

BACKGROUND PAPER FOR THE BOARD OF PHARMACY

**(Oversight Hearing, March 19, 2012, Senate Committee on
Business, Professions and Economic Development)**

IDENTIFIED ISSUES, BACKGROUND AND RECOMMENDATIONS REGARDING THE BOARD OF PHARMACY

BRIEF OVERVIEW 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 approximately 130,000 licensees in 17 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's vision, "Healthy Californians through quality pharmacists 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 2006-2010 Strategic Plan (which was updated in 2010), is as follows:

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

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

The Board is comprised of 13 members, seven pharmacists and six public members. All seven professional members and four 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 must 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.

Name and Short Bio	Appointment Date	Term Expiration Date	Appointing Authority	Professional or Public
<p>Stanley C. Weisser, R.Ph., President Mr. Weisser graduated from the University of Connecticut School of Pharmacy in 1963 and became a licensed pharmacist in California that same year. He is an associate professor of Pharmacotherapy and Outcomes Science at the Loma Linda University School of Pharmacy, and a member of the California Pharmacists Association. He is very active in many San Bernardino County philanthropic activities as well as civic, cultural, and educational programs including the Redlands Community Foundation, FEMA sponsored Emergency Food and Shelter Program, Redlands Unified School District Oversight Committee, San Bernardino County Schools Reorganization Committee, Redlands Theatre Festival, and Grove Charter School. 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.</p>	12/21/2011	06/01/2015	Governor	Professional
<p>Randy Kajioka, PharmD, Vice President Dr. Kajioka's employment at Kaiser Permanente began in 1984, where he served as a staff pharmacist, Assistant Chief Pharmacist and Outpatient Pharmacy Manager. Since 2003, he has held the position of Pharmacy Project Manager at Kaiser Permanente. He also functions as Director of Pharmacy Operations for RNRx Medical Staffing and works as a relief pharmacist for Bel Air. Dr. Kajioka also has experience in hospital and nuclear pharmacy. Dr. Kajioka also serves as President of the Sacramento Asian Peace Officers Association and on the Community Advisory Council for the Asian Pacific Community Counseling Center.</p>	12/21/2011	06/01/2015	Governor	Professional

<p>Gregory Lippe, Treasurer Mr. Lippe holds a B.S. in Business Administration from Woodbury University in Los Angeles and became a Certified Public Accountant in 1970. Since that time, his accounting experience has included that of managing partner of his own CPA firm and chief financial officer and manager of other companies. Mr. Lippe's employment also included auditing and reviewing the financial statements of corporations with revenues ranging from \$5-200 million dollars. An ever active participant in civic and business affairs, Mr. Lippe has served on the boards of multiple community organizations and has authored many newspaper articles.</p>	02/26/2009	06/01/2012	Governor	Public
<p>Anil "Neil" Hiro Badlani , R.Ph. Since 2006, Mr. Badlani has worked as a research and development pharmacist for Healthspecialty Skin Care, and has been a community pharmacist specializing in compounding for the last 15 years. Mr. Badlani previously was a pharmacy manager at Savon Drugs from 1991 to 1995, owner of a General Nutrition Center from 1991 to 1994 and staff pharmacist for Savon Drugs from 1990 to 1991. He is a member of Prescription Compounding Centers of America, International Academy of Compounding Pharmacists and California Pharmacists Association. Mr. Badlani also possesses an MBA.</p>	12/20/2010	06/01/2012	Governor	Professional
<p>Ryan Brooks Since 2002, Mr. Brooks has served as vice president of government affairs for CBS Outdoor Western Region, a leading global media company in broadcast and cable television, radio and outdoor advertising. During the previous years, he functioned as director of administrative services for the city and county of San Francisco, director of business development for EA Engineering, director of community and public relations for the U.S. Navy/Western Division, director of community relations for the engineering firm, Planning Research Corporation (an environmental engineering firm now known as Tetra Tech), and Pentagon advisor to the deputy undersecretary of defense for environmental securities. Mr. Brooks 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.</p>	10/28/2008	06/01/2012	Governor	Public

<p>Ramón Castellblanch, Ph.D., Dr. Castellblanch, an associate professor at SF State University, worked as a sponsor of SB 472 (Chapter 470, Statutes of 2008) which addresses the development of patient-centered prescription labels and was a member of the precursor SCR 49 Panel on Medication Errors. Among Dr. Castellblanch's academic achievements are a Ph.D. in Health Policy and Management, Johns Hopkins University, and a Master of Public Policy, Harvard University. His writings have been widely published and included in, but not limited to, the Journal of Health Policy, Politics and Law and the Journal of Healthcare Administration Education.</p>	04/22/2009	06/01/2012	Senate Committee on Rules	Public
<p>Rosalyn Hackworth Ms. Hackworth is from San Diego, where she is the secretary-treasurer of UFCW, Local 135. She represents pharmacists employed in major grocery stores and chains in San Diego and other individuals employed in various industries in the area. She also serves as a trustee for multiple benefit and pension trust funds in Southern California and is currently the Labor & Industry Chair for the North San Diego County NAACP; a member of the UFCW Minority Coalition; a member of the UFCW Women's Network and a member of the North County African American Women's Association.</p>	07/15/2009	06/01/2012	Assembly	Public
<p>Deborah Veale, R.Ph. Since 2006, Ms. Vale has been director of managed care for CVS/Pharmacy. Previously, she worked for Albertsons/Sav-On as regional manager of managed care from 1996 to 2006, division pharmacy manager from 1994 to 1996, regional pharmacy trainer from 1993 to 1994, regional pharmacy recruiter from 1989 to 1991 and pharmacy manager from 1983 to 1989. She is a member of the California Pharmacist Association, National Council of Prescription Drug Programs and California Retailers Association.</p>	01/12/2010	06/01/2013	Governor	Professional
<p>Shirley Lee Wheat Ms. Wheat served as a congressional staff member for the Committee on the Budget and held the positions of budget analyst from 1994 to 1999 and director of coalitions in 1999. As a budget analyst, Ms. Wheat worked on federal budget policies and legislation to reduce the size of federal budgeting staff that balanced the U.S. Federal budget in 1995. As a director of coalitions, Ms. Wheat coordinated and implemented grassroots plans for the committee. As an appointee of President George W. Bush to the Department of the Treasury, she worked closely with various corporate executives and political leaders. As a Special Assistant to the U.S. Treasurer, Ms. Wheat played a vital role in efforts to launch and implement the National Financial Education Initiative in 2002 and 2003. Ms. Wheat joined Capital Campaigns, a political and non-profit fundraising company as the operations and finance executive. She currently serves as a consultant in private practice.</p>	12/20/2010	06/01/2014	Governor	Public

<p>Tappan Zee Mr. Zee has served as managing attorney for Zee Law Group and, since 2003, has served as reserve deputy sheriff for the Los Angeles County Sheriff's Department. Zee previously served as an elected representative of the American Bar Association from 1999 to 2000 and a municipal commissioner for South Pasadena from 1989 to 1994. He is a member of the board of directors for the Los Angeles Chinese Chamber of Commerce and the Sheriff's Support Council.</p>	01/13/201	06/01/2013	Governor	Public
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The Board is a special fund agency, with funding coming from licensing (87 percent), collected fines from citations (9 percent) and collected cost recovery (3 percent). Of the fee revenue collected by the Board, 77 percent comes from renewals while 22 percent comes from initial applications. The Board has continuous renewal cycles for all of its license categories except for one, intern licenses, which are not renewable. The renewal cycle is annual for facilities and designated representatives. Licenses issued to pharmacists and pharmacy technicians are renewed biennially. The Board currently licenses close to 130,000 licensees.

In 2008, the Board raised all of its fees to the statutory maximums via the regulation process. Following that, the Board commissioned an independent fee audit to secure recommendations on a new fee schedule that would ensure the financial viability of the board for the next five years. The audit found that the Board's expenditures were exceeding its revenues and that its fee structure was insufficient to maintain the required 12 month reserve. In 2009, the Board sponsored legislation (AB 1071, Emmerson, Chapter 270, Statutes of 2009) to reset the statutory minimum and maximum fee levels according the recommendations in the audit. According to the Board, this was the first time such legislation was needed since 1987.

Current Fees By License Type			
Fee	Application	Renewal	Delinquent
Clinic Permit	400	250	125
Designated Representative	255	150	75
Designated Representative	255	150	75
Certificate - Veterinary Food-			
Hypodermic Needle and Syringe	125	125	62.50
Intern Pharmacist	90	N/A	N/A
Non-Resident Pharmacy	400	250	125
Non-Resident Wholesaler	600	600	150
Pharmacy	400	250	125
Pharmacy Technician	80	100*	50
Sterile Compounding	600	600	150
Veterinary Food-Animal Drug	405	250	125
Wholesale Drug	600	600	150
Pharmacist	150	150*	75

The total revenues anticipated by the Board for FY 2011/12, is \$11,884,000 and for FY 2012/13, \$11,829,000. The total expenditures anticipated for the Board for FY 2011/12, is \$14,197,000, and for FY 2012/2013, \$8,618,000. The Board anticipates it would have approximately 9.4 months in reserve for FY 2011/12, and 6.9 months in reserve for FY 2012/13. (See Fund Condition on the next page.)

