BACKGROUND PAPER FOR
The California State Board of Pharmacy

Joint Sunset Review Oversight Hearing, March 11, 2025
Assembly Committee on Business and Professions and the
Senate Committee on Business, Professions, and Economic Development

IDENTIFIED ISSUES, BACKGROUND, AND RECOMMENDATIONS

CURRENT SUNSET REVIEW ISSUES FOR THE CALIFORNIA STATE BOARD OF PHARMACY

ADMINISTRATIVE ISSUES

ISSUE #1: ***Board Member Expertise. Should existing law governing the membership composition of the Board be amended to include a pharmacy technician?***

Background: In addition to requiring both professional and public members, there is further specificity regarding who serves on the Board. The Pharmacy Law requires at least five of the pharmacist appointees to be actively engaged in the practice of pharmacy, with specific representatives required for identified practice settings. While the Board's membership was amended during its last sunset review to further specify the practice settings that must be represented among the pharmacist members, an identifiable lack of representation on the Board continues to be the absence of a pharmacy technician member.

In addition to overseeing the licensure of pharmacists, the Board is also responsible for regulating pharmacy technicians. However, the professional membership of the Board currently only includes pharmacists. In 2017, Senate Bill 716 (Hernandez) proposed to add a pharmacy technician member to the Board, along with an additional public member, but this bill encountered opposition and failed to pass. Other healing arts boards are often allotted one or two appointments for associated licensed auxiliaries and allied professionals; it may be worthy of consideration that a technician be added to the current Board to ensure that it is conscious of distinct issues impacting that occupation.

Staff Recommendation: ***The Board should inform the Committees of any professional perspectives it believes may not be sufficiently represented within its membership, including pharmacy technicians.***

Board Response: ***The Board appreciates this issue being raised by the Committees. The Board routinely evaluates matters impacting the practice of pharmacy, including the critical role pharmacy technicians play in assisting pharmacists. The Board engages with stakeholders and performs specific engagement with pharmacy technicians, including through listening sessions and surveys. During agenda items specifically focused on pharmacy technician authorized functions, the Board receives robust stakeholder engagement.***

The Board is committed to evaluating this issue is the future.

ISSUE #2: *Board Attorney. Does the Board have sufficient legal counsel?*

Background: The Pharmacy Law expressly provides the Board with the authority to employ legal counsel. However, the Board does not currently employ its own dedicated attorney. Legal representation in disciplinary actions is provided by the Attorney General's Licensing Section, and the Department of Consumer Affairs offers designated counsel as part of the centralized services it provides to boards, as needed to assist with rulemaking, address legal issues that arise, and support compliance with open meeting laws.

Dedicated board counsel is, however, considered to provide substantial value when questions of law occur regularly enough to warrant the presence of attorney who specializes in a board's practice act, and may help improve the Board's rulemaking timelines. It is under this line of thinking that the Legislature has authorized the Board to appoint its own lawyer; however, the Board has yet to secure approval to do so. Language was included in the Board's last sunset review to allow this appointment to take place, but was removed prior to final passage. The Committees may wish to once again revisit this topic and consider whether the Board should be further aided and encouraged in hiring its own dedicated attorney.

Staff Recommendation: ***The Board should provide insight into whether the Pharmacy Law should be amended to assist it in hiring its own dedicated counsel.***

Board Response: ***The Board appreciates the legal counsel it receives from the Department of Consumer Affairs and the Office of the Attorney General and does not think a legislative amendment is needed at this time. The Board is grateful that DCA assigned counsel is dedicated to the Board, ensuring subject matter expertise in Pharmacy Law.***

FISCAL ISSUES

ISSUE #3: *Fund Balance. Will the Board's ability to raise its fees through regulation be sufficient to cover future revenue shortfalls currently reflected in the Board's fund condition?*

Background: As previously discussed, the Board is currently expending funds at a greater rate than it is receiving revenue from fees and penalties collected from licensees, resulting in a structural imbalance. Statute provides that it is the intent of the Legislature that the Board seek to maintain a reserve in its fund equal to approximately one year's operating expenditures. However, as of FY 2023-24, the Board's fund balance reflected less than six months in reserve, and it is anticipated that the Board will have a negative fund balance by FY 2027-28.

While the Board's current fund condition projections appear dire, recent adjustments to the Board's fee structure only became effective January 1, 2025. As the Board implements its updated authority to charge higher fees to licensees, it likely has the flexibility needed to reverse its financial course and grow its reserves toward the levels required by statute. The Board should remain mindful of the need to maintain solvency while remaining conservative in the degree and frequency of pursuing fee increases on its licensees.

Staff Recommendation: ***The Board should provide the Committees with an overview of its financial plan for the coming years and provide assurances that it will continue to maintain adequate reserves.***

Board Response: ***The Board closely monitors its fund and provides a status of its fund condition at Board meetings on a quarterly basis. The Board believes with implementation of the new fee schedule becoming effective January 1, 2025, the Board's fund will begin to slowly rebuild over the coming years. The Board notes that currently, none of its fees are at the maximum level established by statute. Should conditions change, the Board does have the ability to raise fees via regulation, but does not believe such action will be required in the near future and would only do so if a structural imbalance occurs.***

LICENSING ISSUES

ISSUE #4: ***Advanced Practice Pharmacists. Should the license classification established for pharmacists authorized to provide additional services be retitled to better reflect the practice?***

Background: In 2013, Senate Bill 493 was signed into law in 2013, creating a new license type under the Board known as the "advanced practice pharmacist." This class of highly educated and trained health care professionals is intended to further the role of pharmacists in providing direct patient care, and advanced practice pharmacists are authorized to perform additional procedures often unavailable in many parts of the state. To implement the bill, the Board adopted regulations setting training and certification requirements for advanced practice pharmacists.

Historically, fewer individuals successfully applied to become advanced practice pharmacists than anticipated. During the Board's most recent sunset review, the Committees solicited recommendations on ways to address unnecessarily complicated or onerous qualifications and overly limited independence in practice. The Board proposed language to recast the requirements for licensure as an advanced practice pharmacist, which was incorporated into its sunset bill. Over the years since the effective date of that legislation, the number of advanced practice pharmacists in California has grown from 871 in FY 2020-21 to 1,383 as of September 2024.

As the state's population of advanced practice pharmacists grows, the Board has suggested that current terminology used to describe these professionals does not appropriately reflect their ability to engage in advanced health care functions. Specifically, the Board recommends retitling the license category to "Advanced Pharmacist Practitioner." While largely a technical change, this update would arguably enhance the accuracy of statute and help elevate these professionals as advanced health care providers.

Staff Recommendation: ***The Board should provide the Committees with more information regarding its proposed changes to the law and further explain its rationale for retitling the license category.***

Board Response: ***The Board thanks the Committees for consideration of the Board's recommendation to retitle this license category to Advanced Pharmacist Practitioner. The Board notes that the issue was raised by the California Pharmacy Council as a means to more accurately reflect the health care services provided and underscore the role of such a practitioner on a health care team. Further, the proposed change is consistent with practitioner terminology used by organizations that also have advanced pharmacist practitioners, including the U.S. Department of Veterans Affairs and the states of North Carolina and Montana.***

The Board's statutory proposal is included in Attachment H-14 in volume 2 of its report.

ISSUE #5: ***Hydration Clinics. Should the Board be given responsibility for licensing clinics where compounding and administering sterile injectable products takes place without sufficient oversight?***

Background: In recent years, there has been a rise in the popularity of hydration clinics, also referred to as "drip bars," which offer intravenous (IV) hydration and nutrient therapy, often in a spa-like setting. These clinics provide fluids, vitamins, electrolytes, and other nutrients directly into a client's bloodstream, which is purported to aid with dehydration, hangovers, fatigue, immune support, and other acute or chronic conditions. Drug product compounding at these clinics is exempt from many provisions of the federal Food, Drug, and Cosmetic Act, and the clinics are not licensed or overseen by the Board or any other similar agency in California.

According to the Board, the federal Food and Drug Administration (FDA) has released warnings in recent years about instances of drug products being compounded under insanitary conditions, including at unregulated IV hydration clinics. Following an incident in California where a patient was hospitalized and treated for suspected septic shock with multi-organ failure after receiving an IV vitamin infusion in her home, the FDA reported that it was aware of sterile compounding activities, such as adding vitamins to IV infusion bags, being performed by hydration clinics where it is unknown and undocumented if the drug products are prepared, packed, or held under insanitary conditions. Additionally, it is unknown whether a licensed practitioner is on site to evaluate patients and write prescriptions for the drug products being administered.

In light of the patient safety concerns associated with compounding taking place in hydration clinics, the Board argues that a state entity should be responsible for oversight of these facilities, and that the Board has the appropriate expertise to regulate these facilities where onsite physician oversight is not in place. The Board has submitted a proposal to require hydration clinics to obtain a license from the Board prior to compounding or administering sterile injectable products, subject to inspection by the Board. Clinics would also be required to designate a licensed prescriber as the professional director responsible for the safe, orderly, and lawful provisions of compounding and administration of the sterile injectable products.

Staff Recommendation: ***The Board should provide the Committees with more detail regarding its efforts to address patient safety concerns relating to hydration clinics and its proposal to create new license requirements for these facilities.***

Board Response: ***The Board thanks the Committees for considering the Board's proposal to regulate certain IV hydration clinics. The Board's policy recommendation is not intended to require licensure where compounding is performed by or under the supervision of onsite authorized health care providers; rather, the proposal would require Board licensure only in cases where a healing arts practitioner authorized to compound under federal law is not on site at the facility during all times that compounding of sterile injectable products occurs. Regrettably, during joint investigations and inspections the Board has identified significant patient safety concerns when evaluating the compounding practices of such facilities for compliance with United States Pharmacopeia (USP) national standards. In such instances the Board noted that no authorized health care practitioner with authority to compound was present either performing or overseeing the compounding. The Board believes this gap in oversight and regulatory jurisdiction must be addressed, either through authority and oversight of the Board or another agency. The Board notes that according to***

information from the FDA, this new business practice is occurring nationwide and California has the highest number of businesses offering IV hydration.

