

BACKGROUND PAPER FOR THE California State Board of Pharmacy

**Joint Sunset Review Oversight Hearing, November 18, 2020¹
Assembly Committee on Business and Professions and the
Senate Committee on Business, Professions and Economic Development**

IDENTIFIED ISSUES, BACKGROUND, AND RECOMMENDATIONS REGARDING THE CALIFORNIA STATE BOARD OF PHARMACY

BRIEF OVERVIEW OF THE CALIFORNIA STATE BOARD OF PHARMACY

Brief History

The California State Board of Pharmacy traces its origins back to 1891, when Senate Bill 84 (Maher) was enacted “to regulate the practice of pharmacy and sale of poisons in the State of California.”² Early statute provided the Board with largely the same powers and duties as it has today. Within its first six years of operation, the Board is reported to have registered a total of 1,063 pharmacists and 369 pharmacist assistants.

Over a hundred years later, the Board now regulates over 47,000 pharmacists, 550 advanced practice pharmacists, 6,500 intern pharmacists, and 70,000 pharmacy technicians across a total of 32 licensing programs. 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.

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.”³ The Board has adopted the following mission statement, as stated in its most recent Strategic Plan:

“The Board of Pharmacy protects and promotes 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.”

¹ Note: This background paper was originally published in advance of a hearing previously scheduled for March 17, 2020.

² An earlier board was created in 1872 with jurisdiction over the City and County of San Francisco, where the California College of Pharmacy was established; that Act was invalidated in 1880 with the ratification of the California Constitution.

³ Bus. & Prof. Code, § 4001.1

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, which 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 respectively are responsible for appointing an additional public member each.⁴

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, 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.⁵

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.⁶

The current composition of the Board is as follows, including two vacancies:

Name and Bio	Original Appointment	Expiration of Current Term	Appointing Authority
<p style="text-align: center;">Gregory N. Lippe (<i>President</i>) Public Member</p> <p>Gregory Lippe of Woodland Hills was appointed to the Board in 2009 and reappointed in 2012 and 2016 by Gov. Edmund G. Brown Jr. Mr. Lippe, a certified public accountant, has been president at Gregory N. Lippe Accountancy Corporation since 1981.</p>	02/26/2009	06/01/2020	Governor
<p style="text-align: center;">Deborah Veale, R.Ph. (<i>Vice President</i>) Professional Member Chain Community Pharmacy Representative</p> <p>Deborah Veale of Palos Verdes Estates was appointed to the California State Board of Pharmacy in 2010 and was reappointed in 2013 and 2017 by Gov. Edmund G. Brown Jr. Ms. Veale has been director of payer relations for CVS Pharmacy since 2006, and from 1983 to 2006 served in several positions with Albertsons/Sav-On Drugs. She is a member of the California Pharmacists Association, National Council of Prescription Drug Programs and California Retailers Association. Ms. Veale also serves on the editorial review committee for the California Pharmacist Journal. She earned her pharmacy degree from the University of Iowa, College of Pharmacy.</p>	01/12/2010	06/01/2021	Governor

⁴ Bus. & Prof. Code, § 4001

⁵ *Id.*

⁶ *Id.*

<p style="text-align: center;">Ryan Brooks Public Member</p> <p>Ryan Brooks of San Francisco was appointed to the California State Board of Pharmacy in 2008 and reappointed by Governor Edmund G. Brown Jr. in 2012 and 2016. Mr. Brooks serves as executive vice president of government affairs for OUTFRONT Media. He is responsible for creating and maintaining governmental and public affairs activities, community outreach, policy direction and fundraising activities for the United States market with over 20 years of experience in the field of environmental justice, environmental sciences, community relations and public policy.</p>	10/28/2008	06/01/2020	Governor
<p style="text-align: center;">Lavanza Butler, PharmD Professional Member Labor Union Representative</p> <p>Lavanza “Kercheryl” Butler was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2013 and was reappointed in 2013 and 2017. Ms. Butler has been with the United Food and Commercial Workers International Union Local 770 since 2002, serving as pharmacist, vice president and union representative. Previously, she was head pharmacist at Rite Aid Pharmacy from 1980 to 2002. She earned her pharmacy degree in 1975 from Xavier University in New Orleans and is a member of the California Pharmacists Association and the United Food and Commercial Workers Professional Division.</p>	02/01/2013	06/01/2021	Governor
<p style="text-align: center;">Shirley B. Kim Public Member</p> <p>Shirley B. Kim of Los Angeles was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2018. Ms. Kim has been an associate at Norton Rose Fulbright US LLP since 2016. She was legislative director at the California Faculty Association from 2011 to 2013 and in the office of Assembly Member Henry T. Perea from 2010 to 2011. She served as senior legislative assistant for Assembly Majority Leader Alberto Torrico from 2007 to 2010. She earned a bachelor's degree in sociology and political science from University of California, Davis, in 2006. She graduated from University of California, Irvine, School of Law in 2016.</p>	05/19/2018	06/01/2022	Governor
<p style="text-align: center;">Ricardo Sanchez Public Member</p> <p>Ricardo Sanchez of Hollister was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2014. Mr. Sanchez has been an investigator at the California Department of Motor Vehicles since 1989 and has served as chief financial officer for the California Statewide Law Enforcement Association since 1999. He earned a bachelor's degree in criminal justice from Union Institute and University. He is a member of the San Benito Masonic Lodge.</p>	11/12/2014	06/01/2022	Governor

<p style="text-align: center;">Maria D. Serpa, PharmD Professional Member Acute Care Representative</p> <p>Maria D. Serpa of Elk Grove was appointed to the California State Board of Pharmacy by Gov. Edmund G. Brown Jr. in 2018. Dr. Serpa has been a system support pharmacist at Sutter Medical Center, Sacramento, since 1996. She held several positions at Sutter Memorial Hospital from 1993 to 1996, including pharmacy services manager and drug use evaluation/adverse drug reaction and investigational drug service pharmacist. She previously worked in positions at Grossmont Hospital in San Diego from 1989 to 1993, including 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 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 a clinical pharmacy residency and critical care residency at University of California, San Diego, Medical Center.</p>	06/19/2018	06/01/2022	Governor
<p style="text-align: center;">Albert C. M. Wong, PharmD Professional Member Long-Term Care/Skilled Nursing Representative</p> <p>Albert C. M. Wong, of Orinda, was appointed to the California State Board of Pharmacy by Governor Edmund G. Brown Jr in 2012 and reappointed in 2016. Dr. Wong has been co-owner of Oakland Pharmacy Inc. since 1980. Previously, he was a pharmacist at the Oakland Children’s Hospital Medical Center from 1980 to 1983 and an intern pharmacist at Kaiser Permanente in San Francisco from 1976 to 1979. Dr. Wong earned a Doctorate of Pharmacy degree from the University of California, San Francisco School of Pharmacy.</p>	06/12/2012	06/01/2020	Governor
<p style="text-align: center;">Seung Oh Professional Member</p> <p>Seung Oh has been pharmacist-in-charge at Vons Pharmacy in Liberty Station, San Diego since 2014. He was owner and founder of Oh Creative Solutions from 2015 to 2016, a staff pharmacist at Safeway Pharmacy in 2014, and a pharmacist and director of operations at Rainbow Pharmacy from 2013 to 2014. Oh is a member of the California Pharmacists Association. He earned a Master of Advanced Studies degree in leadership of healthcare organizations from the University of California, San Diego and a Doctor of Pharmacy degree from the University of Arizona.</p>	02/24/2020	06/01/2023	Governor
<p style="text-align: center;">Jignesh “Jig” Patel Professional Member</p> <p>Jignesh Patel has been a division pharmacy manager for Safeway NorCal Division since 2006, where he has held positions since 1999, including pharmacy manager, pharmacist, intern and technician.</p>	02/24/2020	06/01/2023	Governor

<p style="text-align: center;">Jason Weisz Public Member</p> <p>Mr. Weisz is a senior district representative with California Senate President pro Tempore Toni G. Atkins.</p>	08/19/2020	06/01/2024	Senate Rules
<p><i>Vacant</i> Public Member</p>	--	--	Assembly Speaker
<p><i>Vacant</i> Professional Member Independent Community Pharmacy Representative</p>	--	--	Governor

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.
- **Communication and Public Education Committee:** This committee is responsible for outreach and information for consumers, including the importance of discussing medications with their pharmacists, patients 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 legislation and promulgates regulations that advance the board’s vision and mission.
- **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 temporary task force or ad hoc committees, as well as one specialized standing committee:

- **Compounding Committee:** This committee is charged with evaluating current and proposed compounding standards developed by the United States Pharmacopeia (USP) as well as the Board’s current regulations. This dedicated committee is essential to ensure licensees comply with appropriate processes for compounding safe and effective drug preparations.

- **Competency Committee:** This special standing committee is under the auspices of the Licensing Committee. Two board members are appointed to observe the work of the committee by the Board president.