Fund Condition (Table 4)						
(Dollars in Thousands)	FY	FY	FY	FY	FY	FY
Beginning Balance	\$11,083	\$10,932	\$10,900	\$12,411	\$13,796	\$11,412
Total Revenue	\$8,721	\$10,100	\$10,783	\$12,133	\$11,884	\$11,829
General Fund Loan	N/A	\$1,000	N/A	N/A	N/A	N/A
Budget Authority	\$9,383	\$9,726	\$10,648	\$13,470	\$14,197	N/A
Expenditures	\$8,920	\$9,031	\$9,272	\$10,748	\$14,197	\$14,623
Fund Balance	\$10,884	\$11,001	\$12,411	\$13,796	\$11,412	\$8,618
Months in Reserve	14.5	14.2	13.9	11.6	9.4	6.9

The Board spends approximately 59 percent of its budget on its enforcement program, 18 percent on its licensing program, 15 percent on administration, four percent on its diversion program and four percent administering examinations.

In 2010, the Department of Consumer Affairs (DCA) launched the Consumer Protection Enforcement Initiative (CPEI) to overhaul the enforcement process of healing arts boards. According to the DCA, the CPEI is a systematic approach designed to address three specific areas: Legislative Changes, Staffing and Information Technology Resources, and Administrative Improvements. Once fully implemented, the DCA expects the healing arts boards to reduce the average enforcement completion timeline to between 12 -18 months. The DCA requested an increase of 106.8 authorized positions and \$12,690,000 (special funds) in FY 2010-11 and 138.5 positions and \$14,103,000 in FY 2011-12 and ongoing to specified healing arts boards for purposes of funding the CPEI. As part of CPEI, the Board was authorized to hire inspector staff that would double what it currently has. However, the Board has been impacted by a state hiring freeze and has only been able to fill a portion of these positions.

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. Each committee typically meets quarterly prior to each Board meeting and provides a report and minutes of the committee meeting during each Board meeting. However, during the past several years, to curtail travel expenses and in response to staffing challenges created by furloughs, the Board has reduced the number of committee meetings each year.

- **Licensing Committee** – works to ensure the professional qualifications of licensees entering the practice of pharmacy and establishing the minimum standards for board-licensed facilities while also ensuring ongoing practice standards.
- **Enforcement Committee:** Exercises oversight of all pharmacy activities and protects the public by preventing violations and effectively enforcing federal and state pharmacy laws when violations occur.

- **Communication and Public Education Committee:** Oversees publication of information to consumers, including encouraging the public to discuss their medications with their pharmacists, emphasizing the importance of patients complying with their prescription treatment regimens, and helping consumers become better informed on subjects of importance to their drug therapy and health. The committee also develops educational materials for licensees describing new laws, policies and emerging issues.
- **Legislation and Regulation Committee:** Advances Board advocacy of legislation and promulgates regulations that promote the Board's vision and mission.
- **Organizational Development Committee:** Works to ensure that the Board's mission and goals are met through organizational support and review, conducts strategic planning, budget management, and staff development activities. The membership of this committee, which does not typically meet publicly, is comprised of the president and vice president of the board.

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:

- Work Group on E-Pedigree
- Subcommittee to Evaluate Drug Distribution in Hospitals
- Senate Bill 472 Medication Label Subcommittee
- Subcommittee on Medicare Drug Benefit Plan
- Compounding Regulation Subcommittee

The Competency Committee develops and grades the Board's pharmacist licensure examination, the California Practice Standards and Jurisprudence Examination for Pharmacists. According to the Board, membership on this committee is highly selective, professionally challenging, and time-consuming. Members meet seven times annually in two-day meetings. The Competency Committee is a stand-alone committee within the auspices of the Board's Licensing Committee; one Board member attends committee meetings and provides updates on the status of the Board's pharmacist examination during Board meetings. This Board member also serves as a liaison to the committee.

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 Council on Licensure, Enforcement and Regulation. The Board does not have representation on the national exam committee, but former Board Competency Committee members participate in the scoring and analysis of the North American Pharmacist Licensure Examination (NAPLEX) which measures a candidate's knowledge of the practice of pharmacy and assesses whether candidates can: identify practice standards for safe and effective pharmacotherapy and optimize therapeutic outcomes in patients; identify and determine safe and accurate methods to prepare and dispense medications and; provide and apply health care information to promote optimal health care

Licensing

The Board's 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 close to 130,000 licensees, a 13 percent increase in the past 3 years. Over the past 3 years, the Board has received 61,044 applications, approved 47,463 applications and renewed 158,910 licenses. The following are Board licensing programs:

- **Hospital Pharmacies** ensure that patients in hospitals have a reliable and quality drug supply immediately accessible in known locations and meeting specified components. Drug distribution in hospitals is generally directed through pharmacies by pharmacists and can include high technology automated storage units as well as very manual processes. There are three types of hospital pharmacies (inpatient, specialized storage and distribution without a pharmacist, and outpatient).
- **Licensed Correctional Facilities** are pharmacies located within jails or prisons. Incarcerated individuals are often on medication that must be administered in single doses and carefully handled because drugs are contraband among inmates in these facilities.
- **Community or Retail Pharmacies** are the largest group of board site licensees, with over 6,200 of these facilities throughout the state. These are the pharmacies that most patients are familiar with and use.
- **Closed Door Pharmacies** are very specialized community pharmacies that serve specified patient populations (e.g., in skilled nursing homes, licensed home health care). They are not open to the public for retail sales.
- **Sterile Injectable Compounding Pharmacies** are very specialized pharmacies that compound sterile injectable medications. Because of the risk that such a route of administration poses, annual inspections by the Board's pharmacist inspectors are required before license renewal or issuance, and there are detailed requirements that these pharmacies must follow. (As an alternative to specific board licensure, these pharmacies may be accredited by specified agencies, but they must still follow California law concerning compounding.)
- **Surgical Clinics and Community (or free) Clinics** allow a single drug supply purchased at wholesale that all practitioners can use for patient care.
- **Hypodermic Needles and Syringe Licenses** sell needles and syringes for use on animals without a prescription. These entities are not pharmacies.
- **Wholesalers** exist in three forms; drug wholesalers, brokers, and reverse distributors. *Wholesalers* ship and store prescription drugs and devices for distribution to pharmacies, other

wholesalers and health care practitioners. *Brokers* buy and sell drugs but do not take possession of them. *Reverse distributors* pick up drugs that cannot be sold (e.g., outdated drugs) which have never been dispensed by pharmacies for destruction.

- **Veterinary Food Animal Drug Retailers** are specialized wholesalers that label and distribute drugs prescribed by a veterinarian for use on animals that produce or will become food to prevent drug residue in the food supply.
- **Nonresident Pharmacies** are pharmacies located outside California that ship medication to patients typically by mail or other common carrier (“mail order pharmacies”).
- **Nonresident Wholesalers** are wholesalers that ship drugs into California to other licensed wholesalers, pharmacies and licensed health care practitioners but not to patients.
- **Nonresident Sterile Injectable Compounding Pharmacies** are pharmacies located outside of California that compound medication for injection and require a separate license to do so.
- **Pharmacists** are educated to be drug therapy experts, are responsible for dispensing and compounding operations in pharmacies and may work providing pharmacist care outside pharmacies (e.g., clinical pharmacists in hospital settings or via chart review from a computer).
- **Pharmacist Interns** are students in pharmacy school gaining the required pharmacy experience needed for licensure as a pharmacist, or are foreign- educated pharmacy school graduates or pharmacists licensed in another state earning the experience hours they need to take the California licensure examination. Interns must work under the direct supervision of a pharmacist.
- **Pharmacy Technicians** are specially-trained individuals who assist pharmacists in nondiscretionary duties in a pharmacy. They work under the direct supervision of a pharmacist, who is responsible for all their work.
- **Designated Representatives** are specially-trained individuals who are not pharmacists and who work in drug wholesaler facilities, overseeing distribution and storage, and performing specialized warehousing functions needed to store and distribute prescription drugs.
- **Designated Representatives for Veterinary Food Animal Drug Retailers** are specially trained designated representatives who possess very detailed training regarding veterinary drugs and dispensing components, and who can label medication prescribed by a veterinarian for use on an animal that produces or will become food.

The Board outlines performance expectations for its licensing program in its strategic plan. Specifically, the Board’s goals include: reviewing all applications within seven working days; processing all deficiency documents within five working days and; making a licensing decision within three working days after all deficiencies are corrected. According to the Board, processing times for its applications vary greatly due to the complexity of the application, the availability of knowledgeable staff to process, the number of applications received and the speed with which deficiencies are completed. While the Board used to process most applications in less than 30 days, the Board is not currently meeting its application processing time goals, in large part due to the state hiring freeze and

an inability to fill vacant positions which creates a backlog or work and delays in day-to-day activities. For example, in November 2010, the Board had over 2000 pharmacy technician applications awaiting processing, the oldest of which had been received 10 weeks prior. The Board attributes this to the vacancy of two processing positions, one responsible for cashiering application fees and the other responsible for processing applications.

It is taking the Board over 75 days to process applications from the date of receipt and significantly more time to resolve any deficiencies identified. The Board states that it receives weekly calls from unhappy applicants as well as others expressing concern about delays and lost employment opportunities stemming from long processing times.

