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

BRIEF OVERVIEW OF THE CALIFORNIA STATE BOARD OF PHARMACY

The California State Board of Pharmacy (Board) traces its origins back to 1891, when it is reported to have registered a total of 1,063 pharmacists and 369 pharmacist assistants. Today, the Board is estimated to regulate over 50,700 pharmacists, 1,300 advanced practice pharmacists, 4,400 intern pharmacists, and 65,700 pharmacy technicians across a total of 32 licensing programs. In addition to regulating personal professionals, the Board oversees and licenses related business entities, including pharmacies, clinics, wholesalers, third-party logistic providers, and automated drug delivery systems.

As one of approximately three dozen boards and bureaus under the Department of Consumer Affairs, the Board plays an important role in the regulatory ecosystem that oversees the healing arts. In the face of persistent concerns such as the ongoing opioid crisis, the Board is empowered to ensure that dangerous drugs and controlled substances are dispensed and furnished only under lawful circumstances. Under regulations enforced by the Board, pharmacists are tasked with a corresponding responsibility for ensuring that the prescriptions they fill are legitimate and not for purposes of abuse.

Entrusted with administering and enforcing the state's Pharmacy Law, statute provides that "protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount."[1]

History of Pharmacy Regulation in California

In the early days of statehood, the practice of pharmacy was divided between physicians and general "pharmaceutists" (also commonly referred to as druggists or apothecaries). A majority of drug stores were connected to prescriber offices, leading to criticism among pharmaceutists that many physicians engaged in unethical behavior and unfair competition toward "disinterested apothecaries." It was also alleged that some dishonorable druggists would circumvent physicians by "prescribing at the counter." In response, the American Pharmaceutical Association was founded in 1852 to organize the pharmacy profession, defend its interests as a healing art distinct from medicine, and set ethical standards.[2]

[1] Bus. & Prof. Code, § 4001.1

[2] *Proceedings of the American Pharmaceutical Association at the annual meeting*, Vol. 1, 1852.

According to information reported by Dr. Gustavus L. Simmons as part of a national survey conducted in advance of the American Pharmaceutical Association's first meeting, legislation had been introduced in the California State Assembly in 1851 to provide "for the protection of the interests of pharmacy," but was withdrawn following "strong opposition," presumably from physicians. It was suggested that "a slight action on the part of druggists might easily secure legislative action on the subject of poisons."[3] The American Pharmaceutical Association would subsequently lobby state legislatures across the country to formally establish the practice of pharmacy as an independent profession.[4]

The California Pharmaceutical Society was founded in 1869 to promote "the advancement of pharmaceutical knowledge and the elevation of the professional character of apothecaries throughout the state of California." In 1872, the society successfully lobbied for the passage of Senate Bill 302 (Garratt), a measure it had drafted "to regulate the practice of pharmacy in the City and County of San Francisco," where the society had founded the first California College of Pharmacy that same year.[5] The legislation provided that only registered pharmacists or registered assistant pharmacists would be allowed to "open or conduct any pharmacy or store for retailing, dispensing, or compounding medicines or poisons" within the jurisdiction.[6] The bill additionally established a Board of Pharmacy to administer and enforce the law, appointed by members of the California Pharmaceutical Society. However, this law was subsequently invalidated following the ratification of the California Constitution in 1880.

In 1891, the Legislature enacted Senate Bill 84 (Maher), a measure "to regulate the practice of pharmacy and sale of poisons in the State of California." Under the new law, only registered pharmacists would be authorized "to conduct any pharmacy or store for dispensing or compounding medicines" anywhere in the state. The bill additionally created a State Board of Pharmacy to oversee and license registered pharmacists and assistant pharmacists, comprised of "seven competent pharmacists" appointed by the Governor.[7]

The Legislature passed Senate Bill 367 (Lukens) in 1905, replacing the 1891 law with a substantially similar licensing scheme for pharmacists but with more detailed regulation of the practice of pharmacy and expanded powers for the State Board of Pharmacy.[8] In 1929, the Legislature enacted Senate Bill 30 (Crowley) to require the owners of pharmacies and drug stores to register with the Board.[9] That same year, the Board was incorporated into the Department of Professional and Vocational Standards (precursor to the Department of Consumer Affairs) through the Legislature's enactment of Assembly Bill 739 (Feigenbaum).[10]

The Board today is considerably similar to the iteration that was first created by the Legislature a century ago, comprised of seven licensed pharmacists with the addition of six public members appointed by the Governor and legislative leadership. Meanwhile, the practice of pharmacy—described in the Pharmacy Law as "a dynamic, patient-oriented health service"—has continued to evolve, and the role of the pharmacist has become central to ongoing efforts to improve statewide access to care. The Board's public protection mission remains as vital as ever, as does the importance of robust legislative oversight.

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[3] *Id.*
[4] Kremers, Edward. *History of Pharmacy: A Guide and a Survey*, J.B. Lipincott Company, London, 1940.
[5] *1868-1898 - California Pharmaceutical Society - A History of UCSF*. history.library.ucsf.edu/1868_pharmaceutical.html.
[6] Chapter 454, Statutes of 1872.
[7] Chapter 85, Statutes of 1891.
[8] Chapter 406, Statutes of 1905.
[9] Chapter 156, Statutes of 1929.
[10] Chapter 290, Statutes of 1929.

Mission Statement

The Board has adopted the following mission statement, as stated in its most recent Strategic Plan:

> ***"The Board of Pharmacy protects, promotes, and advocates for the health and safety of Californians by pursuing the highest quality of pharmacists' care and the appropriate use of pharmaceuticals through education, communication, licensing, legislation, regulation, and enforcement."***

Board Membership and Committees

The Pharmacy Law provides that the Board consists of thirteen members, seven of which are licensees of the Board and six of which are unlicensed members of the public. The Governor is responsible for appointing the pharmacist members, who are required to reside in different parts of the state, as well as four public members. The Speaker of the Assembly and the Senate Committee on Rules are responsible for appointing one additional public member each.

Of the seven professional members on the Board, at least five are required to be actively engaged in the practice of pharmacy. The Board is also required to include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, a compounding pharmacy specializing in human drug preparations, and a long-term health care or skilled nursing facility. At least one of the professional members must also be a pharmacist who is a member of a labor union.