The FDA noted in a 2021 Compounding Risk Alert, "FDA has become increasingly aware of drug products compounded at medical offices and clinics that were prepared under insanitary conditions. FDA has also become aware of business models, such as intravenous (IV) hydration clinics, medical spas, and mobile IV infusion services, that are compounding drugs that may not meet the conditions of section 503A of the FD&C Act or comply with state regulations."

A case example provided by the FDA involved a 50 year old patient who was hospitalized for septic shock with multi-organ failure after receiving IV vitamin infusion from a medical clinic. The inspection reviewed several observations of insanitary conditions including:

- ***Lack of a certified ISO 5 classified area for IV preparations***
- ***Peeling paint, stained work surfaces, visibly dirty equipment, and dusty air vents***
- ***Carpeting in the IV storage and mixing room***
- ***Standing water in a refrigerator used to store sterile vials***
- ***Use of expired APIs***

The Board has conducted inspections with or at the request of other healing arts boards and has found practices that do not meet the USP national standards for compounding. The Board released joint education with several other healing arts boards within the DCA referencing the national standards and highlighting some of the requirements of those standards.

The Board's statutory proposal is intended to be narrow in scope and not broad sweeping regulations of all IV hydration clinics. Rather, the Board's proposal seeks to address regulatory gaps that have been identified involving IV hydration clinics. The statutory proposal is included in Attachment H-6 in volume 2 of its report.

ISSUE #6: ***Pharmacy Delivery Services. Does current law provide for sufficient oversight in the delivery of prescription medications?***

Background: In its report to the Committees, the Board raised concerns about the growing use of third party providers to deliver prescription medications to patients. While pharmacies have long offered delivery services to their customers, the COVID-19 pandemic significantly accelerated the popularity of mobile applications offering general delivery of food and consumer goods, and these platforms have also been used by pharmacies to deliver prescription medications. The Board states that while it acknowledges the convenience of these services, delivery of medications becomes a barrier to vital patient consultation, and as a result the Board has worked to update its patient consultation requirements to ensure patients have ready access to pharmacist consultation.

Additionally, the Board raises potential patient care issues resulting from the lack of requirements for individuals delivering prescription medications, such as a lack of background checks and a lack of understanding of drug storage requirements. The Board reports that it has conducted investigations and identified issues where prescription medications are delivered to the wrong patient or are left on porches or driveways or in mailboxes in extreme weather conditions. In some instances, medication left in these uncontrolled environments then subsequently returned to the pharmacy for redispensing. While the Board believes it has sufficient authority to develop regulations in this area, the Committees may wish

to engage in the process of establishing guardrails to ensure individuals providing delivery of prescription medications are adequately trained and that specific provisions for medication handling in the delivery process are maintained.

Staff Recommendation: ***The Board should provide the Committees with any recommendations it has for legislation to strengthen the Pharmacy Law as it applies to pharmacy deliveries.***

Board Response: ***The Board appreciates the Committees' interest in learning more about the challenges that exist with some pharmacy delivery services. The Board does not seek to impede patient choice in receiving delivery of medications from a pharmacy but does believe that basic training for delivery drivers – through, for example, an online training program – may be appropriate.***

Further, the Board believes certain policies at pharmacies that specifically address the requirements for drug delivery are appropriate. The Board believes it has sufficient regulatory authority to develop such regulations but is interested in determining if the Legislature would be agreeable to a statutory change as a more immediate means to establish such a requirement.

ISSUE #7: ***Ownership Prohibitions. Should provisions of the Pharmacy Law prohibiting the Board from issuing a pharmacy license to a person with specified financial interests be clarified?***

Background: The 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. In its report to the Committees, the Board notes that because California is a community property state, property acquired by either spouse during a marriage is presumed to be equally owned by both spouses. This has raised questions of how the ownership interest prohibition applies when an applicant's or licensee's spouse is a prescriber or other prohibited person, including in cases where a prenuptial or postnuptial agreement exists.

As the Board's application and assessment process has evolved 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. As explained by the Board, 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 spouse's 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. The Board has proposed amendments to the Pharmacy Law to clarify provisions relevant to this subject consistent with this analysis.

Staff Recommendation: ***The Board should provide the Committees with its proposed changes to clarify existing ownership prohibitions.***

Board Response: ***The Board thanks the Committees for considering the Board's proposal to clarify existing ownership prohibitions. The Board's statutory proposal is included in Attachment H-19 in volume 2 of its report.***

ISSUE #8: ***Retired Pharmacist License. Is the process for restoring a retired pharmacist license unnecessarily burdensome?***

Background: The Pharmacy Law provides for pharmacists to have their license placed on a retired status. Retired licensees are not authorized to engage in any activity for which an active license is required. 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.
In recent discussions, the Board determined that the requirements to restore a retired pharmacist license to active status were actually more burdensome than the 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 has identified changes to pharmacy law that provides parity for restoring a retired pharmacist license through completion of continuing education and payment of a fee.

Staff Recommendation: ***The Board should provide the Committees with its proposed language to simplify the process for restoring a retired pharmacist license.***

Board Response: ***The Board thanks the Committees for considering the Board's proposal to establish a less burdensome way for recently retired pharmacists to restore their license. The Board's statutory proposal is included in Attachment H-20 in volume 2 of its report.***

ISSUE #9: ***Fair Chance Licensing Act. Should provisions of law enacted through Assembly Bill 2138 (Chiu/Low) be amended to establish additional acts as cause for denial of a license by the Board?***

Background: In 2018, Assembly Bill 2138 (Chiu/Low) was signed into law, making substantial reforms to the license application process for individuals with criminal records. Under this bill, an application may only be denied on the basis of prior misconduct if the applicant was formally convicted of a substantially related crime or was subject to formal discipline by a licensing board. Further, prior conviction and discipline histories are ineligible for disqualification of applications after seven years, with the exception of serious and registerable felonies, as well as financial crimes for certain boards. Among other provisions, the bill additionally requires each board to report data on license denials, publish its criteria on determining if a prior offense is substantially related to licensure, and provide denied applicants with information about how to appeal the decision and how to request a copy of their conviction history. These provisions went into effect on July 1, 2020.

During its prior sunset review, the Board requested that a list of additional crimes be exempted from the seven-year washout provided in the Fair Chance Licensing Act, but this language was not included in its sunset bill. The Board is once again requesting broader discretion to deny an application for licensure, specifically requesting that it have latitude to consider the following acts as disqualifying:

1. An act involving fraud in violation of state or federal laws related to healthcare, e.g. Medi-Cal or Medicare billing fraud, etc.
2. Conviction of a crime involving financial identity theft.
3. An act of dishonesty related to academic institutions or attempts to subvert examinations, even where convictions do not occur, or subsequent dismissal is provided.

4. Acts involving serious or repeated use of a controlled substance or alcoholic beverages to the extent or manner as to be dangerous or injurious to themselves or others.

Accompanying its request, the Board has provided specific examples of cases where applicants were determined to have engaged in serious misconduct but the Board lacked the authority to deny a license. The Legislature's intent in enacting the Fair Chance Licensing Act reflected a cogent desire to expand economic opportunity for individuals with prior criminal histories as a means of facilitating rehabilitation. However, the Committees may wish to consider the Board's request to allow for additional acts to be considered for purposes of disqualifying applicants for licensure.

Staff Recommendation: ***The Board should provide the Committees with additional details regarding its language and whether it believes it has sufficiently narrowed the scope of the included acts.***

Board Response: ***The Board appreciates the Committees' interest in this issue. The Board believes that its legislative proposal is narrow in scope and balances the intent of the Fair Chance Licensing Act while allowing the Board to restore some flexibility in authority to make licensing decisions where prior acts are substantially related to the duties and qualifications of a license. The Board further notes that with this restored discretion, the Board will have the opportunity to issue a probationary license, providing the Board the opportunity to monitor the licensee for rehabilitative efforts for a period of time before restoring the license to an unrestricted status.***

The Board's statutory proposal is included in Attachment G-1 in volume 2 of its report.

EDUCATION AND EXAMINATION ISSUES

ISSUE #10: ***Pharmacist Technician Trainees. Should accredited employer-based training programs be included in the licensure pathway utilized by pharmacy technician trainees?***

Background: Currently, the Pharmacy Law provides for several different pathways to licensure as a pharmacy technician, including through completion of a training program. The Pharmacy Law defines a "pharmacy technician trainee" as a person who is enrolled in a pharmacy technician training program. Under current law, these programs must be operated by a California public postsecondary education institution or by a private postsecondary vocational institution approved by the Bureau for Private Postsecondary Education.

The Board states that as part of its 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. However, the Board has determined that the current definition of pharmacy technician trainee is too limited, arguing that individuals completing an accredited employer-based training program should also be able to gain experience as a trainee to obtain practical experience. The Board has proposed updates to the law that it believes could increase learning and training opportunities while also reducing a potential barrier to entry for individuals seeking licensure as pharmacy technicians.

Staff Recommendation: ***The Board should provide the Committees with its proposed language to expand options for pharmacy technician training programs.***

***Board Response**: The Board thanks the Committees for considering the Board's proposal to broaden the statutory definition of "pharmacy technician trainnee." The Board's statutory proposal is included in Attachment H-21 in volume 2 of its report.*

ENFORCEMENT ISSUES

ISSUE #11: ***Pharmacies Operating Under Common Ownership. Has the Board effectively utilized its new authority to take more robust enforcement action against the owners and operators of pharmacies under common ownership and control for system-wide violations of law?***

Background: Historically, the Pharmacy Law holds each pharmacy and its pharmacist-in-charge responsible for operations at the individual site, even if that pharmacy is part of a larger chain. However, in many cases, administrative or disciplinary action at an individual store may be the result of policies set at a corporate level. During the Board's most recent sunset review, the Committees considered whether the Board should be better empowered to take enforcement action against the owners and operators of pharmacies under common ownership and control for system-wide violations of law.