Application Type							
FY 2010/11	Clinics	54	8	69	14	75	21
	Drug Rooms	*U/A	0	3	* U/A	45	28
	Designated Representatives -	505	58	403	217	102	57
	Designated Representatives - Veterinary	4	1	2	***	88	54
	Hospitals	42	3	40	6	55	36
	Hypodermic Needle and Syringe	19	5	12	10	115	46
	Pharmacist Interns	1,941	123	1,962	155	30	7
	Licensed Correctional Facilities	2	0	1	1	85	20
	Sterile Compounding Pharmacies	39	11	25	26	81	73
	Nonresident Pharmacies	73	8	63	43	153	70
	Nonresident Wholesalers	116	36	81	82	148	120
	Nonresident Sterile Compounding	24	2	10	** U/A	168	75
	Pharmacies	298	20	266	84	73	37
	Pharmacist Exams	2,448	+872	N/A	901	69	28
	Pharmacist Licenses	1,532	0	1557	0	38	7
	Pharmacy Technicians	11,090	667	8,330	4,366	111	62
	Wholesalers	83	21	60	53	110	59
Veterinary Food-Animal Drug Retailers	1	0	1	0	0	8	

	FY	FY	FY
Initial Licensing Data:			
Initial License/Initial Exam Applications Received	16,306	18,429	18,229
* Initial License/Initial Exam Applications Approved	1,294	1,333	997
Initial License/Initial Exam Applications Closed	287	944	1,852
License Issued	12,251	15,863	12,432
Initial License/Initial Exam Pending Application Data:			
Pending Applications (total at close of FY)	U/A	U/A	5,654
Pending Applications (outside of board control)*	U/A	U/A	3,051
Pending Applications (within the board control)*	U/A	U/A	2,603
Initial License/Initial Exam Cycle Time Data (WEIGHTED AVERAGE)			
Average Days to Application Approval (All -	79	122	72
Average Days to Application Approval (incomplete applications)	270	147	102
Average Days to Application Approval (complete applications)	43	55	52

The Board has worked to implement efforts aimed at streamlining the licensing process and reducing overall processing timeframes. One example is the creation as a consolidated “master file” for businesses with five or more locations to reduce duplicative information required for each application

with common ownership structures. Other examples of attempts to streamline the background review of its applicants include: Conducting audits of the high school education of pharmacy technician applicants; restoring pre-licensure inspections for pharmacies; opening inspections for wholesalers and; pursuing regulations to have the ability to require certain applicants (pharmacy technicians, pharmacists and pharmacist interns) to provide a self-query report from the National Practitioner Data Bank/Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as a condition of licensure which will provide the Board complete background information before making a licensing decision.

Education, Experience, and Examination Requirements	
License Class	Requirements
Pharmacist	<p>Education: Degree from a college of pharmacy or department of a university with 150 or more semester units of study and at least a Bachelor of Science degree in pharmacy, AND</p> <p>Experience: 1,500 hours of practical experience earned under the supervision of a pharmacist, AND</p> <p>Examination Requirements: Pass the North American Pharmacist</p>
Pharmacist Intern (Nonrenewable)	<p>Education: Must be currently enrolled in an accredited school of pharmacy or have satisfied the education requirements specified to become a pharmacist, or if a foreign graduate, must be certified by the national Foreign Pharmacy Graduate Examination Committee</p>
Pharmacy Technician	<p>A graduate of high school or possession of a GED AND</p> <ol style="list-style-type: none"> 1. An AA degree in pharmacy technology 2. Completion of a technician training program 3. Graduation from a school of pharmacy, OR 4. Certification by the Pharmacy Technician Certification
Designated Representative	<p>Education: A graduate of high school or possession of a GED and completion of training in five areas, or eligible to take the California pharmacist licensure examination, AND</p> <p>Experience: One year paid experience in the distribution of</p>
Designated Representative - Food Animal Drug Retailer	<p>Education: A graduate of high school or possession of GED and completion of training in five areas AND</p> <ol style="list-style-type: none"> 1. Specialized training for 240 hours, 2. Registration as a veterinary technician, 3. Eligible to take the California pharmacist's or veterinarian's exams, OR 4. Worked 1,500 hours in a licensed veterinary retailer's

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 (FPGEC) before being issued an intern pharmacist license or becoming eligible to take the pharmacist licensure exam.

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 National Association of Boards of Pharmacy (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.

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.

Of all Board licensees, only pharmacists are subject to a continuing education (CE) requirements as a condition of license renewal. Pharmacists are required to complete 30 units of CE every two years, completion of which is acknowledged via self-certification on the renewal application. The Board has dedicated CE as a way to ensure all pharmacists obtain knowledge in a specific, crosscutting area, for example emergency response or drug abuse. Pending regulations will allow CE credits to be received by licensees who successfully pass the examination administered by the Commission for Certification in Geriatric Pharmacy.

Pharmacists are required to retain their CE completion certificates for four years. To ensure that pharmacists fulfill their CE requirements, the board randomly audits renewal applications. If a pharmacist is selected for audit, he or she is notified in writing and must submit copies of CE

completion certificates to the Board. The Board conducted 744 CE audits in the prior four fiscal years, with 94 pharmacists failing the audit because they could not provide full evidence of completing 30 units of CE.

The Board has publicly discussed how to ensure continued competencies for pharmacists during Licensing Committee meetings and Board meetings. The Board has reviewed documents from the Citizens Advisory Council and comments from DCA on this issue and has volunteered to participate in testing and deployment of an assessment being developed by NABP, the Pharmacist Assessment for Remediation and Evaluation.

Enforcement

The Board's enforcement activities are the core of its consumer protection mandate and are supported by the majority of its staff and resources, with nearly 75 percent of its positions dedicated to enforcement functions. From 2008/09 through 2010/11, the Board:

- Closed investigations on 9,445 licensees.
- Referred 907 licensees and applicants for formal discipline.
- Cited and fined 3,836 licensees.
- Collected \$3,656,704 in citation and fine revenue.
- Revoked or accepted surrender of 341 licenses and.
- Placed 150 licensees on probation.

The Board has adopted innovative programs and partnered with other law enforcement agencies on investigations that may involve criminal elements. The Board has 11 major enforcement programs: Complaint Investigations; Inspection Program; Internet Pharmacy Sales; Drug Diversion and Audits Program; CURES; Probation Monitoring; Administrative Discipline Program; Citation and Fine/Letters of Admonishment Program; Criminal Convictions and Arrests Investigation Program and; HIPDB Reporting Program.

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. A contracted vendor (MAXIMUS) provides many of the treatment and monitoring services, but the Board also monitors participants in the program as well. 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 does not stop investigations of pharmacists and pharmacist interns who enter the program voluntarily. It is not unusual for people to have been in the program and be fully compliant, and yet still disciplined for the underlying acts. Failure to follow the treatment contract results in the Board seeking revocation of the pharmacist's or intern's license regardless of whether a licensee enters the program on probation while under investigation by the Board or voluntarily. The Board is currently in the process of implementing the "Uniform Substance Abuse Standards" adopted by the Substance Abuse Coordination Committee.

According to the Board, its greatest tool in performing the broad range of investigations and inspections required to regulate such a diverse licensing population is its licensed pharmacist inspectors. These investigators work from home offices throughout the state and perform random, unannounced inspections to detect violations, investigate complaints, monitor probationers, 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's enforcement program also has non-pharmacist staff that perform desk investigations and duties that do not require the knowledge of a pharmacist.

The investigation process typically starts with a complaint and a major source of complaints is from the public. After evaluation and assignment, the identified pharmacist investigator conducts an investigation and completes a written report that documents the findings of the investigation and identifies the appropriate violations of Pharmacy Law. All investigation reports are reviewed by a supervisor to ensure the Board's investigation process has been completed appropriately before a recommendation is made on how the case should be closed. Investigations of applicants or licensees triggered by a criminal arrest or conviction notice follow the same general procedures detailed above, but the investigation work is completed by non-pharmacist staff. Until January 2009, the Board lacked dedicated personnel to investigate the majority of the arrest and conviction notifications received from DOJ. To ensure the thorough, complete and expedient review of convictions and arrests of Board applicants and licensees, the Board established a Criminal Conviction Unit in 2009 to investigate arrest and conviction information received regarding Board licensees and applicants. Of the 7340 investigations the Board opened during the last three fiscal years, 39 percent were opened based on a criminal arrest or conviction notice received by DOJ. Of the remaining investigations initiated, consumer complaints accounted for 31 percent. The Board also investigates violations such as medication errors, failure to provide patient consultation, cleanliness of pharmacies and outdated medications that are not quarantined and possibly may be dispensed.

The Board has established performance targets for its enforcement program of: 90 days to complete desk investigations; 120 days to complete field investigations; and, 180 days to close all investigations. At the end of FY 2010/11, the Board was completing only 36 percent of its desk investigations within 90 days; 37 percent of its field investigations within 120 days and; closing 60 percent of all investigations within 180 days. The Board attributes delays in enforcement to a number of factors including the current state hiring freeze and staff vacancies, a reduction in operating expenses and other mandatory budget reductions. The Board's highest vacancy rate is among its inspector staff which directly correlates to longer investigation times.

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 AG for 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 issued by the Board to acknowledge a minor violation that does not warrant issuance of a citation and fine or referral for disciplinary action.

In the last 4 fiscal years, the Board issued 4559 citations and fines and held 1464 informal office conferences for citation and fine cases. As a result of the office conferences, 501 were affirmed, 592 were either dismissed or reduced to a letter of admonishment and the remaining 343 were modified in some way. The Board issued 754 letters of admonishment during the last four fiscal years. During

that time, 60 were contested at an informal office conference. During the last 4 fiscal years, the Board referred 197 citation and fine appeals cases to the AG to proceed with a request for hearing on the matter. Only 23 cases have completed the appeal process. Of the 23 appeals completed, the average original fine was \$3,085; the average fine was reduced to \$1,265 following the appeal, typically stemming from a stipulated settlement and not a result of a hearing.