Each board member receives a per diem of one hundred dollars for each day spent performing official board duties, as well as travel expenses. Members of the Board may serve a maximum of two consecutive four-year terms, with the option of remaining on the Board for up to one additional year pending the appointment and qualification their successor. Any vacancies on the Board are filled by appointment for the unexpired term. Each appointing authority has the power to remove any of its appointees at any time.[11]

The current composition of the Board is as follows, including one vacancy:

Name and Bio	Original Appointment	Expiration of Current Term	Appointing Authority
Seung Oh, PharmD *(President)* **Professional Member** Dr. Oh has been a pharmacy supervisor for Sharp Healthcare since 2020. He was a pharmacist-in-charge at Vons Pharmacy in San Diego from 2014 to 2020, staff pharmacist at Safeway Pharmacy in 2014, and a pharmacist and director of operations at Rainbow Pharmacy from 2013 to 2014. He earned a master of advanced studies degree in leadership of health care organizations from University of California, San Diego, and a doctor of pharmacy degree from University of Arizona. He is a member of the California Pharmacists Association.	02/24/2020	06/01/2027	Governor

[11] Bus. & Prof. Code, § 4001

Jessica "Jessi" Crowley, PharmD *(Vice President)* **Professional Member** **Labor Union Representative** Crowley has been a staff pharmacist for Pavilions Pharmacy since 2020. She held several positions for CVS Pharmacy from 2010 to 2020, including pharmacist-in-charge, staff pharmacist, and pharmacy intern. Her interests include health equity, racial and social justice, and cultural competence. Crowley is a member of Lambda Kappa Sigma, United Food and Commercial Workers, the California Pharmacists Association, Los Angeles County Federation of Labor, and Phi Lambda Sigma.	05/19/2022	06/01/2025	Governor
Trevor Chander *(Treasurer)* **Public Member** Trevor Chandler, of San Francisco, was appointed to the California State Board of Pharmacy by Governor Gavin Newsom in 2022. Chandler has been a leader in the LGBTQ civil rights movement having worked as a key strategist for seven marriage equality campaigns and multiple nondiscrimination campaigns. In 2015 he was recognized by the Global Diversity List as one of the Top 50 Global Diversity Leaders in Public Life.	09/09/2022	06/01/2025	Governor
Renee Armendariz Barker, PharmD **Professional Member** **Compounding Pharmacy Representative** Dr. Armendariz Barker has been sterile products manager at the Lucile Packard Children's Hospital Stanford since 1998. She is a member of the California Society of Health System Pharmacists and the American Society of Health System Pharmacists. Dr. Armendariz Barker earned a doctor of pharmacy degree from the University of California, San Francisco.	06/24/2022	06/01/2027	Governor
Indira J. Cameron-Banks **Public Member** Ms. Cameron-Banks is the founding attorney of Cameron Banks Law in Beverly Hills. She previously served as the Los Angeles County-wide Director for the Preventing and Ending Homeless Project at the Inner City Law Center in 2020. She also served as an assistant United States attorney in the criminal and civil divisions of the United States Attorney's Office for the Central District of California from 2007 to 2020, including as the chief of financial litigation and special counsel to the United States attorney. Ms. Cameron-Banks began her legal career in 2003 as a law clerk for the Connecticut Superior Court. She then practiced as an associate in a law firm in Rhode Island, Massachusetts, and Connecticut before moving to Los Angeles. She earned a juris doctor from Boston University School of Law in 2003 and a bachelor's degree from University of Chicago in 1999.	02/03/2022	06/01/2024	Governor

R. Jeffrey Hughes **Public Member** Hughes has been a Wellness Business Agent at the Orange County Professional Firefighters IAFF Local 3631 since 2020. He was a Fire Captain at the Orange County Fire Authority from 1994 to 2020 and a Firefighter/Engineer for the City of Buena Park Fire Department from 1985 to 1994.	03/19/2024	06/01/2026	Governor
Kartikeya "KK" Jha, R.Ph. **Professional Member** **Long-Term Care/Skilled Nursing Representative** Jha has been District Director of Operations at Omnicare—a CVS Health Company since 2019. He was Director of Operations at NimbleRx from 2018 to 2019. Jha earned a Master of Science degree in Pharmacology and Toxicology from Long Island University.	09/09/2022	06/01/2024	Governor
Jason "J" Newell, MSW **Public Member** Newell founded and co-founded several businesses including 3 non-profits over the last 22 years. Most recently, Newell was Principal and Co-Founder of System2Solutions since 2020. He was also Co-Founder and remains Program Director of Leveraging Equal Access Program since 2015. Newell attended the University of California, Davis and The Academy of Art Colleges, earning a Bachelor of Fine arts, followed by a Master of Social Work (emphasis on community mental health) degree from California State University, Hayward.	03/19/2024	06/01/2024	Governor
Satinder Sandhu, PharmD **Professional Member** **Chain Community Pharmacy Representative** Satinder Sandhu, of Davis, was appointed to the State Board of Pharmacy by Governor Newsom in 2024. Sandhu has been Area Healthcare Supervisor of Northern California for Walgreens since 2019. He held multiple positions with Walgreens from 1992 to 2019, including District Manager, District Pharmacy Supervisor and Pharmacy Manager. Sandhu earned a Doctor of Pharmacy degree from the University of the Pacific.	03/19/2024	06/01/2025	Governor
Maria D. Serpa, PharmD **Professional Member** **Acute Care Hospital Representative** Dr. Serpa held several positions at Sutter Medical Center, Sacramento over 25 years and contributed to pharmacy system initiatives at Sutter Health. Her accomplishments include standardization of medication management technologies, regulatory operations, and pharmacy construction. She previously held positions of system-support, pharmacy services manager, quality assurance, and investigational drug pharmacist.	06/19/2018	06/01/2026	Governor

Prior to coming to Sacramento, she worked at Grossmont Hospital (Sharp Healthcare) in San Diego as pharmacy program coordinator of clinical services and staff pharmacist. Dr. Serpa is a past president of the California Society of Health-System Pharmacists and a fellow of both the American Society of Health-System Pharmacists and the California Society of Health-Systems Pharmacists. She earned a doctor of pharmacy degree from University of the Pacific and completed two residencies at University of California, San Diego, Medical Center (clinical pharmacy and critical care).			
Nicole Thibeau, PharmD **Professional Member** **Independent Community Pharmacy Representative** Dr. Thibeau has been director of pharmacy services at the Los Angeles LGBT Center since 2013 and is a member of the policy team, specializing in health services. She was pharmacist in charge at Target Pharmacy from 2012 to 2013 and pharmacist in charge at CVS Pharmacy from 2009 to 2012. She is an advocate for the LGBTQ+ and disability communities. She specializes in HIV and transgender medicine, and serves on committees at the state and national level regarding the 340B drug discount program and pharmacy operations. She earned a doctor of pharmacy degree from the Massachusetts College of Pharmacy and Allied Health Sciences.	07/26/2021	06/01/2024	Governor
Vacant **Public Member**	--	--	Senate Rules
Vacant **Public Member**	--	--	Assembly Speaker

Per the Board's strategic plan, five standing committees consist of representatives on the Board. These committees develop and recommend policies that advance mission-related goals in the Board's strategic plan. The full Board discusses, modifies, and acts upon committee recommendations at its public meetings. The standing committees of the Board are as follows:

- **Licensing Committee:** This committee oversees the professional qualifications of licensees entering the practice of pharmacy, establishes minimum standards for board-licensed facilities, and ensures appropriate practice standards.