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.⁷ Over the preceding four-year sunset review period, the Board met a total of 39 times, in addition to 63 committee meetings:

Fiscal Year	Number of Board Meetings	Board Meeting Days	Committee Meetings
FY 2016/17	11	15	14
FY 2017/18	10	14	16
FY 2018/19	10	14	17
FY 2019/20	8	11	16
Total	39	54	63

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. Statute allows for the Executive Officer to also serve as a member of the Board, though this has not occurred anytime in recent history.⁸

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 prior Executive Officer, Virginia Herold, retired at the end of 2018 after 29 years with the Board.

The Board has 120 authorized positions, including 56 licensed pharmacists who assist with investigations as professional experts. 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 17, 2020, 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.⁹

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.

⁷ Bus. & Prof. Code, § 4002

⁸ Bus. & Prof. Code, § 4003

⁹ 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 renewed and fees are assessed biennially. All other licenses renew on a yearly basis. Fee minimum are codified in statute, with authorization for the Board to increase each fee up to a maximum amount through regulation.¹⁰

The Board's fee schedule has been modified only a few times in recent history. Following a fee audit in 2009, legislation sponsored by the Board in 2009 reset the statutory minimum and maximum fee levels for the first time since 1987. The Board increased its fees to the statutory maximums in 2014 to address a structural imbalance between revenue and expenditures that resulted in part 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.

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."¹¹ Currently, the Board is maintaining a reserve significantly below that watermark. As of the end of fiscal year 2019/20, the Board's fund balance was approximately \$8.9M, equivalent to a reserve level of 3.4 months. This is the result of a steeply declining fund balance over the past several years, as demonstrated in the following chart, in addition to a \$2.4M loan from the Board to the General Fund in FY 2019/20:

Fund Condition	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Fund Balance	\$10,518	\$8,084	\$8,614	\$10,597	\$8,889
Months in Reserve	5.8	3.9	3.7	4.1	3.4

There are several attributable causes to the Board's declining fund balance. A major factor is the recent abrupt increase in billing rates for client services that was announced by the Attorney General's Office in 2019. It is estimated that this significant increase will cost the Board an additional \$1.3 million annually, likely making it impossible for the Board to fully restore its fund balance to the amount necessary to maintain a healthy reserve. The Board's enforcement program is its largest budget expenditure, comprising about 65 percent of its total operating expenses.

To address its diminishing fund balance and fulfill its legislative mandate to maintain a year's reserve, the Board has voted to increase many of its fees to their statutory maximums. These increases became effective on April 1, 2020. Examples of current fees and their anticipated increases are as follows:

- **Pharmacy:** \$520 increased to \$570
- **Pharmacist:** \$195 increased to \$215
- **Pharmacy Technician:** \$140 increased to \$195
- **Wholesaler:** \$780 increased to \$820

¹⁰ Bus. & Prof. Code, § 4400

¹¹ *Id.*

The following is a summary overview of the Board’s current fund condition, including previously provided projections for FY 2020/21 that incorporate the anticipated fee increases:

	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20	FY 2020/21
Beginning Balance	\$11,768	\$10,675	\$8,084	\$8,614	\$4,444	\$2,858
Revenues and Transfers	\$18,835	\$19,102	\$25,574	\$23,942	\$26,651	\$32,846
Total Revenue	\$30,603	\$29,777	\$33,658	\$32,556	\$31,095	\$35,704
Budget Authority	\$21,780	\$21,871	\$24,074	\$26,560	\$26,056	\$26,577
Expenditures	\$20,050	\$20,502	\$23,671	\$26,560	\$26,056	\$26,577
Direct to Fund Charges	\$35	\$1,191	\$1,373	\$1,552	\$2,181	\$1,545
Fund Balance	\$10,518	\$8,084	\$8,614	\$4,444	\$2,858	\$7,582
Months in Reserve	5.8	3.9	3.7	1.9	1.2	3.2

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 previous four years, with 143,242 licensees in FY 2019/2020. The number of new licenses issued declined slightly over the past review period, which the Board attributed to a 15% reduction in pharmacy technician licenses, the Board’s largest application category. However, the number of licenses no longer appears to be in decline.

Licenses Issued			
FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
11,784	11,064	10,672	11,733
Licenses Renewed			
FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
64,729	64,206	64,644	64,474

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 a 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.¹² For pharmacy technicians, the application review includes verifying that the applicant has completed one of several educational pathways to become eligible for licensure.¹³ 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.

¹² Bus. & Prof. Code, § 4200

¹³ Bus. & Prof. Code, § 4202

The Board has proactively established its own performance targets for its licensing 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

A total of 67,000 applications were received by the Board over the past sunset review cycle. The Board denied a total 316 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 cases where an applicant has been convicted of a crime that the Board has determined to be substantially related to the privileges and duties accompanying the license. On average, applicants with criminal histories have made up about two-thirds of total denials:

	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Criminal Conviction	66	48	47	47	28
Total Denial	99	77	77	63	48

Of the application denials based on prior criminal convictions, the overwhelming majority of disqualifying offenses are nonviolent and nonsexual, with the most offenses involving drugs or alcohol:

	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Acts Involving Drugs/Alcohol	42	31	29	30	18
Acts Involving Theft/Fraud	29	19	19	17	11
Criminal Sexual Behavior	1	1	3	4	2
Violent Crime	1	1	4	1	1

Following the enactment of Assembly Bill 2138 (Chiu/Low, Chapter 995, Statutes of 2018), the Board's process for denying applications based on criminal history will be substantively modified. The Board will no longer be permitted to deny an applicant for a nonviolent, nonsexual, or nonserious conviction that occurred more than seven years preceding the application. The bill also prohibited the Board from issuing a denial based on offenses that have been dismissed or expunged. The Board was required to promulgate regulations implementing the bill by July 1, 2020.

Statute requires the Board to inquire in each license application whether the applicant is serving in, or has previously served in, the military.¹⁴ 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 399 applications from veterans. As required by statute, the Board waived renewal fees and continuing education requirements for thirteen individuals called to active duty,¹⁵ expedited the processing of 152 applicants from military spouses and partners,¹⁶ and expedited 66 applications for individuals who have served in the military.¹⁷

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 11 fully accredited schools of pharmacy in California:

- 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
- 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 School of Pharmacy, 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

¹⁴ Bus. & Prof. Code, § 114.5

¹⁵ Bus. & Prof. Code, § 114.3

¹⁶ Bus. & Prof. Code, § 115.5

¹⁷ Bus. & Prof. Code, § 115.4

One schools has currently received candidate status from the ACPE:

- Marshall B. Ketchum University College of Pharmacy, Fullerton, CA

One school has received pre-candidate status:

- American University of Health Sciences School of Pharmacy, Signal Hill, CA

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

Continuing Education

Pharmacists are required to earn at least 30 units of continuing education (CE) every two years after their first renewal cycle.¹⁸ Advanced practice pharmacists must earn an additional 10 units.¹⁹ The subject matter is required to 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.”²⁰

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.²¹

The following is a summary of the results of CE audits conducted by the Board during the previous four years, with compliance rates increasing steadily:

	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Audits Performed	464	603	629	612	208
Passed	405	545	571	586	200
Failed	59	58	58	26	8

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.

¹⁸ Bus. & Prof. Code, § 4231

¹⁹ Bus. & Prof. Code, § 4233

²⁰ Bus. & Prof. Code, § 4232

²¹ Bus. & Prof. Code, § 4234

Examination

Several 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 pharmacy practice in California that are not tested by the NAPLEX.

Both examinations are offered only in English. Each examination is administered via computer-based testing on a continuous basis at various locations nationwide. A vendor is used by the Board 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 Anaheim, Carson, El Monte, Fresno, Hayward, Riverside, Sacramento, San Francisco, San Diego, Santa Rosa, Santa Clara, Ventura, Visalia, and Walnut Creek. Testing sites are also available across the country. The NAPLEX is available at approximately 252 testing sites throughout the United States, including 22 in California.

In 2019, the Board became aware of potential subversion of the CPJE, wherein questions on the examination were made widely available over the internet. As a result, examination scores for about 1,400 individuals were invalidated. Testing resumed in November 2019. This incident is discussed more thoroughly under “Current Issues.”

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. Over 12,100 investigations were completed from FY 2015/16 through FY 2018/19, with 1,335 referrals for formal discipline resulting in the revocation or surrender of 854 licenses and 462 licenses placed on probation. In addition, the Board issued a total of 7,223 citations.

On average, the Board 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 Office of the Attorney General, where formal accusations are filed seeking discipline against the licensee. Tools such as interim suspension orders and Penal Code 23 restrictions are used to protect the public pending the outcome of the disciplinary action. Actions brought by the Attorney General can result in penalties as severe as the revocation of a license. Subject to judicial review, the Board has final authority over its disciplinary cases.

The Board settles approximately 72 percent of its disciplinary cases post-accusation. A total of 852 post-accusation case settlements occurred over the previous four years. The Board does not currently have the authority to settle cases in advance of filing an accusation.

