appropriate for the Legislature to determine if an agency should be designated to regulate telehealth platforms.

The Board does believe that is has jurisdiction over the pharmacies that are involved in this business practice, including instances where the telehealth

platform also owns the pharmacy or outsourcing facility dispensing the prescription medication. Based on the Board's history of regulating pharmacies filling unlawful internet prescriptions, the Board believes additional requirements are necessary including a notification requirement to the Board.

The Board has not previously considered the proposed statutory change in **Attachment 8**.

9. Pharmacy Delivery Services (including Doordash, Uber, etc.)

Although pharmacy delivery has always been a service provided by pharmacies largely for patients in residential facilities (skilled nursing facilities, long term care facilities, etc.), during the COVID pandemic, delivery of prescription medications became far more common place. The Board acknowledges that patients enjoy the convenience of prescription medication delivery, but notes that delivery of medications becomes a barrier to vital patient consultation. To address challenges stemming from low health literacy rates, the Board updated its patient consultation requirements to ensure patients have ready access to pharmacist consultation. While these requirements are relatively new, the Board has substantiated a number of violations where patients were unable to speak with a pharmacist. The Board will continue its efforts to educate about the requirements.

Another patient care issue that arises from the delivery of prescription medications is the lack of requirements for delivery personnel, lack of background checks, lack of understanding of drug storage requirements, etc. Pharmacies employ different methods for delivery of medications, some using their own personnel, others contracting with delivery services, and in other instances pharmacies use general delivery services such as Doordash and Uber to deliver medications.

The Board has conducted investigations and identified issues where prescription medications are delivered to the wrong patient or are left on porches or on driveways or in mailboxes in extreme weather conditions. In some instances, medication that is left in these uncontrolled environments is then subsequently returned to the pharmacy for redispensing.

The Board believes that some of these issues arise because of the lack of education, training, and awareness of unique issues with drug handling. To address this, the Board believes guardrails are necessary to ensure individuals providing delivery of prescription medications are adequately trained and that

specific provisions for medication handling in the delivery process are maintained. Compliance with DEA background checks should also be required.

The Board believes it has sufficient authority to develop regulations in this area; however, it is interested in working with the Legislature to establish either a registration requirement for pharmacies that deliver medications or some type of registration for delivery personnel.

10. Payor Activities (including auditing practices) that Negatively Impact Patient Access

The Board is extremely concerned about the emergent of payor practices that negatively impact patient care. The payor practices appear to go unresolved and continue to place patients at risk. The Board has publicly discussed some of these issues seeking to gain an understanding of the issues and impacts to patients. In addition, Board staff have conducted investigations that demonstrate negative impacts to patients, yet the Board lacks the authority to address the issue.

In 2021 the Board convened an informational meeting to discuss the practice of white bagging. White bagging is a payor practice that requires a patient to use a specified pharmacy to obtain medication that will be administered, typically at an infusion center. During the meeting, the Board learned about many of the patient safety concerns stemming from this practice, including challenges in coordinating care and delays in therapy. Many of the patients requiring infusion have serious medical conditions such as cancer where delays in therapy to result in disease progression. Regrettably, the Board does not have the current authority to prevent this payor driven practice.

In addition, the Board routinely receives complaints from consumers indicating that a pharmacy delayed dispensing of a medication in violation of Business and Professions Code section 733. Through the Board's investigation however, the Board many times discovers that the delay was not caused by the actions of a pharmacy but rather, the delays were caused by payor requires for things such as prior authorizations, for which there is no requirement for such authorizations to be approved within a specified time frame. Regrettably the Board does not have current authority to address the root causes of the delay in therapy which again for a patient can have significant consequences.

The Board has also been advised that some payors, as part of their audit process, claw back payments based on a determination by the auditor that the pharmacy has violated a provision of Pharmacy law. It is important to note that

in these instances, the Board has not made a determination of a violation law. Where these claw backs occur the pharmacies lose reimburse for drugs that have already been dispensed to patients.

The Board believes that many of these payor practices are placing patients at risk and are resulting in the closures of pharmacies, creating pharmacy deserts and barriers to care. These issues must be addressed to protect patients and ensure patients have access to pharmacist care in all communities.

The Board has not previously considered the proposed statutory change in **Attachment 9**.

11. Standard of Care Practice Model for Pharmacists

During the Board's last sunset review, the Board was directed to evaluate if a transition to a standard of care enforcement model would be both feasible and appropriate for the regulation of pharmacy (BPC 4301.3, which was repealed January 1, 2024). As required by this section, the Board undertook its work and submitted the required report to the Legislature.

The Board noted in its report that moving to a standard of care enforcement model would have broad implications and determined it appropriate to establish an ad hoc committee solely dedicated to evaluation of the question posed by the Legislature to allow for robust engagement with interested stakeholders. Through this process members received presentations from stakeholders, reviewed actions taken by other jurisdictions, considered research, conducted a survey of licensees, and robustly discussed a number of policy questions. The policy questions in full are described in the report. Several of the policy questions posed went beyond the original question posed by the Legislature and considered if expanding the use of a standard of care practice model for pharmacists could benefit patients. As part of its evaluation, the Board concluded that based on the information it received and considered, California patients would benefit from pharmacists gaining additional independent authority to provide patient care services, not limited to the traditional dispensing tasks performed at licensed facilities, consistent with their respective education, training, and experience. The Board further recommended revisions to certain provisions detailing a pharmacist's authorized scope of practice for specified clinical patient care services and transition to a standard of care model for specified patient care services, where sufficient safeguards are in place to ensure pharmacists retain autonomy to utilize professional judgment in making patient care decisions. Under those conditions, the Board believes that transitioning to greater use of a standard of care model in the provision of specified patient care services could benefit patients by

providing expanded and timely access to patient care from suitably educated, trained, and experienced health care providers.

Consistent with the Board's commitment in its report, the Board subsequently undertook development of a statutory proposal for consideration during the Board's sunset review process. This work was largely performed by the Licensing Committee and developed over a series of public meetings. The legislative proposal seeks to transition many provisions of pharmacist care to a standard of care model in lieu of the current prescriptive model established. As an example, under the Board's proposed language, a pharmacist will retain the ability to provide hormonal contraception, but will follow a standard of care approach, in lieu of following prescriptive rules established in the Board's regulation.

Data suggests that about 20% of Californians live in areas designated as primary care health professional shortage areas; while only 6 percent of Californians live in areas designated as pharmacy deserts. This data highlights a significant opportunity to expand access to care to patients.

While the Board has received some concerns about pharmacists' ability to maintain sufficient autonomy in some community pharmacy settings, the Board's legislative proposal generally enjoys broad support from several associations and pharmacists. The proposal strikes a balance, by creating an option for pharmacists to perform services, while maintaining current provisions to allow for such services to be performed under a collaborative practice agreement. The language also underscores a pharmacist's self-determination in deciding what services they are appropriately educated and trained to perform. Such an approach is similar to other health care professions, such as physicians that, under the law can perform all functions for which they possess the requisite education and training to perform.

The statutory proposal as recommended by the Licensing Committee with updates made consistent with the direction of the Committee is included in **Attachment 10**.

12. Establish Self-Assessment Process in Statute.

The Board requires completion of a self-assessment form for a number of its licensed businesses as a means to promote self-evaluation and compliance through self-examination and education. The self-assessment forms include a compilation of relevant laws applicable to the license type, e.g., community pharmacy, hospital pharmacy, sterile compounding license, surgical clinic, etc.

In each instance the law establishes the process to be followed, the frequency within which the self-assessment must be completed, and the required signatories of the form.

The Board believes the self-assessment process is an important tool and believes requirements should apply to all facility license types issued by the Board. Currently the Board's self-assessment requirements are in various provisions of pharmacy law and regulations. The Board proposes to centralize the self-assessment requirement into statute to ensure consistency in the Board's approach to promoting self-compliance.

The Board has not previously considered the proposed statutory change in **Attachment 11**.

13. AB 1286 Clarification

In 2023, the Board sponsored a sweeping patient safety measure focusing establishing many first in the nation requirements including provisions addressing known root causes of medication errors and establishing mandatory reporting of medication errors. Through implementation efforts, the Board has identified some areas that require clarification of the language clarifying the Board's expectations in two areas - - related to the authorized duties of a specially trained pharmacy technician as well as clarification on the reports for medication errors related specifically to nonresident pharmacies.

The Board has not previously considered the proposed statutory change in **Attachment 12**.

14. Remote Processing

As part of the Board's response to the COVID-19 public health emergency and the initial need for physical distancing, a "Remote Processing Waiver" was approved by the Board. This waiver expired on May 28, 2023. Under the provisions of the waiver, legal authorization for remote processing was expanded to allow for greater flexibility under pandemic conditions.

"Remote Processing" is defined to mean the entering of an order or prescription into a computer from outside of the pharmacy or hospital for a licensed pharmacy. The Waiver allowed that, in addition to the provisions of BPC section 4071.1(a), pharmacists performing remote processing could also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances classified in Schedule II, III, IV or V.

Under the Waiver, remote processing also included order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, and authorizing release of medication for administration. The Waiver did not permit dispensing of a drug or final product verification by remote processing.

Further, the Waiver expanded the provisions of BPC section 4071.1(a) to allow for remote processing by pharmacy technicians and pharmacy interns to include nondiscretionary tasks, including prescription or order entry, other data entry, and insurance processing of prescriptions and medication orders for which supervision by a pharmacist was provided using remote supervision via technology that, at a minimum, ensured a pharmacist is (1) readily available to answer questions of a pharmacy intern or pharmacy technician; and (2) verify the work performed by the pharmacy intern or pharmacy technician.

There were certain limitations and qualifiers regarding the Waiver, including that a pharmacist, pharmacy technician, or pharmacist intern relying on the Waiver must be licensed in California, and must be engaged in processing medication orders or prescriptions from a remote site or on the premises of a California-licensed pharmacy. The pharmacy must have authorized remote processing and must have appropriate policies and procedures as well as adequate training on those policies and procedures.

The Board considered a number of policy questions and ultimately identified a statutory proposal that can create a path forward to establish provisions for some remote work on a permanent basis.

The Board's previously approved statutory proposal is in **Attachment 13**.

15. Retitle "Advanced Practice Pharmacist" to "Advanced Pharmacist Practitioner"

Pursuant to provisions in Senate Bill 493, (Hernandez, Chapter 469, Statutes of 2013) the Board established the advance practice pharmacist licensing program. As of September 20, 2024 the Board has 1,383 advanced practice pharmacist licensees. Aside from some minor clarifying changes in the qualifications method made during the Board's last sunset review, the program has remained largely unchanged.

In light of what is occurring nationally, where health care providers performing advanced functions are often referred to as "practitioners" (e.g., nurse practitioners) the Board believes a change to the name of the licensing program is appropriate, specifically changing the current name "advanced

practice pharmacist" to "advanced pharmacist practitioner" as well as making conforming and nonsubstantive changes. The board believes such a change more appropriately reflects the services provided and underscores the pharmacist's role in the health care team.

