BACKGROUND PAPER FOR
The Board of Pharmacy

(Joint Oversight Hearing, March 14, 2016, Senate Committee on Business, Professions and Economic Development and the Assembly Committee on Business and Professions)

IDENTIFIED ISSUES, BACKGROUND AND RECOMMENDATIONS REGARDING THE BOARD OF PHARMACY

BRIEF OVERVIEW OF THE BOARD OF PHARMACY

History and Function of the Board of Pharmacy

The California State Board of Pharmacy (Board) was created by the California Legislature in 1891. The Board is responsible for enforcing federal and state laws pertaining to the acquisition, storage, distribution and dispensing of dangerous drugs (including controlled substances) and dangerous devices. The Board has over 140,000 licensees in 23 license categories that include both personal and business licenses. As an agency that regulates the individuals and businesses that dispense, compound, provide, store and distribute prescription drugs and devices and pharmaceutical services to the public, or to other health care practitioners in compliance with state and federal law, the licensing of pharmacists, pharmacies, and pharmacy technicians is the primary focus of Board activity, with consumer protection at the core of the Board's operations. The Board's regulatory authority, as described in the Pharmacy Law, extends over individuals and firms located both within and outside California, if they provide services into California. The Board notes that it also ensures the safety of drug products dispensed to patients and regulates those who handle, store and ship products from the manufacturer through the supply chain to the pharmacy and ultimately to the patient.

The Board's vision, "Healthy Californians through quality pharmacist's care," helps guide Board activities and initiatives. The Board ensures that only those who possess specified requirements are licensed, seeks removal of licenses for those who don't comply with laws or maintain qualifications for licensure, investigates consumer complaints as well as provides a focused effort to ensure consumer education and awareness.

The current Board mission statement, as stated in its 2012-2017 Strategic Plan, is as follows:

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

The Board manages, plans, and tracks its operations through its strategic plan, which is annually updated and periodically reassessed (about every five years).

The Board is comprised of 13 members: seven pharmacists and six public members. All seven professional members and four of the public members are appointed by the Governor. One public member of the Board is appointed by the Senate Committee on Rules and one public member is appointed by the Speaker of the Assembly. Current law requires that at least five of the seven pharmacist appointees be actively engaged in the practice of pharmacy and the Board must include at least one practicing pharmacist from each of the following settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, a pharmacist member of a labor union that represents pharmacists and a long-term care or skilled nursing facility. The Board meets about four times per year. All Committee meetings are subject to the Bagley-Keene Open Meetings Act.

Board Member	Appointment Date	Term Expiration Date	Appointing Authority	Professional or Public
Amy Gutierrez, PharmD, President Dr. Gutierrez has served as chief pharmacy officer and director of pharmacy at the Los Angeles County Department of Health Services since 2006. She has been an adjunct professor of clinical pharmacy at the University of Southern California, School of Pharmacy since 2002 and an adjunct professor of pharmacy at Western University College of Pharmacy since 2010. Dr. Gutierrez earned a Doctorate of Pharmacy degree from the University of Southern California, School of Pharmacy.	June 4, 2014	June 1, 2018	Governor	Professional
Deborah Veale, R.Ph., Vice President 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.	June 21, 2013	June 1, 2017	Governor	Professional
Victor Law, R.Ph., Treasurer Mr. Law has been chief pharmacist and president at Alpha Medical Pharmacy, Inc. since 1987. Mr. Law has been a member of the California Pharmacists Association since 1982 and has served as president of the San Gabriel Valley Chapter. He has been chairman of the United Pharmacists Network, Inc. since 2006 and serves as chairman of the board for the Garfield Medical Center in Monterey Park. Mr. Law is also a member of the governing board for the San Gabriel Valley Medical Center and the National Community Pharmacists Association, and served on the Dean's Advisory Board of the Western University of Health Science Pharmacy School. Mr. Law earned his Bachelor of Pharmacy degree from the University of	August 29, 2012	June 1, 2016	Governor	Professional

Oklahoma in 1976.				
Ryan Brooks Mr. Brooks serves as vice president of government affairs for CBS Outdoor Western Region. He currently serves as a member of the New Motor Vehicle Board, the Little Hoover Commission, and the California International Relations Foundation. He also served on the San Francisco Public Utilities Commission from 2003 to 2008, where he assumed the position of president in 2007.	June 6, 2012	June 1, 2016	Governor	Public
Lavanza "Kercheryl" Butler, PharmD 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.	June 21, 2013	June 1, 2017	Governor	Professional
Ramón Castellblanch, Ph.D. Dr. Castellblanch is a Professor of Health Education at California State University, San Francisco and is a member of the American Public Health Association. He is a vice president of the California Alliance of Retired Americans. He earned his doctorate in health policy at Johns Hopkins University.	January 9, 2013	June 1, 2016	Senate	Professional
Gregory N. Lippe Mr. Lippe, a certified public accountant, has been president at Gregory N. Lippe Accountancy Corporation since 1981. He was also a managing partner at Lippe Hellie Hoffer and Allison LLP from 1994 to 2009 and president at Solomon Ross and Company from 1983 to 1994. Mr. Lippe was chief financial officer at Riverside Lumber Yard from 1981 to 1983 and a certified public accountant at Solomon Ross and company from 1969-1981. Mr. Lippe has been active in civic and business affairs and served on the boards of multiple community organizations.	June 6, 2012	June 1, 2016	Governor	Public
Gregory Murphy Mr. Murphy has been police lieutenant at the University of California, Davis Police Department since 2013. He served as a law enforcement consultant II at the California Commission on Peace Officer Standards and Training from 2004 to 2013 and was police chief at Sierra Community College District in 2009. Mr. Murphy was a police lieutenant at the University of California, Davis Police Department from 2003 to 2004, police sergeant at the Los Angeles Police Department from 1993 to 2003 and a staff sergeant in the United States Air Force from 1985 to 1991. He earned a Master of Science degree in information technology from American InterContinental	December 2, 2013	June 1, 2017	Governor	Public

University.				
Ricardo Sanchez Mr. Sanchez has been an investigator at the California Department of Motor Vehicles since 1989 and was an officer for the California State Police from 1988 to 1989. He is a member of the San Benito Masonic Lodge.	October 30, 2014	June 1, 2018	Governor	Public
Allen Schaad, R.Ph. Mr. Schaad has been a staff pharmacist at RxRelief since 2013. He was director of pharmacy at Mercy General Hospital from 2012 to 2013 and from 1999 to 2007. He was director of pharmacy at Woodland Memorial Hospital from 2007 to 2012, where he was pharmacy supervisor from 1997 to 1999. Mr. Schaad was an acute care pharmacist at the Mercy San Juan Medical Center from 1975 to 1997. He earned a Master of Arts degree in counseling psychology from the University of San Francisco.	June 2, 2015	June 1, 2019	Governor	Professional
Stanley C. Weisser, R.Ph. Mr. Weisser graduated from the University of Connecticut School of Pharmacy in 1963 and became a licensed pharmacist in California that same year. After opening his first pharmacy in 1969, his business, Network Pharmaceuticals, Inc., eventually grew into a chain of 30 pharmacies located in Southern California and Las Vegas, Nevada. Mr. Weisser is an associate professor of Pharmacotherapy and Outcomes Science at the Loma Linda University School of Pharmacy, and is a member of the California Pharmacists Association. Mr. Weisser has been on the executive committee of the board of the Redlands Community Hospital for over 25 years and was elected chairman for five of those years. Additionally, he is a trustee on the University of Redlands Board of Trustees, serving as chairman of the finance committee and a member of its executive committee.	June 2, 2015	June 1, 2019	Governor	Professional
Albert C. M. Wong, PharmD 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. **Vacant**	June 12, 2012	June 1, 2016	Governor Assembly	Professional Public

The Board performs much of its work in committees. Some committees are standing committees, others are task force or ad-hoc committees formed to examine a specific topic, and then disbanded following completion of the task. The Board also has one specialized standing committee, the Competency Committee, which is responsible for developing the California pharmacist licensing examination. The Board's strategic plan establishes five standing committees, a Licensing Committee,

Enforcement and Compounding Committee, Communication and Public Education Committee, Legislation and Regulation Committee and an Organizational Development Committee. Each committee typically meets quarterly prior to each Board meeting and provides a report and minutes of the committee meeting during each Board meeting.

In addition to the five strategic committees, the Board occasionally establishes subcommittees to study a complex, innovative or particularly controversial issue in more depth. These subcommittees also meet in public and encourage public participation in their discussions by releasing an agenda before a meeting and sharing meeting minutes at Board meetings.

Recent examples of subcommittees formed by the Board are:

- SB 493 Implementation Committee
- SB 1441 Uniform Standards Implementation Committee
- Prescription Drug Abuse Subcommittee

The Board is a member of the National Association of Boards of Pharmacy (NABP) and has one vote on matters before the association. The Board is also a member of the National Council on Patient Information and Education and the National Association of State Controlled Substances Authorities.