Subsequently, the Board's sunset bill was amended to include language authorizing the Board to bring an action for increased civil penalties for repeated violations of the Pharmacy Law by one or more chain community pharmacies operating under common ownership or management. Additionally, the bill authorized the Board to bring an action against a pharmacy operating under common ownership or management for civil penalties not to exceed $150,000 for any violation of the Pharmacy Law demonstrated to be the result of a policy or which was otherwise encouraged by the common owner or manager. The provisions of this bill went into effect on January 1, 2022.

Since enactment of these provisions, the Board reports that it has issued 195 citations under this new authority. Implementation of the provisions has been discussed on an annual basis as part of the Board's Enforcement and Compounding Committee. Most recent data for FY 2023-24 indicates that the Board issued 115 citations. Fines issued range based on a variety of factors including the seriousness of the violation, prior history of the specific pharmacy license, license history of pharmacies under common control where the same violation may have occurred, and other factors. The Board reports that the vast majority of the citations issued by the Board under this authority are appealed.

The Board states that it has experienced some challenges in utilizing the authority granted in its most recent sunset bill, including what appears to be attempts to apply the law inconsistent with the policy goals of the legislation. The Board has suggested amendments to the language to ensure the Board's regulated public has a clear understanding of the obligations on both the Board and on licensees when issuing citations pursuant to these provisions, to remove duplicative language, and to ensure consistency in the terms used throughout the Pharmacy Law. The Board has provided language to this effect.

Staff Recommendation: ***The Board should provide greater detail regarding the changes it believes are necessary to ensure effective implementation of the Legislature's intent to enhance enforcement.***

***Board Response**: The Board thanks the Committees for their interest in the Board's implementation efforts. As the data demonstrates, the Board has used the new authority judiciously. The Board believes the language could be amended to remove some duplicative language that may cause*

confusion. Further, as implementation continues, the Board believes the policy goals of the initial measure may be better realized with amendments to more closely mirror the Board's citation and fine authority in other areas of Pharmacy Law. The Board's statutory proposal is included in Attachment 1.

ISSUE #12: *Standard of Care Model for Pharmacy Practice. Should the Board begin moving toward more of a standard of care model for its disciplinary actions against some of its licensees?*

Background: During the Board's prior review, the Committees discussed whether there should be consideration of the Board transitioning to a standard of care model in its enforcement activities. A number of healing arts boards are granted a substantial amount of flexibility in investigations when determining whether a licensee should be subject to discipline. Rather than enforcing strict adherence to codified practice requirements, boards may instead focus on the question of whether a licensee followed the "standard of care" and acted reasonably under the circumstances as a trained professional.

Representatives of the profession have advocated that a similar model should be enacted for the Board in regards to its actions against its licensees. During its prior sunset review, it was determined that the Board currently employed 56 licensed pharmacists who assisted with investigations as professional experts; therefore, it was argued that something resembling the standard of care is already applied when the Board is determining whether an investigation should result in an action for discipline. The Board's sunset bill was ultimately amended to require the Board to convene a workgroup of interested stakeholders to discuss whether moving to a standard of care enforcement model would be feasible and appropriate for the regulation of pharmacy.

The Board established a Standard of Care Ad Hoc Committee, which convened seven meetings and subsequently submitted a report to the Legislature with its findings and recommendations. The Board concluded that 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.
The Board's Licensing Committee has developed language in consultation with stakeholders over a series of public meetings to effectuate the Board's recommendations. 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 would retain the ability to provide hormonal contraception, but would follow a standard of care approach, in lieu of following prescriptive rules established in the Board's regulation.

Some stakeholders have raised concerns about pharmacists' ability to maintain sufficient autonomy in some community pharmacy settings, while others have raised potential issues with the proposed authority for pharmacists to provide additional services. The Board believes its 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 Board further

argues that the language underscores a pharmacist's self-determination in deciding what services they are appropriately educated and trained to perform. The Board believes this approach is like 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.

Staff Recommendation: ***The Board should provide a more detailed explanation of its proposal to the Committees and respond to any concerns or comments received from stakeholders.***

Board Response: ***The Board thanks the Committees for their interest in the Board's standard of care proposal. The Board believes the proposal enjoys broad support from pharmacists. Pharmacists are drug therapy experts. The Board's proposal focuses squarely on drug therapy management and duties and functions already performed by pharmacists in a variety of different settings through a variety of means. The Board's proposal will allow pharmacist practice to evolve as new drug therapies are developed and approved and as science and research inform practice standards. Such a practice model does not generally exist for pharmacist-provided clinical services. As challenges in barriers to care are experienced because of issues at the national level, the transition to a standard of care practice model has become more urgent to preserve patient access.***

The Board notes that it received concerns about staffing challenges in some community chain pharmacy environments. The Board notes that included as part of Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023) the Board secured changes to its unprofessional conduct code to underscore the autonomy of pharmacists in providing patient care services. The Board notes that nothing in its proposal places an obligation on a pharmacist to provide services; rather, the proposal redefines the pharmacist practice model, removing prescriptive provisions in favor of more broadly written provisions. The Board's proposal also references that a pharmacist should not provide services under specified conditions, including where pharmacist staffing at the pharmacy is insufficient to facilitate comprehensive patient care.

According to a recent presentation provided by the California Hospital Association, 48% of emergency room (ER) patients sought care for conditions of low or moderate complexity. The Board was advised that in such instances the patient did not require hospital level of care, but presented at the ER because of a lack of access to required treatment. A cited example was a patient seeking an inhaler. The Board's proposal would streamline access to care and could provide relief to overcrowded emergency departments.

It is appropriate to note that the Board's proposal incorporates tenets of current provisions of Pharmacy Law, including notification to a patient's primary care provider under specified conditions. Further, the Board will continue to assess for compliance with state and federal legal provisions while also evaluating if the clinical services provided were consistent with the standard of care practice model.

As recent actions at the federal level demonstrate, the Board believes that where Pharmacy Law currently references federal agencies as the sole source for defining the provision of care, the Board believes alternative sources or other relevant practice guidelines may need to be considered to ensure California patients maintain access to necessary treatments.

The Board's statutory proposal is included in Attachment H-10 in volume 2 of its report.

ISSUE #13: *Self-Assessment Processes. Should self-assessment be more consistently required for licensees of the Board?*

Background: As explained by the Board in its report to the Committees, 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. These self-assessment forms include a compilation of relevant laws applicable to the license type—for example, community pharmacy, hospital pharmacy, sterile compounding license, surgical clinic, and so forth. In each instance, the law establishes the process to be followed, the frequency with which the self-assessment must be completed, and the required signatories of the form.

The Board states that it believes the self-assessment process is an important tool and it 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 is proposing to centralize the self-assessment requirement into statute to ensure consistency in the Board's approach to promoting self-compliance.

Staff Recommendation: ***The Board should provide greater detail on its proposal and provide the Committees with language to implement it.***

Board Response: ***The Board thanks the Committees for their interest in the Board's self-assessment proposal. The Board believes that promotion of compliance through self-evaluation is a critical tool that, if used appropriately, prevents violations of law from occurring and where identified through self-evaluation, allows a licensee to remedy the issue. The Board believes establishing a self-assessment process for all facilities licensed by the Board will further promote consumer protection and compliance with legal requirements. The Board's statutory proposal is included in Attachment H-11 in volume 2 of its report.***

ISSUE #14: *Nonresident Pharmacies. Would new requirements for nonresident pharmacies aid in the Board's efforts to ensure compliance with California law?*

Background: The Pharmacy Law provides 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. These pharmacies must obtain a license from the Board. During recent public meetings, the Board has expressed concern about whether these pharmacies adequately understand California requirements, and whether there is adequate oversight by the Board. Under current law, while a nonresident pharmacy is required to hold a nonresident pharmacy license issued by the Board, neither the pharmacist-in-charge or other pharmacists are required to be licensed in California. The Board argues that this stands in contrast to many other states which require such licensure. In addition, the Board has expressed concern 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 a nonresident pharmacy has not established minimum competency with California law yet is responsible for operational and legal compliance with California pharmacy law.

In response to these concerns, the Board has proposed several changes to the Pharmacy Law, including the addition of the following requirements:

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

Staff Recommendation: ***The Board should provide the Committees with its proposed language and explain how it believes these changes would improve patient safety in California.***

Board Response: ***The Board thanks the Committees for their interest in the Board's proposal to improve its regulation over nonresident pharmacies. The Board believes changes to the statutory requirements for nonresident pharmacies are necessary to address patient safety issues and improve regulatory oversight of nonresident pharmacies.***

Regulation of the practice of pharmacies varies greatly across the nation and patient protections California patients are provided do not exist in all states. There are some jurisdictions outside of California waiving minimum licensure requirements that historically were used consistently across all jurisdictions. Further, nationally there is not a consistent standard regarding the qualifications of individuals who perform inspections, including states that do not employ pharmacists to perform inspections. It is also important to note that where inspections are performed by other states they do not include evaluation of compliance with California legal requirements.

The Board's proposal seeks to ensure California patients receive the same level of care from pharmacists with consistent licensing requirements, including ensuring passing licensure examinations as well as ensuring that the pharmacist-in-charge of the nonresident pharmacy be a licensed California pharmacist. Further, the Board's proposal seeks to ensure California patients receive the same patient protections when they receive prescriptions from nonresident pharmacies. This issue has become more urgent as patient health insurers require patients to obtain medications from mail order pharmacies, most of which are located outside of California.

The Board also believes its current inability to inspect nonresident pharmacies creates a disparity with its oversight and evaluation for compliance with legal requirements. The Board's statutory proposal is included in Attachment H-1 in volume 2 of its report.