- **Enforcement Committee:** This committee exercises oversight of all drug distribution and dispensing activities—including drug compounding—and enforcement of state and federal pharmacy laws. The responsibilities formerly held by the Medication Error Reduction and Workforce Ad Hoc Committee have been incorporated into the scope of this committee.

- **Communication and Public Education Committee:** This committee is responsible for outreach and information for consumers, including the importance of discussing medications with their pharmacists, complying with their prescription treatment regimens, and becoming better informed about drug therapy and health. The committee also ensures development of educational materials for licensees regarding new laws, Board policies, and emerging issues.

- **Legislation and Regulation Committee:** This committee advocates for legislation and promulgates regulations that advance the Board's mission and strategic objectives.

- **Organizational Development Committee:** The Board President and Vice President are the only members of this committee, which typically does not meet in public. The committee is responsible for strategic planning, budget management, and staff development activities. The committee reports on the Board's expenditures, revenue, and fund condition at quarterly Board meetings.

In addition to its standing committees, the Board has established various temporary task force or ad hoc committees, as well as one specialized standing committee, in the time since its last sunset review:

- **Medication Error Reduction and Workforce Ad Hoc Committee:** This committee was established as an initial step toward enhancing patient safety. Its focus was on identifying strategies to reduce medication errors and address working conditions. The committee reviewed various topics, including workforce survey results, Pharmacy Well-being Index State Reports, best practices for medication error reduction, and actions undertaken by other jurisdictions. The ad hoc committee convened six meetings from 2022-23.

- **Standard of Care Ad Hoc Committee:** This committee was established following the Board's last sunset review to assess and make recommendations to the Board and Legislature on the feasibility and appropriateness of transitioning to standard of care enforcement model. The ad hoc committee convened seven meetings from 2022-23. Following submission of the legislative report, ongoing work stemming from this ad hoc committee was transferred to the Licensing Committee.

- **Competency Committee:** This specialized standing committee is under the auspices of the Licensing Committee. In collaboration with a contracted psychometrician, this committee is responsible for the development, scoring and ongoing evaluation of the Board's pharmacist licensure examination, the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). Membership on this committee is highly selective and reflects the diverse scope of California's pharmacy practice. The committee's work is professionally demanding and time-intensive, with members attending nine two-day meetings annually. These meetings are not open to the public, as they involve confidential licensure examination content and are exempt from the provisions of the Bagley-Keene Open Meeting Act.

- **Disciplinary Petition Committee:** This committee of the Board sits with an administrative law judge to consider petitions made under BPC section 4309 for license reinstatement or modification of a disciplinary penalty. All members serve on this Committee on a rotating basis, with each member assigned to participate in two meetings per year.

The Pharmacy Law requires the Board to hold a meeting at least once every four months. The Board typically meets eight times per year. Seven members of the Board constitutes a quorum.[12] Over the preceding four-year sunset review period, the Board met a total of 41 times, in addition to 67 committee meetings:

Fiscal Year	Number of Board Meetings	Board Meeting Days	Committee Meetings
FY 2020-21	12	17	15
FY 2021-22	10	14	17
FY 2022-23	11	15	25
FY 2023-24	8	14	10
Total	41	60	67

Staff

Statute authorizes the Board to appoint a person to serve as Executive Officer, subject to approval from the Director of Consumer Affairs. The Executive Officer "shall exercise the powers and perform the duties delegated by the board and vested" in them by the Pharmacy Law. Prior statute allowed the Executive Officer to serve as a member of the Board; this authority was removed during the Board's last sunset review.[13] The Board's current Executive Officer is Anne Sodergren, who previously served as Assistant Executive Officer. Ms. Sodergren was formally appointed by the Board on January 22, 2020 after serving for a number of months in an interim capacity.

The Board has 138.8 authorized positions, including 63 licensed pharmacists who assist with investigations as professional experts. There were 12 vacant positions with the Board as of January 2025. The Board's organizational chart is categorized into Enforcement, Licensing, and Administration units. The Board has its own enforcement staff, which includes field inspectors responsible for conducting investigations and inspections of pharmacies as well as sterile compounding and outsourcing facilities. Statute authorizes the Board to employ its own legal counsel; however, as of March 2025, the Board has not hired a dedicated attorney, relying instead on counsel provided by the Department of Consumer Affairs and the Office of the Attorney General.[14]

The Board states that its staff are encouraged to participate in an individual development process (IDP) to avail themselves of programs such as the department's upward mobility program and analyst certification program. Twenty-eight of the Board's non-pharmacist staff are reported to have received at least one promotion during their tenure with the Board since FY 2020-21. In August 2022, the Department of Consumer Affairs established a departmental Executive Steering Committee with the goal of embedding diversity, equity, and inclusion (DEI) into its core framework and strategy. In support of this department-wide initiative, the Board reports that it has updated all job postings to emphasize the importance of diversity, equity, inclusion, and accessibility in attracting developing, and retaining a diverse workforce.

[12] Bus. & Prof. Code, § 4002
[13] Bus. & Prof. Code, § 4003
[14] Bus. & Prof. Code, § 4008

Fiscal and Fund Analysis

As a regulatory board under the Department of Consumer Affairs, the Board is entirely special funded and receives the majority of its funding through license fees. All fees collected by the Board are deposited into the Pharmacy Board Contingent Fund, available upon appropriation of the Legislature. For pharmacists, advanced practice pharmacists, and pharmacy technicians, licenses are renewed and fees are assessed biennially. All other licenses renew on a yearly basis. Fee minimums are codified in statute, with authorization for the Board to further increase each fee up to a maximum amount through regulation.[15]

The Board's fee schedule has been modified a few times in recent history. In 2009, having just completed a fee audit, the Board sponsored legislation which reset the statutory minimum and maximum fee levels for the first time since 1987. In 2014, the Board increased its fees to the statutory maximums to address a structural imbalance between revenue and expenditures caused, in part, by the Board's implementation of the Consumer Protection Enforcement Initiative, the prescription drug abuse epidemic, and the greater need for regulation over specialty pharmacies that compound sterile drug preparations.

Board fees were recast again in 2017 following another fee analysis and recommendations made by the Legislature during the sunset review process. At that time, only seven application fees and 14 renewal fees were increased out of the Board's 118 fees, with three application fees reduced. Following an independent audit of the Board's fee structure, the Board's fee structure was again recast in 2023, with a number of changes taking effect on January 1, 2025, including reductions of application and renewal fees for some individual licensees and increased application and renewal fees for other license types. These fee increases were necessary to address a declining fund balance caused by a number of factors, including the recent abrupt increase in billing rates for client services that was announced by the Attorney General's Office in 2019. The Board's enforcement program is its largest budget expenditure, historically comprising about 64 percent of its total operating expenses.