The Board reports that it primarily conducts public outreach through the internet. The Board regularly sends email blasts to stakeholders about board activities and highlights methods for the public to participate in these activities through these blasts. Through its listserv, which all licensed locations are required to subscribe to, the Board has what it believes is a quick and efficient way to disseminate important notices and alerts to subscribers, ensuring that pharmacies and wholesalers and other interested parties receive notice immediately of recalls of prescription medication and devices where the recall directs the removal of the product from dispensers or from patients. The Board states that it works hard to ensure its website is relevant to consumers, applicants, and licensees and is currently in the process of redesigning its website to improve ease of use. Board meetings and agendas are posted online and an advisory is sent to listserv subscribers notifying them of the availability of this information. The website also features meeting agendas and minutes from March 1999 to March 2003, as well as all meeting agendas, minutes and materials from April 2003 to present. Webcasts from July 2012 to present are also available on the Board's site.

Fiscal, Fund and Fee Analysis

The Board is a special fund agency whose activities are funded through regulatory fees and license fees. At the end of FY 2014/15, the Board reports that it had a reserve balance of 7.1 months which is about $11.7 million but projects to have a fund reserve of 4.9 months at the end of FY 2015/16, 3 months at the end of FY 2016/17 and 0.1 at the end of 2017/18. The Board provided a $1 million loan to the General Fund in FY 2008/09 which was repaid in FY 2013/14. The following is the past, current and projected fund condition of the Board:

(Dollars in Thousands)	*FY 2011/12*	*FY 2012/13*	*FY 2013/14*	*FY 2014/15*	*FY 2015/16*	*FY 2016/17*
Beginning Balance	$13,825	$13,597	$13,885	$12,878	$11,741	$8,227
Revenues and Transfers	$12,703	$13,933	$14,522	$18,227	$16,291	$16,279

Total Revenue	$26,528	$27,530	$28,407	$31,105	$28,032	$24,506
Budget Authority	$14,270	$14,806	$17,904	$20,599	$19,770	$20,094
Expenditures	$12,971	$13,935	$16,789	$19,364	$19,805	$20,094
Loans to General Fund	$0	$0	$0	$0	$0	$0
Accrued Interest, Loans to General Fund	$0	$0	$152	$0	$0	$0
Loans Repaid From General Fund	$0	$0	$1,000	$0	$0	$0
Fund Balance	$13,557	$13,595	$12,770	$11,741	$8,227	$4,412
Months in	11.7	9.7	7.9	7.1	4.9	3.0

The Board reports that it has experienced a 51 percent increase in authorized expenditures since its last sunset review. According to the Board, enforcement expenditures accounted for 57.4 percent of expenditures, licensing expenditures account for 12.5 percent of the Board's budget and Administration represents 13.4 percent of expenditures for FY 2014/15.

Through its divisions, DCA provides centralized administrative services to all boards, committees, commission and bureaus which are funded through a pro rata calculation that appears to be based on the number of authorized staff positions for an entity rather than actual number of employees. DCA Pro Rata accounted for 13 percent of expenditures in FY 2014/15.

In 2009, the Board sponsored legislation (AB 1071, Emmerson, Chapter 270, Statutes of 2009) to raise the statutory minimum and maximum fee levels for the first time since 1987, according to recommendations contained in an independent fee audit (which found that that the Board's expenditures were exceeding its revenues and that its fee structure was insufficient to maintain the required 12 month reserve). In 2014, the Board increased fees to the statutory maximums. According to the Board, a combination of an expansion in enforcement activities to implement the DCA's Consumer Protection Enforcement Initiative (CPEI), the prescription drug abuse epidemic and the need for greater regulation over pharmacies that compound sterile products led to the increase in fees. The Board's fees are discussed in Issue #3 below.

Staffing Levels

The Board is currently authorized in the Governor's 2016/17 budget for a total of 100.7 positions. The Board has also submitted two budget change proposals (BCPs) requesting to transition eight limited term positions that it was authorized in FY 2014/15 to permanent in order to focus on prescription drug abuse issues, and to transition to transition 5.5 limited term positions that it was authorized in FY 2014/15 to permanent in order to inspect, investigate, license and review enforcement needs for sterile injectable compounding facilities.

According to the Board, its inspectors, who are licensed pharmacists, are fundamental to the Board's program. The Board relies on these inspectors who have education and experience in various pharmacy settings to bring an inherent understanding of a pharmacy environment, as well as the classification and dosing of generic, brand-name and compounded drugs beyond that which a non-pharmacist staff member might be able to understand. The Board states that it only uses its pharmacist staff to perform

duties that require the knowledge of a pharmacist and relies on non-pharmacist investigators and other staff in capacities that do not require the same specialized knowledge.

The Board works to recruit and fill vacant positions quickly and has established plans for succession that are able to mitigate impacts resulting from the retirement of long-standing staff. The Board attempts to promote from within for vacant positions and utilizes DCA training courses to improve staff skills and knowledge. The Board uses multiple training modalities, including web-based training and structured bi-weekly training for all field staff.

Licensing

The Board notes that its licensees are integral to the delivery of quality health care. They compound, transport, dispense and store prescription drugs and devices for patients that are essential for patient care and treatment. Pharmacists also convey information related to drug therapy management and are the health care provider most educated on pharmaceutical care and management. The Board has a highly diverse and detailed licensing program for the individuals and facilities the Board regulates, reflecting the careful and deliberative manner in which the U.S. regulates the manufacturing, distributing, and dispensing of prescription drugs and devices.

The Board currently has over 140,000 licensees, a 5 percent increase since the last sunset review. Over the past four years, the Board has received over 68,000 new applications, issued over 52,000 licenses, processed over 11,500 change notices and renewed over 240,300 licenses.

An applicant must satisfy all requirements specified in law before a license is issued and the Board has multiple processes it uses to secure information about applicants to confirm their eligibility for licensure. Examples include receipt of original student transcripts for applicants directly from schools, license verifications directly from other licensing entities, and certain certified or original documents verifying other licensing components from the applicant. Out-of-state pharmacist applicants are subject to the same examination and licensure requirements as those in California, while foreign-educated pharmacists are required to be certified by the Foreign Pharmacy Graduate Examination Committee before being issued an intern pharmacist license or becoming eligible to take the pharmacist licensure exam.

The Board also accepts military training for the purposes of licensure as a pharmacist, pharmacy technician, designated representative and third party logistics provider designated representative. The Board expedites the processing of applications when applicants provide supporting military documentation and is also able to waive licensure related fees for veteran applicants. The Board is in the process of implementing procedures to identify and track veteran applicants.

The Board relies on the Accreditation Council for Pharmacy Education (ACPE), the sole accrediting body for pharmacist education in the nation, for approval of schools of pharmacy. The Board accepts this accreditation and a Board member attends and observes accrediting and reaccrediting visits by ACPE at California schools of pharmacy. However, the ACPE does not grant full accreditation to a new school of pharmacy until the school graduates its first class of pharmacists which can take as long as four years. In these situations, the Board may approve schools of pharmacy for the limited purpose of issuing intern licenses to applicants from schools that are undergoing, and on track to receive, full accreditation by the ACPE.

In addition to meeting educational and experience requirements, an applicant for licensure as a pharmacist must take and pass both the North American Pharmacist Licensure Examination (NAPLEX)

and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). The NABP develops the NAPLEX exam, which is the national examination for licensure as a pharmacist now used by all states. The CPJE exam is developed by the Board to assess California-specific laws, patient consultation and other areas of California pharmacy practice not tested by the NAPLEX. Both the NAPLEX and CPJE are offered on a continuous basis and administered only via computer-based testing at locations nationwide. Additionally, as part of the exam score transfer process for the national pharmacist exam, the pharmacist's licensure status in all states where he or she is already licensed is provided to the Board by the NABP.

The Board conducts criminal background checks of all applicants at both state and federal levels by requiring the submission of fingerprints to the California Department of Justice (DOJ) and the Federal Bureau of Investigation (FBI). The Board has been fingerprinting pharmacists since the late 1940s. The Board also conducts a criminal background check on the top five owners and designated managers for all site license applications. Additionally, there are specific questions, which are answered under oath, on all applications that require self-reporting and descriptions of any arrest or conviction, as well as previous or close association to someone with prior discipline by any regulatory body. Applicants who self-report either a criminal conviction or prior discipline by a regulatory board are required to submit documentation describing the action and resolution. If the Board is unable to obtain this information from the applicant, the Board works to collect this information and reviews it before making a licensing decision. An applicant who fails to self-report these actions may be denied licensure on the grounds of falsification of an application. According to the Board, regardless of whether a prior incident is self-reported or identified from a fingerprint background result from the DOJ or FBI, the application is referred to the Board's enforcement unit for a thorough investigation before a licensing decision is made.

According to the Board, it has established aggressive performance targets in its licensing efforts, outlined below.