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; as of FY 2018/19, the Board is expected to close out complaints it has received within 10 days of receipt. The Board has not been meeting this standard, with a prior average intake cycle time of 26 days in FY 2018/19.

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 has failed to meet this performance measure in recent years, though steady improvements are being made:

Fiscal Year	Investigations Closed	Performance Measure	Average Closure
FY 2017/18	2,840	210	288
FY 2018/19	2,288	210	260
FY 2019/20	2,353	210	261

In total, approximately 55% of desk investigations and 34% of field investigations were closed within the Board’s standards in FY 2018/19. The Board states that the complexity of field investigations varies, depending on the nature and scope of the investigation, which makes completion times challenging. Additionally, the Board argues that it is focused on completing its oldest cases, which can delay more recently opened investigations. The Board states that it expects improvement in the percentage of total investigation time closed as cases continue through the review process to ultimate completion.

Performance measures for formal discipline cycles involve cases referred to the Attorney General’s Office for disciplinary action. The Board is expected to close these cases within 540 days. The following chart shows that this watermark continues to be exceeded:

Fiscal Year	Investigations Closed	Performance Measure	Average Closure
FY 2017/18	265	540	907
FY 2018/19	296	540	862
FY 2019/20	278	540	876

A total of 1,030 accusations were filed by the Attorney General for violations of the Pharmacy Law over the last reporting period, representing a 6% increase. Of these, 1,353 resulted in disciplinary action, representing a 15% increase. The following chart demonstrates the overall enforcement aging of cases brought by the Attorney General on behalf of the Board, including new data from FY 2019/20:

Closed Within:	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20	Cases Closed	Average %
1 Year	121	124	103	92	26	466	32.6%
2 Years	71	81	76	138	122	488	34.2%
3 Years	37	34	34	49	61	215	15.1%
4 Years	21	26	16	7	26	96	6.7%
Over 4 Years	33	44	33	10	43	163	11.4%
Total	283	309	262	296	278	1,428	

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 \$1.6 million in cost recovery in FY 2018/19.

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.²²

When determining what fines to assess, the Board considers a number of factors including the gravity of the violation, history of previous violations, extend 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 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
Citations with No Fine	376	439	504	342	536
Citation with Fine	1,599	1,497	1,664	803	891
Fines Assessed	\$2,264,650	\$2,354,525	\$2,268,625	\$1,176,950	\$1,462,300
Fines Collected	\$2,145,397	\$2,071,478	\$2,079,806	\$1,227,977	\$963,446

An appeals process exists for licensees who are issued a citation through a request for 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 the last four fiscal years, the Board issued 7,224 citations with and without fines and held 1,100 informal office conferences for citation and fine cases. As a result of the office conferences, 495 were affirmed; 257 were either dismissed or reduced to a letter of admonishment; and the remaining 733 were modified. The Board issued 1,253 letters of admonishment during the last four fiscal years, including 146 that were contested at an informal office conference. During the last four fiscal years, the Board referred 194 citation and fine appeals to the Office of the Attorney General to proceed with a request for hearing.

In addition to complaint-driven investigations, the Board regularly performs inspections of both licensees and premises. It is the policy of the Board that all pharmacies be inspected at least once every four years. A total of 3,474 inspections were completed in FY 2018/19, including 1,804 routine pharmacy inspections. Around half of those inspections resulted in orders of correction, which typically include common corrections relating to prescription labeling requirements, order and cleanliness, and interpretive service policies.

²² Bus. & Prof. Code, § 4067

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.

The following is a summary of the enforcement statistics related to the Board’s diversion program:

Pharmacist Recovery Program	FY 2015/16	FY 2016/17	FY 2017/18	FY 2018/19	FY 2019/20
New Participants	15	16	31	26	17
Successful Completions	13	8	14	5	10
Participants (close of FY)	51	47	51	57	59
Terminations	10	6	7	7	4
Terminations for Public Threat	7	7	6	9	3
Drug Tests Ordered	2,729	2,469	2,250	2,230	2,237
Positive Drug Tests	19	5	5	5	6

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 65,000 individuals and organizations who have signed up to receive “subscriber alerts” from the Board. The Board has also created a Twitter account.

With the exception of teleconference meetings, all board meetings are webcast live by the Department of Consumer Affairs. Committee meetings on matters of widespread public interest are often also webcast. 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 three years.

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 – are not linked to licensees but is available by contacting the Board.

In terms of non-digital media, the Board has used a statewide billboard campaign to increase public awareness about prescription drug abuse. Billboards have been placed in Sacramento, Fresno, and Los Angeles markets displaying a “Use, Don’t Abuse” message to encourage consumers to safely dispose of unused, unwanted or expired medications. The billboard design also appears on the Board’s website as a link to an online locator that consumers can use to find drug take-back services in their communities. Resources to put up these billboards was donated at no cost to 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.

Investigators employed by the Board have uncovered some California-licensed pharmacies filling prescriptions for website operators without a legitimate prescription. In many cases, entrepreneurs who are not pharmacists establish websites selling prescription drugs without a prescription or to consumers who simply complete an online questionnaire; the questionnaire then is purportedly reviewed by a prescriber in one state and shipped to a pharmacy to fill in another state without an appropriate medical examination. In these cases, consumers receive medication from an appropriately licensed pharmacy but without the medical supervision required for prescription medication.

Finally, the Board has identified efforts by a growing number of pharmacies to reduce operating costs by “offshoring” portions of the prescription dispensing process. The Board uses its cease and desist authority against these operators.

BreEZe

Originally, the Board was scheduled to be included with the second release of the BreEZe online licensing platform. The Board had been contributing money to the BreEZe program; from FY 2009/10 – FY 2016/17, the Board contributed \$1,679,528 to the BreEZe program. However, because of limitations and costs associated with the system, the Board was ultimately removed from that release.

Recently, the Board began to go through a Business Modernization effort. This modernization effort is a comprehensive business analysis to determine the specific needs of the Board and identify feasible system alternatives. Within the tenets of its Business Modernization plan, the Board has begun its continuous improvement activities within existing resources. The Board has created a service layer that allows individual licensees to submit payments and renew their licenses online. In addition, the Board has deployed functionality allowing pharmacies to register drug take-back locations. The Board will continue to assess opportunities for online transactions for other mandatory notices for which a fee is not required.

Workforce Development and Job Creation

While there were previously concerns of a pharmacist shortage, the American Journal of Pharmaceutical Education recently published an article entitled “Trends in the Pharmacist Workforce and Pharmacy Education” that suggested an imminent pharmacist oversupply. The strength of this workforce, in combination with the significant training and expertise pharmacists possess, has led many policymakers to see an opportunity to leverage pharmacists to increase access to quality care for patients in rural areas and communities facing primary care provider shortages. Recent legislation has expanded pharmacist scope of practice as a solution to promoting access to care.

COVID-19 Pandemic Response

Since early 2020, the ongoing COVID-19 public health crisis has prompted dramatic changes in virtually every sector in California, including the administration of state government and the delivery of pharmacy services. On March 4, 2020, Governor Gavin Newsom proclaimed a State of Emergency as a result of the impacts of COVID-19. As a result, statute authorizes the Board to “waive application of any provisions of [the Pharmacy Law] or the regulations adopted pursuant to it if, in the Board’s opinion, the waiver will aid in the protection of public health or the provision of patient care.”²³

Following the Governor’s emergency declaration, the Board established a waiver request process through which licensees and members of the public may request a waiver of law. The Board may grant either site-specific waivers or more general “broad waivers.” The Board has delegated authority to the Board’s President to review and makes final determination on all waiver approvals, which may be granted for up to 90 days with authority to extend waivers for two additional 90-day periods.

Since March 2020, the Board has approved 21 broad waivers. These waivers typically include conditions for use and recordkeeping requirements to demonstrate compliance with the conditions. The following is a list of broad waivers that has been approved, some of which have since expired:

- Certification in Basic Life Support (*BPC section 4052.8(b)(2)*)
- Signature Requirement for Receipt of Delivery of Drugs (*BPC section 4059.5*)
- Prescriber Dispensing Medications to Emergency Room Patient (*BPC sections 4068(a)(1), 4068(a)(5), and 4068(a)(6)*)
- Remote Processing (*BPC section 4071.1(a)*)
- Staffing Ration of Pharmacists to Intern Pharmacists and General Supervision – Immunizations (*BPC section 4114*)
- Pharmacist Direct Supervision of Interns (*BPC 4114*)
- Staffing Ratio of Pharmacists to Intern Pharmacists (*BPC section 4114(b)*)
- Staffing Ratio of Pharmacists to Pharmacy Technicians (*BPC sections 4115(f)(1) and 4127(c)(2) and CCR section 1793.7*)
- Prelicensure Inspection at Proposed Location of an Automated Drug Delivery System (ADDS) (*BPC sections 4119.11(a)(9) and 4427.2(e)*)
- USP <797> Requires Related to the Use of Personal Protective Equipment (*BPC section 4126.8*)
- Sterile Compounding Renewal Requirements for Facilities Located Within a Hospital (*BPC sections 417.1(c)&(d) and 4127.15(b)*)
- Prohibited Acts Involving Dangerous Drugs or Devices (*BPC 4169(a)(1) and 4161(b)*)