The Board has established performance targets for its citation and fine and letter of admonishment activities of; 30 days to issue all citations and fines and 30 days to issue all letters of admonishment. At the end of FY 2010/11, the Board was issuing 89 percent of all citations and fines within 30 days and 97 percent of all letters of admonishment within 30 days.

The most egregious violations of Pharmacy Law are referred to the AG to pursue administrative discipline. The range of outcomes for such discipline is a letter of reprimand to revocation of the license. Subject to judicial review, the Board has the final authority over the disposition of its cases. The Board has established performance targets for its administrative case activities of: 30 days to submit petitions to revoke probation once non-compliance with probation terms have been substantiated and 365 days (excluding Board investigation time) to achieve 100 percent of case closures on administrative cases. At the end of FY 2010/11, the Board was submitting 100 percent of all petitions to revoke probation within 30 days and closing 48 percent of its closures within the one year timeframe.

According to the Board, there has been a significant increase in the number of disciplinary cases referred to the AG since the last Sunset Review and over the last three fiscal years. At the time of the last Sunset Review, the Board referred 148 cases to the AG. In comparison, the Board referred 340 cases to the AG in FY 2010/11, an increase of 130 percent. In FY 2008/09, the Board referred 206 cases to the AG, and in FY 2009/10 the Board referred 340 cases, a 65 percent increase. From 2008/09 through 2010/11, the Board referred a total of 907 cases to the AG and has filed 701 accusations and statements of issues, and has taken disciplinary action, ranging from probation to revocation, on 492 licensees.

The largest growth in AG case closures involves criminal conviction violations. In 2007/08 such cases represented 24 percent of the administrative case closures, compared to 2010/11, where 55 percent of the cases closed were as a result of criminal conviction violations. The Board attributes this to the increasing number of subsequent arrest notifications the Board receives from DOJ regarding new arrests and convictions of licensees. The Board also reports changes in the profile of cases at the AG's Office; for example, in 2007/08, 61 percent of the cases closed were related to drug diversion violations and of those cases, 41 percent were pharmacy technician respondents and 47 percent were pharmacist respondents. The 2010/11 statistics show that 19 percent of the cases closed were related to drug diversion violations but of those, 64 percent were pharmacy technician respondents and 22 percent were pharmacist respondents.

(For more detailed information regarding the responsibilities, operation and functions of the Board please refer to the Board's "Sunset Review Report 2011." This report is available on its Website at http://www.pharmacy.ca.gov/publications/sunset_2011.pdf .

PRIOR SUNSET REVIEWS: CHANGES AND IMPROVEMENTS

The Board was last reviewed in 2002-03 by the Joint Legislative Sunset Review Committee (JLSRC). During the previous sunset review, the JLSRC raised 31 issues. The final recommendations from JLSRC contained a set of recommendations to address those issues. Below are actions which the Board and the Legislature took over the past 9 years to address many of the issues and recommendations made, as well as significant changes to the Board's functions. For those which were not addressed and which may still be of concern to this Committee, they are addressed and more fully discussed under "Current Sunset Review Issues."

In November, 2011, the Board submitted its required sunset report to this Committee. In this report, the Board described actions it has taken since its prior review to address the recommendations of JLSRC. According to the Board, the following are some of the more important programmatic and operational changes, enhancements and other important policy decisions or regulatory changes made:

- **Electronic Pedigree**
The Board has assumed a significant national leadership role in the area of preserving prescription drug integrity through its advocacy in sponsoring and securing legislation to require electronic pedigrees for all prescription medication dispensed in California after July 2017. Once in place, the requirements will make it difficult for drugs that have been counterfeited or adulterated to enter the supply chain. Additionally, pharmacies and wholesalers will have substantial difficulty in obtaining drugs from unlicensed sources without detection. E-pedigree allows patients and prescribers to have greater trust that they are receiving quality medication from California pharmacies and wholesalers.
- **Recall System Leadership**
The Board took part in recognizing and identifying the failure of a recall system intended to ensure removal of recalled medications from hospitals. In 2008, during a period within which five major recalls of the drug Heparin occurred and more than 80 deaths were linked to use of the recalled drug, the Board initiated inspections of California hospital pharmacies, where this drug is widely used. While initially expecting to find unlicensed activity and perhaps counterfeit heparin due to the shortage and skyrocketing prices, the Board instead quickly identified recalled Heparin still in patient care areas in hospitals. Recognizing a potential public health emergency, the Board inspected all 533 licensed hospital pharmacies in California and found recalled Heparin still in 94 of them. The Board cited and fined the hospitals and then worked with the California Department of Public Health (DPH), federal Food and Drug Administration (FDA), associations, hospitals and pharmacists to ensure that drug delivery systems in hospitals were improved to prevent recalled drugs from remaining in patient care areas. Based on the Board's work, emphasis was placed on the need for better recall management within health care systems and ensuring dissemination of information about recalls to all licensed facilities immediately via the Internet.
- **Partnership and Joint Investigations**
Through the Board, California was the first state to partner with the federal Drug Enforcement Administration (DEA) to co-host day-long seminars for pharmacists on knowledge they need to stop drug diversion of controlled substances from California pharmacies. This is particularly important and timely given that prescription drug abuse is now responsible for more deaths than automobile accidents, and drug diversion from pharmacies is a growing problem.

The Board also partners with a number of other agencies to secure public protection in matters where there is mutual jurisdiction. The Board is currently working on joint investigations with the California DPH, the California Department of Health Care Services, DOJ, DEA, FBI, FDA, local district attorneys and local police and sheriffs.

- **Unlawful Purchase of Prescription Medicine**

The Board led the way for California to become the first state to aggressively deal with the unlawful purchase of prescription medication via the Internet by using its statutory authority to fine pharmacies \$25,000 per prescription for supplying drugs without a prescriber-patient relationship.

- **Mandatory Ethics Counseling**

California became the first state to mandate that pharmacists complete a structured 22 hour ethics counseling program for violations involving ethical lapses as one provision of their discipline.

- **Consumer Outreach**

The JLSRC asked what the Board does to educate the public of its existence and role. Today the Board's Website has grown as a way to better communicate with the public and the profession on important issues and contains substantially more information than ever before. Over the past three fiscal years, the Board has averaged over 500,000 hits per year, double the number reported in the last Sunset Report. The Board posts a significant amount of information about licensees on its Website, including verification information about licensees, consumer materials like fact sheets and tips covering a wide range of topics to educate the public about health and pharmacy specific information and public meeting schedules and agendas. The Board has also developed videos available online that detail the problem with medication errors and how patients can prevent them, as well as how to safely purchase drugs over the Internet. The Board is also exploring how it might leverage social media like Facebook and Twitter to disseminate information to the public, as well as the possibility of an application that could be downloaded onto smart phones or tablets to allow consumers to access information about a licensee, even at the point of care.

- **Expanded Use of Citation and Fine**

Over the years the Board has expanded its use of the citation and fine program to address compliance issues involving board licensees.

- **Innovative Solutions**

In response to a purchasing restriction several years ago, the Board transitioned to paperless meeting packets for its members as a way to conserve resources. This one change has resulted in almost \$20,000 savings in two years in materials and postage expenses, and saved even more in labor costs. In January 2005, the Board established a service to notify anyone who is interested in receiving e-mail alerts about major updates to the Board's Website, allowing the Board to immediately contact licensees to alert them about drug recalls, emergency response issues and other items and creates a link to licensees for immediate information dissemination at no cost. This service became mandatory in 2010 when all licensed premises were required to join the subscriber alert system. Email alerts also include information related to the

implementation of regulations, publication of Board newsletters, releases about public meetings and questions and answers about new laws and actions from Board meetings.

- **Completion of Major Studies and Publications**

Since the last Sunset Review, the Board has completed comprehensive reviews in several areas that impact the board's operations or pharmaceutical care. The results of these reviews were generally incorporated into public reports. Additionally, the Board now publishes *The Script* newsletter two times a year, much more frequently than it was during the previous Sunset Review. A few examples of studies and reports are:

- *A Job Analysis Study of California Pharmacists* completed in 2005 and 2009/10 to determine necessary updates to the CPJE exam.
- *Emergency Response Policy Statement* developed during 2006-2007 to ensure that patients will receive their needed prescription medication during times where normal pharmacy services may be disrupted. The Board's emergency response policy for pharmacies and wholesalers has been referenced by the Department of Public Health as a model for other professions.
- *Health Notes* – “Alternative Medicines” and “Drug Therapy Considerations in Older Adults” served as a comprehensive means for pharmacists and other health care providers to share important information on topics of importance to their patients.
- *The Script* newsletter has been published sixteen times since January 2002, providing an important method for the Board to communicate with licensees. The articles are updates on pharmacy laws and regulations, answers to questions frequently asked of the Board as well as best practices.
- *E-Prescribing of Controlled Substances – Guidelines for Pharmacies and Prescribers* summarizes complex and detailed federal requirements for the e-prescribing of controlled substances and presents the material in a comprehensible format.

- **Implementation of DCA's Consumer Protection Enforcement Initiative (CPEI)**

The Board used CPEI as an opportunity to evaluate its enforcement systems to achieve time savings in its investigations making several internal operational changes, such as assigning cases online and conducting mail votes electronically. The Board also dedicated an associate analyst to perform initial case analysis and review and pursued legislative changes to identify statutory barriers that delay investigations and discipline. The Board now requires pharmacies to report any evidence of a licensee's theft or impairment within 14 days, submit information about drug loss from the pharmacy within 30 days and prohibits a nonresident pharmacy from allowing a pharmacist, whose license has been revoked in California, from providing pharmacist-related services to Californians.