The Board has not previously considered the proposed statutory change in **Attachment 14**.

16. Records

Senate Bill 1442 (Weiner, Chapter 569, Statutes of 2018) established requirements prohibiting specified community chain pharmacies from requiring a pharmacist to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or an employee of the establishment within which the pharmacy is located is made available to assist the employee.

Following enactment of the measure, and in response to a petition filed by United Food and Commercial Workers (UFCW) the Board developed regulations to further clarify the statutory requirements.

Since that time the Board has received a number of allegations of non-compliance with the legal requirements regarding pharmacy operations including staffing requirements and quota prohibitions. These investigations are challenging in part because some pharmacies refuse to provide the Board with records requested because they allege the records sought go beyond the specific types of records (i.e., records of acquisition and disposition) found in BPC 4081 and 4105. Such challenges create barriers to conducting complete and timely investigations.

Given enacted legislation governing pharmacy operations related to staffing and performance metrics establishing the state's policy in this area, the Board believes it is appropriate to update provisions of Pharmacy Law to explicitly state additional records must be maintained and made available to the Board. The types of records would include job duty statements that would confirm whether an individual meets requirements of the Board's regulation, staffing schedules that would demonstrate compliance with staffing requirements and performance metrics, training records that confirm an individual meets requirements to perform specified tasks, and more.

The Board's previously approved statutory proposal is in **Attachment 15**.

17. Converting Paper Records to Digital

Pharmacy law requires the maintenance of records for three years from the date of making. Depending on the size of a facility, storage of paper records may become challenging. Licensees are seeking a means to convert paper records to an electronic format. The Board believes preservation of records in an electronic or digitized manner is appropriate, if the entity ensures that the records cannot be edited from the original version.

The Board has not previously considered the proposed statutory change in **Attachment 16**.

18. Clarification on Pharmacist Prescriptions

Pharmacist authority to prescribe has expanded over the years under both collaborative practice agreements, pursuant to protocol and pursuant to policies and procedures; however, as these changes have occurred related sections of the law have not been updated to incorporate the changes. When this occurs, it can create confusion.

The Board believes nonsubstantive changes are necessary to update BPC sections 4040 and 4051 to reflect the changes in pharmacist prescriptive authority.

The Board has not previously considered the proposed statutory change in **Attachment 17**.

19. Hormonal Contraception

Pharmacy law establishes authority for a pharmacist to furnish self-administered hormonal contraception in accordance with standardized procedures or protocols developed and approved by both the Board and the Medical Board of California in consultation with a number of identified agencies.

Recently enacted legislation, Senate Bill 523 (Leyva, Chapter 630, Statutes of 2022) made various changes to expand coverage of contraceptives by a health care service plan contract or health insurance policy as specified in the measure. As part of the changes, effective January 1, 2024, a health care service plan or health insurer is required to provide point-of-sale coverage for over-the-counter FDA-approved contraceptive drugs, devices, and products at in-network pharmacies without cost sharing or medical management restrictions.

While OTC hormonal contraception is available to patients, implementation of health care service plan coverage is stymied because of requirements related to reimbursement, most notably, insurers generally require a prescription to reimburse for medications, even those determined by the FDA to be OTC.

The current legal provisions for pharmacist-furnished hormonal contraception while intended to expand access to such products, have proven to be a barrier. Regrettably the under prescriptive language included in current law, pharmacists cannot furnish OTC hormonal contraception without meeting all of the requirements for prescription products.

To remedy this issue, the Board believe a change to pharmacy law is necessary to allow pharmacists to prescribe OTC hormonal contraception to meet the requirements of health insurers as well as to clarify that the prescriptive requirements for pharmacist-furnished hormonal contraception apply only to prescription items. The Board notes that if the Legislature agrees with the Board's recommendation to transition to a standard of care practice model for pharmacists, the proposed language specifically related to hormonal contraception will not be necessary.

The Board's approved statutory proposal is included is in **Attachment 18**.

20. Ownership Prohibition

Pharmacy law prohibits the Board from issuing or renewing a pharmacy license to an individual authorized to prescribe; a person who shares a community or other financial interest with a prescriber; or to any corporation that is controlled by 10 percent or more of stock owned by a person or persons prohibited from pharmacy ownership.

California is a community property state. This means that, generally, property acquired by either spouse during a marriage is presumed to be equally owned by both spouses. There are some exceptions, such as prenuptial agreements, where property acquired may not be community property depending on the agreement of the parties to a valid prenuptial agreement. However, the existence of a prenuptial agreement in and of itself may or may not remedy the financial interest that each spouse has in the other's businesses. For example, the money earned by one spouse in their pharmacy would likely be used to support the home, family, or lifestyle of the couple. Therefore, while there may be no specific community property interest as defined in the Family Code, there may still be a community or financial interest that would apply under this code section.

As part of the application process for a pharmacy, the Board requires disclosure of ownership information. To confirm compliance with the above provisions, the Board requests information specifically related to officers and owners of individuals authorized to prescribe in California.

Historically, as part of the application process, if an applicant disclosed a familial relationship with a prescriber, the Board would inquire about the nature of the relationship to confirm compliance with pharmacy law prior to making a licensing decision. For a number of years, the Board accepted representations from the applicant that the prescriber did not have any financial or community interest in the pharmacy. Unfortunately, this was something of a shallow view of the law and failed to take into account the realities of family life, the requirement of the Family Code that spouses owe a duty of care towards each other, and the conflicts of interest that the statute was designed to protect against.

As the Board's application and assessment process has evolved, most notably in response to changes in the ownership assessment process, Board staff began looking deeper into the financial arrangements between the applicant spouse and the prescriber spouse and came to the realization and understanding that pre- or post-nuptial agreements would not necessarily resolve the issue of having a community or financial interest in the pharmacy.

The sole focus on the financial aspects of the property does not take into account policy considerations such as financial incentives for a prescriber to direct prescriptions to their spouses' pharmacy, or pharmacists exercising their duty of corresponding responsibility and whether that duty would be impacted when reviewing a prescription written by a pharmacist's spouse or the spouse's practice group.

Further, under provisions of AB 1533 (Committee on Business and Professions, Chapter 629, Statutes of 2021, authority for pharmacists to initiate, adjust, or discontinue drug therapy for a pharmacy under a collaborative practice agreement was expanded; however, BPC section 4111 was not similarly amended.

The Board's approved statutory proposal is included is in **Attachment 19**.

21. Retired License

Pharmacy law establishes the current provisions for a pharmacist to retire their pharmacist license. Under the current requirements, the holder of a retired pharmacist license may only restore their license to an active status after passing the pharmacist licensure examination required for initial licensure.

Through recent discussion, the Board noted that its requirements to restore a pharmacist license, were more burdensome than requirements for a pharmacist whose license is lapsed for nonrenewal or those seeking to reactivate their inactive pharmacist license. Seeking to address this inequity, and to establish a

less burdensome manner for recently retired pharmacists to restore their pharmacist license, the Board identified changes to pharmacy law that provides parity for restoring a retired pharmacist license through completion of continuing education and payment of a fee.

The Board's approved statutory proposal is included is in **Attachment 20**.

22. Changes to Pharmacy Technician Trainee

Pharmacy law established several different pathways to licensure as a pharmacy technician, including through completion of a training program. Pharmacy law also establishes provisions for a "pharmacy technician trainee" (trainee) and provides that this term is defined as a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary Education.

As part of the Board's ongoing review and evaluation of the pharmacy technician licensing program, the Board has received presentations from various pharmacy technician training program providers describing the requirements for their respective certification or accreditation programs that provide a pathway to licensure for individuals seeking licensure as a pharmacy technician.

Through this education and discussion, the Board determined that the current definition of pharmacy technician trainee is too limited noting that individuals completing an accredited employer-based training programs should also be able to gain experience as a trainee to obtain practical experience. Members believe such expansion could increase learning and training opportunities while also reducing a potential barrier to entry.

The Board's approved statutory proposal is included is in **Attachment 21**.

Attachment 1

Proposal to Amend BPC 4112 and BPC 4303 As Follows:

4112.

(a) Any pharmacy located outside this state that is involved in the preparation, dispensing, shipping, mailing, or delivery ~~ships, mails, or delivers~~, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy.

(b) A person may not act as a nonresident pharmacy unless he or she has obtained a license from the board. The board may register a nonresident pharmacy that is organized as a limited liability company in the state in which it is licensed.

(c) A nonresident pharmacy shall disclose to the board the location, names, and titles of (1) its agent for service of process in this state, (2) all principal corporate officers, if any, (3) all general partners, if any, ~~and~~ (4) the name of a California licensed pharmacist designated as the pharmacist-in-charge and (5) all pharmacists who are dispensing controlled substances, dangerous drugs, or dangerous devices to residents of this state. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, partner, pharmacist-in-charge, or pharmacist.

(d) All nonresident pharmacies shall comply with all lawful directions and requests for information from the regulatory or licensing agency of the state in which it is licensed as well as with all requests for information made by the board pursuant to this section. The nonresident pharmacy shall maintain, at all times, a valid unexpired license, permit, or registration to conduct the pharmacy in compliance with the laws of the state in which it is a resident. As a prerequisite to registering with the board and ongoing licensure, the nonresident pharmacy shall identify a California licensed pharmacist employed and working at the nonresident pharmacy to be proposed to serve as the pharmacist-in-charge, and submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the state in which it is located.

(e) All nonresident pharmacies shall maintain records of controlled substances, dangerous drugs, or dangerous devices dispensed to patients in this state so that the records are readily retrievable from the records of other drugs dispensed.

(f) Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free telephone number shall be disclosed on a label affixed to each container of drugs dispensed to patients in this state.

(g) A nonresident pharmacy shall not permit a pharmacist to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to California patients under any of the following conditions:

(1) The pharmacist's ~~whose~~ license has been revoked by any jurisdiction and has not been subsequently reinstated. ~~by the board to manufacture, compound, furnish, sell, dispense, or initiate the prescription of a dangerous drug or dangerous device, or to provide any pharmacy-related service, to a person residing in California~~.

(2) If the pharmacist is not licensed in California, they have not successfully passed the North American Pharmacist Licensure Examination or the Multi-state Jurisprudence Examination.

(h) The board shall adopt regulations that apply the same requirements or standards for oral consultation to a nonresident pharmacy that operates pursuant to this section and ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state, as are applied to an in-state pharmacy that operates pursuant to Section 4037 when the pharmacy ships, mails, or delivers any controlled substances, dangerous drugs, or dangerous devices to residents of this state. The board shall not adopt any regulations that require face-to-face consultation for a prescription that is shipped, mailed, or delivered to the patient. The regulations adopted pursuant to this subdivision shall not result in any unnecessary delay in patients receiving their medication.

(i) The registration fee shall be the fee specified in subdivision (a) of Section 4400.

(j) The registration requirements of this section shall apply only to a nonresident pharmacy that ships, mails, or delivers controlled substances, dangerous drugs, and dangerous devices into this state pursuant to a prescription.