²³ Bus. & Prof. Code, § 4062

- Requirement for Consulting Pharmacist to Make Quarterly Visits to Clinic (*BPC sections 4182(a)&(b) and 4192(a)&(b)*)
- Duty to Consult (*CCR section 1707.2(a)*)
- Use of Sterile Disinfectant Agents (*CCR section 1751.4(d)(1)*)
- Use of PPE in Certain Compounding Aseptic Isolators or Compounding Aseptic Containment Isolators (*CCR section 1751.5*)
- Use of Alcohol Sanitizer before Donning Sterile Gloves (*CCR section 1751.5(a)(5)*)
- Reassessment/Revalidation/Re-evaluation Requirements for Sterile Compounding Staff Competencies (*CCR section 1751.6(e)(2) and 1751.7(b)&(d)*)
- Inventory Reconciliation Report of Controlled Substances (*CCR section 171.65(c)*)
- Intern Pharmacist Licenses (*BPC section 4208*)

In addition, one broad waiver provided authority for the Board to reinstate a license under specified conditions or extend an intern license that would have otherwise expired. As of July 1, 2020, the Board extended 692 intern licenses and reinstated 194 licenses. The Board has also issued 16 temporary licenses as part of surge capacity planning through a partnership with the Department of Public Health and the Office of Emergency Services and to facilitate distribution of PPE and ventilators and vaccines.

As of November 4, 2020, the Board has granted approximately 300 site-specific waivers, including waivers in the following areas:

- Waivers Granted to Allow for the Issuance of a License: 26
- Waivers Granted to Allow for the Renewal of a License: 104
- Waivers Granted to Allow for Remote Processing: 148

In addition to the Board’s own waiver process, the Governor signed an executive order that created a new process for boards and the public to request waivers of requirements related to healing arts professional licensing through the Department of Consumer Affairs.²⁴ The Board formally requested a waiver from the Director of Consumer Affairs to allow for the pharmacists to independently order and initiate COVID-19 vaccinations. This request was resubmitted following the enactment of AB 1710 (Wood), which established that same authorization in statute. The Board was advised that the Department is pending. In addition, the Board submitted a waiver request to expand the authorized duties of a pharmacy technician to include provisions to allow for a pharmacy technician to administer flu vaccines under specified conditions. The Board has not yet received a response to this request.

The Governor additionally signed an executive order to authorize pharmacists to provide point-of-care, CLIA-waived testing for COVID-19.²⁵ The Board recently adopted, a policy statement that it “recognizes that community pharmacies provide unique access for patients to obtain tests in a safe and convenient location” and “declares its support for all efforts to secure temporary authority for pharmacists to perform CLIA-waived tests for influenza and COVID during the declared disaster, as well as a more permanent solution through statutory changes that facilitate authority for pharmacists to perform CLIA-waived COVID and influenza testing in a safe manner.”

²⁴ Executive Order N-39-20

²⁵ Executive Order N-75-20

PRIOR SUNSET REVIEW: CHANGES AND IMPROVEMENTS

The Board last underwent a sunset review by the Legislature in 2016. During the prior sunset review, committee staff raised a number of issues provided recommendations. Below is a summary of actions which have been taken over the last four years to address these issues. Previous issues that were not completely addressed or may otherwise still be of concern they are further discussed under “Current Sunset Review Issues.”

Prior Issue #1: BreEZe. The committees asked the Board to provide an update on the status of implementation of BreEZe, along with a breakdown of charges the Board would be paying for BreEZe in FY 2016/17 and ongoing. As previously discussed, the Board was ultimately removed from the second release of BreEZe, and Release 3 has since been canceled. The Board is now going through the Business Modernization process, and will be working to ensure that appropriate resources are available throughout the life of the project. In the meantime, licensees now have the option to renew their licenses online. To date, the Board has received 11,996 payments, which represents 33 percent of the licensees eligible for renewal during this time frame.

Prior Issue #2: Regulation Issues. The committees requested information regarding how the Board prioritizes rulemaking packages and determines when to proceed with initiating a new rule or amending current rules. The committees asked the Board to report on regulations necessary to implement new legislation and whether the Board takes preemptive regulatory action when the Legislature is considering statutory changes. The Board has since reported that because it does not have staff dedicated to rulemaking activities, regulation development is often delayed. The Board also points to a new pre-review process has been implemented by the Department of Consumer Affairs, purportedly to reduce the number of regulations from boards rejected by the Office of Administrative Law. This likely has also elongated the time it takes for rulemaking to be completed. There have been recent cases in which legislation has been passed to codify proposed regulations approved by the Board, which has proven substantially faster than completing the rulemaking process. The Board states that it will continue to report on regulation time frames and work with the department to reduce review time.

Prior Issue #3: Budget Issues. The committees asked the Board to outline efforts to maintain a healthy fund condition. The committees also considered if the Pharmacy Law should be amended to raise fees to the statutory cap. As previously discussed, the Board did restructure its fee schedule to raise additional revenue, and recently approved a fee increase through a regulation change. The regulation package is was approved and the new fees will become effective April 1, 2020. However, it is estimated that the increased billing rate by the Attorney General’s Office will result in about \$1.3 million in additional annual costs, which may lead to the need for further increases.

Prior Issue #4: Licensing Issues. The Board was asked to provide the status of its licensing backlog. The committees noted it may be appropriate to amend the Pharmacy Law to require clinic applications to be processed within 30 days; to create a streamlined process for commonly owned clinics to report organization-wide changes in corporate officers, consulting pharmacists and medical directors; and to create one renewal date for all clinic permits, ensuring that commonly owned clinics could be renewed in a timely manner. In response, the Board implemented a streamlined process for commonly owned clinics and established a process for centralized renewal and reporting requirements for such clinics. Until a new computer system is secured, the board will continue to evaluate opportunities to improve processes, educate applicants on the process and requirements, and partner with the DCA’s Organizational Improvement Office to identify process improvements.

Prior Issue #5: Outsourcing Facilities. The committees suggested adding an outsourcing facility license to the Pharmacy Law and recommended that the Board conduct a careful calculation of costs associated with regulating these facilities to ensure that budget imbalances do not result in the event that the workload and travel necessary for the scope of this work exceeds the revenue from fees. As a result, the board began issuing outsourcing facility licenses in June 2017, following staff training for the entirely new program. The enacting legislation requires board inspections before license issuance or renewal for facilities doing business within or into California, and compliance with federal current good manufacturing practices. The board received three inspector positions for outsourcing facilities. In January 2018, the board submitted a report to the Legislature detailing its efforts to implement the new licensing program for facilities located outside of California.

Prior Issue #6: Automated Delivery Devices. The committees considered authorization for the Board to establish a registration requirement that links automated drug delivery systems (ADDS) to the pharmacy that owns and is responsible for the medications stored in the device. As part of the registration, the committees suggested that the proposal include submission of policies and procedures that demonstrate appropriate security of the device and how patient consultation is being provided. The committees noted that registration of these systems would require a reporting function to ensure that the board is made aware of drug losses from the machines, similar to the requirement for pharmacies to report drug losses. Ultimately, the Board implemented the new ADDS registration. In addition, the Board approved a project by the University of San Diego School of Pharmacy to study the expanded use of an automated drug delivery system. At the time, existing law limited use of ADDS to dispensing or administering medication to patients and limited the type of health care settings in which ADDS could be utilized.

Prior Issue #7: Professional Corporations. As part of the Board's last review, the committees indicated that pharmacists should be added to the list for medical corporations. In addition, the Board was encouraged examine the other professional corporations authorized by the Moscone-Knox Professional Corporation Act and determine whether there are others to which it makes sense for pharmacists to be added as officers, shareholders, or directors. During its April 2016 board meeting, the Board voted to support adding licensed pharmacists as one of the individuals that are authorized to be in a professional medical corporation. This provision was included in Senate Bill 1193 (Hill, Chapter 484, Statutes of 2016).

Prior Issue #8: Enforcement Prioritization. The committees sought information on the Board's case and complaint priorities and how inspectors, licensees, and the public are made aware of these. Further, the committees asked the Board to report on other cases that may be adopted as a precedential decision and what this means for enforcement efforts. The Board responded by providing information about how it sets its enforcement priorities. The Board also provided information about two cases that were designated as precedential. The Board explained that it seeks to maintain consistency of its investigations and outcomes and that this is achieved through team review.

Prior Issue #9: Case Timelines. The Board was asked to update the committees on steps it was taking to increase efficiencies in enforcement. The Board responded that it has improved efficiency in enforcement by standardizing elements of investigations and writing reports. As part of public meetings, the Board is provided with the timelines for key benchmarks with the investigation process. Review of this data reveals an overall reduction in investigation times. The Board's Enforcement Committee is currently in the process of developing an alternative enforcement model. While still in its development

stages, the alternative model would allow for streamlined discipline under specific conditions at the request of the respondent.