ISSUE #15: ***Mail Order Pharmacies. Should the Board be provided with increased fine authority for mail order pharmacies engaged in a pattern of repeated violations of the law?***

Background: As described by the Board in its report to the Committees, mail order pharmacies offer insurers and patients a different option to provide pharmacy care. The Board believes that while there are benefits to this pharmacy model, it also creates unique challenges in meeting patient care issues. The Board also 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. However, the Board reports that it 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 arguably 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 argues the current $5,000 maximum fine amount has not been sufficient to bring about changes in the practice to align with legal requirements, similar to challenges previously faced in pursuing enforcement against pharmacies operating under common ownership by major corporate chains that resulted in language in its previous sunset bill. The Board is requesting similar enhanced enforcement authority where it can demonstrate a pattern of similar violations over a period of time.

Staff Recommendation: ***The Board should inform the Committees as to why it believes greater enforcement authority is needed to address issues with mail order pharmacies.***

Board Response: The Board thanks the Committees for their interest in the Board's proposal to provide greater enforcement authority over mail order pharmacies. Through payer practices, patients are steered to mail order pharmacies to receive their prescription medications. The Board's investigations reveal patterns of violations that impede a patient's timely access to their medications and timely access to speak to a pharmacist despite legal requirements. The Board's current fine authority of $5,000 per investigation has proven insufficient to address these repeat violations. The Board's statutory proposal is included in Attachment H-4 in volume 2 of its report.

ISSUE #16: ***Online Health Platforms. Does the Board have sufficient authority to ensure that telehealth platforms are not potentially violating existing anti-kickback provisions?***

Background: As new telehealth technologies have emerged in recent years, the Committees have routinely sought to balance consumer convenience and increased access to care with the potential risks of harm that may be associated with patients receiving less direct, in-person care from providers. In its report to the Committees, the Board states that it has become aware of telehealth platforms that steer patients to a pharmacy owned and operated by the telehealth platform. At a minimum, this practice potentially violates the intent of the anti-kickback statute prohibiting offering or receiving any remuneration to induce referrals for services.

The Board has expressed concerns over the fact that telehealth platforms may not have full visibility into the patient's history, including underlying medical conditions, and medication use, including over-the-counter and prescription medications. The Board is concerned that this can lead to contraindications and duplication in therapies being overlooked, placing patients at risk. The Board has stated its belief that, at a minimum, patient protection must be addressed to avoid potential patient steering or other violations of anti-kickback provisions. While the Board is likely not the appropriate entity to engage in larger scale oversight of telehealth platforms, it does believe that statutory changes would enhance its ability to

oversee pharmacies that are involved in this business practice, including a notification requirement to the Board.

Staff Recommendation: ***The Board should provide additional information to the Committees regarding the potential risks posed by telehealth platforms and its proposals to increase state oversight.***

Board Response: ***Telehealth platforms have the potential to increase access and provide more convenient health care services to patients. The increasing use of such platforms is evident throughout the healthcare system, including, for example, patients seeking to lose weight using GLP1s. The Board notes that this business model, aimed at ease of patient use, has created a new patient care challenge. This challenge is similar to challenges that were created with the advent of internet prescriptions over several decades ago where prescriptions were sent to pharmacies without the required medical examination and generally without patient choice. The Board believes greater transparency into the relationship between the practitioners and dispensers using such platforms is necessary to ensure patients are receiving the appropriate prescriptions and in a manner that is consistent with legal provisions. The Board's proposal seeks to require disclosure of financial relationships between a platform and the pharmacy or outsourcing facility. Such disclosure will allow the Board to evaluate the business relationship and confirm compliance with legal requirements.***

The Board's statutory proposal is included in Attachment H-8 in volume 2 of its report.

ISSUE #17: ***Payor Activities. Should the Board be empowered to enforce additional prohibitions and requirements on pharmacy benefit managers and other payors?***

Background: Over the past several years, the Board has become increasingly concerned about the emergence of payor practices that it believes negatively impact patient care. The Board argues that these 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.

There are two general areas where payor practices have drawn concern: failure to comply with existing requirements of the law, including mandates for health insurers to reimburse for pharmacy services; as well as unfair practices by pharmacy benefit managers placing patients at risk. Legislation has been introduced to address some payor practices, including those of pharmacy benefit managers (PBMs). In 2021, the Board convened an informational meeting to discuss the practice of "white bagging," a payor practice that requires a patient to use a specified pharmacy to obtain medication that will be administered, typically at an infusion center. The Board does not believe it has the current authority to prevent this payor driven practice, which it worries can result in challenges in coordinating care and delays in therapy. The Board reports that many of the patients requiring infusion have serious medical conditions, such as cancer, where delays in therapy can result in disease progression.

In addition, the Board routinely receives complaints from consumers indicating that a pharmacy delayed dispensing of a medication in violation of the law. Through the Board's investigation however, the Board frequently discovers that the delay was not caused by the actions of a pharmacy but rather, the delays were caused by payor requirements for things such as prior authorizations, for which there is no enforcement of provisions that such authorizations be approved within a specified time frame. The

Board once again believes that it 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 the Pharmacy Law or has otherwise not met requirements the payor believes are appropriate. The Board provided the Committees with several examples, such as instances involving pharmacies that dispense HIV postexposure prophylaxis, which is a 28-day treatment but often sold by drug manufacturers in a 30-day supply. When payors claw back payments based on unavoidable, technical, or disputable violations of the law in the opinion of the payor, pharmacies may ultimately pay for the patient's medication without any reimbursements. The Board argues that such a business model is neither fair nor sustainable.

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. The Board asks that these issues be addressed to protect patients and ensure patients have access to pharmacist care in all communities. The Board has recommended a number of statutory changes to address these issues, which it has proposed for inclusion in its sunset bill.

Staff Recommendation: ***The Board should provide the Committees with a detailed overview of its proposed statutory language and why it believes these changes are needed for the benefit of patients.***

Board Response: ***The Board thanks the Committees for their interest in the Board's statutory proposal to address payor activities that negatively impact patient access. The Board acknowledges that this is a complex issue and has focused its proposal in three areas which place patients at risk. Specifically, the Board's proposal would:***

1. ***Address patient care issues resulting from the payor mandated practice of "White Bagging. Specifically, the proposal would establish specific requirements for the originating pharmacy (the pharmacy selected by the payor to provide the prescription) to establish clear delineation of responsibility, ensure coordination and timely delivery of medications for administration to patients, and informed consent of the patient.***
2. ***Address payor clawbacks by:***
    a. ***Providing that the Board has the exclusive authority to interpret and enforce Pharmacy Law.***
    b. ***Prohibiting a payor from clawing back reimbursements under specified conditions.***
3. ***Establishing prohibited activities involving patient steering activities.***

The Board is aware of other efforts under consideration to also address some of these payor practices and looks forward to partnering with the Legislature and the Administration.

The Board's statutory proposal is included in Attachment H-9 in volume 2 of its report.

PRACTICE ISSUES

ISSUE #18: ***Medication-Assisted Treatments. Is a statewide protocol necessary for pharmacists to safely provide non-opioid medication for treatment of opioid use disorder?***

Background: Statute allows for pharmacists to furnish certain medications directly to a patient, including self-administered hormonal contraceptives, nicotine replacement products, and preexposure and postexposure prophylaxis. During the Board's prior sunset review, the Committees considered whether to establish similar authority for pharmacists to directly furnish non-opioid medication-assisted treatment (MAT) to patients pursuant to a statewide protocol. MAT is the use of medications, in combination with counseling and behavioral therapies, to treat substance use disorders. While some forms of MAT are themselves a type of opioid, other forms of MAT do not contain opioids.

Ultimately, the Board's sunset bill was amended to include language authorizing pharmacists to provide non-opioid MAT, pursuant to a statewide protocol. However, the Board reports that there have been challenges to achieving the benefits of this authority. The Board reports that delays in the rulemaking process have hampered implementation of the provisions. Further, the Board believes that a statewide protocol may be unnecessary if pharmacists could instead provide MAT with a standard of care approach. Finally, the Board has stated that it believes MAT to be an outdated term, and that the term "medication assisted treatment" should be replaced with the term "medication for treatment of opioid use disorder."

Staff Recommendation: ***The Board should provide the Committees with more information about the implementation challenges it has experienced and why it believes a statewide protocol is not necessary.***

Board Response: ***The Board thanks the Committees for their interest in the Board's statutory proposal related to Medication-Assisted Treatment. The Board's proposal seeks to update terminology while also seeking to remove the requirement for the Board to develop a protocol. The Board broadly supports the transition away from a prescriptive practice model for pharmacists in favor of a standard of care practice model. Specifically related to pharmacist-furnished MOUD, the Board believes a state protocol can become a barrier to access as the standard of care evolves. SAMHSA and other organizations update resources and recommendations routinely. As new therapies are approved and the standard of care evolves, administrative review of a state protocol can become overly burdensome without benefit to patients.***

The Board's statutory proposal is included in Attachment G-3 in volume 2 of its report.

ISSUE #19: ***Pharmacist to Pharmacy Technician Ratio. Should provisions of the Pharmacy Law restricting the number of pharmacy technicians that may be utilized at a pharmacy relative to the number of pharmacists be amended?***

Background: The Pharmacy Law authorizes pharmacies to employ pharmacy technicians, who assist pharmacists by performing "packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist." Current law limits the number of pharmacy technicians that may work in a pharmacy at any given time relative to the number of pharmacists working in the pharmacy at that time. Specifically, the Pharmacy Law provides that "a pharmacy with only one pharmacist shall have no more than one pharmacy technician"—however, if more than one pharmacist is working in the pharmacy, that ratio increases to allow up to two pharmacy technicians per pharmacist.

The pharmacist to pharmacy technician ratio does have some exceptions. The ratio does not apply to certain practice settings, including an inpatient of a licensed health facility, a patient of a licensed home health agency, an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and to persons receiving treatment in a facility operated by the Department of State Hospitals, the

Department of Developmental Services, or the Department of Veterans Affairs. The Board is authorized to adopt regulations establishing a greater ratio applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed home health agency.