(k) A nonresident pharmacy licensed pursuant to this section shall be subject to inspection by the board as a condition of renewal once every four years, unless the board determines more frequent inspections are necessary. In addition to paying the fees established in Section 4400, the nonresident pharmacy shall deposit, when notified by the board, a reasonable amount, as determined by the board, necessary to cover the board's estimated costs of performing the inspection. If the required deposit is not received or if the actual costs of the inspection exceed the amount deposited, the board shall issue an invoice for the remaining amount and shall not take action on the renewal application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(l) Nothing in this section shall be construed to authorize the dispensing of contact lenses by nonresident pharmacists except as provided by Section 4124.

(m) This section shall become effective July 1, 2026.

4303.

(a) The board may report any violation by a nonresident pharmacy of the laws and regulations of this state, any other state, or of the United States, including, but not limited to, any violation of this chapter or of the regulations established by the board, to any appropriate state or federal regulatory or licensing agency, including, but not limited to, the regulatory or licensing agency of the state in which the nonresident pharmacy is a resident or in which the pharmacist is licensed.

(b) The board may cancel, deny, revoke, or suspend a nonresident pharmacy registration, issue a citation or letter of admonishment to a nonresident pharmacy, or take any other action against a nonresident pharmacy that the board may take against a resident pharmacy license, on any of the same grounds upon which such action might be taken against a resident pharmacy~~, provided that the grounds for the action are also grounds for action in the state in which the nonresident pharmacy is permanently located.~~

(c) If the home state pharmacy license of a nonresident pharmacy is canceled, revoked, or suspended for any reason, any license issued pursuant to Section 4112 or 4127.2 shall be immediately canceled, revoked, or suspended by operation of law.

Attachment 2

Proposal to Amend BPC Section 4115 as follows.

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

(A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.

(C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(D) The pharmacy technician is certified in basic life support.

(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

(c) This section does not authorize the performance of any tasks specified in subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g) (1) A pharmacy with only one pharmacist shall have no more than ~~one~~ two pharmacy technicians performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy

technician performing the tasks specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). ~~The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that~~ ~~t~~his~~T~~his ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs. The Board may adopt regulations establishing for different community pharmacy practice settings a ratio different than those established in this paragraph.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the

pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

Attachment 3

ARTICLE 7. Pharmacies [4110 - 4126.10]
(Article 7 added by Stats. 1996, Ch. 890, Sec. 3.)

4115.
(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:

(A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).

(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.

(C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.

(D) The pharmacy technician is certified in basic life support.

(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

(c) This section does not authorize the performance of any tasks specified in subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks

specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

(k) Notwithstanding the definition of a pharmacy technician in 4038(a), a pharmacy technician may, outside of a licensed pharmacy, perform compounding activities only under the direct supervision and control of a pharmacist. The board shall be notified in writing by the supervising pharmacist of the location where such compounding activities occur.

Attachment 4

Proposed Addition to BPC 4317.6 Actions for Fines: Mail Order Pharmacies

(a) The board may bring an action for fines for repeated violations of materially similar provisions of this chapter within five years for a single mail order pharmacy, or multiple mail order pharmacies operating under common ownership or management as follows: a third and, or subsequent violation may be punished by an administrative fine not to exceed one hundred thousand dollars ($100,000) per violation.

(b) In determining the amount of the fine sought in an action brought pursuant to this section, the board shall consider relevant mitigating and aggregating factors, including, but not limited to, the good faith of the licensee, the communication of written changes to unlawful policies, the gravity of the violation, the potential harm to a patient, whether the violation affects the professional judgment or independence of pharmacists, and the history of previous violations by the mail order pharmacy (or in the case of multiple mail order pharmacies operating under common ownership or management, the history of the previous violations by the common ownership or control.

(c) The authority granted by this section is in addition to the authority of the board to institute any other administrative, civil, or criminal action.

(d) The fines in subdivision (a) shall be imposed in accordance with Section 4314.

(e) For purposes of this section, "mail order pharmacy" is defined as a nonresident pharmacy that dispenses medications and ships them to patients via the postal service or other mail delivery method.

Attachment 5

Proposed Addition 4301.2 – Prohibition on the Use of Artificial Intelligence in Pharmacists Exercising Professions Judgment

(a) For purposes of this section, artificial intelligence (AI) refers to computer systems or software that use algorithms or analysis of data to perform tasks typically requiring human intelligence, including, but not limited to, decision-making, problem-solving, and information processing.

(b) No pharmacy or pharmacist shall utilize AI technologies to replace or override the professional judgment of a licensed pharmacist in any aspect of pharmaceutical care, including, but not limited to:

1. Patient assessments;
2. Medication therapy management;
3. Drug interactions and contraindications;
4. Exercising corresponding responsibility;
5. Counseling patients on medication use.

(c) The board may take action against any pharmacy or pharmacist found to be in violation of this section, including, but not limited to, fines, license suspension, or revocation. Such a violation shall be considered unprofessional conduct.

(d) This section does not prohibit the use of AI tools as supportive resources for pharmacists, provided that such tools are used solely to augment, and not replace, the pharmacist's professional judgment.

Attachment 6

Proposal to ADD BPC Section 4188 – IV Hydration Clinics

a. An IV hydration clinic shall not compound or administer sterile injectable products unless the clinic has obtained an IV hydration clinic license from the board pursuant to this section. The license shall be renewed annually and is not transferrable.
b. Prior to licensure pursuant to this section, an IV hydration clinic shall be subject to inspection by the board for compliance with state and federal laws and regulations and national standards governing compounding practices. A clinic licensed pursuant to this section shall also be subject to an inspection by the board biennially to maintain licensure. If any inspection reveals noncompliance, the license shall not be issued, or in the case of a clinic already licensed, shall not be renewed and will be cancelled by operation of law.
c. The clinic shall designate a professional director who is responsible for the safe, orderly, and lawful provisions of compounding and administration of the sterile injectable products. The professional director shall be an authorized prescriber licensed in California.
d. The clinic shall retain a consulting pharmacist to approve the policies and procedures related to compounding and administering sterile injectable products and to evaluate the clinic for compliance with state and federal laws and regulations and national standards governing compounding practices. The consulting pharmacist is responsible for quarterly inspection of the clinic and following each such inspection shall provide written certification that the clinic is, or is not operating in compliance with the requirements of this section. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended correction actions, if appropriate.
e. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete an IV Hydration Clinic Self-Assessment Form as determined by the board as a means to promote compliance through self-examination and education. The self-assessment shall assess the clinic's compliance with state and federal laws and regulations and national standards governing compounding practices on the most recent version of the IV Hydration Clinic Self-Assessment Form approved by the board and posted on its internet website. The professional director of the clinic and the consulting pharmacist shall certify on the final page of the IV Hydration Clinic Self-Assessment Form that they have read, reviewed, and completed the self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the board. The completed form shall be signed under penalty of perjury, kept on file in the clinic for three years, and made available to the board or its designee, upon request.
f. Sterile preparations compounded at the clinic shall be limited to the use of the drugs for on-site administration to the patients of the clinic under the direction of the authorized prescriber.
g. For the purposes of this section, "IV hydration clinic" is a facility that provides therapy for hydration or other therapeutic purpose and for which a professional

director is not on site during all times in which compounding of sterile injectable products occur.

h. For the purposes of this section, "professional director" means a physician and surgeon acting in their capacity as medical director or other healing arts practitioner authorized to compound under federal law.
i. The clinic shall notify the board within 30 days of any change in professional director on a form furnished by the Board.
j. The fee for application and annual renewal shall be $3,800 and may be increased to $5,000.
k. This section shall become effective January 1, 2027.

Attachment 7

Proposal to amend BPC 4400 as follows:

…

(ag) The Board shall waive the application fee for a pharmacy that opens a physical pharmacy operating and located in a medically underserved area. For purposes of this section, "medically underserved area" means a location that does not have a physical pharmacy that provides in person patient care services by a pharmacist and that serves the general public within 50 road miles of an existing pharmacy. The pharmacy may be eligible for fee waiver for annual renewal through application to the Board with certification of continued operation in the pharmacy desert.

Attachment 8

Proposal to amend BPC section 4067

4067.

(a) No person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the internet for delivery to any person in this state without a prescription issued pursuant to a ~~good faith prior examination~~ appropriate prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations.

(b) Notwithstanding any other provision of law, a violation of this section may subject the person or entity that has committed the violation to either a fine of up to twenty-five thousand dollars ($25,000) per occurrence pursuant to a citation issued by the board or a civil penalty of twenty-five thousand dollars ($25,000) per occurrence.

(c) The Attorney General may bring an action to enforce this section and to collect the fines or civil penalties authorized by subdivision (b).

(d) For notifications made on and after January 1, 2002, the Franchise Tax Board, upon notification by the Attorney General or the board of a final judgment in an action brought under this section, shall subtract the amount of the fine or awarded civil penalties from any tax refunds or lottery winnings due to the person who is a defendant in the action using the offset authority under Section 12419.5 of the Government Code, as delegated by the Controller, and the processes as established by the Franchise Tax Board for this purpose. That amount shall be forwarded to the board for deposit in the Pharmacy Board Contingent Fund.

(e) Nothing in this section shall be construed to permit the unlicensed practice of pharmacy, or to limit the authority of the board to enforce any other provision of this chapter.

(f) For the purposes of this section, "~~good faith prior examination~~" "appropriate prior examination" includes the requirements for a physician and surgeon in Section 2242 and the requirements for a veterinarian in Section 4826.6.

Proposal to add BPC section 4067.1

(a) Except as provided below, a pharmacy or outsourcing facility licensed pursuant to this Chapter shall provide to the Board notification that it is receives prescriptions for dispensing to patients from a telehealth platform, telehealth application or telemedicine application, referred to a "platform".

(b) As part of the notification the pharmacist-in-charge of the pharmacy or director of quality at the outsourcing facility will disclose if it has a financial relationship with the platform. Such disclosure shall also include if the platform is owned in whole or in part by an authorized prescriber and if the platform operates under common ownership, management and control. The disclosure shall certify compliance with the provisions of section 650 and shall provide the contact information and location of the platform owner.

(c) For purposes of this section a telehealth platform, telehealth application or telemedicine application includes any such platform intended to connect a patient to a prescriber and a pharmacy.

(d) Nothing in this section shall be construed to require a telehealth platform used by a health care service plan as defined in Civil Code section 56.05(g).

Attachment 9

Whitebagging Provisions

(a) Any pharmacist may fill a prescription at an originating pharmacy for delivery to another patient care site for administration to a patient under the following conditions:

(1) The originating pharmacy provides the administering facility a process to track the prescription in real time during each stage of the delivery process;

(2) Ensuring accuracy, security, integrity, and accountability in the delivery process from the time the prescription leaves the originating pharmacy until the prescription is received by staff at the administering facility;

(3) Informing and obtaining consent from the patient for using this dispensing and delivery process.

(b) Each owner and pharmacist-in-charge of an originating pharmacy participating in drug delivery for administration shall ensure that the following requirements are met:

(1) Each prescription waiting to be picked up or in the process of being delivered to the administering facility shall be stored according to the manufacturer's requirements and relevant laws and regulations.