Statute states that it is the intent of the Legislature that the Board "seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures."[16] Currently, the Board is failing to meet that goal. At the end of FY 2023-24, the Board's reserve level was at six months, equating to about $19 million, while authorized expenditures for the year were approximately $34 million. This fund imbalance will eventually result in a depletion of the Board's reserves unless the fund imbalance is addressed.

However, because the Board's fees are not currently set at the maximum levels permitted in statute, these fees can be adjusted through rulemaking. The Board indicates that it will continue to monitor its fund and update its fees as necessary by regulation. If it is subsequently determined that further fee increases are needed beyond the statutory authorization, the Board will likely seek the introduction of legislation raising fee caps at that time.

Fund Condition	FY 2024-25	FY 2025-26	FY 2026-27	FY 2027-28
Fund Balance	$17.1 million	$12.2 million	$6.1 million	$-1.2 million
Months in Reserve	5.3	3.7	1.8	-0.4

[15] Bus. & Prof. Code, § 4400
[16] *Id.*

The following is a summary overview of the Board's fund condition over the fiscal years since the Board's last sunset review, along with estimated projections for the next two fiscal years:

	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24	FY 2024-25	FY 2025-26
Beginning Balance	$8,024	$10,708	$13,855	$17,257	$19,138	$17,160
Revenues and Transfers	$32,992	$33,160	$35,312	$36,234	$33,638	$33,630
Total Revenue	$40,016	$43,868	$49,167	$53,491	$52,776	$50,790
Budget Authority	$27,636	$30,604	$32,444	$34,129	$35,465	$36,504
Expenditures	$28,440	$30,021	$31,916	$34,353	$38,016	$38,563
Loans to General Fund	- $2,400	--	--	--	- $2,400	--
Fund Balance	$10,176	$13,847	$ 17,251	$ 19,138	$ 17,160	$12,227
Months in Reserve	4.1	5.2	6.0	6.0	5.3	3.7

Licensing

The 32 licensing programs administered by the Board include both personal licenses for individual professionals as well as licenses for facilities. The Board both accepts applications for new licensure and processes renewals for current licensees. The total number of licensees regulated by the Board has remained relatively stable over the years since the Board's previous sunset review.

Total Licenses			
FY 2020-21	**FY 2021-22**	**FY 2022-23**	**FY 2023/24**
140,042	140,268	138,104	138,478

The number of new licenses issued has declined slightly, which is consistent with a similar decline identified during the Board's previous sunset review. This decline is attributed to a significant reduction in the intern pharmacist licensing program, which saw a decrease of about 35 percent, along with the continued decrease in pharmacy technician licenses, representing about a 2 percent decline. However, other license populations have grown over the same time frame, including a 34 percent increase in the number of advanced practice pharmacists. Overall, renewal of licenses increased by 4 percent.

Prior to granting an initial personal license to an applicant, the Board must verify that the applicant meets the minimum qualifications for licensure, conduct a criminal history background check, and collect the appropriate fees. For pharmacist licenses, this includes confirming that the applicant is at least eighteen years of age and has graduated from a pharmacy school, has received a degree in the practice of pharmacy, has completed 1,500 hours of pharmacy practice experience, and has passed the North American Pharmacist Licensure Examination as well as the California Practice Standards and Jurisprudence Examination for Pharmacists.[17] For pharmacy technicians, the application review includes verifying that the applicant has completed one of several educational pathways to become eligible for licensure.[18] Personal license applicants are also required to provide a "self-query report" from the National Practitioner Data Bank to determine whether the applicant has been previously subjected to discipline by another board.

[17] Bus. & Prof. Code, § 4200
[18] Bus. & Prof. Code, § 4202

The Board has proactively established its own performance targets for its licensing application timelines. These targets are considered to be fairly aggressive, and reflect an expectation that pending applications be processed as quickly as possible to avoid lengthy waiting times for applicants. While the Board's performance targets are often not met, there is an active effort to reduce processing timelines to within the established goals.

The following is a selection of license application types as well as the current target for completion:

License Type	**Target (In Days)**
Pharmacist (application for examination and licensure)	15
Pharmacist (application for initial license)	5
Pharmacy Technician	30
Advanced Practice Pharmacist	30
Clinic	30
Designated Representative for Reverse Distributor, Wholesaler, 3PL, or Veterinary Food-Animal Drug Retailer	30
Hospital	30
Outsourcing Facility	45
Pharmacy	30
Sterile Compounding Pharmacy	45
Wholesaler	30

The Board reports that during the most recently completed fiscal year, performance standards were not met for pharmacy and nonresident pharmacy license types. These timeline deficiencies were reportedly attributable to staffing vacancies as well as the increasing complexity of ownership structures. In response, the Board reviewed the pharmacy application materials and instructions to consider changes that may potentially impact processing time.

A total of 59,389 applications were received by the Board over the past sunset review cycle. The Board denied a total 227 applications. Denials can be based on a number of factors, including failure to meet the minimum qualifications for licensure or failure to comply with certain practices. One common cause for denial is an applicant's conviction of a crime that the Board has determined to be substantially related to the privileges and duties accompanying the license.

Following the implementation of Assembly Bill 2138 (Chiu/Low) from 2018, the Board's process for denying applications based on criminal history changed. The Board is no longer permitted to deny an application for an applicant's prior nonviolent, nonsexual, or nonserious conviction that occurred more than seven years preceding the application. The bill also prohibits the Board from issuing a denial based on offenses that have been dismissed or expunged. Over the past four years, the Board has denied applications due to prior convictions of a variety of crimes including driving under the influence, fraud, theft, battery, and drug-related offenses.

	FY 2020-21	**FY 2021-22**	**FY 2022-23**	**FY 2023-24**
Criminal Conviction	10	31	45	50
Total Denial	33	55	74	65

Statute requires the Board to inquire in each license application whether the applicant is serving in, or has previously served in, the military.[19] The Board accepts military training and experience for purposes of qualifying an applicant for licensure as a pharmacist or pharmacy technician. During the prior reporting period, the Board received 344 applications from veterans. As required by statute, the Board waived renewal fees and continuing education requirements for seven individuals called to active duty, and expedited 74 applications for individuals who have served in the military.

Education

The Board is not responsible for approving schools of pharmacy. "Recognized school of pharmacy" is defined under the Pharmacy Law as a school of pharmacy accredited by the Accreditation Council for Pharmacy Education (ACPE). The ACPE is the sole accrediting body for pharmacist education in the United States. A member of the Board attends and observes visits by the ACPE at California schools of pharmacy for purposes of accreditation. The Board also receives updates from the ACPE on changes in school accreditation status.