Change of Board Composition and Membership

The Board was previously comprised of 11 members, 7 professional members and 4 public members. In 2004, the Board composition was changed to add 2 public members; both appointees of the Governor.

- **Standing Committees Meet Regularly and Provide Public Notice of Meetings**

The JLSRC was concerned about the establishment of Board standing subcommittees, the composition of these committees and whether members of the public were provided opportunities to comment at these meetings. The Board now has committees comprised of at least four members, each of which holds public meetings with multiple opportunities for public comment.

CURRENT SUNSET REVIEW ISSUES

The following are unresolved issues pertaining to the Board, or those which were not previously addressed by the Committee, and other areas of concern for this Committee to consider along with background information concerning the particular issue. There are also recommendations by the Senate Business, Professions and Economic Development Committee staff which have been made regarding particular issues or problem areas which need to be addressed. The Board and other interested parties, including the professions, have been provided with this Background Paper and can respond to the issues presented and the recommendations of staff.

BOARD ADMINISTRATION ISSUES

ISSUE #1: (QUORUM PROBLEMS.) The Board currently has vacancies that may result in an inability to conduct business due to a lack of quorum. What is the impact, if any, of the change in Board composition from 11 to 13 members?

Background: The Board currently has three pharmacy member vacancies, appointed by the Governor, which may result in an inability to conduct business due to a lack of a quorum. While meetings have not had to be cancelled because of a lack of quorum, on occasion, action items before the Board must be delayed for a period of time during meetings until there is a quorum present. A recent example occurred on September 7, 2011, when the Board was unable to take action on an agenda item for over an hour while awaiting the arrival of two board members.

Staff Recommendation: *The Board should explain whether it believes that quorum problems for the Board will continue to exist and has the Department and Agency been informed of the effect of vacancies which currently exist on the Board. The Board should also explain whether changes in the composition of the Board since the last sunset review has improved the overall operation of the Board.*

ISSUE #2 : (BUDGETARY PROBLEMS.) During the last Sunset Review, JLSRC was concerned about the Board's consistent overspending of its AG budget. It appears the Board exceeded its AG budget by \$697,250 in FY 2010/11. Does the Board have the resources and revenue it needs to conduct its business and meet its statutory mandates?

Background: According to the Board, during the last Sunset Review period the line item for its AG budget was insufficient to cover all of the legal services the Board needed, particularly with an increase in the number of licensees disciplined each year. The Board stated the lack of AG funding was a problem that had been growing for a number of years and that the Board had made repeated attempts to obtain an augmentation to its AG budget. This is still a problem for the Board. The Board's AG expenditures continue to grow, as enforcement remains a Board priority, and in FY 2010/11, the Board overspent its AG budget by close to \$700,000. While the Board has yet to curtail its administrative cases, staff watches this closely to determine if these costs must be somehow augmented.

Another problem the Board has is that its authorized expenditures continue to exceed estimated revenue. The Board has not yet had a deficit situation in its overall financial condition, but because of budget restrictions (such as hiring freezes, travel restrictions and operating expenses reductions) imposed on state agencies, the Board has not used all of its authorized expenditures. Additionally, unpaid loans to the general fund from special fund entities deplete resources and the Board has been impacted by this as well. The Board anticipates that another fee increase may be necessary in 2015, as the Board's fund is projected to decline over the next few years.

Staff Recommendation: *The Board should outline its plans to address budgetary challenges.*

LICENSING AND ENFORCEMENT ISSUES

ISSUE #3 : (NEED FOR STATUTORY REPORTING REQUIREMENTS.) Is the Board receiving important information about its licensee population ?

Background: Current law, the Business and Professions Code 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, employers may have disciplined the licensee and either altered their workplace privileges or terminated their employment, or they have committed a criminal act. The Board states that it does not believe that it is receiving reports pursuant to the requirements of the Section 800 series. In an effort to educate licensees and others responsible for reporting, the Board has run two articles in its newsletter *The Script*, most recently in 2010, and has also discussed these reporting requirements during board meetings. According to the Board, it is currently continuing its education efforts in this area in the hopes to achieve better compliance with these reporting requirements, and as recently as this January, mailed a letter to all pharmacy headquarters, about 60 percent of community pharmacies, reminding them about their reporting obligations.

Staff Recommendation: *The Board should provide an update on its receipt of reports about its licensees and how an influx of Section 800 reports would be absorbed in its enforcement staff workload.*

ISSUE #4 : (PROOF OF INTERN HOURS EARNED.) Would it be more efficient for the Board to receive out-of-state intern hour verification directly from the state licensing board, rather than rely on the Board staff to verify hours?

Background: Pharmacy law requires pharmacist exam applicants to submit proof of intern hours earned. Hours must be certified under penalty of perjury by the supervising pharmacist or pharmacist-in-charge in the pharmacy where the intern experience was obtained. According to the Board, this requirement imposes a record-keeping burden for recent graduates from out-of-state seeking licensure in California who, until they apply for licensure in California, may not be aware of the requirements for obtaining signatures of pharmacists in the pharmacies in which they have earned intern hours.

The current method of verifying intern hours earned outside of California requires Board staff to verify the intern pharmacist's licensure status as well as the licensure status of the supervising pharmacist. As California relies on other state licensing entities to provide enforcement, disciplinary, and licensure verification, accepting intern hours from another licensing board seems in line with current methods of obtaining reliable information while reducing hardship for the applicant as well as the application processing time. Revising Pharmacy Law to allow the Board to accept hours earned in other states and reported by other state pharmacist licensing agencies may reduce the length of time it takes to verify such hours without compromising the integrity of the requirement.

Staff Recommendation: *The Board should explain how other states verify intern hours for out-of-state licensees. The Committee may wish to grant the Board statutory authority to accept transfer of intern hours, if they have been verified by another state, directly from a state board of pharmacy.*

ISSUE #5: (UNLICENSED ACTIVITY AND THE UNDERGROUND ECONOMY.) What can the Board do to curb unlicensed activity and ensure the quality of prescription drugs received by California consumers and patients? What impact do drug shortages have on this behavior?

Background: The selling of pharmaceuticals in an underground economy, often by unlicensed individuals, can have serious impacts on pharmaceutical care, the quality of the supply chain and can contribute to the rising problem of prescription drug abuse. In the area of pharmacy, Internet drug sales are the prevalent form of unlicensed activity. Some consumers look to the Internet as a way to obtain prescription medications at lower costs or without obtaining a prescription. Unfortunately many of these Website "pharmacies" are operated by Internet drug dealers as opposed to legitimate health care providers. According to the NABP, more than 96 percent of all Internet "pharmacies" are unlicensed and operate illegally. NABP has assessed over 8,400 Internet drug outlets selling prescription medication and found that 96.2 percent are operating illegally and out of compliance with state and pharmacy laws and practice. Eighty-one percent (6,808) do not require a valid prescription, 3,700 (44 percent) offer non-FDA approved drugs, 2,100 (25 percent) are located outside of the U.S. and ship illegally to patients inside the US. Less than 4 percent of the websites appear to be legitimate prescription drug outlets. The World Health Organization estimates that over 50 percent of all drugs purchased via the Internet from outlets that conceal their actual address are counterfeit or adulterated. Worldwide counterfeit drug sales are increasing at nearly twice the pace of legitimate drug sales. Counterfeit drugs have the potential to harm patients with inaccurate or inconsistent dose levels or contaminated or toxic substances and deprive patients of life saving medications. Ease of access to the

products over the Internet contributes to the distribution of counterfeit drugs, as they are available to almost anyone worldwide.

The Board investigates complaints it receives from consumers and the industry alleging unlicensed activity by Internet pharmacies. Until recently the Board had staff dedicated to identifying unlicensed Internet pharmacies and conducting investigations. However, the Board reports that because of staff resource limitations and complications with researching offshore website ownership, the Board stopped these investigations and refers these types of complaints to the FDA. In recent months the Board began referring cases to DCA's Division of Investigation (DOI) to complete undercover purchases from domestic operators. Although this is still relatively new, DOI has completed three such buys for the Board.

A second emerging area of unlicensed activity is purchasing drugs for pets from unlicensed Internet veterinary pharmacies. Driving this behavior are pet owners seeking to reduce the cost of medications by going online without a prescription to obtain drugs for their pets. The Board has issued cease and desist notices and issued citations to these unlicensed entities, but to secure prosecution they must rely on local district attorneys' offices. To date, this has not resulted in any criminal prosecution.

In addition to unlicensed activity, the Board states that Medi-Cal fraud is rampant in some areas. Unscrupulous operators seek pharmacy licensure in order to obtain a Medi-Cal provider number and then in turn do not conduct any legitimate business, but submit fictitious claims for large reimbursements from Medi-Cal, often closing the pharmacy after receipt of the payment. The Board states that it has reinstated opening inspections for new pharmacies to identify individuals who are not seeking a license for legitimate purposes.

Staff Recommendation: *The Board should describe its public education and enforcement efforts to combat unlicensed activity and other challenges. The Board should address how unlicensed activity is impacting enforcement staff workload.*

ISSUE #6: (EFFECTIVENESS OF THE BOARD'S SUBSTANCE ABUSE RECOVERY PROGRAM.) How effective is the Board's "Pharmacist Recovery Program" (PRP) and have "Uniform Standards" been adopted for this program? Should the PRP be audited to determine its effectiveness and efficiency. Should the Board continue to maintain and operate its own Diversion Program?