License Type	Application Type	Status	Target (InDays)
Clinic	Clinic Permit Application	Complete	30
		Incomplete	65
Centralized Hospital Packaging	Centralized Hospital Packaging Pharmacy License Application	Complete	45
		Incomplete	80
Drug Room	Drug Room Application	Complete	30
		Incomplete	65
Designated Representative–3PL	Application for Designated Representative – 3PL	Complete	30
		Incomplete	50
Designated Representative – Veterinary Food-Animal Drug Retailer	Designated Representative – Veterinary Food-Animal Drug Retailer Application	Complete	30
		Incomplete	50
Designated Representative - Wholesaler	Application for a Designated Representative License	Complete	30
		Incomplete	50
Hospital	Hospital Pharmacy Permit Application	Complete	30
		Incomplete	65
Hypodermic Needle and Syringe	Application for Hypodermic Needle and Syringe Permit	Complete	30
		Incomplete	50
Intern Pharmacist	Application for Registration as an Intern Pharmacist	Complete	15
		Incomplete	25

Correctional Pharmacy	Correctional Pharmacy	Complete	30
		Incomplete	50
Pharmacist	Application for Pharmacist Examination and Licensure	Complete	15
		Incomplete	25
	Application for Pharmacist Initial License	Complete	5
		Incomplete	7
Pharmacy	Pharmacy Permit Application	Complete	30
		Incomplete	65
Pharmacy - Nonresident	Nonresident Pharmacy Permit Application	Complete	30
		Incomplete	50
Pharmacy Technician	Pharmacy Technician Application	Complete	30
		Incomplete	50
Sterile Compounding Pharmacy	Application for a Sterile Compounding Pharmacy License	Complete	45
		Incomplete	80
Sterile Compounding Pharmacy - Nonresident	Application for a Nonresident Pharmacy Sterile Compounding License	Complete	45
		Incomplete	80
Third-Party Logistics Provider	Application for Third-Party Logistics Provider License	Complete	30
		Incomplete	50
Third-Party Logistics Provider – Non Resident	Application for Nonresident Third-Party Logistics Provider License	Complete	30
		Incomplete	50
Veterinary Food-Animal Drug Retailer	Veterinary Food-Animal Drug Retailer Application	Complete	30
		Incomplete	50
Wholesaler	Application for Wholesaler License	Complete	30
		Incomplete	50
Wholesaler - Nonresident	Application for Nonresident Wholesaler License	Complete	30
		Incomplete	50

The Board is not meeting these targets, as discussed in Item #9 below.

Continuing Education (CE)

Pharmacists are the Board's only licensee category that is required to earn CE as a condition of renewal, specifically 30 units of CE every two years for pharmacists and 10 units of CE every two years for Advanced Practice Pharmacists (APP). The renewal application requires a pharmacist to self-certify under penalty of perjury the number of CE hours completed during the renewal period and the Board is currently designing its applications for APP application and renewal. The Board conducts random audits of renewal applications to verify that the reported CE units are correct. The Board only conducted 210 CE audits in FY 2011/12 but increased to 438 in FY 2014/15, for a total of 1,410 audits in the prior four FYs.

Enforcement

The Board's enforcement activities are the core of its program, with the majority of its staff and resources dedicated to enforcement functions. From FY 2011/12 through FY 2014/15, the Board:

- Closed investigations on 11,962 licensees
- Referred 1,707 licensees and applicants for formal discipline
- Cited and fined 8,359 licensees
- Collected $7,486,177 in citation and fine revenue.
- Revoked or accepted surrender of 831 licenses and
- Placed 339 licensees on probation

These numbers are up, in many instances significantly, since the Board's prior sunset review.

The Board aims to prevent events that could result in patient harm and ensure that there are consequences to deter events from occurring in other pharmacies. According to the Board, its greatest tool in performing the broad range of investigations and inspections required to regulate such a diverse licensing population are the licensed pharmacist inspectors discussed above. These investigators work from home offices throughout the state and perform random, unannounced inspections to detect violations, investigate complaints, monitor licensees on probation, educate licensees about Pharmacy Law requirements, serve as expert witnesses in disciplinary hearings and identify violations and issues that non-pharmacists may not be able to identify.

The Board received 10,399 complaints in the years leading up to this review. Under current law, the Business and Professions Code (BPC) Section 800 series provides several reporting mandates to assist licensing boards in protecting consumers from licensees who have had an action taken against them in which there may be a settlement or arbitration award, have been disciplined by their employers and have either altered workplace privileges or are no longer employed, , or those who have committed a criminal act. These reports also serve as the basis for the Board determining when an investigation may be necessary.

The Board has established the following performance targets for its enforcement program: 90 days to complete desk investigations, 120 days to complete field investigations, and, 180 days to close all investigations. At the end of FY 2014/15, the Board was completing 43 percent of its desk investigations within 90 days, only 11 percent of its field investigations within 120 days, and closing 55 percent of all investigations within 180 days. The Board's timelines are discussed later in Issue #9.

Among the enforcement tools used by the Board following an investigation are the issuance of a citation, citation and fine, or letter of admonishment. The Board first initiated the use of citations and fines in July 1995. These actions are pursued when the violations are not serious enough to warrant referral to the Office of the Attorney General (AG) or formal discipline. Citations and fines are used as a means to educate the licensee about Pharmacy Law, ensure compliance, and to note that a violation has occurred. Letters of admonishment are lesser penalties issued by the Board to acknowledge a minor violation that does not warrant issuance of a citation and fine or referral for disciplinary action. The Board is authorized through regulation to issue citations of up to $5,000 for violations of Pharmacy Law and regulations. The Board reports that for most violations, fines are capped at $5,000 to each licensee investigated in a specific investigation. For example the Board could issue fines of up to $5,000 to a pharmacy, pharmacist, and pharmacist-in-charge involved in the same violations of Pharmacy Law discovered through an investigation. The board also has specific statutory authority to issue higher fines for specific violations, including up to $25,000 per prescription for internet sales of drugs where no underlying appropriate examination occurred. In the last four fiscal years, the Board issued 5,649 citations with and without fines. The Board also issued 709 letters of admonishment during the last four fiscal years.

	FY 2011/12	*FY 2012/13*	*FY 2013/14*	*FY 2014/15*
Letters of Admonishment	143	159	260	147
Citations with No fine	156	199	390	208
Citation with Fine	842	1,287	1,595	972
Fines Assessed	$116,424,525	$16,043,600	$13,011,000	$1,694,080
Fines Collected	$1,298,536	$2,360,413	$2,174,490	$1,606,120

The Board has the final authority over the disposition of disciplinary cases, for which it consults its Disciplinary Guidelines in reaching a decision. The Board notes that these Guidelines are used by board staff, board members, deputy attorneys general, administrative law judges, and attorneys to set penalties in disciplinary cases for various categories of violations. The Board states that its guidelines also ensure that consistent penalty language is incorporated, and that appropriate terms and conditions of probation are included in all decisions.

According to the Board, there has been a significant increase in the number of cases referred to the AG. In the three years prior to the last sunset review, the Board referred 907 cases to the AG's Office. In the three years prior to this review, the Board referred 1,144 cases, a 26 percent increase.
The board also notes growth in the number of pleadings filed: 701 accusations and statements of issues reported during its last review, with discipline completed against 492 respondents. In the three years prior to this review, the Board has filed 954 pleadings and secured discipline against 918 licensees, a 36 percent increase in the number of pleading and a 87 percent increase in the number of disciplinary actions secured against respondents. Over the last four FYs, 82 percent of all cases were closed within the first two years, a significant increase from 39 percent in the years leading up to the prior sunset review.

The Board also has a Pharmacists Recovery Program (PRP). The PRP is a monitoring program that allows pharmacists and pharmacist interns 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 practice under specific, controlled conditions with supervision, so long as abstinence is maintained. The contracted vendor, MAXIMUS, 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 Board is working to implement the Uniform Standards for Substance Abusing Licensees stemming from SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008), discussed later in Issue #12.

(For more detailed information regarding the responsibilities, operation and functions of the Board please refer to the Board's "Sunset Review Report 2016." This report is available on its Website at http://www.pharmacy.ca.gov/publications/sunset_2016.pdf

PRIOR SUNSET REVIEW: CHANGES AND IMPROVEMENTS

The Board was last reviewed by the Legislature through sunset review in 2011-12. During the previous sunset review, 12 issues were raised. In December 2015, the Board submitted its required sunset report to the Senate Committee on Business, Professions and Economic Development and

Assembly Committee on Business and Professions (Committees). In this report, the Board described actions it has taken since its prior review to address the recommendations made. The following are some of the more important programmatic and operational changes, enhancements and other important policy decisions or regulatory changes made. For those which were not addressed and which may still be of concern to the Committees, they are addressed and more fully discussed under "Current Sunset Review Issues."

- **The Board is not facing quorum issues**. The Board responded to the prior sunset review concern that it had vacancies which could result in an inability to conduct business due to a lack of quorum by expressing concern about these vacancies. The Board now does not have any vacancies.

- **An increased number of mandatory reports are being provided to the Board .** Concerns were raised about the Board potentially not receiving important information about its licensees, including the reports under BPC section 800 outlined above, and whether its enforcement staff was in a position to handle an influx of new reports. The Board states that it periodically reminds its licensee population about these mandatory reporting requirements outlined in BPC § 800 and has completed investigations on the reports it has received, taking action in 83 percent of the incidents provided in the reports (14 letters of admonishment, 466 citations [including citations with fines] and six cases referred to the AG's office for administrative action). The Board also took action based on reports about drug losses, employee impairment and termination for theft, diversion or self-use of dangerous drugs (188 citations [including citations with fines] and 207 referrals to the AG's office for disciplinary action stemming from investigations initiated by these reports. Over the last four years, the Board received 674 Section 800 reports and 737 reports of drug losses involving controlled substances and/or employee impairment.

