California State Board of Pharmacy

STRATEGIC PLAN 2012-2017

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California State Board of Pharmacy Strategic Plan

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strategic plan 2012 - 2017

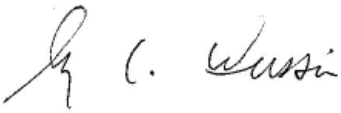
I. PRESIDENT'S MESSAGE

The strategic planning process of the California State Board of Pharmacy is a joint effort of Board members, Board staff, and the public to identify key issues and create action plans for addressing those issues in the years ahead. In preparing its strategic plan, the Board builds on its current strategic plan and analyzes trends in pharmacy practice, consumer needs and demands, and health care. The resulting strategic plan focuses the Board on established goals, while allowing flexibility to address new questions and challenges that lie ahead.

Board activity is organized through five policy committees: Enforcement, Communication and Public Education, Licensing, Legislation and Regulation, and Organizational Development. Much of the Board's work is carried out by these committees, which in turn develop objectives and actions that advance mission-related goals.

Each Board committee is responsible for overseeing implementation of a specific set of objectives to achieve its individual strategic plan goal. Collectively, the committees review progress in attaining each goal at quarterly full Board meetings. Careful planning and continuous monitoring of the strategic plan ensures that the Board achieves its stated objectives in an efficient and cost-effective manner.

The Board publishes advance notice for each strategic planning meeting and encourages participation and contribution by all interested citizens of California. Involvement of the Board, its staff and the public results in a strategic plan that represents the public interest while serving the needs of consumers and licensees throughout the State.



Stanley C. Weisser, R.Ph., President

II. ABOUT THE BOARD OF PHARMACY

The California State Board of Pharmacy is a consumer protection 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. Today, the Board oversees all aspects of the practice of pharmacy in California: the practitioner (the pharmacists), the practice site (the pharmacies), and the product (drugs and devices). Additionally, the Board regulates drug wholesalers and other practitioners and specialized facilities that store and furnish prescription drugs. With an annual budget of nearly $14.5 million and a staff of 84, the Board licenses over 130,000 individuals and firms, and enforces 13 distinct and varied regulatory programs.

The Board protects the public health, safety and welfare by ensuring the provision of quality pharmacists' care. Board activity is organized through five policy committees: Enforcement, Communication and Public Education, Licensing, Legislation and Regulation, and Organizational Development. Much of the Board's work is carried out by these committees, which in turn develop objectives and actions that advance mission-related goals.

As a consumer protection agency, the Board ensures that only those who possess prescribed require- ments are licensed; seeks removal of licenses for those who don't comply with laws or maintain qualifications for licensure; investigates consumer complaints; and provides a focused effort to ensure consumer education and awareness. The Board is also involved in initiatives to improve the pharmacists care provided to patients, prevent diversion of drugs from the pharmaceutical supply chain, improve outcomes of patient medication therapy, and ensure the quality of the state's prescription medicine.

The Board supports an active website, www.pharmacy.ca.gov, that provides consumer education mate- rial, application material for licensing, and information for ensuring compli- ance with California Pharmacy Law. The website also provides times and information on Board meetings, as well as information on other critical forums vital to pharmacy services where public comments and input are sought and encouraged.

III. RECENT ACCOMPLISHMENTS

The strength and effectiveness of the Board's strategic planning efforts are demonstrated by its record of recent accomplishments, summarized in the pages that follow.

2006-2007

Disaster Response Policy

The Board developed and published a disaster response policy to advise licensees that it will waive pharmacy law requirements to ensure that patients receive medications during declared disasters and emergencies.

E-Pedigree

The Board sponsored 2006 legislation to amend existing requirements, also sponsored by the Board, to safeguard the integrity of prescription drugs sold in or shipped into California. This California law requires electronic tracking of medication at the sellable unit to combat the introduction of counterfeit or substandard drugs into the legitimate drug supply. As part of the larger effort to implement these provisions, the Board convened quarterly meetings with regulators, drug manufacturers, drug wholesalers, and pharmacies to implement electronic pedigree requirements that track ownership of prescription medicine as it moves through the distribution channel, establishing a reviewable system to guard against illicit introduction of potentially damaged medicine into the state's pharmacies.

Applicant Tracking

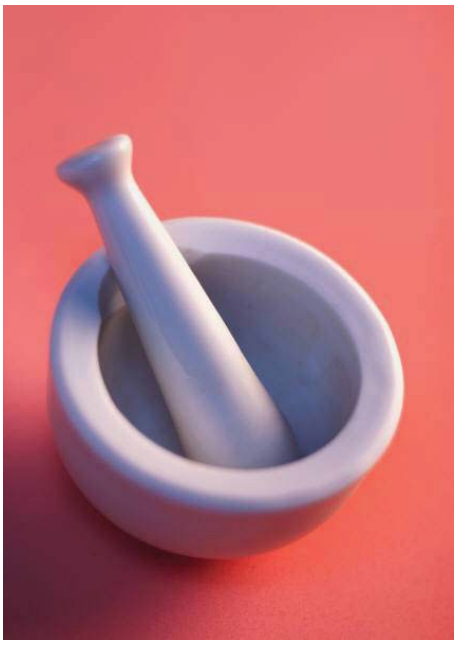
The Board converted its in-house developed applicant tracking systems for its 25 licensing programs to a system developed by the department, a precursor to securing online renewal of licenses.