The ACPE does not grant full accreditation status until a school graduates its first class of pharmacists, which generally takes four years. There is limited statutory authority for the Board to recognize schools of pharmacy for purposes of issuing intern pharmacist licenses to applicants from schools who are likely to eventually receive full accreditation from the ACPE. While the Board could remove this recognition if necessary, that has never occurred.

There are currently 13 fully accredited schools of pharmacy in California:

- American University of Health Sciences School of Pharmacy, Signal Hill, CA
- California Northstate University College of Pharmacy, Elk Grove, CA
- Chapman University School of Pharmacy, Irvine, CA
- Keck Graduate Institute (KGI) School of Pharmacy and Health Sciences, Claremont, CA
- Loma Linda University School of Pharmacy, Loma Linda, CA
- Marshall B. Ketchum University College of Pharmacy, Fullerton, CA
- Touro University – California College of Pharmacy, Vallejo, CA
- University of California, San Diego Skaggs School of Pharmaceutical Sciences, La Jolla, CA
- University of California, San Francisco School of Pharmacy, San Francisco, CA
- University of Southern California Alfred E. Mann School of Pharmacy and Pharmaceutical Sciences, Los Angeles, CA
- University of the Pacific Thomas J. Long School of Pharmacy and Health Sciences, Stockton, CA
- West Coast University School of Pharmacy, Los Angeles, CA
- Western University of Health Sciences College of Pharmacy, Pomona, CA

One program received candidate status from the ACPE:

- University of California, Irvine School of Pharmacy and Pharmaceutical Sciences, Irvine, CA

The Pharmacy Law does not provide the Board with any legal requirements regarding the approval of foreign pharmacy schools.

[19] Bus. & Prof. Code, § 114.5

Continuing Education

Pharmacists are required to earn at least 30 units of continuing education (CE) every two years after their first renewal cycle.[20] Advanced practice pharmacists must earn an additional 10 units.[21] The subject matter must be "pertinent to the socioeconomic and legal aspects of health care, the properties and actions of drugs and dosage forms and the etiology, and characteristics and therapeutics of the disease state."[22] Beginning January 1, 2024, pharmacy technicians and pharmacists are required to participate in at least one hour of CE relating to cultural competency with a focus on LGBT patients.[23]

Pharmacists typically self-certify completion of their CE requirements. The Board conducts random audits of its renewal applicants to ensure compliance with CE. Whenever an audit reveals a deficiency, the Board typically instructs the licensee to obtain the required CE units and issues a citation and fine for misrepresenting completion of CE on the renewal form. For pharmacists who do not comply, their licenses are converted from active to inactive status until a renewal fee is paid and CE is completed. The Board is authorized to make exceptions from these requirements in emergency or hardship cases.[24]

Approximately 30 percent of audited licensees failed in the last full fiscal year, which can in part be attributed to lack of awareness of new requirements. The Board states that it has worked to educate licensees about these requirements to improve pass rates. The following is a summary of the results of CE audits conducted by the Board during the previous four years:

	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
Audits Performed	30	191	255	136
Passed	24	175	142	68
Failed	6	16	102	68

The Board is not responsible for approving CE providers or courses. Two accreditation agencies are responsible for approving continuing education providers and courses: the ACPE and the California Pharmacists Association. CE providers are not audited.

Statute does allow the Board to accept CE approved by other healing arts boards if it meets standards of relevance to pharmacy practice. Pharmacists are also eligible to receive CE credit for attending meetings of the Board or its committees. Credit is also awarded for successfully passing the examination administered by the Commission for Certification in Geriatric Pharmacy.

Examination

Two examinations are required for applicants seeking licensure as a pharmacist. First, an applicant must successfully pass both the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). The NAPLEX is developed by the National Association of Boards of Pharmacy (NABP) and is the national examination utilized in all fifty states. The Board developed the CPJE to test applicants on California-specific law, patient consultation, and other areas specific to practice in California that are not tested by the NAPLEX.

[20] Bus. & Prof. Code, § 4231
[21] Bus. & Prof. Code, § 4233
[22] Bus. & Prof. Code, § 4232
[23] Bus. & Prof. Code, § 4231
[24] Bus. & Prof. Code, § 4234

Both examinations are offered only in English. Each examination is administered via computer-based testing on a continuous basis at various locations nationwide. The Board uses a vendor to administer the CPJE, and the NAPLEX is administered through a contractor secured by the NABP. Applicants are responsible for scheduling their examination dates through these companies. In California, testing sites for the CPJE are available in Agoura Hills, Atascadero, Bakersfield, Carson, Diamond Bar, El Monte/Santa Fe Springs, Fresno, Irvine, Lawndale, Redding, Riverside, Sacramento, San Diego, San Francisco, Santa Clara, Santa Rosa, Union City, Ventura, Visalia, and Walnut Creek. Testing sites are also available across the country.

Enforcement

The Board's Enforcement Unit regularly engages in investigations of licensees that may result in disciplinary action, as well as cases involving unlicensed activity. From FYs 2021-22 through 2023-24, the Board completed 8,719 investigations, referred 839 investigations for formal discipline, issued 4,092 citations, revoked or accepted surrender of 551 licenses, and placed 344 licensees on probation. Additionally, during the prior reporting period, the Board secured 10 interim suspension orders, 11 Penal Code Section 23 restrictions, and 6 cease and desist orders.

On average, the Board consistently receives around 3,500 complaints per year. These complaints are then categorized into priorities based on the potential risk to public health and safety. The highest priority complaints—ranked 1 and 2—involve offenses such as impaired licensee on duty, prescription drug theft, and the unauthorized furnishing of prescription drugs. Priority 3 and 4 complaints are less serious and involve offenses like failure to provide patient consultation, prescription errors, working with an expired license, and general noncompliance issues. These complaints are most likely to result in the issuance of a fine or a letter of admonishment.

High-priority complaints are referred to the Attorney General, where the Board files formal accusations seeking discipline against the licensee. Tools such as interim suspension orders and Penal Code Section 23 restrictions are used to protect the public pending the outcome of the disciplinary action. Subject to judicial review, the Board has final authority over its disciplinary cases. The Board settles approximately 80 percent of its disciplinary cases post-accusation. A total of 413 post-accusation case settlements occurred over the previous four years.