Background: In 1985, the Board sponsored legislation that required the Board to develop a Pharmacist Recovery Program (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.

According to the Board, the program fulfills two distinct purposes; 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.

The Board of Pharmacy uses a Pharmacy Review Committee (PRC) to review and determine the proper treatment for all participants. The PRC is comprised of the assigned clinical case manager from the contracted employee assistance program provider, as well as one Board supervising inspector and one Board manager who are both trained in drug recognition and the treatment of substance abuse, as required by Business and Professions Code Section 4371. The PRC meets monthly to discuss participants' treatment contracts, compliance and assessment notes as well as to review any participant requests. Each participant's treatment contract and compliance are reviewed on a quarterly basis by the PRC. However, participants' treatment contracts may be reviewed more frequently if needed based upon a participant's request or because of compliance issues.

Regardless of the method of initial referral into the program, the treatment contracts of all participants are monitored by the PRC, except the clinical case manager and the Board manager review the self-referral participants' performance, ensuring the confidentiality of these participants as required by statute. In the event that any participant is deemed to be a threat to him or herself or to the public, the contractor is required by law to notify the Board. The Board states that this notification ensures that the Board's public protection mandate is met.

Most treatment plans are five years in length. Participants are required to pay for the costs of their own treatment as well as the costs of random biological drug testing (both hair follicle and urine testing are performed for all participants).

A typical treatment contract for a substance abuse or a dual diagnosis (substance abuse with a mental health diagnosis) participant includes: mandatory attendance at AA meetings (12-30 meetings per month, and typically 30 meeting monthly initially), attendance at health support group meetings (one to two per week), biological drug testing, initially at least 52 times annually, submission of monthly self-reports, and sometimes participation in individual therapy or other types of support groups. Periodic assessments by independent clinicians also are completed on participants at the direction of the Board. Additionally, participants working in the field of pharmacy must have a work-site monitor in place who is approved by the Board whose function is to monitor the functioning of the participant on a continual basis, provide monthly reports to the program, and notify the program immediately of any suspected use or irregularity.

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 contractor 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 Attorney General's Office for expedited formal discipline due to the imminent danger to the public of such individuals continuing to practice.

The Board provided in its 2002 Sunset Review Report the following table regarding the costs, number of participants and successful completions of its PRP:

Pharmacist Recovery Program: FY 98/99 to FY 01/02

	FY 98/ 99	FY 99/ 00	FY 00/ 01	FY 01/ 02	Total
Total Program Contract Costs	\$ 65,648	\$ 76,684	\$ 63,268	\$ 81,155	\$ 249,494
Total Participants	54	57	56	63	232
Successful Completions	7	8	9	10	34
Unsuccessful Completions	4	4	6	5	19
Not Eligible/Not Appropriate	2	2	4	1	7

The table below provides more recent information from the Board in its current Sunset Report regarding the costs, number of participants and successful completions of its PRP.

Pharmacist Recovery Program: FY 08/09 to FY 10/11

	FY 08/09	FY 09/ 10	FY 10/ 11	Total
Total Program Contract Costs	\$156,133	\$ 165,688	\$ 168,050	\$489,871
Total Participants	79	72	72	223
Successful Completions	15	11	12	38
Unsuccessful Completions	10	17	11	38

As the two tables indicate, for a period of at least seven years there have been at least 455 participants in the PRP and 72 successful completions, which requires three to five years of counseling, attendance at meetings or group meetings, drug testing, and possibly work-site monitoring, and an alcohol or drug free rehabilitated lifestyle. Basically the success rate, if you can call it that since it is only a measure of those that successfully complete the program, is approximately 16% of those total participants in the program at any one time. Reasons for initial participation in the program and successful completion seem to vary. It is unknown, however, of those that successfully complete the program whether or not they recidivate. The costs of providing the PRP have almost doubled since FY 01/02.

The use of a “Recovery Program” or a “Diversion Program,” as it is more frequently called is unique for this Board and six other health boards under the DCA. Rather than discipline the practitioner with substance abuse problems, the Board allows them secretly to enter a Diversion Program to try and address their problem. The Board’s position is one of compassion to the affected pharmacist, since it attempts to allow them to work on curing the problem they have without being disciplined by the Board. (It should be noted, however, that those on probation have been disciplined, but a suspension or revocation of their license may be stayed while they participate in the program.)

In contrast, other health related boards, such as the Board of Psychology and more recently the Medical Board, have no such programs. For those boards, substance abuse, like other problems, can be a cause for ordinary discipline, and is not treated by a separate disciplinary (or, in the case of the Board’s Recovery Program, non-disciplinary) system. Rather, each licensee’s case is reviewed on its own merits, and discipline imposed, or not, accordingly.

By allowing substance-abusing pharmacists in recovery to continue in practice, there is obvious potential for danger to the public. Substance abuse is a disease that is especially subject to backsliding, as virtually every responsible recovery program acknowledges.

Such dangers can be minimized by effective monitoring programs. The key, however, is that the monitoring truly be “effective.” In the past, this Committee has observed, and audits of particular programs have shown, that the monitoring which should be required has utterly failed; from problems with the mechanism of random urine testing, to a lack of personnel to staff the monitoring, to workplace monitors who are at-will employees of the very pharmacists in the recovery program.

This diversion program for pharmacists has never been audited nor extensively reviewed, so it is difficult to determine whether the monitoring, testing and oversight of those who participate in the program are sufficient to assure that the public is adequately protected. Also the success rate, or “completion rate,” is rather low and there is no way to determine how successful the participant has been in returning to a drug free lifestyle since all records are kept confidential.

Of concern also is that the Board has not fully adopted the “Uniform Standards” for substance abusing licensees. As the Board indicates, it “has been well positioned to implement the standards,” and since completing an analysis of the draft standards in 2010, the Board began developing an implementation strategy for adopting the standards, but as yet it does not appear as if all the standards have been included in the Board’s Disciplinary Guidelines.

Staff Recommendation: *The Board should provide justification for continuing to provide the Pharmacist Recovery Program even with the low completion rate for this program and the increased costs of providing such a program. If this program is to continue, an audit should be done of this program within the next two years. The Board should update the Committee on the implementation of the “Uniform Substance Abuse Standards.”*

ISSUE #7 : (DRUG DIVERSION AND PRESCRIPTION DRUG MONITORING PROGRAM – “CURES.”) Prescription drug abuse is a rising national problem, with pharmacies on the front line of access to drugs. What role does the Board play in addressing this issue? How do Board enforcement priorities attempt to combat this problem? What is the status of the CURES program?

Background: For the past number of years, abuse of prescription drugs (taking a prescription medication that is not prescribed for you, or taking it for reasons or in dosages other than as prescribed) to get high has become increasingly prevalent. Federal data shows the past year abuse of prescription pain killers now ranks second, just behind marijuana, as the nation's most widespread illegal drug problem. According to the 2008 National Survey on Drug Use and Health (NSDUH), approximately 52 million Americans aged 12 or older reported non-medical use of any psychotherapeutic at some point in their lifetimes, representing 20.8% of the population aged 12 or older. The National Institute on Drug Abuse's (NIDA) research report *Prescription Drugs: Abuse and Addiction* states that the elderly are among those most vulnerable to prescription drug abuse or misuse because they are prescribed more medications than their younger counterparts. Persons 65 years of age and above comprise only 13 percent of the population, yet account for approximately one-third of all medications prescribed in the United States. Older patients are more likely to be prescribed long-term and multiple prescriptions, which could lead to unintentional misuse. The report also notes that studies suggest that women are more likely (in some cases, 55 percent more likely) than men to be prescribed an abusable prescription drug, particularly narcotics and antianxiety drugs. A 2010 report, *Monitoring the Future Study*, showed that as many as 4 percent of high school students and 3 percent of young adults say they have used OxyContin in the past year.

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. NIDA data states that in actuality, prescription drugs act directly or indirectly on the same brain systems affected by illicit drugs, thus, their abuse carries substantial addiction liability and can lead to a variety of other adverse health effects.

Controlled substances are ranked according to their potential for abuse, accepted medical use, and safety under medical supervision. Schedule I substances (e.g. heroin and LSD) have high potential for abuse, no currently accepted medical use, and lack accepted safety for use. Schedule II drugs (e.g. morphine, codeine, Demerol, and Percodan) have a high potential for abuse and high potential for physical or psychological dependence if used improperly, but have accepted medical value in treating pain. Schedule III drugs (e.g. Vicodin, anabolic steroids, codeine with aspirin or Tylenol), Schedule IV drugs (e.g. Darvon, Valium, Halcyon, and Xanax), and Schedule V drugs (over the counter cough medicines with codeine) generally have less potential for abuse than Schedule I or II drugs, have accepted medical use in treatment, and lower potential for physical or psychological dependence. The three classes of prescription drugs that are most commonly abused are opioids, which are most often prescribed to treat pain, central nervous system (CNS) depressants, which are used to treat anxiety and sleep disorders, and stimulants, which are prescribed to treat the sleep disorder narcolepsy and attention-deficit hyperactivity disorder (ADHD). Each class can induce euphoria, and when administered by routes other than recommended, such as snorting or dissolving into liquid to drink or inject, can intensify that sensation. Opioids, in particular, act on the same receptors as heroin and, therefore, can be highly addictive. Common opioids are: hydrocodone (Vicodin), oxycodone (OxyContin), propoxyphene (Darvon), hydromorphone (Dilaudid), meperidine (Demerol), and diphenoxylate (Lomotil).