- **Verification of intern hours and educational experience is more efficient.** Prompted by a recommendation for more efficient means of verifying intern hours for out-of-state licenses, legislation was enacted authorizing the acceptance of intern hours transferred directly by another state board of pharmacy. Prior to this change, Board staff independently verified completion of hours. The Pharmacy Law was also amended to allow the Board to accept graduation from recognized schools of pharmacy as proof of intern experience.

- **The Board continues to take actions to prevent unlicensed activity and the underground economy.** The Committee requested information about how unlicensed activity impacts the Board's enforcement program workload. The Board reports that it continues to aggressively investigate unlicensed activity, taking action in 53 percent of the cases, including issuing 12 letters of admonishment, 262 citations, including citations and fines, and referring 12 cases to the AG for administrative action. The Board has also focused on allegations of unauthorized activity by pharmacies and wholesalers and reports it was recognized for its leadership in enforcement actions taken in 2012 to address exorbitant prices beings charged to hospitals for sales of drugs in short supply by unethical drug secondary wholesalers who had enticed community pharmacies to order these drugs for the secondary wholesalers. Through this scheme, secondary wholesalers could secure larger supplies of these medications than they could directly obtain on their own because of quota systems set up to prevent market manipulation and without the Board's action, hospitals and patients would have had a harder time obtaining drugs in short supply and when they did receive the medication, they would

have paid substantially more (up to 6,000 percent increases were charged by these secondary wholesalers in some cases).

- **The Board is tracking information to determine whether there is a shortage of pharmacists.** The Committee asked the Board to explain its rationale in determining that California does not have a pharmacist shortage as well as outline efforts to ensure greater utilization of the profession in the midst of new demand for health care professionals. The Board has used information from a survey to determine that the aggregate demand index for pharmacists in California dropped to 3.25 in July 2015 (the scale is that 4 indicates moderate demand: some difficulty filling open positions, and 3 indicates demand in balance with supply). According to the Board, the experts who develop and create these figures believe there is little indication of difficulty in filling pharmacist positions in California currently. Since the prior review, legislation was enacted (SB 493, Hernandez, Chapter 469, Statutes of 2013), providing new opportunities for pharmacists to provide direct consumer services they have been trained to perform (discussed further in Issue #15). The Board plans to continue implementation of legislation expanding pharmacists' role in health care delivery and track needs in the pharmacist workforce.

CURRENT SUNSET REVIEW ISSUES

The following are unresolved issues pertaining to the Board of Pharmacy, or areas of concern for the Committees to consider, along with background information concerning the issue of oversight for private postsecondary institutions. There are also recommendations Committee staff have made regarding particular issues or problem areas which need to be addressed. The Board and other interested parties have been provided with this Background Paper and the Board will respond to the issues presented and the recommendations of staff.

BOARD ADMINISTRATION ISSUES

ISSUE #1: (BreEZe.) The Board was originally slated to be a part of the DCA's second release of a new information technology (IT) system but is now included in a third release, which has been cancelled from the current project, and the plans for which are unclear. What is the Board doing in the meantime to address IT needs? Does the Board have systems in place to track key data necessary to identify performance measures and to track important information about its licensees?

Background: The DCA has been working since 2009 on replacing multiple antiquated standalone IT systems with one fully integrated system. In September 2011, the DCA awarded Accenture LLC (Accenture) with a contract to develop and implement a commercial off-the- shelf customized IT system, which it calls BreEZe. BreEZe is intended to provide applicant tracking, licensing, renewals, enforcement, monitoring, cashiering, and data management capabilities. In addition, BreEZe is web-enabled and designed to allow licensees to complete and submit applications, renewals, and the necessary fees through the internet. The public also will be able to file complaints, access complaint status, and check licensee information if/when the program is fully operational.

The project plan called for BreEZe to be implemented in three releases. The first release was scheduled for July 2012. The Board was originally scheduled for inclusion in Release 2 of the project. As the Board began the steps towards transition to the new system, two board staff were assigned to assist in the development of components that could meet the Board's needs. According to the Board, these staff spent a considerable amount of time working on the preliminary configuration for the Board's conversion into the new system. However, as the configuration progressed, Board staff identified key functionality absent from the system that was critically needed by the Board.

The Board has now been pushed back to Release 3 of BreEZe, but under Special Project Report 3.1 that outlined the changing scope and cost of the BreEZe project, Release 3 was removed from the project entirely. DCA currently has no formal plan to expand BreEZe to the 19 boards in Release 3. Instead, DCA first intends to conduct a cost-benefit analysis for Release 3 boards after Release 2 is completed in 2016 and then make a decision about whether boards previously slated for Release 3 of the project will come onto BreEZe and if so, how that will be implemented. It is not clear whether the system has been evaluated to meet the needs of Release 3 entities like the Board, many of which are facing significant operational challenges due to their lack of dynamic IT capacity. To date the Board has contributed $1.5 million towards this upgraded system.

It would be helpful for the Committees to understand what the plan is moving forward for the Board and any IT upgrades. It would also be helpful to understand, particularly given the Board's fiscal issues as discussed later, what future costs are anticipated.

Staff Recommendation: ***The Board should provide the Committees an update on the status of Release 3 of BreEZe, as they have been advised by the DCA, and should provide the Committees a breakdown of charges the DCA has told the Board they will be paying for BreEZe in FY 2016/17 and ongoing. The Board should report whether it is currently using any workaround systems to meet data tracking needs.***

ISSUE #2: (REGULATIONS.) The Board is tasked with implementing a number of pieces of recently enacted legislation through the promulgation of regulations. The Board also may initiate a rulemaking package to address other important issues. How are regulations prioritized? How are staff resources dedicated to the Board's many rulemaking packages?

Background: Since the prior sunset review, the Board has initiated and adopted 11 regulatory proposals, has initiated and withdrawn 4 regulatory proposals, had 1 regulatory proposal denied by the Office of Administrative Law and, as of November 5, 2015, has 14 regulatory proposals in progress. The scopes of these rulemaking packages is broad and include (but are not limited to) a range of topics from updating applications for pharmacy technicians to outlining procedures for the take back of prescription drug medication to establishing a state protocol to allow pharmacists to provide self-administered hormonal contraception. The Board maintains that it must "remain vigilant in evaluating regulations, working to remove outdated provisions while securing changes necessary to amend existing regulations to strengthen its role as a consumer protection agency or provide additional guidance and clarification to licensees on legal requirements".

Some regulatory packages take significantly longer than others and it would be helpful for the Committees to know how rulemaking needs are prioritized. It would be helpful to understand what leads to delays in rulemaking related to implementation of statute (for example, the drafting of a statewide protocol for pharmacists to provide hormonal contraceptives as discussed further in Issue #15).

It would also be helpful to understand what legal support the Board receives to swiftly draft regulations and when the Board proposes rulemaking in response to perceived attention or action by the Legislature. For example, the Board moved in Fall 2015 to initiate rulemaking related to the take back of drugs at pharmacies and by Board licensees, an issue that the Legislature has proposed and enacted legislation on since 2006. A number of local ordinances throughout the state *require* pharmacies to take back medication but the Board's proposed language asserts that pharmacies *may* take back medication according to certain standards and with certain safeguards in mind. The Board itself sought clarification on preemption and whether local ordinances would supersede the Board's rule or vice versa. Particularly as this remains an important national issue, it would be helpful for the Committees to understand the Board's efforts, rationale for regulatory efforts and impacts of Board rules on issues that continue to be debated by the Legislature.

Staff Recommendation: ***The Board should advise the Committees its regulation package prioritization and how the Board determines when to proceed with initiating a new rule or amending current rules. The Board should also report to the Committees on regulatory action necessary to implement recently enacted legislation. The Board should report to the Committees on whether it takes preemptive regulatory action when the Legislature is discussing statutory changes.***

BOARD BUDGET ISSUES

ISSUE #3: (FUND CONDITION AND STAFFING LEVELS.) The Board's staff continues to grow yet delays in certain application processing and workload continue. Is the Board appropriately directing staff resources to meet its needs? Does the Board focus too much on boosting enforcement staff? The Board is also facing a serious deficit and may need to raise fees to continue to do its job. However, fee caps were just raised through legislation in 2009. Is the Board's program growing beyond what fees can cover? Did the Board properly evaluate licensing fees for new categories like sterile compounding facilities located in other states that provide drug products to California?

Background: Since the prior review, the Board has experienced a 51 percent increase in authorized expenditures. Revenue has not kept pace with this level of spending and the Board is projected to have depleted its fund sometime in FY 2017/18 given the current structure. As the Board's program has grown, it has received authority for an increase in staff positions, specifically the approval of five BCPs since FY 2013/14. However, the Board is facing backlogs in processing applications and appears to focus primarily on enforcement rather than other program functions. The Board has also made significant budget adjustments, to the tune of over $1.5 million, for costs related to the BreEZe program which the Board now has no future plans to be a part of.

The Board is currently authorized in the Governor's 2016/17 budget for a total of 100.7 positions. The Board has also submitted two budget change proposals (BCPs) requesting to transition eight limited term positions that it was authorized in FY 2014/15 to permanent in order to focus on prescription drug abuse issues, and to transition to transition 5.5 limited term positions that it was authorized in FY 2014/15 to permanent in order to inspect, investigate, license and review enforcement needs for sterile injectable compounding facilities.

The Board attributes its action to raise fees to the statutory maximum in 2014 to three primary efforts: CPEI, the prescription drug abuse epidemic and the need for greater regulation over pharmacies that compound sterile products.