Prior Issue #10: Timely Receipt of Information. The committees noted that the Board must receive timely information to determine violations of law by licensees. The committees established a reporting requirement to assist the Board in receiving records in a timely manner while protecting the confidentiality of personal identifying information. The Board advised law enforcement agencies of the board's authority to receive information. The Board explained that unfortunately, many agencies within California take weeks or months to respond to board requests, and many law enforcement agencies continue to refuse to release reports outright or under certain circumstances.

Prior Issue #11: Cease and Desist for Unlicensed Activity. The committees recommended amending Pharmacy Law to allow the board to issue a cease and desist order for unlicensed activity. This amendment was enacted and the Board has since issued five cease and desist orders for unlicensed activity.

Prior Issue #12: Uniform Standards for Substance Abuse and the Board's Pharmacist Recovery Program (PRP). The committees requested an update on the status of the regulations to incorporate the Uniform Standards into the Disciplinary Guidelines. The Board was instructed to provide information for the next sunset review indicating how often it deviates from the Uniform Standards. The Board was also directed to provide an update on the audit of the PRP, as required by the Uniform Standards, and provide the committees with a copy of the audit report upon completion. The DCA contracted for a performance audit of the Department of Consumer Affairs Diversion Program provided by Maximus Health Services. The audit found that overall Maximus is effectively and efficiently managing the various board diversion programs and recommends the program be continued. The audit identified a variety of noncompliant issues and opportunities for improvement but nothing systematic in nature. It is the board expects the next audit of the program could begin in 2020.

Prior Issue #13: Prescription Label Standards. The Board was encouraged to update the committees when regulations relating to prescription label standards were finalized. The Board was also asked where it tracked decreases in medication errors stemming from the label standard. Subsequently, the patient-centered labeling requirements were amended effective July 1, 2017. The Board states that it has no baseline for tracking medication errors as there is no requirement for a pharmacy to report medication errors to the board unless the error has resulted in a settlement of \$3,000 or more.

Prior Issue #14: Implementation of Recently Enacted Legislation. The committees requested the status of regulations necessary to implement Senate Bill 493 (Chapter 469, Statutes of 2013) and discussion about why the regulations were taking so long. Since then, the Board has completed promulgation of all the regulations necessary to implement the provisions of that bill.

Prior Issue #15: 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 most recent sunset bill.

Prior Issue #16: Continued Regulation by the Board of Pharmacy. The sunset repeal date for the Board was extended by four years following the most recent sunset review.

CURRENT SUNSET REVIEW ISSUES FOR THE CALIFORNIA STATE BOARD OF PHARMACY

ADMINISTRATIVE ISSUES

ISSUE #1: Board Composition. *Does the current membership on the Board appropriately balance professional expertise and public objectivity?*

Background: Statute prescribes the composition of the Board, which includes both licensed pharmacists (professional members) and individuals who are not licensees (public members). Statute provides for a total of thirteen board members. When all appointments to the Board have been made, there are a total of seven professional members and six public members, resulting in a slight majority of members as active licenseholders. In 2015, the United States Supreme Court ruled in *North Carolina State Board of Dental Examiners v. Federal Trade Commission* that when a state regulatory board features a majority share of active market participants, any allegedly anticompetitive decision-making may not be subject to *Parker* antitrust litigation immunity unless there is “active state supervision” to ensure that all delegated authority is being executed in the interest of the public and not the private commercial interests of the members.

To date, there has been no meaningful litigation against public bodies established under California law, and it is likely that the Board receives more than enough active state supervision to qualify for immunity. The Board is considered only semi-autonomous, with much of its rulemaking and disciplinary activity subject to involvement by multiple other governmental entities. Its current Executive Officer is not a licensee; however, there is no statutory prohibition against the appointment of a future Executive Officer who is also a market participant. Finally, the Department of Consumer Affairs has also worked to ensure that members are adequately trained in certain procedures to ensure an adequate record of deliberation for purposes of defense against any potential allegations of antitrust.

Notwithstanding the legal sensitivities accompanying boards with majority professional memberships, the disproportionality for the Board is arguably minor, with an advantage of only one additional member who is a licensee. Considering the numerous benefits of having professional perspectives in deliberations by the Board regarding the practice of pharmacy, this technical imbalance is unlikely to be in need of any further statutory change. However, the Board should remain mindful whenever it engages in formal decision-making that may appear to serve the economic interests of licensee populations represented on the Board.

Staff Recommendation: *The Board should 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.*

ISSUE #2: Board Member Expertise. *Does existing law requiring the appointment of pharmacists representing specific practice settings provide sufficient expert perspectives on matters coming before the Board?*

Background: In addition to requiring both professional and public members, there is further specificity regarding who serves on the Board. Statute requires at least five of pharmacist appointees be actively engaged in the practice of pharmacy. The Board must also 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, and a long-term health care or skilled nursing facility.”

Notwithstanding these requirements, there are a number of perspectives that are currently not required to be reflected on the Board. One such category of professional expertise is in the area of pharmacy compounding. This area of practice has recently drawn national attention for both its importance and complexity, and the Board recently put forth a number of regulations regarding pharmacy compounding. While the Board does feature some expertise in this area there has not been a compounding pharmacist specifically represented on the Board. Amending law to require at least one of the professional members to be a compounding pharmacist may provide new meaningful expertise in Board decision-making.

Another identifiable lack of representation on the Board is 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. Other healing arts boards are often allotted one appointment 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 discuss whether it believes amending the Pharmacy Law to require the presence of additional professional perspectives on the Board would assist it in carrying out its public protection mission.*

ISSUE #3: Board Vacancies. What solutions might be considered to address the substantial member vacancy rates that have persisted on the Board?

Background: In recent years, the Board has experienced challenges in achieving a quorum at meetings, with an average of three vacancies existing on the Board. These vacancies have participated in large part due to difficulty recruiting qualified appointees to serve on the Board. The time commitment involved has been identified as a large driver of this problem, with the Board currently holding as many as eight meetings in a year in addition to its committee meetings. Particularly for professional members, this means time away from paid practice and can present a substantial hardship.

One potential solution to these recruitment issues is increasing the availability of teleconferencing when possible to allow Board members to participate remotely. The Board already holds some meetings via teleconference, and the format has been adopted by other boards. Increasing its use could potentially increase the range of available applicants. Further, current requirements that the full Board review all disciplinary matters should be evaluated for whether it is a necessary burden on member time.

Staff Recommendation: *The Board should discuss what steps it has taken to incentivize board member participation and whether it believes teleconferencing or other solutions could help address the current vacancy rate.*

ISSUE #4: Executive Officer Eligibility. Should statute be revised to ensure future Executive Officers remain sufficiently independent in their service to the Board?

Background: The Pharmacy Law currently states that the Executive Officer “may or may not be a member of the board as the board may determine.” No Executive Officer has concurrently served as a board member in recent history, and such practice is either discouraged or prohibited for similar boards because of the potential for conflicts of interest and the diminishment of independence between Board staff and the voting members. It may be practicable for Pharmacy Law to be amended to strike reference to board members serving as Executive Officer.

Additionally, there is currently nothing in the Pharmacy Law prohibiting the Executive Officer from being a licensee of the Board. While the governing statutes for most boards are silent on this issue, it may be argued that in cases where executive board staff are also licensed by the Board, there is less active state supervision over the profession and administrative functions are carried out with less objectivity. While the current Executive Officer is not a licensee, codifying a prohibition against that hypothetical may ensure the Board engages in prudent recruitment activities in the future.

Staff Recommendation: *The Board should inform the committees of whether it believes the qualifications for its Executive Officer should be revised to specify that they be neither a member of the board or a licensee, as is currently already the case.*

ISSUE #5: Board Attorney. Does the Board have sufficient legal counsel?

Background: Business and Professions Code § 4008 expressly provides the Board with the authority to employ legal counsel. However, the Board does not currently have its own dedicated attorney. Legal representation in disciplinary prosecution is provided by the Attorney General’s Licensing Section, and the Department of Consumer Affairs offers 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, and any reasons for that position remaining unfilled should be discussed before the committees.

Further, the Attorney General’s Office has recently transferred both deputy attorneys general who previously advised the Board. Particularly as the Attorney General’s billing rate has increased substantially, these may each be factors in costlier and lengthier enforcement activities by the Board.

Staff Recommendation: *The Board should provide insight into how the Pharmacy Law may be amended to assist it in hiring its own dedicated counsel, and should speak to whether it believes it is currently receiving adequate expert advice from the Office of the Attorney General.*

FISCAL ISSUES

ISSUE #6: Attorney General Billing Rate. Will the abrupt increase in the Attorney General’s client billing rate for hours spent representing the Board in disciplinary matters result in cost pressures for the Board’s special fund?