With rising levels of abuse, prescription drug monitoring programs are a critical tool in assisting regulatory bodies with their efforts to reduce drug diversion. According to the NABP, 39 states currently have monitoring programs, while 11 other states are currently in the process of establishing their programs. California has the oldest prescription drug monitoring program in the nation. Of these 50 programs throughout the nation, seven are or will be housed at the state's Department of Justice, 18 are or will be housed at a state Department of Health or substance abuse agency and 25 are or will be housed at a state Board of Pharmacy or state professional licensing agency. There is currently momentum to share data across these programs from state to state.

In California, the Controlled Substance Utilization Review and Evaluation System (CURES) is an electronic tracking program that reports all pharmacy (and specified types of prescriber) dispensing of controlled drugs by drug name, quantity, prescriber, patient, and pharmacy. AB 3042 (Takasugi, Chapter 738, Statutes of 1996) established a three year pilot program, beginning in July 1997, for the electronic monitoring of prescribing and dispensing of Schedule II controlled substances. Subsequent legislation (SB 1308, Committee on Business and Professions, Chapter 655, Statutes of 1999) extended the sunset date on the CURES program to July 1, 2003 and required DOJ to submit annual status reports on the program to the Legislature. In 2002, the Legislature passed AB 2655 (Matthews, Chapter 345, Statutes of 2002) which extended the CURES program to 2008 and provided access to CURES data by licensed health care providers. Finally, in 2003, SB 151 (Burton, Chapter 406, Statutes of 2003) made the program permanent. In 2009, then Attorney General Brown launched an online CURES system at DOJ to replace the previous system that required mailing or faxing written

requests for information, giving health professionals (doctors, pharmacists, midwives, and registered nurses), law enforcement agencies and medical profession regulatory boards instant computer access to patients' controlled-substance records.

Data from CURES is managed by DOJ to assist state law enforcement and regulatory agencies in their efforts to reduce prescription drug diversion. CURES provides invaluable information that offers the ability to identify if a person is “doctor shopping” (when a prescription-drug addict visits multiple doctors to obtain multiple prescriptions for drugs, or uses multiple pharmacies to obtain prescription drugs). Information tracked in the system contains the patient name, prescriber name, pharmacy name, drug name, amount and dosage, and is available to law enforcement agencies, regulatory bodies and qualified researchers. The system can also report on the top drugs prescribed for a specific time period, drugs prescribed in a particular county, doctor prescribing data, pharmacy dispensing data and is a critical tool for assessing whether multiple prescriptions for the same patient may exist. In addition to the Board, CURES data can be obtained by the Medical Board of California, Dental Board of California, Board of Registered Nursing, Osteopathic Medical Board of California and Veterinary Medical Board.

Since 2009, more than 8,000 doctors and pharmacists have signed up to use CURES, which has more than 100 million prescriptions. The system also has been accessed more than 1 million times for patient activity reports and has been key in investigations of doctor shoppers and nefarious physicians. For the Board, this data is critical in allowing for the identification of pharmacies involved in massive dispensing of controlled substances, which can be a potential sign of drug diversion, and serves as a trigger for important investigations. According to the AG’s office, CURES assisted in targeting the top 50 doctor shoppers in the state, who averaged more than 100 doctor and pharmacy visits to collect massive quantities of addictive drugs and the crackdown led to the arrest of dozens of suspects. CURES also provided information with the prescribing history of a Southern California physician accused of writing hundreds of fraudulent prescriptions to feed his patients' drug addictions, seven of whom died from prescription-drug overdoses. The system has also been successful in alerting law enforcement and licensed medical professionals to signs of illegal drug diversions, including a criminal ring that stole the identities of eight doctors, illegally wrote prescriptions, stole the identities of dozens of innocent citizens who they designated as patients in order to fill the fraudulent prescriptions, resulting in the group obtaining more than 11,000 pills of highly addictive drugs like OxyContin and Vicodin.

While California has the largest number of practitioners, pharmacies and patients, the CURES program may not be stable in terms of funding or location at DOJ. The 2011/12 state budget eliminated the Bureau of Narcotic Enforcement at DOJ which had been responsible for administering and maintaining the CURES database and program. DOJ is still currently staffing the program and the database remains accessible to registered participants.

Staff Recommendation: *The Board should discuss its drug diversion enforcement efforts and the role of CURES. The Board should provide recommendations for the future success and viability of this program, including efforts to increase utilization and suggestions for stable funding and location.*

PHARMACIST WORKFORCE ISSUES

ISSUE #8 : (WORKFORCE DEVELOPMENT EFFORTS.) Is California facing a pharmacist shortage? What is the impact of the federal Patient Protection and Affordable Care Act on the pharmacist workforce and health care delivery? How have delays in licensing process times impacted the pharmacy workforce in California?

Background: During the last Sunset Review, JLSRC was concerned that California was experiencing a pharmacist shortage and projections for the future indicated the population will continue to increase at a higher rate than the pharmacist population, thereby exacerbating the problem. In response, the Board noted its creation of a Pharmacy Manpower Task Force and use of a national examination to provide an easier path for licensure in California.

For a number of years, California had only three schools of pharmacy. Since the early 1990s, that number has increased to eight schools today, with plans underway for eight additional entities to open new schools of pharmacy in California in the next few years. This change alone would double the current number of schools, and presumably the number of California graduates. The passage of the federal Patient Protection and Affordable Care Act has the potential to require greater numbers of health professionals throughout the nation and state, particularly pharmacists who are well placed in communities to provide medication therapy management services. The Board does not currently believe there is a pharmacist shortage but it would be helpful for the Committee to understand if there is still a possible shortage, given the passage of the federal law, and what actions the Board takes to ensure that the workforce is ready and appropriately prepared to serve a growing number of Californians relying on pharmacist services.

Staff Recommendation: *The Board should explain its rationale in determining that California does not have a pharmacist shortage. The Board should outline efforts it has undertaken to ensure greater utilization of the profession in the midst of new demand for health care professionals.*

PHARMACY RELATED STATUTORY IMPLEMENTATION EFFORTS

ISSUE #9: (IMPLEMENTATION OF CALIFORNIA'S ELECTRONIC PEDIGREE LAW.) Will the Board meet the deadline for implementation? What challenges does the Board face in implementing the law? What has been the response of industry to implementation?

Background: The Food, Drug and Cosmetic Act (FDCA) was passed by Congress to ensure public confidence in our drug distribution system and to require that drugs are both safe and effective. The FDCA requires FDA to regulate drug manufacturers and to approve drugs for sale but also requires state governments to regulate the drug distribution system by licensing and regulating drug wholesalers. In California, the Board licenses wholesalers. In the simplest situation, a manufacturer sells drugs directly to one of the major wholesalers who then sell the drugs to a hospital or pharmacy. However, this simple distribution pattern is not the only distribution route taken through the supply chain. Typically, there is more than one wholesaler who receives the drugs before they reach the pharmacy. These transactions include transfers between separate facilities owned by major wholesalers and transfers between the major wholesalers and the large drug store chains that have their own wholesale facilities in the company distribution system. Common carriers may transport the

drugs between licensed entities and in some cases will store, select and then ship products to pharmacies at the direction of manufacturers.

The distribution system is further complicated by the practice of “repackaging.” Unlike European countries and Canada, most drugs in the United States are not packaged in a “unit of use” size by the drug manufacturers. Instead, many drugs are sold by the manufacturers in large bulk containers and then are repackaged by additional companies into smaller containers for resale to the pharmacy. And the distribution system is complicated yet again by the existence of a “secondary” wholesale market. “Secondary” wholesalers are smaller companies (often regional down to small family owned companies) that focus their business on selling drugs to other wholesalers and serving smaller niche clients that are not routinely served by the major wholesalers (individual practitioners, small clinics, rural locations, etc.).

Drugs routinely move between both primary and secondary wholesalers and from pharmacies to secondary wholesalers as well. These intermediate steps pose the greatest opportunities for compromising the integrity of the drug distribution system. The primary threat to system integrity is the introduction of counterfeit products. Counterfeit drugs are most likely to be introduced into a distribution system that involves multiple wholesalers because drugs are largely untraceable unless they are only handled by a major wholesaler who purchases directly from the manufacturer. Without being able to trace a drug back, there is no assurance to the consumer that the drug has been stored and handled appropriately to preserve its potency and safety.

In response to a growing threat to the pharmaceutical supply chain from counterfeit, misbranded, adulterated or diverted drugs, California enacted SB 1307 (Figueroa, Chapter 857, Statutes of 2004) which made comprehensive changes to the drug distribution system to protect the integrity of the pharmaceutical supply chain. That legislation enacted the nation's strongest pharmaceutical consumer protection measure and included provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing and the requirement, beginning January 1, 2007, of an electronic pedigree (e-pedigree) to accompany and validate drug distributions for the purpose of tracking each prescription drug at the saleable unit (item) level through the distribution system. Subsequent Board sponsored legislation, SB1476 (Figueroa, Chapter 658, Statutes of 2006) delayed the implementation date for the e-pedigree component to January 1, 2009 and granted the Board the authority to extend the deadline an additional two years to allow the industry additional time to implement technologies necessary for electronic pedigrees. In 2008, the Board sponsored SB 1307 (Ridley-Thomas, Chapter 713, Statutes of 2008), which amended the law to resolve implementation issues, specifically staggering and extending the implementation dates for e-pedigree compliance, establishing grandfathering of existing stock in the supply chain, allowing the Board to establish criteria for inference, and preempting California's requirements in the event federal legislation is enacted in this area. Per SB 1307, California's e-pedigree requirements for prescription drugs will take effect on a staggered basis from January 1, 2015 through July 1, 2017: 50 percent of a manufacturer's products by 2015 will have to have an e-pedigree; the remaining 50 percent of the manufacturer's products will have to have an e-pedigree by 2016; wholesalers and repackagers must accept and forward products with the e-pedigree by July 1, 2016 and; pharmacy and pharmacy warehouses must accept and pass e-pedigrees by July 1, 2017.