(2) The pharmacist responsible for filling the prescription shall meet the following requirements:

(A) Notify the administering facility of the anticipated arrival date of the shipment to the administering facility, the exact address where the prescription will be shipped, the name of the patient to whom the drug is being dispensed, and any special storage requirements for the prescription;

(B) provide counseling to the patient or ensure that a process is in place for the patient to receive counseling from a practitioner or pharmacist;

(C) provide a procedure for returning to the originating pharmacy any unopened prescription medication not administered to the patient; and

(D) coordinate the preparation and delivery of the materials needed by the administering facility to administer the dispensed prescription.

(3) Each prescription shall be scheduled for delivery during the administering facility's normal business day to a designated area identified by the administration facility and signed by authorized personnel of the administration facility, unless otherwise agreed upon by the administering facility.

(c) Prescriptions for controlled substances shall not be delivered under this regulation unless the delivery is in compliance with state and federal law.

Authority of the California State Board of Pharmacy

(a) The California State Board of Pharmacy shall have exclusive authority to interpret and enforce the provisions of this chapter regarding the practice of pharmacy and the licensing of pharmacists and pharmacies.

(b) No violation of this chapter shall be determined by any entity other than the California State Board of Pharmacy. The Board shall have the sole authority to conduct investigations, hold hearings, and impose disciplinary actions for violations of Pharmacy Law.

Attachment 10

Proposal to Amend Business and Professions Code Section 4052.

(a) Notwithstanding any other law, a pharmacist may do all of the following:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) ~~Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1~~. Initiate and perform routine patient assessment procedures including skin puncture and clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 (U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration as authorized by section 1206.5 or section 1206. 6.

~~(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.~~ Upon patient consent, perform therapeutic interchanges unless the prescriber has indicated "Do not substitute" "Do not alter" or similar words or the medical literature does not support such a change. Such interchanges include, but are not limited to, use of biosimilars, different dosage forms, drugs within the same drug classification, and generic substitutions intended to optimize patient care.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Prescribe, m~~M~~anufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) ~~Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention~~. Prescribe over-the-counter medications if requested.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to patients and ~~other~~ health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish FDA approved or authorized medications as part of preventative health care services that do not require a diagnosis~~. The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.~~ This section shall not allow a pharmacist to furnish a medication for off-label use unless current evidence based standard of care supports such off-label use.

(11) Furnish an FDA approved or authorized noncontrolled medication for the treatment of conditions that

(a) are minor, non-chronic health conditions

(b) or for which a CLIA waived test provides diagnosis and the treatment is limited in duration.

~~The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a primary care provider. This section shall not allow a pharmacist to furnish a medication for off-label use.~~

(12) Order and interpret laboratory tests. ~~tests for the purpose, monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.~~

(13) Initiate, adjust, or discontinue drug therapy for a patient under any of the following:

(A) A collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.

(B) Pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the entity providing health care services unless a patient's treating prescriber otherwise prohibits such action.

(14) ~~Provide medicatio~~n Furnish medication used to treat substance use disorder~~-assisted treatment pursuant to a state protocol,~~ to the extent authorized by federal law.

(15) Complete missing information on a prescription for a noncontrolled medication if there is evidence to support the change.

(16) Initiate and administer any FDA approved or authorized immunization for persons three years of age and older consistent with Advisory Committee on Immunization Practices recommendations.

(17) Adjust prescription treatment drug regimens consistent with the current standard of care for management of ~~medication therapy management reviews for~~ chronic conditions. A pharmacist exercising these authorities must do so in collaboration with a patient's primary care provider or diagnosing prescriber, if applicable.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

(d) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide a service or function authorized by subdivision (a) where 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 such service or function properly or safely; or (2) performing or providing such service or function would place a patient at risk; or (3) where pharmacist staffing at the pharmacy is insufficient to facilitate comprehensive patient care.

(e) Where applicable, the pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not

have a primary care provider or requests to not notify the primary care provider, the pharmacist shall provide the patient with a written or electronic record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(f) Nothing in this section shall be construed as establishing an obligation on a pharmacist to perform or provide authorized services without payment for the services including payment directly by the patient, through a third-party payer or payment of any required copayment by the patient.

Amend BPC 4050 as follows:

(a) In recognition of and consistent with the decisions of the appellate courts of this state, the Legislature hereby declares the practice of pharmacy to be a profession.

(b) ~~Pharmacy~~ Pharmacist practice is a dynamic, patient-oriented health service that applies a scientific body of knowledge to improve and promote patient health by means of patient-care activities to optimize appropriate drug use, drug-related therapy, disease management and prevention, and communication for clinical and consultative purposes. ~~Pharmacy~~ Pharmacist practice is continually evolving to include more sophisticated and comprehensive patient care activities.

(c) The Legislature further declares that pharmacists are health care providers who have the authority to provide health care services.

(d) No state agency other than the board may define or interpret Pharmacy Law and its regulations for those licensed pursuant to the provisions of this chapter or develop standardized procedures and protocols pursuant to this chapter, unless so authorized by this chapter, or specifically required under state or federal statute. "State agency" includes every state office, officer, department, division, bureau, board, authority and commission.

Amend BPC 4051 as follows:

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052~~.1, 4052.2, 4052.3, or 4052.6,~~ and

otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient or patient's agent.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

(4) The pharmacist provides the service or activity consistent with accepted standard of care defined as the degree of care a prudent and reasonable pharmacist licensed pursuant to this chapter, with similar education, training, experience, resources, and setting would exercise in a similar situation.

Amend BPC 4036 as follows:

4036. Pharmacist "Pharmacist" means a natural person to whom a license has been issued by the board, under Section 4200, except as specifically provided otherwise in this chapter. The holder of an unexpired and active pharmacist license issued by the board is entitled to practice pharmacy as defined by this chapter, within or outside of a licensed pharmacy ~~as authorized by this chapter~~.

Amend BPC 4040 as follows:
(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order ~~pursuant to Section 4052.1, 4052.2, or 4052.6~~.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, pharmacist, or naturopathic doctor licensed in this state~~, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist~~ licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

~~4052.01.~~

~~(a) Notwithstanding any other provision of law, a pharmacist may furnish naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California, in consultation with the California Society of Addiction Medicine,~~

~~the California Pharmacists Association, and other appropriate entities. In developing those standardized procedures or protocols, the board and the Medical Board of California shall include the following:~~

~~(1) Procedures to ensure education of the person to whom the drug is furnished, including, but not limited to, opioid overdose prevention, recognition, and response, safe administration of naloxone hydrochloride, potential side effects or adverse events, and the imperative to seek emergency medical care for the patient.~~

~~(2) Procedures to ensure the education of the person to whom the drug is furnished regarding the availability of drug treatment programs.~~

~~(3) Procedures for the notification of the patient's primary care provider with patient consent of any drugs or devices furnished to the patient, or entry of appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider, and with patient consent.~~

~~(b) A pharmacist furnishing naloxone hydrochloride pursuant to this section shall not permit the person to whom the drug is furnished to waive the consultation required by the board and the Medical Board of California.~~

~~(c) Prior to performing a procedure authorized under this section, a pharmacist shall complete a training program on the use of opioid antagonists that consists of at least one hour of approved continuing education on the use of naloxone hydrochloride.~~

~~(d) The board and the Medical Board of California are each authorized to ensure compliance with this section. Each board is specifically charged with enforcing this section with respect to its respective licensees. This section does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(e) The board may adopt emergency regulations to establish the standardized procedures or protocols. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The emergency regulations authorized by this subdivision are exempt from review by the Office of Administrative Law. The emergency regulations authorized by this subdivision shall be submitted to the Office of Administrative Law for filing with the Secretary of State and shall remain in effect until the earlier of 180 days following their effective date or the effective date of regulations adopted pursuant to subdivision (a).~~

~~*(Added by Stats. 2014, Ch. 326, Sec. 1. (AB 1535) Effective January 1, 2015.)*~~

~~4052.02.~~

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~~(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.~~
~~(b) For purposes of this section, "preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.~~
~~(c) For purposes of this section, "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.~~
~~(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.~~
~~(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:~~

~~(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.~~

~~(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.~~

~~(3) The patient does not report taking any contraindicated medications.~~

~~(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects,~~

~~safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of childbearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.~~

~~(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.~~

~~(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.~~

~~(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.~~

~~(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.~~
~~(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.~~
~~*(Amended by Stats. 2020, Ch. 370, Sec. 5. (SB 1371) Effective January 1, 2021.)*~~

~~4052.03.~~
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~~(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.~~
~~(b) For purposes of this section, "postexposure prophylaxis" means any of the following:~~

~~(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.~~

~~(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.~~

~~(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.~~

~~(c) For purposes of this section, "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.~~

~~(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.~~

~~(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:~~

~~(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.~~

~~(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.~~

~~(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The~~

pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.
(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.
(Added by Stats. 2019, Ch. 532, Sec. 3. (SB 159) Effective January 1, 2020.)

4052.1.
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(a) Notwithstanding any other provision of law, a pharmacist may perform the following procedures or functions in a licensed health care facility in accordance with policies, procedures, or protocols developed by health professionals, including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator:
(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to an order or authorization made by the patient's prescriber and in accordance with the policies, procedures, or protocols of the licensed health care facility.

(b) Prior to performing any procedure authorized by this section, a pharmacist shall have received appropriate training as prescribed in the policies and procedures of the licensed health care facility.

(Added by Stats. 2006, Ch. 777, Sec. 5. Effective January 1, 2007.)

4052.2.

(a) Notwithstanding any other law, a pharmacist may perform the following procedures or functions as part of the care provided by a health care facility, a licensed home health agency, licensed correctional clinic, a licensed clinic in which there is physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, in accordance with the policies, procedures, or protocols of that facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician, and in accordance with subdivision (c):

(1) Ordering or performing routine drug therapy-related patient assessment procedures including temperature, pulse, and respiration.

(2) Ordering drug therapy-related laboratory tests.

(3) Administering drugs and biologicals by injection pursuant to a prescriber's order.

(4) Initiating or adjusting the drug regimen of a patient pursuant to a specific written order or authorization made by the individual patient's treating prescriber, and in accordance with the policies, procedures, or protocols of the health care facility, home health agency, licensed correctional clinic, licensed clinic, health care service plan, or physician. Adjusting the drug regimen does not include substituting or selecting a different drug, except as authorized by the protocol. The pharmacist shall provide written notification to the patient's treating prescriber, or enter the appropriate information in an electronic patient record system shared by the prescriber, of any drug regimen initiated pursuant to this paragraph within 24 hours.

(b) A patient's treating prescriber may prohibit, by written instruction, any adjustment or change in the patient's drug regimen by the pharmacist.
(c) The policies, procedures, or protocols referred to in this subdivision shall be developed by health care professionals, including physicians, pharmacists, and registered nurses, and shall, at a minimum, do all of the following:

(1) Require that the pharmacist function as part of a multidisciplinary group that includes physicians and direct care registered nurses. The multidisciplinary group shall determine the appropriate participation of the pharmacist and the direct care registered nurse.