Background: In July of 2019, the California Department of Justice announced that it was utilizing language included in the Governor’s Budget authorizing it to increase the amount it billed to client agencies for legal services. The change was substantial: the attorney rate increased by nearly 30% from \$170 to \$220, the paralegal rate increased over 70% from \$120 to \$205, and the analyst rate increased 97% from \$99 to \$195. While justification was provided for why an adjustment to the rates was needed, the rate hike occurred almost immediately and without any meaningful notice to any client agencies.

For special funded entities such as the Board, unexpected cost pressures can be devastating. The Board has indicated that it estimates added costs of \$1.3 million annually solely as a result of the Attorney General's rate increase. As the Board recently secured a fee increase prior to rate increase, the committees should be informed of whether the Attorney General's Office or the Administration has informed the Board of any efforts to provide assistance with ensuring that the Board is able to maintain a healthy fund condition going forward.

Staff Recommendation: *The Board should discuss with the committees the impact of the Attorney General's rate increase and whether any action is needed by the Administration or the Legislature to safeguard the health of its special fund.*

LICENSING ISSUES

ISSUE #7: *Advanced Pharmacy Technicians. Should the Board be authorized to grant licenses for pharmacy technicians qualified to engage in advanced practice?*

Background: Over the last several years, the Board has voted to support the development of a legislative proposal to create a new mid-level practitioner in pharmacy settings. This proposed advanced pharmacy technician would be authorized to carry out certain duties that pose a low risk of harm but may currently only be performed by pharmacists, allowing a pharmacist to spend more time engaged in patient care.

While the Board has formally pursued legislation to establish a new license category for advanced pharmacy technicians and enable these mid-level practitioners to serve in pharmacies, no legislative attempt has been successful to date. There are doubtlessly many issues to be resolved regarding what qualifications an advanced pharmacy technician would have to possess and what duties they would be allowed to perform. Nevertheless, the topic may still be worthy of discussion, and the committees should be made aware of any renewed efforts underway to implement the proposal.

Staff Recommendation: *The Board should provide the committees with an overview of whether and why the advanced pharmacy technician license type should be established, and what steps may be taken to begin constructive dialogue with stakeholders on the issue.*

ISSUE #8: *Fair Chance Licensing Act. What is the status of the Board's implementation of Assembly Bill 2138 (Chiu/Low) and are any statutory changes needed to enable the Board to better carry out the intent of the Act?*

Background: In 2018, Assembly Bill 2138 (Chiu/Low, Chapter 995, Statutes of 2018) was signed into law, making substantial reforms to the license application process for individuals with criminal records. Under AB 2138, 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 were scheduled to go into effect on July 1, 2020.

Because AB 2138 significantly modifies current practice for boards in their review of applications for licensure, it was presumed that its implementation would require changes to current regulations for every board impacted by the bill. Recently, the Board was in the process of finalizing its regulations to revise its denial criteria to incorporate the changes from the bill. It is also likely that the Board has identified changes to the law that it believes may be advisable to better enable it to protect consumers from license applicants who pose a substantial risk to the public.

Staff Recommendation: *The Board should provide an update in regards to its implementation of the Fair Chance Licensing Act, as well as relay any recommendations it has for statutory changes.*

ISSUE #9: *Third-Party Logistics Providers. Should the Board be authorized to conduct inspections of third-party logistics providers that are not fully licensed in their resident states to allow for operation within California?*

Background: Federal law enacted in 2013 prohibits states from regulating third-party logistics providers, or 3PLs, as wholesalers. Because 3PLs are considered vital members of the supply chain that store, select, and ship prescription drugs, the Board pursued legislation in 2014 to establish licensure of 3PLs as a separate category of licensee. While other states have taken similar action in their jurisdictions, some states continue to regulate 3PLs as wholesalers. As a result, these entities are prohibited from doing business in California, because they are not appropriately licensed in their home state and therefore cannot be licensed in California.

To remedy the problem, the Board proposes to seek statutory authority to change the licensing requirements for such 3PLs. The business would be inspected before licensure, similar to the process used for initial licensure of nonresident sterile compounding pharmacies. If the inspection confirms the business is in compliance with state and federal law, licensure as a 3PL in the home state will not be required. The board does not believe that an annual inspection would be required. Instead, inspection could be limited to every four years or until such time as the resident state makes the necessary changes to its law.

Staff Recommendation: *The Board should further explain its proposal for modifying the licensure process of 3PLs that are not properly licensed in their home states, and provide the committees with any suggested language.*

ISSUE #10: *Advanced Practice Pharmacists. Would modifications to the minimum qualifications for licensure for Advanced Practice Pharmacists, or expansion of the practice settings in which Advanced Practice Pharmacists may work, enable these specialized licensees to further enhance access to care?*

Background: In 2013, Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013) was signed into law, creating a new license type under the Board known as the Advanced Practice Pharmacist. This new 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 that are often unavailable in low-access parts of the state. To implement the bill, the Board adopted regulations setting training and certification requirements for advanced practice pharmacists, who are authorized to perform specific care functions for patients.

To date, fewer individuals have successfully applied to become advanced practice pharmacists than anticipated, and this may be due to unnecessarily complicated or onerous qualifications and overly limited independence in practice. The Board has proposed language that would recast the requirements for licensure as an advanced practice pharmacist license so that completion of one requirement is subsumed within completion of another requirement. Further, the Board recommends that it be acceptable if certification is earned as part of the requirements for completion of a residency or completion of 1,500 hours of collaborative practice experience or a residency is completed that included the 1,500 hours of collaborative practice experience. The Board's recommendations would potentially expand both what an advanced practice pharmacist is authorized to do, as well as the number of settings in which they are allowed to do it.

Staff Recommendation: *The Board provide an overview of its proposal and how it believes changes to law would increase the number of advanced practice pharmacists in the state.*

EDUCATION AND EXAMINATION ISSUES

ISSUE #11: *California Pharmacy Jurisprudence Examination. Is action necessary to address the recent transgressions involving the administration of the California Pharmacy Jurisprudence Exam?*

Background: The Board is responsible for administering the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) to assess an applicant's minimum competency to safely practice pharmacy. The CPJE tests for application of the law as well as the practice standards that are unique to California and are not covered by the national examination. The Board states that in July of 2019, it received credible information about possible subversion of the CPJE. In September of 2019, the Board received further information about more pervasive acts of subversion, indicating the validity and reliability of the CPJE was compromised.

In response, the Board launched an investigation and found significant public exposure of CPJE questions that thereby invalidated the exam as a reliable measure of applicants' knowledge, skills and ability to safely practice as pharmacists. Therefore, in October 2019, the Board invalidated the current CPJE and established a plan to enable those applicants to retake the examination at no additional cost in November of 2019. In addition, the Board identified additional dates for December of 2019 for all eligible CPJE candidates to resume taking the exam.

While the discovery of the cheating scandal no doubt justified swift action by the Board to protect the integrity of the profession, the cancellation of exam results for those applicants who did not commit any breach had a predictably serious impact. Stories have been told of rescinded job offers, unrecouped travel expenses, and other significant hardships. In response, some have questioned whether the Board should be required to accept the Multistate Pharmacy Jurisprudence Exam (MPJE), a national alternative to the CPJE that includes board-approved questions for each state in which it is administered. Most states already accept the MPJE, and its adoption in California has been offered as a substantive step to address the unfortunate events surrounding the CPJE over the past year. However, it is worth noting that the MPJE was itself the subject of suspected subversion in 2007, and changing to a different examination would not necessarily prevent future pharmacy students from seeking to subvert licensing examinations.

Staff Recommendation: *The Board should provide insight into whether it believes adoption of the MPJE is feasible, or whether it believes any other action is advisable in response to recent incidents.*

ISSUE #12: Continuing Education for Opioids. Should pharmacists who prescribe Schedule II drugs pursuant to a collaborative practice agreement complete continuing education on the risks associated with opioid use?

Background: In October 2017, the White House declared the opioid crisis a public health emergency, formally recognizing what had long been understood to be a growing epidemic responsible for devastation in communities across the country. According to the Centers for Disease Control and Prevention, as many as 50,000 Americans died of an opioid overdose in 2016, representing a 28 percent increase over the previous year. Additionally, the number of Americans who died of an overdose of fentanyl and other opioids more than doubled during that time with nearly 20,000 deaths. These death rates compare to, and potentially exceed, those at the height of the AIDS epidemic.

Partly in response to the opioid crisis, some boards that regulate health professionals authorized to prescribe serious painkillers now require continuing education courses in the risks associated with the use of Schedule II drugs. Currently, pharmacists can prescribe Schedule II drugs under limited circumstances pursuant to a Collaborative Practice Agreement. The Board has suggested that those pharmacists who prescribe Schedule II opioids be required to complete similar continuing education (CE) related to the hazards of opioid use.

Staff Recommendation: *The Board should discuss the advantages of requiring pharmacists who prescribe opioids through collaborative practice agreements to take CE on the associated risks.*

ENFORCEMENT ISSUES

ISSUE #13: Pharmacies Operating Under Common Ownership. Should the Board 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?

Background: 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. Currently, the Board's remediation and sanctions against an individual pharmacy is arguably unfair and inadequate to address a system wide issue across a large multi-store chain.