The national attention to prescription drug abuse, as well as documented impacts of this significant problem, is at an all-time high, with Board licensees directly in the middle of many of these conversations. Federal data for 2014 showed that abuse of prescription pain killers now ranks second, just behind marijuana, as the nation's most widespread illegal drug problem. Abuse can stem from the fact that prescription drugs are legal and potentially more easily accessible, as they can be found at home in a medicine cabinet. Data shows that individuals who misuse prescription drugs, particularly teens, believe these substances are safer than illicit drugs because they are prescribed by a health care professional and thus are safe to take under any circumstances. The Board has a RX Drug Abuse team within its enforcement unit and utilizes the AG's Controlled Substance Utilization Review and Evaluation System (CURES) prescription drug monitoring program more than any other regulatory boards. Pharmacies are required to report the dispensing of controlled drugs to CURES by drug name, quantity, prescriber, patient, and pharmacy and the Board in turn conducts research and monitoring of this data. The Board's current BCP specifically notes that with additional position authority, dedicated staff will continue efforts to use CURES data in Board enforcement efforts.

The Board has also significantly expanded its oversight role of sterile compounding pharmacies. Compounding pharmacies make drugs, but they are limited to either producing small amounts in response to a specific patient's prescription, or to create a small supply for an identifiable patient population to ensure continuity of treatment. In October 2012, the New England Compounding Center (NECC), based in Massachusetts, shipped contaminated product throughout the country, including California, that resulted in the death of more than 40 people and illness in more than 450 patients from NECC's tainted steroid injections. The Board was concerned that it did not have the opportunity or authority to inspect NECC or prevent NECC from shipping products into California until patients in other states had already been harmed, and subsequently sponsored SB 294 (Emmerson, Chapter 565, Statutes of 2013) which requires an inspection by the Board prior to licensure for all compounding pharmacies that make or distribute compounded drugs in California, including those located within the state and those located in other states that ship products into California for use by California patients. The current fee for nonresident sterile compounding pharmacies is $780, which the Board now believes is substantially less than the true cost of regulating these entities.

The Board has provided a fee audit to the Committees and responded to a fee background questionnaire from the Committees, in which it proposes new statutory minimum and maximum fees.

Initial Fees

Fee Type	*Current Fee*	*Proposed Statutory Minimum*	*Proposed Statutory Maximum*	*Change from Current to Proposed Statutory Minimum*
Centralized Hospital Packaging	$800	$820	$1,150	3%
Clinic Permit	$520	$520	$570	0%
Designated Representative Certificate – Third Party Logistics Provider	$330	$150	$210	-55%

Designated Representative Certificate - Veterinary Food-Animal Drug Retailers	$330	$150	$210	-55%
Designated Representative Certificate - Wholesalers	$330	$150	$210	-55%
Hypodermic Needle and Syringe	$165	$170	$240	3%
Intern Pharmacist	$115	$165	$230	43%
Non-Resident Pharmacy	$520	$520	$570	0%
Non-Resident Sterile Compounding	$780	$2,380	$3,335	205%
Non-Resident Third Party Logistics Provider	$780	$780	$820	0%
Non-Resident Wholesaler	$780	$780	$820	0%
Pharmacist Initial License Fee	$195	$195	$215	0%
Pharmacist Licensure Exam	$260	$260	$285	0%
Pharmacy	$520	$520	$570	0%
Pharmacy Technician	$105	$140	$195	33%
Sterile Compounding	$780	$1,645	$2,305	111%
Third Party Logistics Provider	$780	$780	$820	0%
Veterinary Food-Animal Drug Retailer	$425	$435	$610	2%
Wholesale Drug	$780	$780	$820	0%

Renewal Fees

Fee Type	***Current Fee***	***Proposed Statutory Minimum***	***Proposed Statutory Maximum***	***Change from Current to Proposed Statutory Minimum***
Centralized Hospital Packaging Renewal	$800	$805	$1,125	1%
Clinic Renewal	$325	$325	$360	0%
Designated Representative Certificate – Third Party Logistics Provider Renewal	$195	$215	$300	10%
Designated Representative – Veterinary Food-Animal Drug Retailers Renewal	$195	$215	$300	10%
Designated Representative – Wholesalers Renewal	$195	$215	$300	10%
Hypodermic Needle and Syringe Renewal	$165	$200	$280	21%
Non-Resident Pharmacy Renewal	$325	$325	$360	0%
Non-Resident Sterile Compounding Renewal	$780	$2,270	$3,180	191%
Non-Resident Third Party Logistics Provider Renewal	$780	$780	$820	0%
Non-Resident Wholesaler Renewal	$780	$780	$820	0%

Pharmacist Renewal	$195	$360	$505	85%
Pharmacy Renewal	$325	$665	$930	105%
Pharmacy Technician Renewal	$130	$140	$195	8%
Sterile Compounding Renewal	$780	$1,325	$1,855	70%
Third Party Logistics Provider Renewal	$780	$780	$820	0%
Veterinary Food-Animal Drug Retailer Renewal	$325	$330	$460	2%
Wholesale Drug Renewal	$780	$780	$820	0%

There is no doubt that the Board is a key player in all of these important issues but it would be helpful for the Committees to better understand the Board's justification for prioritizing certain efforts and how cost estimates are made to ensure that regulatory fees pay for the Board's regulatory activities. It would also be helpful for the Committees to understand whether the Board believes it will require additional fee increases in coming years, what feedback it receives from licensees on fee increase efforts and what the Board can do to partner with agencies and existing resources to continue to do its important work without having to negotiate fee cap raises within a short period of time.

Staff Recommendation: ***The Board needs to provide information to the Committees outlining efforts to maintain a healthy fund condition, even as it works on important issues with national attention. The Committees may wish to require the Board to conduct workload analyses related to certain licensing categories to determine where certain processes can be streamlined for less complicated licenses. The Committees may wish to amend the Pharmacy Law to allow the Board to raise the statutory cap on fees.***

LICENSING ISSUES

ISSUE #4: (BACKLOGS.) The Board is facing licensing backlogs. What steps is the Board taking to ensure that applications are processed in a timely fashion, particularly for entities under the same ownership structure, to ensure that patients have access to the medication they need?

Background: The Board's failure to timely issue a license to an individual or entity prevents or at least delays that individual or business from working. For example, if the Board delays a licensing decision because it is investigating an applicant's criminal background, the job intended for that applicant may be given to another individual. As a result, the Board's delay in licensing, while often necessary, has a direct impact on consumers and practitioners.

The Board aims to issue a permit as quickly as possible once the applicant has been determined to be qualified for licensure. The Board notes that it works with applications from new businesses that must be licensed by the Board, and strives to ensure that they can open on the date they desire, even when they turn applications in very close to the desired opening date. According to the Board, this usually can be accomplished but there are a number of components that must be completed before an applicant can receive a new pharmacy or wholesaler license. The Board does have the ability to issue temporary licenses to pharmacies and wholesalers if a certain number of requirements are fulfilled, which in turn permits the new business to operate and the Board can then finalize review of the licensing documents over the course of 180 days.

Below are the Board's timelines for licensing for the past four FYs:

Application Type	*FY 2011/12*		*FY 2012/13*		*FY 2013/14*		*FY 2014/15*	
	Rec'd	*Days*	*Rec'd*	*Days*	*Rec'd*	*Days*	*Rec'd*	*Days*
Pharmacy Technician	9,491	110	8,741	70	8,211	89	7,151	93
Pharmacist Exam	2,467	35	1,805	32	2,682	38	3,122	46
Pharmacy	333	89	505	95	421	112	1,541	137

The Board states that fluctuations in licensing are due to a number of factors including staff vacancies, new licensing programs which lead to staff resources being redirected, sudden surges in workload related to peak cycles times (graduation dates) and large buyouts of chain store pharmacies. The Board states that it is currently focusing on timely processing of applications and recently reinstituted a quarterly review of all of its pending applications which is intended to serve as another opportunity for the Board to reach out to applicants and request necessary information before an application would otherwise be withdrawn. The Board projects, based on recent efforts in this area, that completing this review quarterly will result in deficiencies being remedied more quickly and licenses being issued faster. As of October 30, 2015, the Board had over 2,500 pending applications for initial licensure.

As a means of decreasing processing times, the Board highlights that it is working to secure additional resources as well as improving application instructions and educating applicants about the requirements for licensure. The Board is working to simplify and clarifying instructions and applications as a means of reducing the number of deficiencies on initial applications, thereby reducing the overall application processing times. The Board has discussed application requirements during Board and committee meetings that are webcast, highlighting application requirements as well as common deficiencies and is working to develop videos that will also serve to assist applicants through the application process.

The Board may also benefit from a statutory clarification related to processing timelines for applications filed by clinics opening a new location, reporting a change to an existing location or updating certain information like changes to corporate officers. Similarly, a streamlined process for commonly-owned clinics to use just one application may speed up timelines and improvements may be realized if clinic corporations owning more than one Board-licensed clinic are authorized to renew all of their permits at one time.

Staff Recommendation: ***The Board should provide the status of its licensing backlog. The Committees may wish 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.***

ISSUE #5: (OUTSOURCING FACILITIES). Should the Board license outsourcing facilities to align its regulatory system with the FDA and other states?