There are a number of performance measures intended to determine whether the Board is effectively and expeditiously resolving complaints. The first measure is intake cycle time, which quantifies the period between receipt of a complaint and its closure or assignment for investigation. The Board is expected to close out or assign complaints for investigation within 10 days of receipt. Over the past four years, the Board has narrowly failed to meet this standard, as demonstrated on the following chart:

Fiscal Year	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
Complaints Received	2,570	3,413	3,757	3,417
Performance Measure	10	10	10	10
Average Assignment	12	12	14	17

Another performance measure involves average investigation time, which reflects the average number of days from the time the matter was received until the case was closed for investigations not referred to the Attorney General for disciplinary action. The Board is expected to close these investigations within 210 days. The following chart demonstrates that the Board is failing to meet this performance measure:

Fiscal Year	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
Investigations Closed	1,970	2,236	2,174	2,339
Performance Measure	210	210	210	210
Average Closure	273	243	253	290

The Board reports that it has recently implemented a new digital process to streamline the investigative process and reduce investigation time frames with more expedient case closures. Additionally, the Board is requesting a statutory change to expand the types of records that must be provided to the Board by subjects of an investigation. The Board believes that this change would further improve investigation cycle times.

The Board has experienced a 61 percent increase in complaints received from the public since FY 2020-21. There has also been an increase in the number of cases that are closed without referral for investigation. Such cases typically involve complaints about customer services issues, which are generally non-jurisdictional. The Board has also experienced a 12 percent increase in the number of complaints received by licensees, which it believes is in part a result of SB 1442 (Wiener) of 2018 and subsequent regulations defining the provisions for community pharmacy staffing. The Board has also received a number of complaint allegations relating to changes in pharmacy law prohibiting workload quotas.

The Board is authorized to seek cost recovery for expenses incurred during a successful investigation in cases where the licensee is ultimately subjected to discipline. However, these are not always awarded by administrative law judges. The Board was awarded approximately $1.4 million in cost recovery in FY 2023-24.

For most cases resulting in a citation and fine or a letter of admonishment, the Board is limited to issuing fines of $5,000 to each licensee investigated in a single case. In rare instances, the Board could issue fines of up to $5,000 each to a pharmacy, pharmacist, and pharmacist-in-charge involved in the same violations of the Pharmacy Law. Some specified violations carry higher maximum fines; for example, the Board may issue fines of $25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred.[25] When determining what fines to assess, the Board considers a number of factors, including the gravity of the violation, history of previous violations, extent to which the cited individual is cooperating with the investigation, and other elements suggesting good or bad faith on behalf of the licensee.

The following is a summary of the Board's citation and fine activity over the previous four years:

	FY 2020-21	FY 2021-22	FY 2022-23	FY 2023-24
Citations with No Fine	401	451	390	290
Citation with Fine	533	822	584	372
Fines Assessed	$787,100	$1,954,012	$1,790,500	$1,243,756
Fines Collected	$711,729	$1,093,911	$1,643,100	$1,228,701

[25] Bus. & Prof. Code, § 4067

As a result of the Board's last sunset bill, effective January 1, 2022, the Board has authority to bring an action for fines for repeated violations of materially similar provisions of the Pharmacy Law within five years by three or more pharmacies operating under common ownership or management within a chain community pharmacy. For each third and following violation, an administrative fine may be imposed of up to $100,000 per violation. Additionally, the Board may bring an action against a chain community pharmacy operating under common ownership or management for fines not to exceed $150,000 for any violation of the Pharmacy Law demonstrated to be the result of a written policy or which was expressly encouraged by the common owner or manager.[26]

The following chart provides information about increased citations and fines brought by the Board against pharmacies operating under common ownership for repeated or knowing violations, pursuant to the new authority:

	FY 2021-22	FY 2022-23	FY 2023-24
Citations with Fine	1	79	115
Fines Assessed	$75,000	$1,627,000	$1,800,750
Fines Collected	$0	$70,000	$558,500

Licensees may appeal a citation issued by the Board by requesting an informal office conference. The office conference allows the licensee the opportunity to present additional or mitigating information to the Board's executive officer or designee and a supervising inspector. Upon conclusion, staff may affirm, modify, or dismiss the citation or affirm or dismiss the letter of admonishment. A licensee may also submit a formal appeal to the Board within thirty days of the issuance of a citation. Appeals are conducted pursuant to the Administrative Procedure Act by an administrative law judge who renders a decision, which is presented to the Board for adoption or rejection.

In addition to complaint-driven investigations, the Board regularly performs inspections of both licensees and premises. A total of 2,969 inspections were completed in FY 2023-24. The Board's policy is to inspect all pharmacies at least once every four years. As of July 1, 2024, 80 percent of all licensed pharmacies have received a routine inspection within the last four years; out of the Board's 6,091 licensed pharmacies, only 317 have never been inspected either through a routine inspection or inspection for another reason, such as investigation of a complaint.

Diversion

The Board operates a Pharmacist Recovery Program, which allows pharmacists whose competence may be impaired due to alcohol or drug abuse or mental illness to seek treatment, so long as they comply with specific and closely monitored requirements, such as abstinence verified by frequent random drug testing and attending group meetings. Where appropriate, the licensees are allowed to continue practicing under specific, controlled conditions with supervision, so long as abstinence is maintained. A contracted vendor provides many of the treatment and monitoring services, but the Board also monitors participants in the program. Participants pay for the costs of these services, absent a monthly administrative fee to the program vendor that is paid in part by the Board.

[26] Bus. & Prof. Code, § 4317.5

Public Information Policies

The Board regularly uses the internet as its primary means of communicating with the public. All announcements, activities, documents, and public records of importance to consumers and licensees—including meetings, rulemakings, new laws and regulations, drug recalls, licensure forms, reports and publications, and enforcement actions—are posted on the Board's website, www.pharmacy.ca.gov. In addition, notices with links to important information are emailed via six separate listservs to a total of about 125,785 individuals and organizations who have signed up to receive "subscriber alerts" from the Board.

With the exception of teleconference meetings, board and committee meetings are webcast live by the Department of Consumer Affairs. Webcast recordings are posted online on YouTube; links to the recordings are posted on the Board's meeting page. Webcasts are currently maintained online by the Department of Consumer Affairs for ten years. The Board also began allowing members of the public to participate in meetings via WebEx during the COVID-19 pandemic.

The Board also provides key information on its website to enable the public to quickly search and verify the status of a license and any disciplinary action against a licensee. A link to the license search function on the Board's website is prominently listed in the "Quick Hits" column on the homepage. The Board recently removed addresses of record for individual licensees. However, addresses of record are public information that remain available by contacting the Board. Each license record also discloses any formal discipline against the licensee, along with a link to public documents in the case. Information about lesser administrative actions—including citations, fines, and letters of admonishment—is not linked to licensees but is available by contacting the Board.

Online Practice Issues

Two primary categories of unlicensed online practice generally fall within the Board's jurisdiction. First, patients may purchase prescription drugs from unlicensed sellers through the internet, often without a prescription. Second, the Board often becomes aware of activity by practitioners licensed outside California who ship prescription products into, or perform prescription order verification for, California consumers without being licensed in the state.