Additionally, if a pharmacy technician is only performing clerical functions, they are not counted toward the ratio. Finally, Assembly Bill 1286 (Haney) allows pharmacy technicians who have received additional training to perform additional functions, such as administering vaccines or collecting specimens for certain lab tests. If a pharmacy technician is performing these advanced tasks in the pharmacy, a second pharmacy technician is both authorized and required to assist the pharmacist.

For a number of years, representatives of chain community pharmacies have advocated to change the ratio restrictions to allow for more pharmacy technicians to assist pharmacists in their pharmacies. In 2017, Assembly Bill 1589 (Bocanegra) was amended to increase the ratio from 1:1 to 4:1, but the bill failed to pass out of the Assembly. A similar proposal was introduced in 2018 through Senate Bill 1286 (Pan), which was not subsequently heard in committee. The following year, Senate Bill 617 (Glazer) proposed to increase the ratio to 3:1, subject to an agreement between the pharmacy employer and the labor organization representing its pharmacists; this bill was held on the Senate Appropriations Committee's suspense file. Most recently, Senate Bill 1365 (Glazer) was introduced to increase the ratio to 6:1, but this bill also failed to pass out of the Senate, even after being amended down to a 4:1 ratio.

Despite ongoing concerns from representatives of practicing pharmacists about insufficient staffing in community pharmacies, there has been opposition to increasing the pharmacy technician ratio in these settings out of fear that pharmacies would displace their pharmacist workforce with additional pharmacy technicians. Concerns have also been raised about requiring overworked pharmacists to supervise additional personnel. However, supporters of an expansion of the ratio argue that California continues to have one of the most restrictive pharmacist to pharmacy technician ratios in the country, with over half of all states in the country allowing four or more pharmacy technicians per pharmacist. Meanwhile, the National Association of Boards of Pharmacy has recommended the eliminations of ratios entirely.
In March 2024, the Board released a survey that solicited feedback on the current ratio requirements in both the outpatient and inpatient pharmacy settings, receiving over 4,510 responses from pharmacists. According to the Board, the survey results revealed consensus among pharmacists, irrespective of their role within the pharmacy, that the current 1:1 ratio is not appropriate. The Board further concluded from the survey data that, in the outpatient setting, the majority of respondents believe that a ratio of one pharmacist to two pharmacy technicians (1:2) is appropriate.

Following its analysis of the survey results, the Board discussed a proposal to expand the pharmacist to pharmacy technician ratio, which it included in its report to the Committees. Specifically, the Board is recommending language that would authorize the Board to adopt regulations establishing, for different community pharmacy practice settings, a ratio different than what the Pharmacy Law currently allows. The Board believes that this approach, which would mirror the regulatory discretion that is already provided for inpatient settings, would allow for continued discussion among stakeholders about what ratio is appropriate for certain pharmacies, and for the outcome of these discussions to be effectuated through the rulemaking process rather than necessitating further statutory change.

Staff Recommendation: ***The Board should provide the Committees with additional detail regarding its proposal relating to the pharmacist to pharmacy technician ratio and its support for this approach.***

Board Response: ***The Board thanks the Committees for their interest in the Board's statutory proposal related to the pharmacist to pharmacy technician ratio. A survey performed by the Board supported***

the Board's position that the current 1:1 ratio in the outpatient setting is not appropriate. The Board notes that as part of Assembly Bill 1286 (Haney, Chapter 470, Statutes of 2023) the measure made a slight adjustment to the ratio requirements where one additional allowance of the specially trained pharmacy technicians assisting a pharmacist performing advanced duties as long as there is another technician performing traditional duties of a pharmacy technician. The Board believes the change was an important step, but believes the ratio could be increased generally to 1:2 in the community pharmacy setting. The Board also notes that not all practice sites are the same. With varying pharmacy practice models, the Board believes additional flexibility should be granted to the Board to establish a different ratio for these different practice models (e.g., closed door pharmacies, central fill pharmacies, etc.) and believes its proposal to allow the Board to establish different ratio requirements via regulation is appropriate and consistent with the Board's authority to establish the pharmacist to pharmacy technician ratio for inpatient pharmacy settings. The Board's statutory proposal is included in Attachment H-2 in volume 2 of its report.

ISSUE #20: ***Pharmacy Technicians Compounding Outside a Pharmacy. Should pharmacy technicians be authorized to perform specified tasks outside a pharmacy setting?***

Background: The Pharmacy Law specifies that a pharmacy technician is an individual who assists a pharmacist "in a pharmacy." However, the Board states that it 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, including in unlicensed settings such as hydration clinics and wellness spas. 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 in violation of federal law.

The Board has expressed its grave concern about these deviations and the potential for harm to patients. The Board provided multiple examples of deviations, including using nonsterile ingredients and repacking the nonsterile ingredient, adding water, and then labeling the end product as a sterile injectable product. Another provided example of serious patient harm included a pharmacy technician who 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.

While the Board states that pharmacy technicians play an integral role in assisting pharmacists with performing their duties, it notes that they 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 is concerned that no such direct supervision and control of the pharmacy technician's practice appears to occur. In response to these concerns, the Board is recommending an amendment to the Pharmacy Law 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.

Staff Recommendation: ***The Board should explain what type of authority it feels is needed to ensure that pharmacy compounding outside a pharmacy setting occurs safely.***

Board Response: ***The Board thanks the Committees for their interest in the Board's proposal related to pharmacy technicians functioning outside of a pharmacy. The Board notes that the current definition of a pharmacy technician limits activities to only those within the four walls of a pharmacy. The Board cannot comment on enforcement matters that may be pending, but notes that its proposal***

will allow for pharmacy technicians to work under the direct supervision and control of a pharmacist outside of a pharmacy to the benefit of patients, not only in performing compounding duties, but also providing opportunities to assist with vaccine administration, for example at health fairs. The Board's statutory proposal is included in Attachment H-3 in volume 2 of its report.

ISSUE #21: ***Artificial Intelligence. Do artificial intelligence (AI) technologies raise concerns for the practice of pharmacy that should be addressed through new regulation and oversight by the Board?***

Background: The recent acceleration in the evolution of AI technologies has elicited a great deal of attention from policymakers, and this has been especially true when the technology is employed in a health care setting. The Board states that, while it believes the use of artificial intelligence in pharmacy practice has the potential to improve patient care and treatment, it also creates new risks to patients that must be carefully considered. Specifically, the Board reports that it has witnessed a trend in some community pharmacies where it believes 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. The Board believes that with the advent of AI and its use in pharmacy, this current trend will continue, to the detriment of patient care.

The Board is proposing language for possible inclusion in its sunset report that would define AI for purposes of the Pharmacy Law as "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." The Board's proposal would then prohibit pharmacies or pharmacists from utilizing AI technologies to replace or override the professional judgment of a licensed pharmacist in any aspect of pharmaceutical care. The Board believes that this language would help transition pharmacy practice into a world where AI technologies are used to augment a pharmacist's professional judgment while ensuring that they do not replace that judgment.

Staff Recommendation: ***The Board should further educate the Committees regarding how AI has impacted the practice of pharmacy and what statutory changes are needed to safeguard patients.***

Board Response: The Board thanks the Committees for their consideration of this issue. As the use of AI increases, the Board has identified patient safety concerns, where the use of AI appears to be intended to supplant the judgment of a pharmacist. As the Board's report suggests, the Board has conducted investigations that reveal that the use of AI can negatively impact patients by, for example, resulting in delays in therapy not only in access to controlled substances, but also other lifesaving medications such as antiseizure medications. The Board's statutory proposal is included in Attachment H-5 in volume 2 of its report.

ISSUE #22: ***Digital Recordkeeping. Should licensees be authorized to meet recordkeeping requirements by converting paper records to an electronic format and preserving them digitally?***

Background: As explained by the Board in its report to the Committees, the 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.

Staff Recommendation: ***The Board should provide the Committees with its proposed language.***

Board Response: The Board thanks the Committees for considering the Board's proposal regarding digital recordkeeping. The Board's statutory proposal is included in Attachment H-16 in volume 2 of its report.

ISSUE #23: ***Compounding Regulations. Do the Board's proposed regulations relating to compounding standards appropriately preserve patient access while reflecting federal requirements?***

Background: In addition to enforcing state requirements contained in the Pharmacy Law, the Board is responsible for ensuring that licensees meet provisions of federal law governing the practice of pharmacy. The Pharmacy Law specifically requires that the compounding of drug preparations must be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary (USP–NF). The USP develops and publishes standards for drug substances, drug products, excipients, and dietary supplements. These standards are recognized in the federal Food, Drug, and Cosmetic Act.

Recently, the Board has engaged in rulemaking to clarify requirements in drug compounding by licensees in response to recently enacted changes to the USP. These efforts first began when changes to the USP were initially proposed in 2019, at which time the Board held a series of public meetings to discuss proposed language with stakeholders; however, these discussions were paused following delays in the USP's process. Following finalization of the USP Chapters, the Board resumed its efforts to revise its compounding regulations and held another series of meetings to receive further comments from stakeholders. The changes proposed by the Board included restructuring the Board's regulations to align with the USP Chapters, elimination and clarification of requirements, and addition of new requirements.

The Board approved proposed regulation text in April 2023 to amend the Board's regulations regarding compounded drug preparations to implement, clarify, or make more specific requirements related to the USP-NF for nonsterile compounding, sterile compounding, the handling of hazardous drugs, and the preparation, compounding, dispensing, and repackaging of radiopharmaceuticals. The new USP Chapters subsequently became effective on November 1, 2023; because the Board's proposed regulations were not yet effective, the Board released an updated Policy Statement in September 2023 providing stakeholders with additional guidance.