Background: The federal Drug Quality and Security Act (DQSA) was signed into law by President Obama on November 27, 2013. Prompted by the fatal fungal meningitis outbreak in 2012 linked to unsanitary conditions at a Massachusetts compounding pharmacy, as well as concerns regarding

increases in counterfeit, falsified, substandard and dangerous prescription medications, DQSA contained two parts – the Compounding Quality Act and the Drug Supply Chain Security Act.

The Compounding Quality Act created a voluntary compliance regime in which large-scale compounding pharmacies may voluntarily register as "outsourcing facilities" and be subject to oversight by the Food and Drug Administration (FDA) in much of the same way that traditional pharmaceutical manufacturers are monitored. These facilities must adhere to more stringent current good manufacturing practices and are subject to a risk-based inspection schedule. The FDA has registered 59 outsourcing facilities, three of which are in California.

California law does not currently recognize outsourcing facilities because state law authorizes only limited anticipatory pharmacy compounding, either for prescriber office use or to meet customary demand. For a number of years, the Board and other federal and state regulatory agencies have grappled with establishing a tipping point at which a pharmacy compounds enough medications to become a manufacturer.

The Board currently licenses entities that would be considered outsourcing facilities as sterile compounding pharmacies – "resident" if they are located in California and "non-resident" if located out of state and ships into California. There is no distinction between large scale and small scale facilities.

However, this regulatory system is losing its viability as a solution for two reasons. First, it does not recognize the federal outsourcing requirements that permit large scale compounding. Second, it does not align with other states' systems; multiple states are moving to establish regulatory frameworks to license outsourcing facilities as separate entities and some prohibit licensure of these facilities as sterile compounding pharmacies, contrary to California's structure.

In 2015, the Board sponsored legislation (SB 619, Morrell) to license outsourcing facilities. The Board believes that licensing these entities both within and outside California will ensure that the state's hospitals and practitioners have access to high quality, carefully compounded sterile medication.

Staff Recommendation: ***The Committee suggests adding an outsourcing facility license to the Pharmacy Law and recommends 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) exceed the revenue from fees.***

ISSUE #6: (AUTOMATED DELIVERY DEVICES). The Board has discussed instances where machines dispense and provide medication, focusing on the need for accountability for the inventory when emerging technologies are used for medication delivery. Should operators of Automated Delivery Devices be required to register use of these devices with the Board? What would registration mean for the Board's licensing backlogs and enforcement priorities?

Background: Current law authorizes the use of "automated drug delivery systems," which are a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system is required to collect, control, and maintain all transaction information to accurately track the movement of

drugs into and out of the system for security, accuracy, and accountability. Under some circumstances the pharmacist must authorize the release of medication.

Pharmacies are able to operate automated delivery devices in various settings away from a licensed pharmacy or within a licensed facility. This includes in skilled nursing homes and other specified health care facilities, certain clinics, and hospitals for drug storage and access outside of the pharmacy.

The demand for additional use of these delivery devices is growing. A pilot study is currently underway that would allow patients to pick up medication from a delivery device that is not specifically located in a pharmacy so long as patient consultation is first provided.

The Board reports that it is not currently able to track how many of these delivery devices are in use, where they are in use, or which pharmacy is responsible for specific delivery devices. A registration would enable the Board to identify which pharmacies operate these delivery devices and where each is located.

Staff Recommendation: ***The Committees may wish to authorize the Board to establish a registration requirement that links automated delivery device systems to the pharmacy that owns and is responsible for the medications stored and released from the device. As part of the registration, the Committees may wish to require that the Board is provided with the policies and procedures that demonstrate appropriate security of the device and how patient consultation is being provided. Registration of these systems may also 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 loss information.***

ISSUE #7: (PROFESSIONAL CORPORATIONS). Should pharmacists be included on the list of individuals who may be a shareholder, officer, or director of a medical corporation?

Background: Corporations Code 13401.5 authorizes the formation of various healing arts professional corporations and establishes which healing arts licensees who are not of the same license type as the corporation may be shareholders, officers, and directors of that corporation. Any person licensed under the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act may be employed by these professional corporations. Thus, the services of professional corporations are not limited to the named profession. For example, a nursing corporation may have a director who is a chiropractor, a shareholder who is an acupuncturist, and employ an accountant, podiatrist, and a marriage and family therapist, none of which would traditionally be seen as providing the professional services of nursing.

Current law authorizes a medical corporation to have the following licensees as officers, directors, and shareholders:

(1) Licensed doctors of podiatric medicine.

(2) Licensed psychologists.

(3) Registered nurses.

(4) Licensed optometrists.

(5) Licensed marriage and family therapists.

(6) Licensed clinical social workers.

(7) Licensed physician assistants.

(8) Licensed chiropractors.

(9) Licensed acupuncturists.

(10) Naturopathic doctors.

(11) Licensed professional clinical counselors.

(12) Licensed physical therapists.

Stakeholders have requested that pharmacists be added to this list, given the recent expansion of the pharmacists' scope of practice by SB 493 (Hernandez, Chapter 469, Statutes of 2013).

Pharmacy corporations were authorized in 1996 in the Pharmacy Practice Act, rather than the Corporations Code. Current law allows a pharmacy corporation's officers, directors, and shareholders to be anyone who is a "licensed person" as defined in Section 13401 of the Corporations Code:

> "Licensed person" means any natural person who is duly licensed under the provisions of the Business and Professions Code, the Chiropractic Act, or the Osteopathic Act to render the same professional services as are or will be rendered by the professional corporation or foreign professional corporation of which he or she is, or intends to become, an officer, director, shareholder, or employee.

Since the "same professional services" rendered by the corporation is an expansive concept, it can be argued that a physician can be an officer, director, or shareholder of a pharmacy corporation. It follows, then, that it would be equitable for a pharmacist to be an officer, director, or shareholder of a medical corporation.

Staff Recommendation: ***Pharmacists should be added to the list for medical corporations. In addition, the Board should 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.***

ENFORCEMENT ISSUES

ISSUE #8: (ENFORCEMENT PRIORITIZATION.) The Board has taken on a substantially expanded role in response to heightened attention to certain issues, and this attention is impacting its workload. There have been concerns that pharmacy inspectors may be looking for violations or responding to heightened attention on certain issues that are impacting pharmacy inspections. How does the Board prioritize enforcement efforts and outcomes?

Background: The Board's enforcement roles continue to evolve and grow. While the Board is a regulatory body with the ability to take administrative action against licensees, it participates in joint investigations with the Department of Health Care Services, Department of Public Health, FDA, FBI, Drug Enforcement Administration and other local, state and federal law enforcement agencies.

The Board reports that as part of all complaint investigation assignments, a case priority is established by a supervising inspector. The Board reports that it uses a case prioritization system tailored to meet the diversity of individual licensees and practice settings that the Board regulates, specifically:

- Priority 1 and 2 investigations are the most serious and pose the highest risk to the health and safety of the public. Examples of priority 1 and 2 investigations include reports of an impaired licensee on duty, prescription drug theft by a licensee, a pharmacy operating without a pharmacist on duty, large controlled substances losses, sterile compounding violations and unauthorized furnishing of prescription drugs and/or controlled drugs. Priority 1 and 2 complaints are those complaints that generally will be referred to the AG for formal disciplinary action. Accusations are filed in these serious cases and the Board states that it vigorously pursues the appropriate disciplinary penalty, either through the administrative hearing process or through a stipulated settlement.

- Priority 3 and 4 complaints are less serious and pose a lower risk to the health and safety of the general public but are still important. Examples of priority 3 and 4 investigations include reports of failure to provide patient consultation, prescription errors that do not result in patient harm, working on an expired license and general noncompliance issues. Priority 3 and 4 complaints typically result in the issuance of a citation, citation and fine or letter of admonishment. Priority 3 and 4 complaints, while lesser in priority, are nevertheless very important to the consumer who files the complaint.

The Board highlights the following violations investigated by the Board:

- A pharmacy has numerous medication containers that are overfilled with medication, some of which contain pills other than those of the manufacturer indicated on the label. In this case the pharmacy had obtained medications from unauthorized sources. The Board secured an interim suspension order (ISO) against the licensees involved and ultimately the licenses were revoked.

- A pharmacist unlawfully accessed the confidential health information of coworkers hundreds of times. The Board secured an ISO against this pharmacist and ultimately secured a disciplinary license surrender.

- A pharmacy was dispensing pain medication to large numbers of patients, and neighbors of the pharmacy reported observing drug deals taking place in the parking lot. The pharmacy and pharmacist licenses were both revoked.

- A pharmacy located out of state shipped contaminated eye medication to physicians in California and patients were seriously injured. The Board issued a cease and desist order to prevent the shipping of additional medication into the state and ultimately secured a disciplinary surrender of the license.

In August 2013, the Board of Pharmacy made a 2012 license revocation case a “precedential decision.” In this case, the Board revoked the licenses of both a Huntington Beach pharmacy and its pharmacist because the pharmacist failed to comply with corresponding responsibility requirements in the distribution of opioid drugs. The Decision and Order concluded that a pharmacist must inquire whenever a pharmacist believes that a prescription may not have been written for a legitimate medical purpose and that the pharmacist must not fill the prescription when the results of a reasonable inquiry do not overcome concern about a prescription being written for a legitimate medical purpose. The

facts in this case constituted clear violation of law and significant patient harm; however, it would be helpful for the Committees to understand how this precedential decision is being applied and how this case is shaping Board enforcement work.