Both instances are becoming increasingly common as costs for prescription drugs go up. These cases are often difficult to identify and enforce, particularly when the individuals reside outside of the United States. The Board has made consumer education a priority and has partnered with the NABP to help patients identify legitimate online pharmacies. However, the Board is largely unable to investigate many complaints relating to online activity and will instead refer these complaints to the federal Food and Drug Administration and the NABP.

PRIOR SUNSET REVIEW: CHANGES AND IMPROVEMENTS

The Board last underwent sunset review in 2020-21. During the prior sunset review, committee staff raised a number of issues and provided recommendations. Below is a summary of actions taken since that time to address these issues. Previous issues that were not completely addressed or are otherwise still of concern are further discussed under "Current Sunset Review Issues."

Prior Issue #1: Board Composition. The Committees posed the question of whether the current membership on the Board appropriately balances professional expertise and public objectivity and discussed Supreme Court caselaw relating to antitrust litigation immunity for public board members. The Committees asked the Board to describe what efforts it has taken to ensure its decision-making is subject to state supervision so as to safeguard its members from antitrust allegations. The Board responded that it continues to be mindful of perceptions of others and is diligent to focus its discussion on consumer protection in both its written materials and public comments. However, the Board raised concern that its meeting materials are sometimes used out of context, and at times others are misrepresenting the Board's actions or providing false information during public meetings of the Board; the Board states that it intends to work with the Administration and the Legislature to combat such misinformation.

Prior Issue #2: Board Member Expertise. The Committees questioned whether existing law requiring the appointment of pharmacists representing specific practice settings provides sufficient expert perspectives on matters coming before the Board. Specifically, it was noted that the Board's membership did not necessarily include a pharmacist with expertise in compounding, nor is there a pharmacy technician member on the Board. In response, the Board's sunset bill was amended to include a member from a compounding pharmacy specializing in human drug preparations. The Board states that it is grateful to the Legislature for this change, and a compounding pharmacist member has been appointed. To date, there remains no pharmacy technician member on the Board.

Prior Issue #3: Board Vacancies. The Committees raised concern over a history of vacancies on the Board and asked what solutions might be considered to address the issue. The Board responded that the transition to videoconferencing of meetings during the COVID-19 pandemic provided significant flexibility for members and the public to participate. The Board is concerned that these temporary allowances are due to expire in 2025 and states that it hopes the flexibility will be made permanent.

Prior Issue #4: Executive Officer Eligibility. The Pharmacy Law previously allowed the Executive Officer to be a member of the Board; the Committees questioned whether statute should be revised to address that. While the Board responded that existing law provided for a distinct separation between the powers of the Executive Officer and a Board member, it agreed that the separation of roles could become blurred if the Executive Officer was simultaneously a Board member. During its last sunset review, the Board supported a change in the Pharmacy Law to prohibit a Board member from also being appointed as the Executive Officer. The Committees further discussed whether the Executive Officer should be prohibited from being a licensee of the Board; no action was taken on this issue.

Prior Issue #5: Board Attorney. The Committees asked whether the Board had sufficient legal counsel given that it was authorize to hire its own attorney but had never done so. The Board supported language originally included in its sunset bill to require it to hire its own counsel; however, this language was ultimately removed from the bill. The Board states that it would welcome the opportunity to collaborate with the Legislature and Administration on this issue.

Prior Issue #6: Attorney General Billing Rate. The Committee raised the issue of recent increases in the Attorney General's client billing rate for hours spent representing the Board in disciplinary matters. The Board responded that it appreciates the ongoing flexibility provided by the Legislature to seek midyear augmentation to the Board's authorized expenditures for enforcement related expenses including expenses for Attorney General services as well as expenses incurred for services of the Office of Administrative Hearings and court reporter services.

Prior Issue #7: Advanced Pharmacy Technicians. The Committees proposed the possibility of establishing a new license category that would allow qualified pharmacy technicians to engage in advanced practice. The Board's Licensing Committee previously convened a series of public meetings to develop a mid-level practitioner licensing program intended to provide meaningful assistance to pharmacists. However, there was not agreement among stakeholders to develop such a proposal, and language was not included in the Board's sunset bill. Since that time, legislation sponsored by the Board authorized pharmacy technicians to engage in additional functions with specified training, which the Board is in the process of implementing.

Prior Issue #8: Fair Chance Licensing Act. The Committees asked the Board to provide an update on its implementation of Assembly Bill 2138 (Chiu/Low), which limited the ability of licensing boards to deny an application for licensure based on prior criminal history. The Board responded that it had taken all necessary steps to comply with the law, including updating application forms, educating applicants, and updating procedures. The Board has also identified consumer protection concerns with the loss of some discretion in considering arrest or conviction background information when making a licensing decision, and proposed changes to the law in response to these issues. The Board's sunset bill authorized denial of an application if the applicant has been convicted of a crime or subject to formal discipline that would be grounds for denial of a federal registration to distribute controlled substances.

Prior Issue #9: Third-Party Logistics Providers. The Committees suggested that the Board should be authorized to conduct inspections of third-party logistics (3PLs) providers that are not fully licensed in their resident states to allow for operation within California. The Board stated that, because federal law prohibits the regulation of third-party logistics providers as wholesalers, a barrier to licensure had been created. Language was subsequently included in the Board's sunset bill providing the Board with the authority to conduct such inspections. Since enactment, the Board has conducted six inspections.

Prior Issue #10: Advanced Practice Pharmacists. The Committees asked whether modifications to the minimum qualifications for licensure for Advanced Practice Pharmacists, or expansion of the practice settings in which Advanced Practice Pharmacists may work, would enable these specialized licensees to further enhance access to care. The Board identified several instances when a pharmacist seeking licensure as an advanced practice pharmacist is using completion of a single criterion that included as a condition of completion of the program. The Board proposed resolving the situation by streamlining the qualification methods for an individual seeking licensure as an advanced practice pharmacist, which was included in the Board's sunset bill. Since enactment of these changes, the Board has experienced a 51 percent increase in the number of licensed advanced practice pharmacists since FY 2021-22.

Prior Issue #11: California Pharmacy Jurisprudence Examination. The Committees discussed the recent transgressions in the administration of the CPJE. The Board committed, as part of its ongoing program evaluation, to evaluate the pharmacist licensure examination and determine what action, if any, is appropriate, including consideration of transitioning to the Multistate Pharmacy Jurisprudence Examination (MPJE). Ultimately, the Board determined that transitioning to the MPJE was not feasible due to insufficient evidence of validity for use in occupational analysis and standard setting methodology.