As an example of how it has sought to address this issue, the Board points to how in response to a large number of store violations regarding patient consultations several years ago, the Board worked with local district attorneys to secure large penalties against certain pharmacy chains. However, this coordination is not always possible. In addition, the Board states that violations regarding patient consultations continue, despite citations issued by the Board and fines assessed by district attorneys.

Because the Board is limited to citing each pharmacy individually, making it difficult to address in an effective manner, violations resulting from corporate policy. In some settlements involving individual stores, the Board has stipulated that the ownership as a whole must address the issue; in such cases, however, the corporate owner must agree. This approach leaves unresolved the underlying challenge of regulating numerous entities under common ownership.

The Board has stated that it believes it may be appropriate to put into law some threshold evidence of a system-wide pharmacy failure that would allow additional enforcement tools to be used. Another possible solution suggested by the Board is to create a master license for pharmacies under common ownership and control; this would allow the Board to address system-wide issues with the owners and operators directly, rather than at the store level.

There have long been accusations of major chain-store pharmacies engaging in misconduct (for example, pushing pharmacists to meet certain output metrics for pharmacy sales that may supersede their professional judgement), but violations are technically only attributable to individual sites. The Board has asked whether there should be some additional ability for the Board to take action against entire chains for systemic violations of the law.

Staff Recommendation: *The Board should further discuss its proposals for providing more meaningful repercussions for pharmacies under common ownership and control to ensure that the Pharmacy Law is followed in all settings.*

ISSUE #14: *Alternative Dispute Resolution. Would enabling the Board to participate in alternate disciplinary processes for licensees whose misconduct is likely to result in a citation and fine provide for speedier disciplinary cases and prove more cost efficient for Board staff?*

Background: An appeals process exists for licensees who are being subjected a citation and fine through a request for an informal office conference. As previously discussed, this 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. Stakeholders within the profession have suggested that a similar opportunity to meet informally with Board staff should be available when a licensee is being subjected to disciplinary action. Currently, the Board has no authority to settle a case prior to the filing of an action by the Attorney General. Allowing licensees to meet with Board staff and pursue a mutually agreeable outcome would likely alleviate case resolution timelines and provide cost savings to the Board.

Staff Recommendation: *The Board should inform the committees of whether it believes some form of pre-accusation alternative dispute resolution would be of benefit and provide any suggested language that it believes would achieve this goal.*

ISSUE #15: *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 licensees?*

Background: A number of healing arts licensing 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. It has been argued that a similar model should be enacted for the Board in regards to its actions against its licensees. The Board does currently employ 56 licensed pharmacists who assist with investigations as professional experts; therefore, it is arguable 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.

Staff Recommendation: *The Board should discuss whether it believes a standard of care model would be appropriate and what steps it might take over the next few years to move toward that model.*

PRACTICE ISSUES

ISSUE #16: *Independent Contractors. Does the new test for determining employment status, as prescribed in the court decision *Dynamex Operations West Inc. v. Superior Court*, have any unresolved implications for licensees working in the pharmacy profession as independent contractors?*

Background: In the spring of 2018, the California Supreme Court issued a decision in *Dynamex Operations West, Inc. v. Superior Court* (4 Cal.5th 903) that significantly confounded prior assumptions about whether a worker is legally an employee or an independent contractor. In a case involving the classification of delivery drivers, the California Supreme Court adopted a new test for determining if a worker is an independent contractor, which is comprised of three necessary elements:

- A. That the worker is free from the control and direction of the hirer in connection with the performance of the work, both under the contract for the performance of such work and in fact;
- B. That the worker performs work that is outside the usual course of the hiring entity’s business; and
- C. That the worker is customarily engaged in an independently established trade, occupation, or business of the same nature as the work performed for the hiring entity.

Commonly referred to as the “ABC test,” the implications of the *Dynamex* decision are potentially wide-reaching into numerous fields and industries utilizing workers previously believed to be independent contractors. Occupations regulated by entities under the Department of Consumer Affairs have been no exception to this unresolved question of which workers should now be afforded employee status under the law. In the wake of *Dynamex*, the new ABC test must be applied and interpreted for licensed professionals and those they work with to determine the rights and obligations of employees.

In 2019, the enactment of Assembly Bill 5 (Gonzalez, Chapter 296, Statutes of 2019) effectively codified the *Dynamex* decision’s ABC test while providing for clarifications and carve-outs for certain professions. Specifically, physicians and surgeons, dentists, podiatrists, psychologists, and veterinarians were among those professions that were allowed to continue operating under the previous framework for independent contractors. However, pharmacists were not included in the bill, and some have suggested that they should be afforded an exemption to prevent unnecessary disruption to the pharmacy profession.

Staff Recommendation: *The Board should inform the committees of any discussions it has had about the *Dynamex* decision and AB 5, and whether there is potential to impact the current landscape of the pharmacy profession unless an exemption is enacted.*

ISSUE #17: *Medication Errors. Are there opportunities for statutory revision that would potentially reduce the frequency of medication errors resulting in patient harm?*

Background: The Board has listed medication error as the number one violation resulting in a citation in nearly every year within the last review cycle. According to the *Journal of the American Medical Association*, 46 percent of adults cannot understand the information listed on their prescription drug labels. Furthermore, the Institute of Medicine of the National Academies indicates that medication errors are among the most common medical errors, harming at least 1.5 million people annually.

The California Patient Medication Safety Act directed the Board promulgate regulations to require a “standardized, patient-centered, prescription drug label on all prescription medicine dispensed to patients in California.” The resulting language specifies that drug container label information must be clustered into one area of the label comprising at least 50 percent of the label, and that each item must be printed in at least a 12 point sans serif typeface. The regulations provide template language and recommend formatting to provide added emphasis.

Following the implementation of the patient-centered prescription label requirements, the Board also promulgated a regulation to amend its *Notice to Consumers* poster, which has also been printed in six additional languages, and which is available upon request from BOP or available for download from the Board’s website. The Board also developed a “Point to Your Language” poster, which is required to be posted in pharmacies at or adjacent to the pharmacy counter so that consumers can point to a language to receive interpreter services; the text is printed in twelve languages.

Despite these efforts, patient advocates, particularly for those within the senior citizen community, continue to advocate for statutory changes that would reduce medication errors. This has included requiring all prescription containers to indicate the purpose of a medication unless requested otherwise by the patient, as well as efforts to increase enforcement of patient consultation requirements. As these proposals continue to be debated, the Board should play an active role in making any recommendations it believes would improve patient safety.

Staff Recommendation: *The Board should provide the committees with any recommendations it may have regarding how medication errors could be reduced with help of statutory changes.*

ISSUE #18: Patient-Specific Outsourcing. Under what conditions should a licensed outsourcing facility be allowed to fill patient-specific prescriptions?

Background: Since June of 2017, the Board has issued licenses to outsourcing facilities concurrently with applicable licensure by the federal Food and Drug Administration. Outsourcing facilities are authorized to compound sterile and nonsterile products in compliance with regulations issued by the Board and are subject to inspection wherever they are located, with inspections occurring prior to license issuance or renewal for facilities doing business within or into California. The Board has issued 31 outsourcing licenses and performed 77 inspections since implementing the program.

While outsourcing facilities receive significant oversight and have proven successful at providing compounding services, statute currently prohibits a licensed outsourcing facility from filling individual prescriptions for individual patients. It is worth considering whether easing or eliminating this prohibition may result in greater access to pharmacy services. If such a change were to be made, licensed outsourcing facilities providing patient-specific care should be provided the same obligations and corresponding responsibilities as traditional pharmacists, and the Board should ensure any additional safeguards are incorporated.

Staff Recommendation: *The Board should discuss whether it believes allowing licensed outsourcing facilities to fill patient-specific prescriptions would be of potential value and suggest any language it believes would be necessary to successfully achieve this purpose.*

ISSUE #19: Collaborative Practice Agreements. Could statute be updated to expand the capacity of pharmacists to engage in expanded services pursuant to collaborative practice agreements?

Background: Current law authorizes pharmacists to enter into collaborative practice agreements with physicians to provide additional care to patients. These agreements are believed to take advantage of a pharmacist's knowledge, skills, and abilities as a means to reduce demands on health professionals and improve patient care. Existing law allows for pharmacists to engage in limited activities pursuant to a collaborative practice agreement.

Opportunities may exist to expand the use of the conditions under which pharmacists could operate under a collaborative practice agreement, as well as the conditions under which an advanced practice pharmacist could perform authorized duties. The Board has made some recommendations for ways in which statute could be updated to allow for these expansions. These recommendations should be considered in the balance of ensuring patients receive quality care while also increasing access to that care wherever possible.

Staff Recommendation: *The Board should provide its recommendations for expanding the authority of pharmacists to engage in activities pursuant to a collaborative practice agreement.*

ISSUE #20: Medication-Assisted Treatments. Should pharmacists be further authorized to directly dispense non-opioid medication assisted treatments (MAT) to increase access to care for patients with substance abuse disorders?