The Board also has the final authority over the disposition of its cases and is able to take action that may differ from that recommended by an Administrative Law Judge (ALJ). It would be helpful for the Committees to understand how many times the Board has voted to take a different action than that recommended by an ALJ or when the Board continued to take action against a licensee when an ALJ decided in favor of the licensee.

Staff Recommendation: ***The Board should advise the Committees on its case and complaint priorities and how inspectors, licensees and the public are made aware of these. The Board should report to the Committees on other cases that may be adopted as a precedential decision and what this means for enforcement efforts. How does the Board maintain consistency in investigations and enforcement outcomes?***

ISSUE #9: (CASE TIMELINES.) The Board is experiencing delays in enforcement. What efforts is the Board taking to ensure the timely processing of complaints and investigations? How are licensees and the public made aware of these timeframes?

Background: The Board is responsible for regulating the practice of pharmacy and also works to ensure the safety of drug products dispensed to patients in California. The Board regulates those who handle, store and ship drug products from the manufacturer, through the supply chain, to the pharmacy and ultimately to the patient. The Board's performance objectives for its investigation activities include completing all desk investigations within 90 days, completing all field investigations within 120 days and closing all investigations within 180 days. At the end of FY 2014/15, the Board completed 43 percent of desk investigations within 90 days, completed 11 percent of field investigations within 120 days and closed 55 percent of investigations within 180 days.

In the three years prior to the last sunset review, the Board received 7,340 complaints. In the three years prior to this review, the Board received 10,399 complaints, a 42 percent increase. To respond to the growing workload, the Board has restructured its organization to include additional enforcement management to assist in coordinating investigation and enforcement activities, aiming to reduce case closure time and bring about more consistent work product and case resolutions. Between 2011/12 and 2014/15, the Board referred 20 percent more cases for investigation. The Board notes that reviewing allegations for the complaints the Board received does not show any significant increases or decreases, with the exception of unprofessional conduct that continues to increase as an allegation.

The Board cites a few reasons for enforcement delays. The Board is working to train new staff, given its 23 percent growth in the past two years in enforcement staff, primarily in the number of field staff. Coordination and consistency among the Board's inspectors and supervisors is an ongoing issue for the Board but the Board reports that it expects case closure times to improve as field staff become more experienced. The Board notes that it sometimes still does not receive data from licensees within the required timeframe, in part because in large corporate structures where a corporate office first has to review information before it is sent to the Board, but attempts to work with licensees to obtain data necessary for investigations. The Board also cites the complexity of the cases necessary for investigation has increased and notes that errant licensees and individuals seem to be more aggressively violating Pharmacy Law.

Staff Recommendation: ***The Board should update the Committees on the steps it is taking to increase efficiencies in enforcement.***

ISSUE #10: (TIMELY RECEIPT OF INFORMATION.) Healing arts boards are required to take certain steps when they become aware that licensees have been convicted of a crime or entered into a settlement in a civil case. However, delays in receiving documents from other entities can delay investigations. Should other state agencies and courts be required to provide timely information to healing arts boards like the Board?

Background: While the Board is receiving mandatory reports about its licensees (under BPC Section 800) more regularly as outlined above, the Board continues to have challenges obtaining documentation from some law enforcement agencies and state and federal courts that are key to the Board investigating these cases. Historically, documentation like certified court and arrest records, confirmation of criminal probation status, and any outstanding arrest warrants were readily provided to the Board upon request. Now, according to the Board, many arresting agencies and courts now require a fee to release records which requires a state-issued requisition. In addition, the Board is concerned that some agencies take weeks and even months to respond to the Board's requests, regardless of whether they charge a fee. According to the Board, the fees and delays in receiving records hamper the Board's ability to complete investigations in a more timely manner. While the Board uses online court information when available, the information may not provide the necessary details or sufficient evidence.

This issue is not unique to the Board and is a problem faced by other healing arts programs under the DCA.

Staff Recommendation: ***To ensure timely receipt of important information to assist the Board in making determinations about violations of law by licensees, the Committees may wish to require state agencies, upon a written request from a healing arts board, to provide records relevant to a current investigation in a timely manner, ensuring that a board maintains the confidentiality of personal identifying information. The Committees may also wish to clarify that records can be produced prior to receiving payment from a healing arts board so that the procedures involved in receiving approval for, and subsequently submitting payment for, important documents are not the source of delay for a board to obtain information.***

ISSUE #11: (CEASE AND DESIST FOR UNLICENSED ACTIVITY.) The Board continues to work to prevent unlicensed pharmacy practice. Should the Board be granted additional authority to support these efforts?

Background: As outlined above, the Board continues to focus on unlicensed activity and take swift action to prevent harm to California patients. One particular are of unlicensed activity that the Board has identified is the provision of services to Californians from a business or individual located out of state, that may be licensed to do business in that state, but is not licensed under the Board as a nonresident pharmacy or wholesaler. Sometimes the Board may come across pharmacy services being performed outside of a pharmacy but not licensed by the Board. Periodically, the Board identifies brokers who make prescription drug transactions without licensure; for example, a wholesaler broker

offers to sell to a pharmacy prescription drugs, however the broker is not licensed in California as required.

The Board does not currently have the authority to issue a cease and desist order to businesses involved in unlicensed activity. Simply citing and fining an unlicensed business is often an insufficient consequence to stop unlicensed activity because the Board reports that frequently the business will continue to do the very action which violates the law.

Staff Recommendation: ***The Committees may wish to amend the Pharmacy Law to allow the Board to issue a cease and desist order for unlicensed activity.***

ISSUE #12: (UNIFORM STANDARDS FOR SUBSTANCE ABUSE AND THE BOARD'S PHARMACIST RECOVERY PROGRAM.) The Board delayed implementing uniform standards for substance abusing licensees. What is the status of implementation of SB 1441? How does this impact the Board's diversion program?

Background: During the prior sunset review of the Board, the Committee was concerned about the effectiveness of the Board's Pharmacist Recovery Program (PRP) and what steps the Board was taking to adopt uniform standards for substance abusing licenses set forth in legislation.

In 1985, the Board sponsored legislation that required the Board to develop PRP. This program identifies and rehabilitates chemically dependent or mentally impaired pharmacists or interns. The general process requires evaluating the nature and severity of the chemical dependency and/ or mental illness, developing a treatment plan and contract, monitoring participation, and providing encouragement and support for the successful completion of the program, typically in three to five years. The Board sees the PRP as an important enforcement tool and believes it is critical, especially given the nature of pharmacies as a "candy story to a substance abuser who can readily divert drugs sometimes for considerable periods without detection." The Board requires pharmacies to report any admission of chemical, mental or physical impairment affecting an individual's ability to practice safely, any admission or evidence demonstrating such conditions and any termination of a licensee based on theft, diversion or self-use, allowing the Board to be made aware about drug diversion as well as substance abuse involving Board licensees.

The PRP serves as a diversion program to which the Board may refer pharmacists and interns either in lieu of discipline or in addition to disciplinary action. The PRP is also a confidential source of treatment for pharmacists and interns who may enter the program on a voluntary basis and without the knowledge of the Board. Regardless of the type of referral into the program, all participants are afforded the same treatment opportunities in the PRP. The Board states that the PRP ensures that licensees afflicted with mental illness or chemical dependency receive the treatment and the rehabilitation and monitoring they need to return to normal and productive work. Board policy is to speed the entry into the PRP rather than wait until the completion of an investigation by informally referring pharmacists during the course of an investigation. However, the pharmacist or intern must voluntarily contact the program and undergo an intake evaluation and assessment. This early intervention assists the licensee in beginning his or her recovery, and results in the pharmacist or intern receiving treatment and being monitored while the case is being investigated.

Specially trained board inspectors also make periodic visits to PRP participants' worksites and

meet to discuss pharmacy practice issues as well as sobriety. The Board uses this information to validate information provided by the PRP administrator as well as to evaluate the contractor's performance. Participants who are terminated from the program for failure to derive benefit or noncompliance are immediately referred to the Board's Enforcement Unit for investigation and referral to the AG for expedited formal discipline due to the imminent danger to the public of such individuals continuing to practice.

SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) created the Substance Abuse Coordination Committee within the DCA to formulate uniform standards for all healing arts boards to use in dealing with substance abusing licensees. DCA published the "Uniform Standards Regarding Substance-Abusing Healing Arts Licensees" (Uniform Standards) for adoption by all healing arts boards in April 2011.

An October 2011 Legislative Counsel opinion stated that all healing arts boards are required to fully implement the Uniform Standards, whether or not a board has a formal diversion program. The Board disagreed with this analysis and challenged the validity and applicability of the Standards in a 2013 opinion request from the AG. In April 2015, the AG determined that the Uniform Standards were valid, and though the Board is not required to adopt them as regulations in order to be effective, they "must use the uniform standards as written in all cases in which they are found to apply, but the boards retain discretion in applying the uniform standards to particular circumstances and in deciding individual cases." Thus, the Board must use the Uniform Standards generally, but may deviate when necessary.