Prior Issue #12: Continuing Education for Opioids. The Committees asked whether pharmacists who prescribe Schedule II drugs pursuant to a collaborative practice agreement should complete continuing education on the risks associated with opioid use. The Board discussed existing CE requirements for prescribers licensed by other healing arts boards that include education specifically regarding pain medications including opioids. The Board determined that a similar requirement would be appropriate for pharmacists prescribing such medications. Language was subsequently included in the Board's sunset to effectuate this recommendation.

Prior Issue #13: Pharmacies Operating Under Common Ownership. The Committees raised the question of 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. The Board had previously discussed challenges with obtaining compliance with Pharmacy Law provisions where the same violations occur at several pharmacies under common control, as it did not believe that its prior options to either issue a citation with a maximum fine of $5,000 or place a specific pharmacy on probation had resulted in the necessary changes in corporate practice to facilitate improved patient care. In response, the Board's sunset bill was amended to allow the Board to bring higher penalties for repeated or knowing violations of the Pharmacy Law by pharmacies operating under common ownership. The Board indicates that it has experienced some challenges with implementation, including what appears to be attempts to apply the law inconsistent with the policy goals of the legislation, and further amendments to this authority have been proposed.

Prior Issue #14: Alternative Dispute Resolution. The Committees considered enabling the Board to participate in alternate disciplinary processes for licensees whose misconduct is likely to result in a citation and fine. The Board developed a proposal to implement such a process, but chose to stop these efforts at the request of stakeholders.

Prior Issue #15: Standard of Care Enforcement Model for Pharmacy Practice. The Committees discussed the growing interest among stakeholders for the Board to begin moving toward more of a standard of care model for its disciplinary actions against licensees. The Board's sunset bill was ultimately amended to require the Board to convene a workgroup and produce a report on this topic. This report was completed and included a number of recommendations, including a legislative proposal that could be used to facilitate transition of pharmacist practice to a model generally more consistent with a standard of care model.

Prior Issue #16: Independent Contractors. The Committees asked whether the recently established test for determining employment status, as prescribed in the court decision *Dynamex Operations West Inc. v. Superior Court*, had any unresolved implications for licensees working in the pharmacy profession as independent contractors. The Board stated that it has not discussed the matter nor received any requests from stakeholders to hold such a discussion.

Prior Issue #17: Medication Errors. The Committees solicited recommendations from the Board regarding how medication errors could be reduced through statutory changes. The Board noted its belief that several factors contribute to medication errors and there is no single solution and recognized that absent implementation of a mandatory reporting requirement for medication errors, the Board will not have an understanding of the full scope of the issue. Mandatory reporting requirements were subsequently imposed through legislation sponsored by the Board, which the Board is in the process of implementing.

Prior Issue #18: Patient-Specific Outsourcing. The Committees asked the Board to discuss whether it believed allowing licensed outsourcing facilities to fill patient-specific prescriptions would be of potential value and to suggest any language it believes would be necessary to successfully achieve this purpose. The Board's sunset bill was subsequently amended to establish authority for outsourcing facilities to compound patient-specific prescriptions under specified conditions. Following enactment of the statutory changes, the Board developed FAQs to ensure the regulated public understood the new requirements. The Board further developed regulation language to include a requirement for outsourcing facilities to complete a self-assessment process; however, this formal rulemaking process has not begun.

Prior Issue #19: Collaborative Practice Agreements. The Committees raised the question of whether statute could be updated to expand the capacity of pharmacists to engage in expanded services pursuant to collaborative practice agreements. Language was subsequently included in the Board's sunset bill to incorporate statutory language to expand the use of collaborative practice agreements, which the Board supported. Since enactment of the change, the Board has conducted education on the expanded provisions, as a survey conducted by the Board in 2022 revealed that a number of pharmacists are still unaware of the change in the law.

Prior Issue #20: Medication-Assisted Treatments. The Committees considered authorizing pharmacists to directly dispense medication assisted treatments (MAT) to increase access to care for patients with substance abuse disorders. Language to this effect was included in the Board's sunset bill. Following enactment of the provisions, the Board engaged with experts in the field to develop a statewide protocol; however, delays in rulemaking have led to this not yet being implemented. The Board recommends that the Legislature further consider whether a statewide protocol is necessary; if so, language has been proposed to replace the term "medication assisted treatment" with "medication for treatment of opioid use disorder."

Prior Issue #21: Pharmaceutical Compounding. The Committees asked whether the Board should engage in greater collaboration with the Veterinary Medical Board of California (VMB) in its promulgation of any compounding requirements intended to apply to licensed veterinarians. The Board committed to working collaboratively with the VMB, though other issues relating to the Board's regulation of compounding have since been raised.

Prior Issue #22: Automated Drug Delivery Systems. The Committees proposed revising statute to allow the placement of Automated Drug Delivery Systems (ADDS) in additional locations. The Board identified locations where use of such a system would be appropriate given the many safeguards inherent in such systems. After review and discussion with stakeholders, the Board supported changes in its sunset bill to expand authority for pharmacies to operate an ADDS in other health and care facilities where pharmacy services are provided.

Prior Issue #23: Unused Cancer Medication Transfers. The Committees discussed existing laws authorizing county-level voluntary drug repository and distribution programs and asked whether statute should be updated to enable the donation of unused cancer medications. The Board explained that it was not aware of any statutory prohibition that precludes a county-level voluntary drug repository and distribution program from including the transfer of unused cancer medications. The Board developed dedicated staff to perform inspections and monitor implementation of new authorities established under this law; however, it is believed that currently no counties are engaged in the expanded authorities for the pilot projects.

Prior Issue #24: Temporary Licensure. The Committees considered whether the Board's authority to grant temporary licenses in the event of a declared emergency should be strengthened or expanded. During the COVID-19 pandemic, the Board relied upon the temporary license provisions to secure licensure of alternative care sites and other entities that are necessary to aid in patient care and distribution of necessary products. While the Committees considered including language giving the Board new authority to issue temporary licenses, those changes were not included in the Board's sunset bill.

Prior Issue #25: Licensee Outreach. The Committees questioned whether current law sufficiently ensured that the Board's licensees have access to important information during a state of emergency. The Board indicated that its current requirements for licensees to join its listservs coupled with its requirement for licensees to maintain a current email address with the Board remain appropriate. However, as the Board continues its efforts to undertake business modernization activities, the Board is hopeful that it can transition to more robust use of email as a primary form of communication with individual applicants and licensees.

Prior Issue #26: Technical Changes. The Committees suggested that the Pharmacy Law may be amended to include technical clarifications. In response, a number of technical changes were included in the Board's sunset bill.

Prior Issue #27: Continued Regulation. The Board's sunset bill extended the Board's repeal date by four years.

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.***

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.***

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.***

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.***

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.***

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 is 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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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 pharmacy to pharmacy technician ratio and its support for this approach.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***

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.***