Implementation of this legislation will impact all drug manufacturers and wholesalers who sell and distribute drugs into California. The Board states that it will spend considerable effort over the next six years in securing regulations and implementation of the requirement and it would be helpful for the

Committee to understand what that entails and what impediments the Board anticipates to full, timely implementation.

Staff Recommendation: *The Board should provide the Committee with an update on the status of e-pedigree implementation, including timelines, Board activity, potential impediments and manufacturer and industry efforts and response.*

ISSUE #10 : (IMPLEMENTATION OF A PRESCRIPTION LABEL STANDARD.)

What has the Board done to implement California’s label standard for prescription containers? What public outreach efforts did the Board take to ensure robust participation in the regulatory process? What additional changes to the law or issues does the Board anticipate?

Background: California is 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 insure 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 was charged promulgating regulations that require a standardized, patient-centered prescription drug container label for all prescription drugs dispensed to patients in California. The Board reported on its efforts in a January 2010 report to the Legislature. The Board established a “SB 472 Medication Label Subcommittee” in January of 2008 to conduct public forums and to work with organizations and individuals to develop recommendations to implement the provisions of the law to establish a patient-centered prescription drug label. The Board considered testimony and information provided from the public, the pharmaceutical industry, pharmacy professionals and literacy subject matter experts on medical literacy research, improved directions for use, improved font types and sizes, the placement of information that is patient-centered, the needs of patients with limited English proficiency, the needs of senior citizens, and technology requirements necessary to implement the standards developed. Board members were also provided with research articles on designing patient-centered labels.

The Board approved a regulation per the requirements set forth in SB 472 in 2010, after engaging in a lengthy process. The Board conducted outreach, hearings and information gathering sessions throughout 2008, to collect data from the public on prescription labels and standards for those labels. In 2009, the Board discussed the requirements of the regulation at regularly scheduled meetings. Throughout early 2010, the Board held regulation hearings to adopt the proposed regulation, a new section at Title 16 California Code of Regulations Section 1707.5 – “Requirements For Patient-Centered Prescription Container Labels.” The regulation outlines that the following items must be clustered into one area of the label that comprises at least 50 percent of the label, using at least 10-

point font using sans serif typeface, listing these items in the following order: Name of the patient; name of the drug and strength of the drug (“name of the drug” means either the manufacturer’s trade name, or the generic name and the name of the manufacturer); directions for use; purpose or condition, if entered onto the prescription by the prescriber, or otherwise known to the pharmacy, and its inclusion on the label is requested by the patient. The regulation also requires pharmacies to have policies and procedures in place to help patients with limited or no English proficiency, understand the information on the label in the patient’s language. The pharmacy’s policies and procedures must be specified in writing, and must include, at minimum, the selected means to identify the patient’s language, and to provide interpretive services in the patient’s language. Pharmacies must provide, at minimum, interpretive services in the patient’s language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.

Staff Recommendation: The Board should provide a status update on the creation of a patient-centered label for all prescriptions dispensed in California. The Board should describe what additional public outreach it will undertake to ensure compliance. The Board should explain impediments to compliance, industry feedback or pushback, if any and anticipated changes that may be made to the law or regulation.

ISSUE #11 : (IMPLEMENTATION OF DRUG TAKE-BACK AND REUSE PROGRAMS.)

Is it clear what role the Board has in the implementation of drug take-back programs and redistribution and reuse programs?

Background: There are growing concerns about the impact of drugs and pharmaceutical waste based on improper disposal, which in turn leads to contamination of water systems and inappropriate access by potential abusers. The U.S. Geological Survey conducted a study in 2002, sampling 139 streams across 30 states and found that 80 percent had measurable concentrations of prescription and nonprescription drugs, steroids, and reproductive hormones. Exposure, even to low levels of pharmaceuticals, has been shown to have negative effects on fish and other aquatic species and may have negative effects on human health. Proper disposal is believed to decrease the threat of these substances to the environment and waterways. Proper disposal is also believed to decrease the availability of expired and unused prescription drugs to abusers.

The guidelines for proper disposal of prescription drugs can be confusing, lack uniformity throughout the state and nation, and are cumbersome to the consumer. For example, the federal FDA highlights certain very harmful drugs that should be flushed down a toilet, but the organization also recommends a lengthy process for proper disposal of the majority of prescriptions drugs, including mixing whole tablets or capsules with an unpalatable substance such as kitty litter or used coffee grounds then placing that mixture in a sealed container before throwing it in household trash. The Board’s recommended process for disposal is similarly extensive and requires even additional steps.

Take-back programs for medication disposal have risen in popularity due to problems surrounding safe, accessible, easy disposal options. These programs are seen as a good way to remove expired, unwanted, or unused medicines from the home and reduce the chance that others may accidentally take the medicine or it ends up being flushed. In California, though, The Medical Waste Management Act (MWMA) currently requires home generated pharmaceutical waste to be managed as “medical waste” which includes such material as infectious and biohazardous waste and other types of waste that pose a potential harm to public health and safety and the environment if not managed properly. The MWMA

establishes rigorous management and tracking requirements for medical waste; including requiring the use of hazardous or medical waste haulers and strict manifesting requirements.

Many pharmacies and other retail establishments have expressed an interest in providing collection opportunities for their customers and while they are willing and able to provide safe and appropriate collection, they do not want to become licensed medical waste collectors. Concerns have been raised regarding the issue of theft of home generated pharmaceutical waste at collection points, including pharmacies. As pharmacies have the responsibility of keeping the drug supply safe, it is important that assurances are in place for drugs taken back at a pharmacy to remain secure and not diverted to unauthorized users. Similarly, expired or unused medications that have been dispensed to a consumer must not re-enter the drug supply, to ensure quality of products.

In 2007, the Legislature passed SB 966 (Simitian, Chapter 542, Statutes of 2007) which required the California Integrated Waste Management Board (CIWMB) to develop, in consultation with appropriate state, local, and federal agencies, model programs for the collection and proper disposal of pharmaceutical drug waste. However, it does not appear that California has implemented widespread take-back programs and consistent opportunities throughout the state for consumers to properly dispose of unwanted, expired or unused medication. It would be helpful for the Committee to understand barriers to take-back programs and the Board's role in implementing SB 966.

Access to affordable prescription drugs is also a growing problem in California and in other states. Prescription drugs represent one of the fastest growing health care expenditures as drug prices continue to grow and the population is rapidly aging. Many states have enacted prescription drug recycling or repository programs for unused medications to provide access to vulnerable populations. While details of these laws vary, most allow return of prescription drugs in single use packaging from state programs, nursing homes, and other medical facilities to be redistributed to needy residents. In 2000, the American Medical Association (AMA) looked at one such program in Oklahoma where nursing homes directed unused and unopened medicines back to pharmacies for distribution to indigent patients. According to the AMA, there was an estimated \$3 to \$10 million dollars a year in unused prescription drugs from such facilities in the state of Oklahoma.

The Board may also have responsibility for assisting in the implementation of prescription drug redistribution or reuse programs. In 2005, the Legislature passed SB 798 (Simitian, Chapter 444, Statutes of 2005) which allowed counties to establish a voluntary drug redistribution program, allowed skilled nursing facilities and drug manufacturers to donate unused medications and allowed county pharmacies to dispense the donated drugs to underserved populations free of charge, modeled after the Oklahoma program. At the heart of the issue is the large amount of surplus medication that goes unused, but may not be expired and has never been distributed to the public, thus may not face supply chain quality concerns. SB 798 specified that the only medications eligible for recycling or repository are those that have been maintained in specified settings under the watch of a licensed pharmacist or manufacturer and have not been distributed to consumers. Designed to combat both the issue of rampant improper disposal of medication and the rising costs of prescription drugs for some of California's most vulnerable patients, programs under SB 798 have only been established in two counties, San Mateo and Santa Clara. It would be helpful for the Committee to understand the Board's role in overseeing recycling and redistribution programs.

Staff Recommendation: *The Board should explain the status of implementation of drug take-back programs in California and what barriers exist to successful implementation of these programs?*

What role does the Board play in establishing safe, secure methods for consumers to properly dispose of medication? What steps has the Board taken to promote and create take-back programs? What should be the role, if any, of board-licensed reverse distributors in the drug take-back process? What role does the Board play in drug redistribution and reuse programs, whereby unused medication that has not been dispensed can be donated to community clinics and organizations that can in turn provide medication to vulnerable populations? What are the barriers to successful redistribution and reuse programs?

**CONTINUED REGULATION OF THE PROFESSION BY THE CURRENT
BOARD OF PHARMACY**

ISSUE #12. (CONTINUED REGULATION BY BOARD OF PHARMACY.)

Should the licensing and regulation of pharmacies and pharmacists 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 and pharmacies 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.*