The Board states that they have been working in a "thoughtful and deliberate manner" to implement the Uniform Standards since they were finalized. Beginning in 2011, the Board heard presentations on the Uniform Standards and initiated a rulemaking to incorporate them into the Disciplinary Guidelines. In FY 2011/12 the Board began publishing the statistics required pursuant to Standard 16 and later worked with DCA to secure the necessary contract changes to align the Board's PRP with the requirements outlined in the Uniform Standards.

Following receipt of the dispositive 2015 AG opinion, the Board reestablished its SB 1441 Uniform Standards Implementation Committee to resume efforts to update the Board's Disciplinary Guidelines. On September 4, 2015, the notice of proposed action along with the proposed text was published by the Office of Administrative Law for the required 45-day comment period. The proposed regulations were modified following the comment period on October 22, and the new comment period extended to January 6, 2016.

Staff Recommendation: ***The Board should update the Committees on the status of the regulations to incorporate the Uniform Standards into the Disciplinary Guidelines. The Board should provide information for the next sunset review indicating how often it deviates from the Uniform Standards. The Board should 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.***

PHARMACY RELATED STATUTORY IMPLEMENTATION EFFORTS

ISSUE #13: (PRESCRIPTION LABEL STANDARD). The source of a lengthy rulemaking process and subsequent legislative efforts following the initial enacting legislation, California's

standardized prescription label appears to still be a topic of discussion and regulatory updates. What is the status of the standardized label? Does the Board anticipate additional changes to the label?

Background: California was the first state to require redesigned prescription container labels to emphasize information most important to consumers – offering an element of safety and consistency since prescription labels are the key source patients' reference for information when taking medications in their homes. Part of this requirement also ensures that oral interpreter services are available to limited English speaking patients in pharmacies, to ensure such patients have access to information about how to take their medications.

SB 472, The California Patient Medication Safety Act, (Corbett, Chapter 470, Statutes 2007) sought to deal with the lack of uniformity in prescription drug labels throughout the state and the resulting confusion and medication errors that may arise. Much of the conversation during the SB 472 debate focused on the fact that individual pharmacies design and format their own labels, resulting in a lack of standards across all pharmacies, which adversely affects medication users who are elderly, suffer from poor vision, have difficulty reading and understanding instructions on labels or have limited English proficiency.

The Board completed its work on the first iteration of the patient-centered prescription container labels in June 2010, and the regulation took effect in January 2011. However, there were several contentious issues that the Board agreed to revisit. In January 2015, the Board changed the typeface requirement from 10- to 12-point font for all elements in the patient- centered portion of the label, and the Board has also proposed the following changes, presently pending in rulemaking:

- Removing the manufacturer's name from the patient-centered area of the label to area outside this designated space; and

- Requiring a label for generic drugs that indicate what the generic is replacing.

As part of the initial regulation, the Board required that all pharmacies be able to provide oral interpretation services in 12 languages. In 2015, the Board sponsored legislation to promote the use of translated standardized directions for use that had been vetted in five non-English speaking communities that were made available on the Board's website (Ting, AB 1073, Chapter 784).

These efforts have been a success; since 2011, the patient-centered requirements developed by the Board have been established as standards for prescription container labels by the US Pharmacopeia Board of Pharmacy, the Institute for Safe Medication Practices, and the National Association of Boards of Pharmacy.

Staff Recommendation: ***The Board should update the Committee when the regulations are finalized. Does the Board track decreases in medication errors stemming from the label standard?***

ISSUE #14: (IMPLEMENTATION OF RECENTLY ENACTED LEGISLATION.) The Board is tasked with implementing a number of pieces of recently enacted legislation, some significantly impacting the Board's licensing population and Board's work. SB 493, for example, tasked the Board with creating several protocols authorizing pharmacists to provide certain services and also created a new category of Advanced Practice Pharmacists with additional

authorities. While the Board is focused on implementing these laws, some efforts may take longer than others and regulation packages are delayed.

Background: Since the Board's prior review, there have been a number of pieces of legislation (in addition to those discussed previously) impacting the Board and Board licensees:

- *SB 1329* (Simitian, Chapter 709, Statutes of 2012) – made a number of changes to the way a surplus prescription drug collection and distribution program could be authorized and the entities eligible to donate medications under such a program. The bill authorized a county public health officer delegated by a county board of supervisors to implement a program, in addition current law which required a program to be implemented via a county ordinance. The bill also added several categories of licensed health care facilities that may donate medications and allowed both primary care clinic pharmacies and primary care clinics that have Board licensees, to administer and dispense medication, provided these Board licensees are in good standing with the Board.

- *SB 493* (Hernandez, Chapter 469, Statutes of 2013) – authorized pharmacists to perform additional functions according to specified requirements, including: administering physician prescribed injectable medications; furnishing immunizations for people ages three and up, if the pharmacist has completed training and follows specified procedures; furnishing self-administered hormonal contraceptives based on a state protocol developed jointly by the Board and Medical Board of California (MBC), pursuant to guidelines of the Centers for Disease Control (CDC); furnishing nicotine replacement products in accordance with a state treatment protocol developed jointly by the Board and MBC; and furnishing travel medications recommended by the CDC for individuals traveling outside of the United States. SB 493 also established "advanced practice pharmacist" (APP) recognition, allowing such pharmacists to write or issue a prescription in certain settings; perform patient assessments; order and interpret drug therapy-related tests; refer patients to other providers; initiate, adjust and discontinue drug therapy in specific circumstances, providing notification to the diagnosing prescriber; and participate in the evaluation and management of diseases and health conditions in collaboration with other providers. The Board established a subcommittee focusing on implementing SB 493 and is in the process of receiving final approval from OAL for regulations related to APP licensure and regulations and establishing the state protocols for: pharmacists dispensing self-administered hormonal contraceptives; pharmacists dispensing nicotine replacement products; pharmacists who administer and initiate vaccinations and; pharmacists who dispense travel medications.

- *SB 809* (De Saulnier, Chapter 400, Statutes of 2013) – established a funding mechanism to update and maintain CURES while also requiring all prescribing health care practitioners to apply to access CURES information.

- *SB 600* (Lieu, Chapter 492, Statutes of 2014) – repealed California's electronic pedigree (e-pedigree) law to conform California to the federal DQSA. The Board was in the process of promulgating regulations to establish requirements for e-pedigree and specifications for the unique serialized number of each saleable unit.

- *AB 467* (Stone, Chapter 10, Statutes of 2014) – established a new Board licensure category for a surplus medication collection and distribution intermediary for the purpose of facilitating the donation of medications to, or transfer of medications between, participating entities under a

county's unused medication repository and distribution program. The Board now licenses one intermediary.

- *AB 1535* (Bloom, Chapter 326, Statutes of 2014) – authorizes pharmacists to furnish naloxone hydrochloride, an opioid antidote that can reverse a drug overdose, in accordance with standardized procedures or protocols developed and approved by the Board and MBC, in consultation with the California Society of Addiction Medicine, the California Pharmacists Association and other appropriate entities. The Board is in the process of establishing the permanent state protocol to allow pharmacists to furnish naloxone hydrochloride without a prescription from a physician, replacing the protocol the Board had previously adopted under emergency rulemaking provisions.

- *AB 1073* (Ting, Chapter 784, Statutes of 2015) – required a dispenser, upon the request of a patient or patient's representative, to provide translated directions for use and authorizes a dispenser to use translations made available by the Board. The bill also required a dispenser to be responsible for the accuracy of the English-language directions for use provided to a patient.

The Board also relies on the rulemaking process to further its priorities and work, including regulations that are currently pending related to compounding drug products. The Board has faced challenges in implementing legislation, as discussed during the prior review, such as those required for the development of a standardized label, and the Legislature has weighed in at various times to clarify Legislative intent as the Board is negotiating rules. It would be helpful for the Committees to understand why some regulation packages, like the rules necessary to implement SB 493, have been significantly delayed and what barriers the Board faces to implementing laws.

Staff Recommendation: ***The Board should provide an update on the status of the regulations for SB 493. Why has it taken so long?***

TECHNICAL CHANGES

ISSUE #15: (TECHNICAL CHANGES MAY IMPROVE EFFECTIVENESS OF THE PHARMACY LAW AND BOARD OPERATIONS.) There are amendments to the Act that are technical in nature but may improve Board operations and the enforcement of the Pharmacy Law.

Background: There are instances in the Pharmacy Law where technical clarifications may improve the Board's operations and application of the statutes governing the Board's work.

Staff Recommendation: ***The Committees may wish to amend the Act to include technical clarifications.***

CONTINUED REGULATION OF PHARMACIES AND PHARMACISTS BY THE CALIFORNIA STATE BOARD OF PHARMACY

ISSUE #16: (CONTINUED REGULATION BY BOARD OF PHARMACY.) Should the licensing and regulation of pharmacies, pharmacists and key players in the drug supply chain be continued and be regulated by the current Board membership?

Background: The Board of Pharmacy has shown over the years a strong commitment to improve its overall efficiency and effectiveness and has worked cooperatively with the Legislature and this Committee to bring about necessary changes. The Board should be continued with a four-year extension of its sunset date so that the Committee may review once again if the issues and recommendations in this Background Paper and others of the Committee have been addressed.

Staff Recommendation: ***Recommend that the pharmacist profession, pharmacies and other licensees necessary in the delivery of medication to patients continue to be regulated by the current Board members in order to protect the interests of the public and be reviewed once again in four years.***