On April 19, 2024, the Board formally distributed its proposed regulation text to interested parties for a 45-day comment period, which ended on June 3, 2024. An additional regulation hearing was held on June 18, 2024. Through this process and throughout these public meetings, stakeholders submitted numerous comments to the Board expressing concerns about the proposed regulations. Representatives of compounding pharmacies specifically raised concern that the provisions relating to sterile compounding exceeded the requirements of the USP and national standards and would result in fewer pharmacies providing compounding services in California. Stakeholders further criticized the Board for what was characterized as excessive enforcement activity against licensees for minor infractions.

In the months following the conclusion of the formal comment period, the Board approved multiple sets of changes to its proposed text in response to the concerns it had received. During its November 2024

meeting, the Board voted to approve a modified regulation text for a 30-day comment period, which ended on December 9, 2024. An additional 15-day comment period was then initiated following further modifications by the Board during its January 2025 meeting, and yet another 15-day comment period was initiated following changes made during the Board's February 2025 meeting.

Meanwhile, organizations opposed to the Board's proposed rulemaking have organized a robust public campaign, specifically citing concerns that the regulations would limit patient access to compounded products such as glutathione, methylcobalamin, and NAD+ infusions. Representatives of the veterinary medical profession have raised additional issues specific to animal patients. In its report to the Committees, the Board argues that it has provided a fair and transparent rulemaking process, providing numerous opportunities for interested stakeholders to participate. The Board believes there has been significant misinformation in the public domain misrepresenting the requirements of federal law.

Because the rulemaking process is still ongoing and the Board has demonstrated a repeated willingness to revise its proposed regulations in response to feedback, it is likely premature for the Committees to consider intervening through statutory preemption. However, the ongoing controversy nevertheless warrants discussion through the sunset process. If it is subsequently determined that the Board has not sufficiently acted to address concerns from stakeholders, the Committees may choose to engage further.

Staff Recommendation: ***The Board should provide an update on its proposed regulations and whether it remains committed to seeking resolution to stakeholder concerns.***

Board Response: ***The Board appreciates the Committees' interest in the Board's efforts to update its compounding regulations consistent with the provisions established in Business and Professions Code section 4126.8. The Board remains committed to addressing comments raised by stakeholders and recently voted to initiate an additional 15-day comment period. This comment period commenced on March 6, 2025, and ended on March 21, 2025. The Board's proposed compounding regulations seek to align with federal and state law, federal guidance, and national standards. The Board's current and proposed compounding regulations cover a variety of practices, including veterinary practices, which fall under separate provisions and guidance in federal law. The Board's regulations must encompass varying provisions reflecting the differing authorities. The Board voted to adopt final text on March 26, 2025.***

As an example, section 503A of the federal Food, Drug, and Cosmetic Act (FD&C Act) applies to human drug compounding by a licensed pharmacist within a state-licensed pharmacy or federal facility, or by a licensed physician. Pharmacies compounding in compliance with the provisions of section 503A are eligible for an exemption from certain provisions of the FD&C Act, specifically section 501(a)(2)(B) (concerning the requirement to comply with Current Good Manufacturing Practice (CGMP) requirements), section 502(f)(1) (concerning requirements related to labeling of drugs with adequate directions for use), and section 505 (concerning the new drug approval process). As required, compounding must be based on receipt of a valid prescription for an identified patient, though FDA does specify that a pharmacy can compound a limited quantity before the receipt of such a prescription with specified conditions. Note: Outsourcing facilities registered with the FDA under section 503B of the FD&C Act are not subject to this same restriction.

This stands in contrast to provisions for veterinary compounding where federal guidance allows for the compounding of animal drugs from bulk drug substances by or under the direct supervision of veterinarians or pharmacists in either state-licensed pharmacies or federal facilities. In this guidance, FDA provides the circumstances under which it does not generally intend to take enforcement action

against drugs compounded from bulk drug substances. These circumstances are for drugs compounded: to fill patient-specific prescriptions for nonfood-producing animals, for office stock for nonfood-producing animals, and for food-producing animals. The FDA has released specific guidance for each of these circumstances. In the case of compounding for office stock for nonfood-producing animals, one of the conditions that must be met for the FDA's enforcement discretion policy to apply is that the veterinarian who stocks the drug dispenses or transfers it only to the owner or caretaker of the animal patient or to another veterinarian in the same practice. Note: As stated above, the FDA does not allow a pharmacy operating under section 503A of the FD&C Act to compound for office stock for human patients.

These contrasting provisions highlight in part the complexity pharmacies face when determining what legal requirements to comply with based on the type of patient (human versus animal).

The Board's compounding public rulemaking record is extensive. The Board has sought to align the structure of its compounding regulations in a way that mirrors that of the national standards as a means to assist licensees with using the national standards and Board's regulations. The Board's regulations generally seek to clarify and make more specific the requirements in federal law, federal guidance, and the national standards, while also addressing some areas either not addressed by these other sources, or where, for example, the national standards defer to regulatory bodies with oversight over compounding practices. As an example, Chapter 797 of the national standards includes, "Handling of blood components and other biological materials must additionally comply with laws and regulations of the applicable regulatory jurisdiction." The Board's proposed regulations as adopted by the Board provide, "CSPs (compounded sterile drug products) with human or whole blood or human whole blood derivates shall be produced in compliance with Health and Safety Code section 1602.5. This section shall not apply to the compounding on an FDA-approved human whole blood or human whole blood derivative product." As another example, there are number of terms used in the national standards that are not defined. The Board's proposed regulations provide definitions for these terms.

The Modified Initial Statement of Reasons, Underlying Data, and Documents Relied Upon describe the significant efforts undertaken by the Board through the development of the regulation proposal and the formal rulemaking process. Both during the public regulation development process and through the formal rulemaking process the Board has made significant changes in response to public comments, balancing its consumer protection mandate with concerns about access to safe compounded medications. Further, as part of the regulation development process and through the rulemaking, the Board has sought to provide education to interested stakeholders above and beyond the materials included or referenced in the Modified Initial Statement of Reasons. This education has included presentations, FAQs and summary documents along with the Board's responses to public comments. The Board looks forward to continuing its efforts to work with stakeholders as the rulemaking process continues and keeping the Legislature and Administration apprised.

Lastly, the Board believes it is appropriate to respond to some of the public comments received during the Board's oversight hearing.

1. ***Some commenters suggested that firefighters are unable to access compounded glutathione for inhalation treatment in California. The Board has data that indicates otherwise. The Board is also aware of communication addressed to the oversight committees confirming the availability in California of compounded glutathione for inhalation.***

2. ***Some commenters suggested that the Board's regulation of compounding extends to physicians and other healing arts professionals. To the contrary, the Board's regulatory authority is clear and limited to its licensees. The Board has provided education in this area through the rulemaking process.***
3. ***Some commenters suggested the Board is enforcing underground regulations. The Board does not agree. To the contrary, the Los Angeles County Superior Court in a compounding case (Absolute Pharmacy, LLC et al. v. California State Board of Pharmacy et al., LASC 22STCP04253) found that (1) the compounding pharmacy "violated California law when it sold or distributed sterile compounded drugs using ineligible drug ingredients to consumers in California because they were unapproved new drugs in violation of state law," (2) the pharmacy's "use of ungraded active ingredients that lacked a USP drug monograph caused the products to lack quality and be deemed adulterated," contrary to law, and most importantly, (3) the Board's actions were not based on an unlawful underground regulation.***

ISSUE #24: ***Medication Flavoring. Is current law relating to pharmacy compounding overly restrictive as applied to the addition of a flavoring agent to medications?***

Background: For purposes of its General Chapter 795, the USP defines nonsterile compounding as "combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation." The USP has published a position statement affirming that it has considered the flavoring of conventionally manufactured medications to be within the scope of General Chapter 795 since 2004. In formal commentary published in November 2022, the USP responded to a comment indicating that the addition of flavoring agents should not be required to meet nonsterile compounding requirements with the following statement:

> "Flavorings are organic chemicals with reactive functional groups including acids, alcohols, aldehydes, amides, amines, esters, ketones, and lactams. Flavorings are not always labeled with their full ingredients and may contain solvents. Minor components in a flavoring system can impact the stability of a CNSP. Impacts on stability can lead to degradation, production of harmful impurities, and/or reduced bioavailability. Flavorings can impact levels of impurities while having no impact on assay values."

The FDA has not officially issued guidance relating to the question of whether adding flavoring constitutes compounding. However, correspondence between the FDA and the Board confirmed that "the addition of a flavoring by a pharmacy to a drug generally would be considered compounding," but that, "if the labeling for an FDA-approved drug includes directions to do so, adding flavoring to the drug in accordance with these directions would not be considered compounding." This would indicate that the addition of flavoring does not need to comply with General Chapter 795 if directions for flavoring were included on an FDA-approved drug label.

While the USP and the FDA have historically considered most instances of flavoring to constitute compounding, the Board's regulations previously exempted addition of flavors. Specifically, the Board's prior regulations stated: "'Compounding' does not include reconstitution of a drug pursuant to a manufacturer's direction(s), nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability." This language appeared to conflict

with USP standards, which the Pharmacy Law has expressly required compounding in California to be consistent with since the enactment of Assembly Bill 973 (Irwin) in 2019.

Because the Board's regulations were considered to be out of compliance with the USP, the Board took action to reconcile its regulations and remove the exemptions for flavoring. This resulted in concerns raised by stakeholders that many pharmacies who do not wish to comply with the USP General Chapter 795 standards will cease to engage in the addition of flavoring. As a result, legislation has been introduced to statutorily restore the exemption for flavoring for purposes of California, notwithstanding the provisions of the USP, beginning with Assembly Bill 782 (McKinnor) in 2023. This bill was vetoed by the Governor, who stated that while he "appreciate[d] the author's intention to maintain the current availability of flavored medication, this bill would create standards for California that do not meet the United States Pharmacopeia-National Formulary's guidelines regarding compounding that have been put in place to minimize patients' risk of harm." A similar proposal was contained in Assembly Bill 3063 (McKinnor) the following year, but this legislation was also vetoed by the Governor, who "encourage[d] the author to work with the Department of Consumer Affairs on legislation that facilitates the availability of medication flavoring while maintaining foundational consumer protections.