(2) Require that the medical records of the patient be available to both the patient's treating prescriber and the pharmacist.

(3) Require that the procedures to be performed by the pharmacist relate to a condition for which the patient has first been seen by a physician.

(4) Except for procedures or functions provided by a health care facility, a licensed correctional clinic, as defined in Section 4187, a licensed clinic in which there is physician oversight, or a provider who contracts with a licensed health care plan with regard to the care or services provided to the enrollees of that health care service plan, require the procedures to be performed in accordance with a written, patient-specific protocol approved by the treating or supervising physician. Any change, adjustment, or modification of an approved preexisting treatment or drug therapy shall be provided in writing to the treating or supervising physician within 24 hours.

(d) Prior to performing any procedure authorized by this section, a pharmacist shall have done either of the following:

(1) Successfully completed clinical residency training.

(2) Demonstrated clinical experience in direct patient care delivery.

(Amended by Stats. 2019, Ch. 497, Sec. 5. (AB 991) Effective January 1, 2020.)

4052.3.

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(a) (1) Notwithstanding any other law, a pharmacist may furnish self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically

~~charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:~~

~~(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.~~

~~(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.~~

~~(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.~~

~~(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.~~

(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.

(c) For each emergency contraception drug therapy or self-administered hormonal contraception initiated pursuant to this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations. *(Amended by Stats. 2013, Ch. 469, Sec. 7. (SB 493) Effective January 1, 2014.)*

4052.4.

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(a) Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5 or 1206.6. For purposes of this section, "routine patient assessment procedures" means: (a) procedures that a patient could, with or without a prescription, perform for themselves, or (b) clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, as authorized by paragraph (11) of subdivision (a) of Section 1206.5 or Section 1206.6. A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. Any pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

(b) A pharmacist may perform any aspect of any FDA-approved or -authorized test that is classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration, under all of the following conditions:

(1) The test meets the criteria in subparagraph (A) or (B) and does not require the use of specimens collected by vaginal swab, venipuncture, or the collection of seminal fluid.

~~(A) The test is used to detect or screen for any of the following illnesses, conditions, or diseases:~~

~~(i) SARS-CoV-2 or other respiratory illness, condition or disease.~~

~~(ii) Mononucleosis.~~

~~(iii) Sexually transmitted infection.~~

~~(iv) Strep throat.~~

~~(v) Anemia.~~

~~(vi) Cardiovasular health.~~

~~(vii) Conjunctivitis.~~

~~(viii) Urinary tract infection.~~

~~(ix) Liver and kidney function or infection.~~

~~(x) Thyroid function.~~

~~(xi) Substance use disorder.~~

~~(xii) Diabetes.~~

~~(B) Other tests classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal Health Care Financing Administration and approved by the board by regulation, in conjunction with the Medical Board of California and Laboratory Field Services in the State Department of Public Health.~~

~~(2) The pharmacist completes the testing in a pharmacy laboratory that is appropriately licensed in California as a laboratory pursuant to Section 1265, unless otherwise authorized in law.~~

~~(3) The pharmacist has completed necessary training as specified in the pharmacy's policies and procedures maintained pursuant to subdivision (b) of Section 4119.10, and that allows the pharmacist to demonstrate sufficient knowledge of the illness, condition, or disease being tested, as applicable.~~

~~*(Amended by Stats. 2021, Ch. 604, Sec. 3. (SB 409) Effective January 1, 2022.)*~~

~~4052.5.~~

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~~(a) In addition to the authority allowed under Section 4073, a pharmacist filling a prescription order for a drug product may select a different form of medication with the same active chemical ingredients of equivalent strength and duration of therapy as the prescribed drug product when the change will improve the ability of the patient to comply with the prescribed drug therapy.~~
~~(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute" or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute" if the prescriber personally initials the box or checkmark.~~
~~(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The pharmacist who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product using the prescribed form of medication. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section.~~
~~(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.~~
~~(e) When a substitution is made pursuant to this section, the use of the different form of medication shall be communicated to the patient, and the name of the dispensed drug product shall be indicated on the prescription label, unless the prescriber orders otherwise.~~
~~(f) This section shall not permit substitution between long-acting and short-acting forms of a medication with the same chemical ingredients or between one drug product and two or more drug products with the same chemical ingredients.~~
~~*(Added by Stats. 2001, Ch. 631, Sec. 1. Effective January 1, 2002.)*~~

~~4052.7.~~

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~~(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.~~
~~(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:~~
~~(1) All the information required by Section 4076.~~

(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.
(Added by Stats. 2001, Ch. 728, Sec. 27. Effective January 1, 2002.)

4052.8.

(a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer any vaccine that has been approved or authorized by the federal Food and Drug Administration and received a federal Advisory Committee on Immunization Practices individual vaccine recommendation published by the federal Centers for Disease Control and Prevention (CDC) for persons three years of age and older.
(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:
(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.
(Amended by Stats. 2021, Ch. 655, Sec. 1. (AB 1064) Effective January 1, 2022.)

4052.9.

~~(a) A pharmacist may furnish nicotine replacement products approved by the federal Food and Drug Administration for use by prescription only in accordance with standardized procedures and protocols developed and approved by both the board and the Medical Board of California in consultation with other appropriate entities and provide smoking cessation services if all of the following conditions are met:~~

~~(1) The pharmacist maintains records of all prescription drugs and devices furnished for a period of at least three years for purposes of notifying other health care providers and monitoring the patient.~~

~~(2) The pharmacist notifies the patient's primary care provider of any drugs or devices furnished to the patient, or enters the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist provides the patient with a written record of the drugs or devices furnished and advises the patient to consult a physician of the patient's choice.~~

~~(3) The pharmacist is certified in smoking cessation therapy by an organization recognized by the board.~~

~~(4) The pharmacist completes one hour of continuing education focused on smoking cessation therapy biennially.~~

~~(b) The board and the Medical Board of California are both authorized to ensure compliance with this section, and each board is specifically charged with the enforcement of this section with respect to their respective licensees. Nothing in this section shall be construed to expand the authority of a pharmacist to prescribe any other prescription medication.~~
~~*(Added by Stats. 2013, Ch. 469, Sec. 10. (SB 493) Effective January 1, 2014.)*~~

Amend BPC 4064 as follows:
(a) A prescription for a dangerous drug or dangerous device may be refilled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to this section.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any refills dispensed pursuant to this section.

~~(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record, including the basis for proceeding under this section.~~

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

~~(g) During a proclaimed state of emergency, nothing in either this section or any other provision of this chapter prohibits a pharmacist, a clinic licensed under Section 4180, or a mobile pharmacy or clinic described in subdivision (c) of Section 4062 from refilling a prescription if the prescriber is unavailable, or if after a reasonable effort has been made, the pharmacist, clinic, or mobile pharmacy is unable to contact the prescriber.~~

Amend BPC 4064.5 as follows**:**
(a) A pharmacist may dispense not more than a 90-day supply of a dangerous drug other than a controlled substance pursuant to a valid prescription that specifies an initial quantity of less than a 90-day supply followed by periodic refills of that amount if all of the following requirements are satisfied:

(1) The patient has completed an initial 30-day supply of the dangerous drug.

(2) The total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills.

(3) The prescriber has not specified on the prescription that dispensing the prescription in an initial amount followed by periodic refills is medically necessary.

(4) The pharmacist is exercising his or her professional judgment.

(b) For purposes of this section, if the prescription continues the same medication as previously dispensed in a 90-day supply, the initial 30-day supply under paragraph (1) of subdivision (a) is not required.

(c) A pharmacist dispensing an increased supply of a dangerous drug pursuant to this section shall notify the prescriber of the increase in the quantity of dosage units dispensed.

~~(d) In no case shall a pharmacist dispense a greater supply of a dangerous drug pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "No change to quantity," or words of similar meaning.~~

~~Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "No change to quantity," provided that the prescriber personally initials the box or checkmark. To indicate that an increased supply shall not be dispensed pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "No change to quantity," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "No change to quantity." In either instance, it shall not be required that the prohibition on an increased supply be manually initialed by the prescriber.~~

(e) This section shall not apply to psychotropic medication or psychotropic drugs as described in subdivision (d) of Section 369.5 of the Welfare and Institutions Code.

(f) Except for the provisions of subdivision (d), this section does not apply to FDA-approved, self-administered hormonal contraceptives.

(1) A pharmacist shall <u>furnish</u> or dispense, at a patient's request, up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills.

~~(2) A pharmacist furnishing an FDA-approved, self-administered hormonal contraceptive pursuant to Section 4052.3 under protocols developed by the Board of Pharmacy may furnish, at the patient's request, up to a 12-month supply at one time.~~

(3) Nothing in this subdivision shall be construed to require a pharmacist to dispense or furnish a drug if it would result in a violation of Section 733.

(g) Nothing in this section shall be construed to require a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including, but not limited to, a state program or state employer, to provide coverage for a dangerous drug in a manner inconsistent with a beneficiary's plan benefit.

~~4073.~~

~~(a) A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients.~~

(b) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning. Nothing in this subdivision shall prohibit a prescriber from checking a box on a prescription marked "Do not substitute"; provided that the prescriber personally initials the box or checkmark. To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.

(c) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (b). The person who selects the drug product to be dispensed pursuant to this section shall assume the same responsibility for selecting the dispensed drug product as would be incurred in filling a prescription for a drug product prescribed by generic name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a drug product pursuant to this section. In no case shall the pharmacist select a drug product pursuant to this section unless the drug product selected costs the patient less than the prescribed drug product. Cost, as used in this subdivision, is defined to include any professional fee that may be charged by the pharmacist.

(d) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the California Medical Assistance Program set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(e) When a substitution is made pursuant to this section, the use of the cost-saving drug product dispensed shall be communicated to the patient and the name of the dispensed drug product shall be indicated on the prescription label, except where the prescriber orders otherwise.

4073.5.

(a) A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:

(1) The alternative biological product is interchangeable.

(2) The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision (d).