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. It has been suggested that similar authority be established for pharmacists to directly furnish non-opioid 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. MAT has proven successful in helping addicted patients enter recovery and are commonly used for the treatment of addiction to opioids. While some forms of MAT, such as buprenorphine, are themselves a type of opioid, other forms of MAT do not contain opioids. It may be appropriate to allow pharmacists to furnish these medications directly to patients as a way to help address the sustained opioid crisis.

Staff Recommendation: *The Board should discuss any recommendations it has for authorizing pharmacists to directly furnish non-opioid MAT to patients.*

ISSUE #21: Pharmaceutical Compounding. Should the Board engage in greater collaboration with the Veterinary Medical Board of California in its promulgation of any compounding requirements intended to apply to licensed veterinarians?

Background: The Board's regulation of prescribing, dispensing, and administering medication extends to the practice of veterinary medicine, where licensees of the Veterinary Medical Board (VMB) are required to comply with the Board's regulations when working with prescription drugs. In the context of veterinary pharmaceuticals, both regulatory boards are expected to interact and coordinate when resolving cross-cutting issues that impact both professions. For example, SB 1193 (Hill, Chapter 484, Statutes of 2016) provided authority for veterinarians and registered veterinary technicians to perform limited drug compounding. In promulgating regulations to implement this mandate, the VMB worked with the Board to determine appropriate parameters for veterinary in-office compounding.

However, the VMB has expressed concerns over the Board's recently proposed regulation that would authorize a pharmacy to only compound a compounded sterile preparation (CSP) after the pharmacy has received a valid patient specific prescription document or prepare and provide a limited quantity of CSPs to a veterinarian based on a contract between the pharmacy and veterinarian for office use administration only. The VMB is concerned that this proposal does not take into account how veterinary clinics and hospitals operate, and would severely limit a veterinarian's ability to provide medication and treat animal patients in a timely manner.

The VMB and the Board are undergoing Sunset Review concurrently. The committees believe that this is a timely opportunity to address how both boards can improve long-term communication and coordination regarding regulatory proposals that impact both professions.

Staff Recommendation: *The Board should provide its perspective on any recent issues involving veterinary compounding and the promulgation of its regulations and speak to whether there are any opportunities for greater communication and collaboration between the two boards.*

ISSUE #22: *Automated Drug Delivery Systems. Should statute be revised to allow the placement of Automated Drug Delivery Systems (ADDS) in additional locations?*

Background: An ADDS is a mechanical system controlled remotely by a pharmacist that performs operations or activities relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or devices. A specific type of ADDS is an Automated Unit Dose System (AUDS), used for storage and retrieval of unit doses of drugs for administration to patients by health practitioners. The law requires that there be specific written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenances of the quality, potency and purity of drugs located at the clinic. Use of an ADDS is authorized only in specific locations, including certain types of clinics serving low-income Californians and fire departments under certain conditions.

The Board recommends amending existing statutes to expand authority for pharmacies to license and operate AUDS in additional settings to provide medication management services. Such entities would include jails, correctional treatment centers, hospice facilities, psychiatric health facilities, and other locations.

Staff Recommendation: *The Board should discuss its recommendations regarding the expansion of ADDS placements with the committees and share language for any proposals it may have.*

IMPLEMENTATION ISSUES

ISSUE #23: *Unused Cancer Medication Transfers. Should statute authorizing county-level voluntary drug repository and distribution programs be updated to enable the donation of unused cancer medications?*

Background: In 2005, the Legislature passed Senate Bill 798 (Simitian, Chapter 444, Statutes of 2005) authorizing county-level voluntary drug repository and distribution programs for the purpose of distributing surplus medications to persons in need of financial assistance to ensure access to necessary pharmaceutical therapies.

Under these programs, hospitals and other health facilities, as well as drug manufacturers and wholesalers, may donate unused medications to a pharmacy owned by or in contract with a county. These pharmacies may then dispense medications to indigent patients at no cost. Currently, at least three counties have implemented such a program, including the counties of San Francisco, Santa Clara, and San Mateo. As of April 2018, Santa Clara’s Better Health Pharmacy has distributed more than 31,000 free prescriptions from 180 donors around California, at an estimated cost to residents of over than \$2,000,000. The program has been amended several times to allow for more donor entities and create a new category of licensure for purposes of medication transfers.

Currently, most cancer medications are not eligible for donation through any existing voluntary drug repository and distribution program. Some patient advocates believe that this excludes numerous low-income cancer patients who are unable to afford their medications and who would benefit from a secondhand medication donation program. This specific issue joins numerous other medications that may benefit from increased recycling authority.

Staff Recommendation: *The Board should discuss whether there are any statutory changes it believes would potentially expand county-level voluntary drug repository and distribution programs to include the transfer unused cancer medications.*

COVID-19 PANDEMIC ISSUES

ISSUE #23: *Temporary Licensure. Should the Board’s authority to grant temporary licenses in the event of a declared emergency be strengthened or expanded?*

Background: Since the onset of the COVID-19 pandemic, state health experts have continued to highlight the ongoing need to bolster the California’s capacity to respond to a surge in patient needs across the state’s health care system. On March 30, 2020, Governor Newsom announced his an initiative to “expand California’s health care workforce and recruit health care professionals to address the COVID-19 surge” and signed Executive Order N-39-20. This executive order established the waiver request process under the Department of Consumer Affairs and included other provisions authorizing the waiver of licensing, certification, and credentialing requirements for health care providers.

Additionally, existing law authorizes the Director of the Emergency Medical Services Authority (EMSA) to exempt from state licensure any health care practitioner who possesses a license in another state or territory and seeks to provide care within California during a state of emergency. Under this process, pharmacists who are licensed outside of California may provide service within the state with the approval of the EMSA Director for as long as the COVID-19 declaration remains in place. The Board has worked with EMSA to direct potential candidates for this temporary waiver to that process.

The Board has also worked to provide temporary approval to pharmacies that have been established to address identified surge areas. The Pharmacy Law provides that the Board “may, at its discretion, issue a temporary permit upon the conditions and for any periods of time as the board determines to be in the public interest.” While this statute is not related to the sections of the Pharmacy Law specifically related to declared states of emergency, the Board has utilized it to allow for temporary pharmacies intended to improve access to care in response to COVID-19. To date, the Board has issued 16 temporary licenses.

However, the temporary license process for pharmacy and wholesaler permits is limited. The Pharmacy Law only allows these permits to be issued for a maximum of 180 days, whereas other license waivers may be extended for the duration of the emergency. The provisions; however, do not apply to all facility licenses, such as community clinics. The Board may believe its authority to issue temporary licenses should be extended to all facility license types.

Staff Recommendation: *The Board should make recommendations for statutory changes to expand its authority to grant temporary licensure to pharmacies and other facilities during an emergency.*

ISSUE #24: *Licensee Outreach. Does current law sufficiently ensure that the Board’s licensees have access to important information during a state of emergency?*

Background: As the state works to address the COVID-19 crisis, there have been numerous changes in state law and shifts in priorities articulated by health officials. During this type of health emergency, it is vital that health professionals like pharmacists have immediate access to up-to-date information. Under existing law, the Board is not authorized to require its licensees to provide an e-mail address as part of an application for initial licensure or license renewal. However, the Board has stated that it believes “electronic communication is the fastest way to disseminate important information on policy, regulatory, enforcement and consumer matters to patients, licensees and stakeholders. This has been especially true during the pandemic.” Currently, the Board communicates with its licensees using a “subscriber alert system,” a system that licensees are required to enroll in within 60 days of receiving or renewing a license. Licensees also must update their email addresses with the board within 30 days of any change of email address.

Professional associations representing individuals licensed by the Board have expressed interest in obtaining authority to expand outreach efforts to pharmacists and other licensees during states of emergency via electronic communication. Current law does not include e-mail addresses among the categories of licensee contact information that can be requested by members of the public. One organization has requested that licensee e-mail addresses be made available to bona fide professional associations for purposes of contacting licensees with important information. While this proposal may implicate considerations of licensee privacy and discussions around the appropriate use of e-mail addresses collected by the Board, it could meaningfully result in greater access to time-sensitive information regarding the practice of pharmacy during states of emergency such as the COVID-19 pandemic.

Staff Recommendation: *The Board should discuss its current authority to collect licensee e-mail addresses and whether it believes statute should be modified to expand access to information among its licensees.*

TECHNICAL CLEANUP

ISSUE #25: *Technical Cleanup. Is there a need for technical cleanup?*

Background: As the pharmacy profession continues to evolve and new laws are enacted, many provisions of the Business and Professions Code relating to pharmacy become outmoded or superfluous. The Board should recommend cleanup amendments for statute.

Staff Recommendation: *The Board should work with the committees to enact any technical changes to the Business and Professions Code needed to add clarity and remove unnecessary language.*

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

ISSUE #26: *Continued Regulation. Should the licensing of pharmacy professionals be continued and be regulated by the California State Board of Pharmacy?*

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, to be reviewed again on a future date to be determined.*