In its report to the Committees, the Board expressed its support for the use of flavoring agents as a tool to assist patients and stated that it looks forward to continued discussion and opportunities to provide education on requirements and gaining additional insights into barriers to meeting the national standards. The Board has additionally offered its own proposed compromise solution in the form of language that was originally proposed for Assembly Bill 3063. If this solution is agreeable to stakeholders, it may be considered by the Committees for inclusion in the Board's sunset bill.

Staff Recommendation: ***The Board should provide an update on its discussions with stakeholders regarding medication flavoring and explain why it believes its proposed solution is appropriate.***

Board Response: The Board thanks the Committees for their interest in the Board's proposal to clarify a pharmacist's authority to compound by adding a flavoring agent to an FDA approved oral liquid dosage form without consultation with the prescriber or prescriber's authorized agent. As noted in its report, the Board continues to seek input from stakeholders about barriers to compounding using flavoring agents. The Board's statutory proposal is included in Attachment G-4 in volume 2 of its report.

Further, in addition to the Board's statutory proposal, the Board is also pursuing regulation changes that would provide an exemption from most parts of the Board's nonsterile compounding regulations to pharmacies that limit compounding activities to adding a flavoring agent.

ISSUE #25: ***Remote Processing. Should prior emergency authorization for the remote processing of prescriptions be restored for additional settings?***

Background: As explained by the Board in its report to the Committees, a "Remote Processing Waiver" was approved by the Board as part of its response to the COVID-19 public health emergency. "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. While the Pharmacy Law does not explicitly require a pharmacist performing verification of medication orders to do so onsite, there was not any clear authority for this form of remote processing to occur. The Board's waiver expressly provided legal authorization for remote processing to allow for greater flexibility under pandemic conditions.

Specifically, the waiver allowed that pharmacists performing remote processing could also receive, interpret, evaluate, clarify, and approve medication orders and prescriptions, including medication orders and prescriptions for controlled substances. 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 authority 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 technology that facilitates remote supervision.

Following the formal end to the COVID-19 pandemic, the Board has sought legislation to continue allowing for remote verification of medication orders. In 2023, the Board sponsored Assembly Bill 1557 (Flora), which maintained the authorization for a licensed pharmacist to verify medication chart orders on behalf of a licensed hospital, from a location outside of the hospital. However, remote processing outside of a hospital setting continues to be prohibited since the expiration of the waiver, and some stakeholders have raised concerns about the impact on the pharmacist workforce in California. The Board reports that it has considered a number of policy questions and ultimately identified a statutory proposal that it believes can create a path forward to establish provisions for some remote work on a permanent basis.

Staff Recommendation: ***The Board should provide the Committees with more information about its proposal and why it believes it is the appropriate solution to continue allowing for remote processing outside a hospital setting.***

Board Response: ***The Board thanks the Committees for their interest in the Board's remote processing proposal. The Board notes that during the COVID-19 public health emergency and more recently in response to other declared emergencies including the recent wildfires in Los Angeles, the Board has issued a waiver to its remote processing provisions to ensure continuity of patient care while ensuring that final product verification and dispensing occurs at the pharmacy before the patient receives their medication. The general provisions of the waiver allowed for greater flexibility to handle certain provisions in the dispensing process, including, for example, allowing a pharmacist to perform order entry, perform drug utilization review, and provide drug information services. In 2023, the Board sponsored legislation to establish permanent authority for pharmacists to perform these remote functions on behalf of a hospital servicing inpatients. The Board believes permanent authority is also appropriate for community pharmacies. The Board has received significant public comments from pharmacists working in specialty pharmacies requesting that the Board secure statutory changes in this area.***

The Board's statutory proposal is included in Attachment H-13 in volume 2 of its report.

ISSUE #26: ***Health System Pharmacies. Should there be greater distinction in the Pharmacy Law between community pharmacies and health system pharmacies?***

Background: Historically, the various provisions of the Pharmacy Law are generally applicable to the practice of pharmacy in most settings, regardless of whether medication is being dispensed at a local

retail store or within a hospital. Various requirements have traditionally not applied when medication is dispensed as part of inpatient care, and recently-enacted legislation, specifically related to workforce conditions, has specified their applicability to community pharmacies. However, there are still a number of provisions that apply equally to health system settings and community pharmacy settings, and some of these provisions may not be an appropriate "one size fits all" solution to patient protection. As new proposals are introduced in the Legislature, the Committees may wish to evaluate whether they are appropriately tailored in their applicability.

Staff Recommendation: ***The Board should provide the Committees with its opinion as to whether there are any existing requirements in the Pharmacy Law that should be narrowed based on setting.***

Board Response: ***The Board thanks the Committees for raising this important question. The Board agrees that patient safety concerns may vary based on the specific type of practices and notes that core to its consumer protection mandate is a focus on medication therapy, including ensuring the right medication is given to the right patient at the right time. Compliance with this basic tenet of consumer protection is not limited to a singular type of practice site under the Board's jurisdiction.***

The Board believes that this issue warrants additional consideration and if the Legislature and Administration agree, the Board believes such an evaluation could be performed through the Board's Licensing Committee or an ad hoc committee of the Board.

The Board notes that under the current statutory framework, non-institutional pharmacies (e.g., independent community, chain community, mail order, long term care, closed door, and hospital outpatient settings) are generally regulated under the same legal provisions, with exceptions and carveouts for specific types of entities. As an example, the Board recently received a presentation on medication reconciliation activities that occur in hospitals consistent with the provisions in Business and Professions Code section 4118.5. These provisions require hospital pharmacies to obtain medication profiles for each high-risk patient upon admission, as specified. This presentation demonstrated the positive outcomes to patients since implementation of the requirements. The presentation also highlighted the need for additional changes to address medication errors that occur during discharge. Specifically, the Board was advised that 2/5 of patient have discrepancies in their medications at discharge. Further, 29% of patient experience one or more serious adverse drug events post-discharge. To address this issue, and consistent with the recommendation of the presenter and public comment, the Board requests the Committee's consideration of the following amendment to BPC 4118.5:

> ***4118.5.***
> ***(a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission and discharge of the high-risk patient under the following conditions:***
> ***(1) The hospital has more than 100 beds.***
> ***(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.***
> ***(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:***
> ***(1) The hospital pharmacy has a quality assurance program to monitor competency.***

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.
(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.
(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.
(e) This section shall not apply to the State Department of State Hospitals.
(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

EQUITY ISSUES

ISSUE #27: ***Pharmacy Deserts. Should the Board waive application fees for pharmacies seeking to operate in a medically underserved area?***

Background: California has long faced significant gaps and inequities in its health care workforce. There has historically been a persistent shortage of accessible health professionals overall, which disproportionately impacts communities with concentrated populations of immigrant families and people of color. A recent study found that between 2010 and 2019, the number of primary care physicians in proportion to population remained largely unchanged nationally. Meanwhile, counties with a higher proportion of minorities saw a decline during that period.

In response to these challenges, policymakers have repeatedly turned to pharmacists to help fill the provider gap in parts of the state where primary care providers can be inaccessible but local pharmacies are more readily available. Exercising their training and judgment, pharmacists are often relied upon to administer vaccines, furnish time sensitive medication like hormonal contraception and HIV prevention drugs, and ensure that there is no delay in care. However, the Board reports that there are still parts of the state where even pharmacies can be difficult to access. According to the Board, there has been over a 117 percent increase in community chain pharmacy closures over the last three years; over that same time, the overall licensee population of pharmacies has also been reduced by seven percent.

The Board estimates that there are over 100 "pharmacy deserts" in California, which the Board proposes to define as a medically underserved area that does not have a physical pharmacy within 50 road miles. The Board is proposing to waive the license fees associated with opening a new brick-and-mortar pharmacy in a pharmacy desert. Further, the Board is proposing to use dedicated staff to serve as an ombudsperson to assist the pharmacy owner with pharmacy application requirements. The Board's proposal would allow pharmacies established in the pharmacy deserts to operate without paying fees to the Board until such time as more than two pharmacies conduct business in the underserved area.

Staff Recommendation: ***The Board should provide the Committees with a copy of its proposed language to assist patients living in pharmacy deserts.***

Board Response: ***The Board thanks the Committees for their interest in the Board's pharmacy desert proposal. The Board's statutory proposal is included in Attachment H-7 in volume 2 of its report. The Board looks forward to working with the Legislature and the Administration to establish this fee***

waiver authority as well as any other opportunity to address many of the root causes of pharmacy deserts.

The Board also believes that evaluation of urban pharmacy deserts is appropriate. The Board will be evaluating this issue and look forward to working with the Legislature and the Administration.

ISSUE #28: ***Hormonal Contraception. Are provisions of the Pharmacy Law impeding the implementation of laws intended to expand access to self-administered hormonal contraception?***

Background: In July 2023, the FDA announced its approval of the medication Opill, a norgestrel tablet to prevent pregnancy. Opill was the first daily oral contraceptive approved for use in the United States without a prescription, significantly increasing access to patients by allowing them to purchase oral contraceptive medicine at local pharmacies over the counter (OTC). This approval significantly increased availability and access to birth control for women and other patients seeking to prevent pregnancy.

However, the OTC status of Opill has complicated the implementation of related efforts to increase access to contraception, specifically those related to health coverage and reimbursement. In 2022, the Legislature enacted Senate Bill 523 (Leyva), which requires a health care service plan or health insurer 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. Because insurers generally require a prescription to reimburse for medications, even those approved as OTC by the FDA, patients are not able to take advantage of this legislation when accessing Opill directly from a pharmacy.

Pharmacists are already authorized to furnish self-administered hormonal contraception, including those requiring a prescription. However, they must do so in accordance with standardized procedures and protocols that can present a barrier to access for patients. To resolve this issue, Assembly Bill 50 (Bonta) has been introduced to clarify that a pharmacist may furnish OTC contraceptives without the standardized procedures or protocols required for prescription-only medications. The Board has also proposed a solution to this issue, which it believes could alternatively be addressed following transition to a standard of care model for the practice of pharmacy.