(b) Within five days following the dispensing of a biological product, a dispensing pharmacist or the pharmacists' designee shall make an entry of the specific biological product provided to the patient, including the name of the

~~biological product and the manufacturer. The communication shall be conveyed by making an entry that can be electronically accessed by the prescriber through one or more of the following electronic records systems:~~

~~(1) An interoperable electronic medical records system.~~

~~(2) An electronic prescribing technology.~~

~~(3) A pharmacy benefit management system.~~

~~(4) A pharmacy record.~~

~~(c) Entry into an electronic records system as described in subdivision (b) is presumed to provide notice to the prescriber.~~

~~(d) If the pharmacy does not have access to one or more of the entry systems in subdivision (b), the pharmacist or the pharmacist's designee shall communicate the name of the biological product dispensed to the prescriber using facsimile, telephone, electronic transmission, or other prevailing means, except that communication shall not be required in this instance to the prescriber when either of the following apply:~~

~~(1) There is no interchangeable biological product approved by the federal Food and Drug Administration for the product prescribed.~~

~~(2) A refill prescription is not changed from the product dispensed on the prior filling of the prescription.~~

~~(e) In no case shall a selection be made pursuant to this section if the prescriber personally indicates, either orally or in his or her own handwriting, "Do not substitute," or words of similar meaning.~~

~~(1) This subdivision shall not prohibit a prescriber from checking a box on a prescription marked "Do not substitute," provided that the prescriber personally initials the box or checkmark.~~

~~(2) To indicate that a selection shall not be made pursuant to this section for an electronic data transmission prescription, as defined in subdivision (c) of Section 4040, a prescriber may indicate "Do not substitute," or words of similar meaning, in the prescription as transmitted by electronic data, or may check a box marked on the prescription "Do not substitute." In either instance, it shall not be required that the prohibition on substitution be manually initialed by the prescriber.~~

~~(f) Selection pursuant to this section is within the discretion of the pharmacist, except as provided in subdivision (e). A pharmacist who selects an alternative biological product to be dispensed pursuant to this section shall assume the~~

same responsibility for substituting the biological product as would be incurred in filling a prescription for a biological product prescribed by name. There shall be no liability on the prescriber for an act or omission by a pharmacist in selecting, preparing, or dispensing a biological product pursuant to this section. In no case shall the pharmacist select a biological product that meets the requirements of subdivision (a) unless the cost to the patient of the biological product selected is the same or less than the cost of the prescribed biological product. Cost, as used in this subdivision, includes any professional fee that may be charged by the pharmacist.

(g) This section shall apply to all prescriptions, including those presented by or on behalf of persons receiving assistance from the federal government or pursuant to the Medi-Cal Act set forth in Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code.

(h) When a selection is made pursuant to this section, the substitution of a biological product shall be communicated to the patient.

(i) The board shall maintain on its public Internet Web site a link to the current list, if available, of biological products determined by the federal Food and Drug Administration to be interchangeable.

(j) For purposes of this section, the following terms shall have the following meanings:

(1) "Biological product" has the same meaning that applies to that term under Section 351 of the federal Public Health Service Act (42 U.S.C. Sec. 262(i)).

(2) "Interchangeable" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in Section 262(k)(4) of Title 42 of the United States Code, or has been deemed therapeutically equivalent by the federal Food and Drug Administration as set forth in the latest addition or supplement of the Approved Drug Products with Therapeutic Equivalence Evaluations.

(3) "Prescription," with respect to a biological product, means a prescription for a product that is subject to Section 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 353(b)).

(k) This section shall not prohibit the administration of immunizations, as permitted in Sections 4052 and 4052.8.

(l) This section shall not prohibit a disability insurer or health care service plan from requiring prior authorization or imposing other appropriate utilization controls in approving coverage for any biological product.

Add 4119.3.

(a) A pharmacy may, at a patient's request, repackage a drug previously dispensed to the patient or to the patient's agent pursuant to a prescription.
(b) Any pharmacy providing repackaging services shall have in place policies and procedures for repackaging these drugs and shall label the repackaged prescription container with the following:

(1) All the information required by Section 4076.

(2) The name and address of the pharmacy repackaging the drug and the name and address of the pharmacy that initially dispensed the drug to the patient.

(c) The repackaging pharmacy and the pharmacy that initially dispensed the drug shall only be liable for its own actions in providing the drug to the patient or the patient's agent.

Attachment 11

Proposed section 4040.6 Self-Assessment Process Definition

"Self-assessment process" means the process of self-evaluation of a facility's compliance with state and federal laws as a means to promote compliance through self-examination and education. The self-assessment process is performed on a form approved by the board and posted on its website.

Proposed section 4102 Self-Assessment Requirement

(a) As provided in this section, all facilities licensed by the board must complete the self-assessment process on a form provided by the board by July 1 of every odd year, unless otherwise established in this section.

(b) The form must be completed to assess the facility's compliance with federal and state laws identified on the form. For each "no" response, a written corrective action or action plan to come into compliance with the law is required. The form shall be signed by the designated individual as defined in this section and co-signed by the owner or authorized officer of the facility acknowledging they have read, reviewed, and completed the self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the board. The completed form shall be signed under penalty of perjury and kept on file in the facility and made available to the board or its designee, upon request.

(c) The facility must use the appropriate designated form based on the type of license and as described in this section and posted on the board's website.

1. Community Pharmacy Self-Assessment/Hospital Outpatient Self-Assessment must be completed by the pharmacist-in-charge. In addition to the requirements in subdivision (a), the form must be completed within 30 days of any of the following:
    A. A new pharmacy license is issued, or
    B. There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy, or
    C. There is a change in the location of a pharmacy to a new address.
2. Hospital Pharmacy Self-Assessment must be completed by the pharmacist-in-charge. In addition, to the requirements in subdivision (a), the form must be completed within 30 days of any of the following:
    A. A new pharmacy license is issued, or
    B. There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy, or
    C. There is a change in the location of a pharmacy to a new address.
3. Automated Drug Delivery System Self-Assessment must be completed by the pharmacist-in-charge of the pharmacy operating the system. In addition, to the requirements in subdivision (a), the form must be completed within 30 days of any of the following:

A. A new pharmacy license is issued, or
B. There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy, or
C. There is a change in the location of a pharmacy to a new address.

4. Compounding Self-Assessment form must be completed by the pharmacist-in-charge of each pharmacy that compounds drug products. In addition, to the requirements in subdivision (a), the form must be completed within 30 days of any of the following:
    A. A new pharmacy license is issued, or
    B. There is a change of pharmacist-in-charge, and they become the new pharmacist-in-charge of a pharmacy, or
    C. There is a change in the location of a pharmacy to a new address.
5. Surgical Clinic Self-Assessment form must be completed by the consulting pharmacist of the surgical clinic and co-signed by the professional director.
6. Wholesaler/Third-Party Logistics Provider Self-Assessment form must be completed by the designated representative-in-charge or the wholesaler or responsible manager of the third-party logistics provider. In addition to the requirements in subdivision (a), the form must be completed within 30 days of any of the following:
    A. A new license is issued, or
    B. There is a change of designated representative-in-charge or responsible manager, and they become the new designated representative-in-charge or responsible manager, or
    C. There is a change in the location to a new address.
7. Outsourcing Facility Self-Assessment form must be completed by the designated quality control personnel. In addition to the requirements in subdivision (a), the form must be completed within 30 days of any of the following:
    A. A new license is issued, or
    B. There is a change in the designated quality control personnel, or
    C. There is a change in the location to a new address.

Attachment 12

Proposal to Amend Business and Professions Code section 4115 as follows:

4115.

(a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under their supervision by a technician.

~~(b) (1) In addition to the tasks specified in subdivision (a) a pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions:~~

~~(A) The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a).~~

~~(B) The pharmacy technician is certified pursuant to paragraph (4) of subdivision (a) of Section 4202 and maintains that certification.~~

~~(C) The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique.~~

~~(D) The pharmacy technician is certified in basic life support.~~

~~(2) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).~~

(b) (1) In addition to the tasks specified in subdivision (a), and where the pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks provided in subdivision (a), a certified pharmacy technician as defined in section 4202 may, under the direct supervision and control of a pharmacist,

(A) Prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, provided that

(i)The pharmacy technician has successfully completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique prior to performing administration of vaccines.

(ii) The pharmacy technician is certified in basic life support.

(B) Perform specimen collection for tests that are classified as CLIA. "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a; Public Law 100-578).

(C) Initiate and receive prescriptions transfers and accept clarification on prescriptions.

(c) This section does not authorize the performance of any tasks specified in subdivisions (a) and (b) by a pharmacy technician without a pharmacist on duty.

(d) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(e) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(f) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(g) (1) A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (a). A pharmacy with only one pharmacist shall have no more than one pharmacy technician performing the tasks specified in subdivision (b). If a pharmacy technician is performing the tasks specified in subdivision (b), a second pharmacy technician shall be assisting a pharmacist with performing tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed 2:1, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of their professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist-in-charge in writing of their

determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(h) Notwithstanding subdivisions (a) to (c), inclusive, the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (g).

(i) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

(j) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

4113.1.

(a) Except as specified in subdivision (e), a community pharmacy licensed pursuant to this article shall report, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the board. A community pharmacy shall submit the report no later than 14 days following the date of discovery of the error. These reports are deemed confidential and are not subject to discovery, subpoena, or disclosure pursuant to the California Public Records Act (Division 10 (commencing with Section 7920.000) of Title 1 of the Government Code), except that the board may publish deidentified case summary information compiled from the data in the reports so long as deidentification is done in accordance with the requirements set forth in Section 164.514(b)(2) of Title 45 of the Code of Federal Regulations, and includes omitting the name of the reporting pharmacy. The community pharmacy shall maintain records demonstrating compliance with this requirement for three years and shall make these records immediately available at the

request of an inspector. A medication error report made pursuant to this section shall not be subject to investigation, discipline, or other enforcement action by the board based solely on a report received pursuant to this section. However, if the board receives other information regarding the medication error independent of the medication error report, that information may serve as basis for discipline or other enforcement by the board.

(b) Any entity approved by the board shall have experience with the analysis of medication errors that occur in the outpatient setting.

(c) For purposes of this section, "community pharmacy" includes any pharmacy that dispenses medication to an outpatient, but does not include facilities of the Department of Corrections and Rehabilitation.

(d) For purposes of this section, "medication error" includes any variation from a prescription drug order not authorized by the prescriber, including, but not limited to, errors involving the wrong drug, the wrong dose, the wrong patient, the wrong directions, the wrong preparation, or the wrong route of administration. A medication error does not include any variation that is corrected prior to dispensing to the patient or patient's agent or any variation allowed by law.

(e) An outpatient hospital pharmacy shall not be required to report a medication error that meets the requirements of an adverse event, as specified in subdivision (a), that has been reported to the State Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code. The State Department of Public Health may share a report with the California State Board of Pharmacy.

(f) A pharmacy licensed pursuant to Section 4112, shall only be required to report medication errors related to prescriptions dispensed to California residents.

Attachment 13

Board of Pharmacy – Remote Processing

Draft Language

Possible amendment to BPC 4071.1.

(a) A prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in Section 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. For purposes of this section, a "prescriber's authorized agent" is a person licensed or registered under Division 2 (commencing with Section 500).

(b) This section does not reduce the existing authority of other hospital personnel to enter medication orders or prescription orders into a hospital's computer.

(c) A dangerous drug or dangerous device shall not be dispensed pursuant to a prescription that has been electronically entered into a pharmacy's computer without the prior approval of a pharmacist.

(d) (1) A pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside of the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures.

(2) (A) A health care facility shall maintain a record of a pharmacist's verification of medication chart orders pursuant to this subdivision.

(B) A record maintained pursuant to subparagraph (A) shall meet the same requirements as those described in Sections 4081 and 4105.

(e) In order to enable any accredited school of pharmacy recognized by the Board to experiment with new and innovative methods for drug handling, or to develop new and better methods or concepts involving the ethical practice of pharmacy, the Board may waive the application of provisions of Pharmacy Law and its regulations applicable to remote processing of prescriptions, if the Dean of said school has filed with the Board an experimental plan or program which specifies the particular provisions to be waived, and which has been approved by the Board.

(f) The Board may adopt regulations that establish provisions for remote processing of prescriptions. At a minimum, remote processing of prescriptions may only be performed by a California licensed pharmacist, from a location within California. The regulations shall include provisions for security to protect health information, recordkeeping requirements and autonomy for the

pharmacist-in-charge to determine when such processing is allowed. For purposes of this subdivision, "remote processing of prescriptions" includes, but is not limited to, order entry, other data entry, performing prospective drug utilization review, interpreting clinical data, insurance processing, performing therapeutic interventions, providing drug information services, authorizing release of medication for administration, and patient consultation. For purposes of this subdivision, "remote processing of prescriptions" shall not include final product verification or the dispensing of a drug.

Attachment 14

Advanced Pharmacist Practitioner Proposal

4016.5.
"~~Advanced practice pharmacist~~" "Advanced Pharmacist Practitioner" means a licensed pharmacist who has been recognized as an advanced practice pharmacist by the board, pursuant to Section 4210. A board-recognized ~~advanced practice pharmacist~~ advanced pharmacist practitioner is entitled to practice advanced practice pharmacy, as described in Section 4052.6, within or outside of a licensed pharmacy as authorized by this chapter.

4040.
(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, advanced pharmacist practitioner, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician

assistant, or naturopathic doctor licensed in this state, or pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

4052.6.

(a) A pharmacist recognized by the board as an ~~advanced practice pharmacist~~ advanced pharmacist practitioner may do all of the following:

(1) Perform patient assessments.

(2) Order and interpret drug therapy-related tests.

(3) Refer patients to other health care providers.

(4) Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers.

(5) Initiate, adjust, or discontinue drug therapy.

(b) A pharmacist practitioner who adjusts or discontinues drug therapy shall promptly transmit written notification to the patient's diagnosing prescriber or enter the appropriate information in a patient record system shared with the prescriber, as permitted by that prescriber. A pharmacist practitioner who initiates drug therapy shall promptly transmit written notification to, or enter the

appropriate information into, a patient record system shared with the patient's primary care provider or diagnosing provider, as permitted by that provider.

(c) This section shall not interfere with a physician's order to dispense a prescription drug as written, or other order of similar meaning.

(d) Prior to initiating or adjusting a controlled substance therapy pursuant to this section, a pharmacist shall personally register with the federal Drug Enforcement Administration.

(e) A pharmacist practitioner who orders and interprets tests pursuant to paragraph (2) of subdivision (a) shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

4059.

(a) A person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, advanced pharmacist practitioner, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7.

(b) This section does not apply to the furnishing of any dangerous drug or dangerous device by a manufacturer, wholesaler, or pharmacy to each other or to a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7, or to a laboratory under sales and purchase records that correctly give the date, the names and addresses of the supplier and the buyer, the drug or device, and its quantity. This section does not apply to the furnishing of any dangerous device by a manufacturer, wholesaler, or pharmacy to a physical therapist acting within the scope of his or her license under sales and purchase records that correctly provide the date the device is provided, the names and addresses of the supplier and the buyer, a description of the device, and the quantity supplied.

(c) A pharmacist, or a person exempted pursuant to Section 4054, may distribute dangerous drugs and dangerous devices directly to dialysis patients pursuant to regulations adopted by the board. The board shall adopt any regulations as are necessary to ensure the safe distribution of these drugs and devices to dialysis patients without interruption thereof. A person who violates a regulation adopted pursuant to this subdivision shall be liable upon order of the board to surrender his or her personal license. These penalties shall be in addition to penalties that may be imposed pursuant to Section 4301. If the

board finds any dialysis drugs or devices distributed pursuant to this subdivision to be ineffective or unsafe for the intended use, the board may institute immediate recall of any or all of the drugs or devices distributed to individual patients.

(d) Home dialysis patients who receive any drugs or devices pursuant to subdivision (c) shall have completed a full course of home training given by a dialysis center licensed by the State Department of Public Health. The physician prescribing the dialysis products shall submit proof satisfactory to the manufacturer or wholesaler that the patient has completed the program.

(e) A pharmacist may furnish a dangerous drug authorized for use pursuant to Section 2620.3 to a physical therapist. A record containing the date, name and address of the buyer, and name and quantity of the drug shall be maintained. This subdivision shall not be construed to authorize the furnishing of a controlled substance.

(f) A pharmacist may furnish electroneuromyographic needle electrodes or hypodermic needles used for the purpose of placing wire electrodes for kinesiological electromyographic testing to physical therapists who are certified by the Physical Therapy Board of California to perform tissue penetration in accordance with Section 2620.5.

(g) Nothing in this section shall be construed as permitting a licensed physical therapist to dispense or furnish a dangerous device without a prescription of a physician, dentist, podiatrist, optometrist, or veterinarian.

(h) A veterinary food-animal drug retailer shall dispense, furnish, transfer, or sell veterinary food-animal drugs only to another veterinary food-animal drug retailer, a pharmacy, a veterinarian, or to a veterinarian's client pursuant to a prescription from the veterinarian for food-producing animals.

4210.

(a) A person who seeks recognition as an ~~advanced practice pharmacist~~ advanced pharmacist practitioner 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) (A) Satisfy any two of the following criteria:

(i) 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.

(ii) 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.

(iii) 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.

(B) For purposes of this paragraph, if, as a condition of completion of one of the required criteria fulfillment of a second criterion is also required, that completion shall be deemed to satisfy this paragraph.

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

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

~~(d) This section shall become operative on January 1, 2025.~~

4211.

(a) An applicant for renewal of an ~~advanced practice pharmacist~~ advanced pharmacist practitioner ~~recognition~~ license shall maintain a current and active pharmacist license, and shall submit all of the following as part of the renewal:

(1) Application and payment of the renewal fees.

(2) (A) Proof satisfactory to the board that the licensee has completed 10 hours of continuing education pursuant to Section 4233.

(B) The 10 hours shall be in addition to the continuing education requirements necessary for a pharmacist license renewal pursuant to Section 4231.

(C) An ~~advanced practice pharmacist~~ advanced pharmacist practitioner shall retain documentation of completion of continuing education for four years.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an ~~advanced practice pharmacist~~ advanced pharmacist practitioner ~~recognition~~ license.

(c) The board may issue an inactive ~~advanced practice pharmacist~~ advanced pharmacist practitioner recognition under any of the following conditions:

(1) The pharmacist's license becomes inactive.

(2) The ~~advanced practice pharmacist~~ advanced pharmacist practitioner fails to provide documentation of the completion of the required continuing education.

(3) As part of an investigation or audit conducted by the board, the advanced practice pharmacist fails to provide documentation substantiating the completion of continuing education.

(d) The board shall reactivate an inactive ~~advanced practice pharmacist~~ advanced pharmacist practitioner ~~recognition~~ license only if the ~~advanced practice pharmacist~~ advanced pharmacist practitioner pays the required renewal fees pursuant to Section 4210, submits satisfactory proof to the board of completion of the continuing education requirements under Section 4233, and meets all renewal requirements in this section.

4233.

A pharmacist who is recognized as an ~~advanced practice pharmacist~~ advanced pharmacist practitioner shall complete 10 hours of continuing education each renewal cycle in addition to the requirements of Section 4231. The subject matter shall be in one or more areas of practice relevant to the pharmacist's clinical practice.

4400.

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

…

(ae) The fee for an application for an ~~advanced practice pharmacist~~ advanced pharmacist practitioner license and renewal of ~~advanced practice~~

~~pharmacist~~ advanced pharmacist practitioner license shall be three hundred dollars ($300) and may be increased to four hundred eighteen dollars ($418).

Attachment 15

Proposal to Amend Business and Professions Code section 4081

(a) All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every manufacturer, wholesaler, third-party logistics provider, pharmacy, veterinary food-animal drug retailer, outsourcing facility, physician, dentist, podiatrist, veterinarian, laboratory, licensed correctional clinic, as defined in Section 4187, clinic, hospital, institution, or establishment holding a currently valid and unrevoked certificate, license, permit, registration, or exemption under Division 2 (commencing with Section 1200) of the Health and Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and Institutions Code who maintains a stock of dangerous drugs or dangerous devices.

(b) The owner, officer, and partner of a pharmacy, wholesaler, third-party logistics provider, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge, responsible manager, or designated representative-in-charge, for maintaining the records and inventory described in this section.

(c) The pharmacist-in-charge, responsible manager, or designated representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge, responsible manager, or designated representative-in-charge had no knowledge, or in which he or she did not knowingly participate.

(d) Pharmacies that dispense nonprescription diabetes test devices pursuant to prescriptions shall retain records of acquisition and sale of those nonprescription diabetes test devices for at least three years from the date of making. The records shall be at all times during business hours open to inspection by authorized officers of the law.

(e) In addition to the records described in subdivision (a) records that must be maintained include staffing schedules, pharmacy personnel job duty statements, consultant reports, and policies and procedures related to pharmacy personnel and pharmacy operations. Records that are described in subdivision (e) that are maintained electronically must provide an audit trail for revisions and updates of each record document. Prior versions of each record must be maintained in a readily retrievable format and include changes to the document, identification of the individual who made the change, and the date of each change.

Proposal to amend BPC 4105

(a) All records or other documentation required by this Chapter ~~of the acquisition and disposition of dangerous drugs and dangerous devices~~ to be maintained by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

Attachment 16

Proposal to amend BPC 4105

(a) All records or other documentation required by this Chapter ~~of the acquisition and disposition of dangerous drugs and dangerous devices~~ to be maintained by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.

(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.

(c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making. Paper records may be converted into a digital format and maintained only in a non-editable format. Certification that the digitized documents have not been altered may be required by the Board.

(d) (1) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hardcopy, digitized copy or ~~and~~ electronic copy of all records required by this Chapter ~~of acquisition or disposition or other drug or dispensing-related records~~ maintained electronically.

(2) In the case of a veterinary food-animal drug retailer, wholesaler, or third-party logistics provider, any records that are maintained electronically shall be maintained so that the designated representative-in-charge or the responsible manager, or the designated representative on duty or the designated representative-3PL on duty if the designated representative-in-charge or responsible manager is not on duty, shall, at all times during which the licensed place of business is open for business, be able to produce a hardcopy, digitized copy or ~~and~~ electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

(e) (1) Notwithstanding subdivisions (a), (b), and (c), the board may, upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter.

(f) When requested by an authorized officer of the law or by an authorized representative of the board, the owner, corporate officer, or manager of an entity licensed by the board shall provide the board with the requested records

within three business days of the time the request was made. The entity may request in writing an extension of this timeframe for a period not to exceed 14 calendar days from the date the records were requested. A request for an extension of time is subject to the approval of the board. An extension shall be deemed approved if the board fails to deny the extension request within two business days of the time the extension request was made directly to the board.