Staff Recommendation: ***The Board should inform the Committees of whether it has taken a position on Assembly Bill 50 and whether it believes an alternative solution would be easier to implement.***

Board Response: ***The Board thanks the Committees for their interest in the Board's concerns with barriers patients encounter with accessing over-the-counter and prescription hormonal contraception. The Board notes that the current prescriptive regulation of pharmacists-furnished hormonal contraception creates barriers to care. The Board's statutory proposal for this specific patient care issue is similar to the approach offered in Assembly Bill 50 and is included in Attachment H-18 in volume 2 of its report. The Board established a support position on Assembly Bill 50 during its April 9-10, 2025 Board meeting.***

The Board notes that a transition to a more robust standard of care practice model would also resolve these types of patient care issues. The Board looks forward to working the Legislature and the Administration to address barriers to care.

IMPLEMENTATION ISSUES

ISSUE #29: ***Stop Dangerous Pharmacies Act. As the Board works to implement the provisions of Assembly Bill 1286 (Haney), has it identified the need for clarifying or corrective amendments?***

Background: In 2023, the Legislature enacted Assembly Bill 1286 (Haney), which was sponsored by the Board and established a number of new requirements aimed at increasing worker and patient safety at community pharmacies. Among other provisions, the bill authorized pharmacists-in-charge to make staffing decisions in a pharmacy; required a pharmacist-in-charge or pharmacist on duty to notify store management of any conditions that present an immediate risk of death, illness, or irreparable harm, and required store management to take action to address and resolve those conditions, and authorized the Board to close a pharmacy if the conditions aren't resolved; and required a chain community pharmacy to be staffed with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The bill also authorized pharmacy technicians with specified training to perform additional tasks under supervision, including administering influenza and COVID-19 vaccines and epinephrine and performing specimen collection for laboratory tests.

The Board reports that, as it has moved forward with implementation of Assembly Bill 1286, it has received public comments from interested stakeholders suggesting that clarification is needed on authorized tasks for pharmacy technicians, specifically those related to the transfer of prescriptions. In addition, stakeholders have reportedly requested changes to clarify some of the current requirements for these specially trained pharmacy technicians. The Board has provided language intended to provide for this clarification. If any other provisions of Assembly Bill 1286 are in need of refinement or revision, the Board may propose additional language to aid in its implementation of the legislation.

Staff Recommendation: ***The Board should provide an update on its implementation of Assembly Bill 1286 and provide the Committees with any language needed to assist in that implementation.***

Board Response: ***The Board thanks the Committees for their interest in the Board's implementation of Assembly Bill 1286 and its request to pursue some technical changes that were identified during implementation activities. Given the comprehensive nature of the measure, the Board has undertaken a number of activities to implement the provisions, including approving the entity responsible for receiving medication errors. Following the state contracting process, the Board approved, and awarded a contract to, the Institute for Safe Medication Practices. As implementation efforts specifically related to medication error reporting continues, the Board's outreach and education to licensees will be vital.***

The Board is also in the process of evaluating working conditions in community pharmacies. In addition to performing investigations into allegations of noncompliance with staffing requirements, the Board released a follow-up online survey for pharmacists to provide feedback to the Board on working conditions. The Board will also be releasing a survey specifically soliciting feedback from pharmacy technicians. It is anticipated that the results of these surveys will be reviewed by the Board later this year.

In its implementation of AB 1286, the Board continues to use education as a primary means to promote compliance. The Board drafted FAQs and published a special edition newsletter discussing the various provisions of the measure and resources to assist licensees with compliance. Through this

process, the Board received comments from stakeholders seeking clarification on the requirements for nonresident pharmacies to report medication errors and clarification on the expanded authority for specially trained pharmacy technicians. The Board's proposed language is included in Attachment H-12 in volume 2 of its report.

ISSUE #30: ***No Pharmacist Left Alone Law. Does the Board's access to records need to be strengthened to allow for effective enforcement of Senate Bill 1442 (Wiener)?***

Background: The Legislature enacted Senate Bill 1442 (Wiener) in 2018, which prohibited a community pharmacy from requiring a pharmacist employee to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless another employee is made available to assist the pharmacist at all times. The bill's findings and declarations cited reports that "licensed pharmacists are left alone for indeterminate periods of time in the pharmacy and are, simultaneously, required by such establishments to perform nonpharmacist functions such as staffing cash registers and assisting consumers in purchasing prescriptions, groceries, and other nonpharmacy goods." The bill was intended to ensure minimum staffing at pharmacies to ensure that pharmacists have the time and resources "to perform their licensed functions safely and lawfully, exercise their professional discretion, and comply with their legal and ethical obligations to protect the health and well-being of patients."

Following the completion of the Board's rulemaking to implement the bill, it reports that it has received a number of allegations of non-compliance with the legal requirements regarding pharmacy operations, including staffing requirements and quota prohibitions. The Board reports that investigating these complaints has been 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 expressly found in statute. The Board indicates that such challenges create barriers to conducting complete and timely investigations.

To address these challenges, the Board is proposing updates to the Pharmacy Law to explicitly state that additional records must be maintained and made available to the Board upon request. The types of records would include job duty statements, which would confirm whether an individual meets the requirements of the Board's regulation; staffing schedules that would demonstrate compliance with staffing requirements and performance metrics; and training records that confirm an individual meets the requirements to perform specified tasks, among other records. The Board argues that clear access to these records will aid in its implementation and enforcement of Senate Bill 1442 to ensure that its intent is achieved.

Staff Recommendation: ***The Board should provide an update on its implementation of Senate Bill 1442 (Wiener) and inform the Committees of what language is needed to allow for its enforcement.***

Board Response: ***Board staff thank the Committees for their interest in the Board's implementation of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) and other legislation addressing workplace issues. As the Board noted in its report, as legislation is implemented related to workplace conditions, the Board has been tasked with investigations that require access to information and pharmacy records that are not currently referenced in Business and Professions Code sections 4081 and 4105. To ensure the Board has timely access to this information, the Board is requesting updates to Pharmacy Law to explicitly state the additional records that must be maintained and made available***

upon request of the Board. The Board's proposed language is included in Attachment H-15 in volume 2 of its report.

TECHNICAL CLEANUP

ISSUE #31: ***Technical Cleanup. Is there a need for technical cleanup?***

Background: As the pharmacy profession continues to evolve and new laws are enacted, provisions of the Pharmacy Law may become outmoded or superfluous.

Staff Recommendation: ***The Board should recommend cleanup amendments for inclusion in its sunset bill.***

Board Response: ***The Board appreciates the opportunity to recommend cleanup statutory amendments. The Board does not have any additional provisions requiring cleanup beyond those identified in its report.***

CONTINUED REGULATION OF THE PHARMACY PROFESSION BY THE CALIFORNIA STATE BOARD OF PHARMACY

ISSUE #32: ***Continued Regulation. Should the licensing of pharmacy professionals be continued and be regulated by the Board?***

Background: In consideration of the Board's critical public protection mission in its regulation of the pharmacy profession in California, it is likely that the committees will ultimately determine that the Board's repeal date should be extended for an additional term.

Staff Recommendation: ***The Board's current regulation of the pharmacy profession should be continued, with potential reforms, to be reviewed again on a future date to be determined.***

Board Response: ***The Board thanks the Committees for their consideration of the issues raised by the Board. The Board looks forward to working with the Legislature and the Administration as its continues to regulate the pharmacy profession.***

Attachment 1

Proposal to Amend Business and Professions Code Section 4317.5 as follows:

4317.5.

(a) The board may bring an action for fines for repeated violations of materially similar provisions of this chapter withing five years by three or more pharmacies operating under common ownership or management within a chain community pharmacy, 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) The board may bring an action against a chain community pharmacy operating under common ownership or management for fines not to exceed one hundred fifty thousand dollars ($150,000) for any violation of this chapter demonstrated to be the result of a written policy or which was expressly encouraged by ~~the common~~ any owner or manager.

~~(c) The board shall not bring an action for fines pursuant to subdivision (a) until at least six months have elapsed from the date the board determines that a violation has occurred unless the violation giving rise to the action resulted in actual harm to any consumer or serious potential harm to the public.~~

(~~d~~ c) In an action brought by the board pursuant to subdivision (a), it shall be a ~~defense~~ mitigating factor for any pharmacy to establish either of the following:

(1) That the violation was contrary to a written policy that was communicated by ~~the~~ any ~~common~~ owner or manager of the pharmacy to all employees of the pharmacies where the violation occurred, and that the entity can demonstrate its compliance with the policy.

(2) That, within six months after the violation, ~~the~~ any ~~common~~ owner or manager corrected all unlawful policies, communicated the change in policy or policies in writing to all pharmacies under its ownership or management, and provided proof of abatement of the violation to the board, so long as the violation did not result in actual harm to any consumer or serious potential harm to the public.

(~~e~~ d) In determining the amount of the fine sought in an action brought pursuant to this section, the board shall consider relevant mitigating and aggravating 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 patients, whether the violation affects the professional judgment or independence of pharmacists and pharmacy technicians, and the history of previous violations by the common owner or manager.

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

(~~g~~ h) For purposes of this section, "chain community pharmacy" shall have the same meaning as defined in Section 4001.

(~~h~~ i) The fines in subdivisions (a) and (b) shall be imposed in accordance with Section 4314.

~~(i) In connection with the board's first Joint Sunset Review Oversight Hearing pursuant to Section 9147.7 of the Government Code occurring after this section becomes operative, the board shall provide to the appropriate committees of the Legislature all of the following information:~~

~~(1) The number of actions brought pursuant to this section.~~

~~(2) The number of actions brought pursuant to this section that did not result in any fines.~~

~~(3) The types of violations giving rise to actions brought pursuant to this section.~~