Attachment 17

4040.

(a) "Prescription" means an oral, written, or electronic transmission order that is both of the following:

(1) Given individually for the person or persons for whom ordered that includes all of the following:

(A) The name or names and address of the patient or patients.

(B) The name and quantity of the drug or device prescribed and the directions for use.

(C) The date of issue.

(D) Either rubber stamped, typed, or printed by hand or typeset, the name, address, and telephone number of the prescriber, the prescriber's license classification, and the prescriber's federal registry number, if a controlled substance is prescribed.

(E) A legible, clear notice of the condition or purpose for which the drug is being prescribed, if requested by the patient or patients.

(F) If in writing, signed by the prescriber issuing the order, or the certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor who issues a drug order pursuant to Section 2746.51, 2836.1, 3502.1, or 3640.5, respectively, or issued by a pharmacist licensed in this state as authorized by this Chapter. ~~the pharmacist who issues a drug order pursuant to Section 4052.1, 4052.2, or 4052.6~~.

(2) Issued by a physician, dentist, optometrist, doctor of podiatric medicine, veterinarian, nurse practitioner practicing pursuant to Section 2837.103 or 2837.104, or naturopathic doctor pursuant to Section 3640.7 or, if a drug order is issued pursuant to Section 2746.51, 2836.1, 3502.1, or 3460.5, by a certified nurse-midwife, nurse practitioner, physician assistant, or naturopathic doctor licensed in this state, or issued by a pharmacist licensed in this state as authorized by this Chapter.~~pursuant to Section 4052.1, 4052.2, or 4052.6 by a pharmacist licensed in this state.~~

(b) Notwithstanding subdivision (a), a written order of the prescriber for a dangerous drug, except for any Schedule II controlled substance, that contains at least the name and signature of the prescriber, the name and address of the patient in a manner consistent with paragraph (2) of subdivision (a) of Section 11164 of the Health and Safety Code, the name and quantity of the drug prescribed, directions for use, and the date of issue may be treated as a prescription by the dispensing pharmacist as long as any additional information required by subdivision (a) is readily retrievable in the pharmacy. In the event of a conflict between this subdivision and Section 11164 of the Health and Safety Code, Section 11164 of the Health and Safety Code shall prevail.

(c) "Electronic transmission prescription" includes both image and data prescriptions. "Electronic image transmission prescription" means any prescription order for which a facsimile of the order is received by a pharmacy from a licensed prescriber. "Electronic

data transmission prescription" means any prescription order, other than an electronic image transmission prescription, that is electronically transmitted from a licensed prescriber to a pharmacy.

(d) The use of commonly used abbreviations shall not invalidate an otherwise valid prescription.

4051.

(a) Except as otherwise provided in this chapter, it is unlawful for any person to manufacture, compound, furnish, sell, or dispense a dangerous drug or dangerous device, or to dispense or compound a prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, as authorized by this Chapter ~~pursuant to Section 4052.1, 4052.2, 4052.3, or 4052.6~~, and otherwise provide clinical advice, services, information, or patient consultation, as set forth in this chapter, if all of the following conditions are met:

(1) The clinical advice, services, information, or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

Attachment 18

Proposal to amend BPC 4052.3 as follows:

4052.3.
(a) (1) Notwithstanding any other law, a pharmacist may furnish prescription-only self-administered hormonal contraceptives in accordance with standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The standardized procedure or protocol shall require that the patient use a self-screening tool that will identify patient risk factors for use of self-administered hormonal contraceptives, based on the current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use developed by the federal Centers for Disease Control and Prevention, and that the pharmacist refer the patient to the patient's primary care provider or, if the patient does not have a primary care provider, to nearby clinics, upon furnishing a prescription-only self-administered hormonal contraceptive pursuant to this subdivision, or if it is determined that use of a self-administered hormonal contraceptive is not recommended.

(2) The board and the Medical Board of California are both authorized to ensure compliance with this subdivision, and each board is specifically charged with the enforcement of this subdivision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(b) (1) Notwithstanding any other law, a pharmacist may furnish emergency contraception drug therapy in accordance with either of the following:

(A) Standardized procedures or protocols developed by the pharmacist and an authorized prescriber who is acting within his or her scope of practice.

(B) Standardized procedures or protocols developed and approved by both the board and the Medical Board of California in consultation with the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other appropriate entities. The board and the Medical Board of California are both authorized to ensure compliance with this clause, and each board is specifically charged with the enforcement of this provision with respect to its respective licensees. This subdivision does not expand the authority of a pharmacist to prescribe any prescription medication.

(2) Prior to performing a procedure authorized under this subdivision, a pharmacist shall complete a training program on emergency contraception that consists of at least one hour of approved continuing education on emergency contraception drug therapy.

(3) A pharmacist, pharmacist's employer, or pharmacist's agent shall not directly charge a patient a separate consultation fee for emergency contraception drug therapy services initiated pursuant to this subdivision, but may charge an administrative fee not to exceed ten dollars ($10) above the retail cost of the drug. Upon an oral, telephonic, electronic, or written request from a patient or customer, a

pharmacist or pharmacist's employee shall disclose the total retail price that a consumer would pay for emergency contraception drug therapy. As used in this paragraph, total retail price includes providing the consumer with specific information regarding the price of the emergency contraception drugs and the price of the administrative fee charged. This limitation is not intended to interfere with other contractually agreed-upon terms between a pharmacist, a pharmacist's employer, or a pharmacist's agent, and a health care service plan or insurer. Patients who are insured or covered and receive a pharmacy benefit that covers the cost of emergency contraception shall not be required to pay an administrative fee. These patients shall be required to pay copayments pursuant to the terms and conditions of their coverage. This paragraph shall become inoperative for dedicated emergency contraception drugs if these drugs are reclassified as over-the-counter products by the federal Food and Drug Administration.

(4) A pharmacist shall not require a patient to provide individually identifiable medical information that is not specified in Section 1707.1 of Title 16 of the California Code of Regulations before initiating emergency contraception drug therapy pursuant to this subdivision.

(c) For each emergency contraception drug therapy or prescription-only self-administered hormonal contraception initiated pursuant to subdivisions (a) or (b) of this section, the pharmacist shall provide the recipient of the drug with a standardized factsheet that includes, but is not limited to, the indications and contraindications for use of the drug, the appropriate method for using the drug, the need for medical followup, and other appropriate information. The board shall develop this form in consultation with the State Department of Public Health, the American Congress of Obstetricians and Gynecologists, the California Pharmacists Association, and other health care organizations. This section does not preclude the use of existing publications developed by nationally recognized medical organizations.

(d) Notwithstanding any other law, a pharmacist may furnish FDA-approved over-the-counter contraceptives without the need to comply with the standardized procedures or protocols required by subdivision (a)(1) for prescription-only self-administered hormonal contraceptives.

Attachment 19

Board of Pharmacy – Ownership Prohibitions

Draft Language

Possible amendment to BPC Section 4111

(a) Except as otherwise provided in subdivision (b), (d), or (e), the board shall not issue or renew a license to conduct a pharmacy to any of the following:

(1) A person or persons authorized to prescribe or write a prescription, as specified in Section 4040, in the State of California.

(2) A person or persons with whom a person or persons specified in paragraph (1) shares a community or other financial interest in the permit sought unless both the person or persons specified in paragraph (1) and the person seeking a license to conduct pharmacy provide statements disavowing any community or financial interest on behalf of the person or persons specified in paragraph (1) and transmute any such community property under the Family Law Codes of the State of California into the separate property of the person seeking a license to conduct pharmacy. In addition, the pharmacy seeking a license with an owner specified in paragraph (1) if such license is granted, shall be prohibited from filling any prescriptions, emergency or otherwise issued or prescribed by the person or persons specified in paragraph (1) or another prescriber at the same place of business as the person specified in paragraph (1) if the prescriber owns a greater than 10% interest in the practice issuing the prescription.

(3) Any corporation that is controlled by, or in which 10 percent or more of the stock is owned by a person or persons prohibited from pharmacy ownership by paragraph (1) or (2).

(b) Subdivision (a) shall not preclude the issuance of a permit for an inpatient hospital pharmacy to the owner of the hospital in which it is located.

(c) The board may require any information the board deems is reasonably necessary for the enforcement of this section.

(d) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a person licensed on or before August 1, 1981, under the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code) and qualified on or before August 1, 1981, under subsection (d) of Section 1310 of Title XIII of the federal Public Health Service Act, as amended, whose ownership includes persons defined pursuant to paragraphs (1) and (2) of subdivision (a).

(e) Subdivision (a) shall not preclude the issuance of a new or renewal license for a pharmacy to be owned or owned and operated by a pharmacist

authorized to issue a drug order ~~pursuant to Section 4052.1, 4052.2, or 4052.6~~ under the following conditions:

1. The pharmacist issuing the drug order offers to provide a prescription to the patient that the patient may elect to have filled by a pharmacy of the patient's choice unless prohibited by the collaborative practice agreement.
2. The pharmacist issuing the drug order must provide a full patient consultation prior to issuing the drug order.

Attachment 20

Proposed Amendments Related to Retired Pharmacist License

Business and Professions Code Section 4200.5 is amended as follows:
4200.5.

(a) The board shall issue, upon application and payment of the fee established by Section 4400, a retired license to a pharmacist who has been licensed by the board. The board shall not issue a retired license to a pharmacist whose license has been revoked.

(b) The holder of a retired license issued pursuant to this section shall not engage in any activity for which an active pharmacist's license is required. A pharmacist holding a retired license shall be permitted to use the titles "retired pharmacist" or "pharmacist, retired."

(c) The holder of a retired license shall not be required to renew that license.

(d) The holder of a retired license may request to restore their pharmacist license to active status within three years of issuance of the retired license. Such a request must be accompanied by the renewal fee established by Section 4400(e) and demonstration that, within the two years preceding the request for restoration, the pharmacist has successfully completed continuing education consistent with the requirements set forth in Section 4231(b).

(e) If more than three years have elapsed since the issuance of the retired license, ~~I~~in order for the holder of a retired license issued pursuant to this section to restore their ~~his or her~~ license to active status, they~~he or she~~ shall be required to reapply for licensure as a pharmacist as consistent with the provisions of 4200. ~~pass the examination that is required for initial licensure with the board.~~

Attachment 21

Proposed Amendments Related to Pharmacy Technician Trainees

Business and Professions Code Section 4038 is amended as follows:
4038.
(a) "Pharmacy technician" means an individual who assists a pharmacist in a pharmacy in the performance of his or her pharmacy related duties, as specified in Section 4115.

(b) A "pharmacy technician trainee" is a person who is enrolled in a pharmacy technician training program operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary and Vocational Education or an accredited employer-based pharmacy technician training program.

Business and Professions Code Section 4115.5 is amended as follows:
4115.5.
(a) Notwithstanding any other law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by the training program ~~by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution~~.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no fewer than 120 hours and no more than 140 hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to 340 hours.

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in ~~a course of instruction at the institution~~the training program.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates the pharmacy technician trainee's status as a trainee.