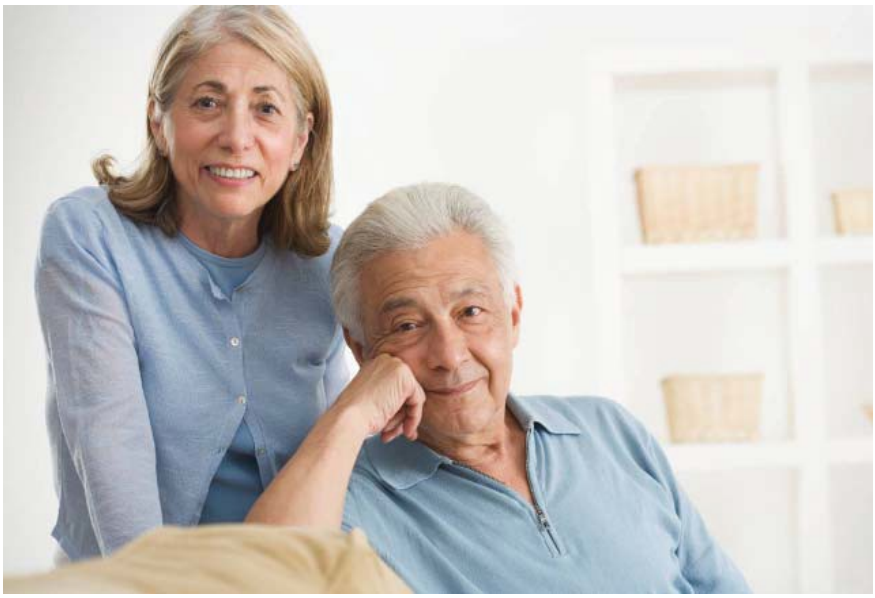
Hosted NABP's District 7 and 8 Meeting in California

Over 100 people attended this regional meeting of national pharmacy regulators and educators, which occurs annually to share information and discuss program enhancements. Topics included California's e-pedigree requirements, the DEA's pseudoephedrine requirements, and ethics counseling requirements for pharmacists.

Intern Experience Requirements

The Board participated in discussions convened by California's schools of pharmacy to implement major changes in pharmacist internship experience. This occured as part of pharmacy school curriculum revisions adapted by the U.S. accreditation agency for pharmacist education.





Regulation Activity

In 2006-07, the Board succeeded in securing the following regulatory changes:

- Pharmacy technicians were permitted to check the work of pharmacy technicians in acute care hospitals with clinical care programs that are provided by pharmacists.
- Automated machines to dispense refill prescription medication were authorized, provided that the patient consents.
- The Board's Disciplinary Guidelines were updated.
- Requirements were established for self-assessment of wholesaler premises.

Passage of Board-Sponsored Legislation

The following legislative changes occurred as a result of the Board's sponsorship and advocacy:

- Reporting to the Board about impaired staff in a pharmacy, or when an employee has stolen drugs from the pharmacy, became required.
- Board inspectors were authorized to embargo unsafe drugs in commerce.
- E-pedigree implementation in California was extended until 2009, with extension to 2011 (2006 legislation).
- Pharmacist protocol provisions for pharmacists to manage drug therapy elements of patient care were expanded.

2007-2008

Disaster Response and Communication with Licensees

The Board expanded its online subscriber alert system to notify interested parties, particularly licensees, about emerging health care

matters including recalls, implementation of new laws, and declarations of emergency.

E-Pedigree

The Board continued to safeguard the pharmaceutical supply chain by refining existing requirements for electronic pedigrees. The Board hosted a number of meetings to hear presentations by technology vendors identifying implementation strategies, standard setting organizations responsible for ensuring the interoperability of systems, as well as from members of the supply chain on their readiness for implementation of a full e-pedigree system. The Board's staff also spoke at national and international conferences on California's e-pedigree requirements to provide information and respond to inquiries.

Medication Error Prevention

The Board convened a forum during its July 2007 meeting to discuss medication errors and how to prevent them.

Regulation Activity

In 2007-08, the Board succeeded in securing regulatory changes for a new notice to consumers to ensure patients know their rights to obtain lawfully prescribed medication from a pharmacy.

Passage of Board-Sponsored Legislation

The following legislative changes occurred as a result of the Board's sponsorship and advocacy:

- Modifications to implement e-pedigree requirements were extended on a staggered basis from January 2015 through July 2017, and a number of other adjustments to California's e-pedigree requirements were made.

2008-2009

E-Prescribing

The Board continued to work with various groups to ensure the earliest adoption possible of e-prescribing of prescription medication. During the year, the Board hosted a public forum on e-prescribing with the Medical Board of California. E-prescribing, which is strongly supported by a number of patient and health care advocates, can help reduce many of the medication errors that cost the health care system billions of dollars and cause thousands of deaths annually.

Disaster Response

The Board continued to work with local and state officials on emergency preparedness and planning for pandemics and disasters. For example, the Board worked closely with the California Department of Public Health disseminating information to pharmacies and other licensees regarding the H1N1 flu virus.

Notice to Consumers Posters

The Board published and distributed new notice to consumers posters that must be displayed in pharmacies. These posters contain information to advise consumers of their rights to lawfully prescribed medication, and how to obtain optimal drug therapy from prescription medications.

Patient Disposal of Unwanted Medication

The Board participated with the California Integrated Waste Management Board in the development of guidelines for the take-back and destruction of prescription medication from patients. These guidelines were required by California law.

Filling of Internet Drug Orders by Pharmacies

The Board used its authority to cite and fine pharmacies $25,000 per prescription for filling orders obtained from website operators where the medication was not legally prescribed for patients.

Regulation Activity

In 2009-10, the Board succeeded in securing the following regulatory changes:

- An ethics counseling program was established as an option for pharmacists in disciplinary settlement actions.
- Compounding requirements were established for pharmacies that compound drugs or sterile injectable drugs.

- All self-assessment forms for pharmacies, compounding pharmacies and drug wholesalers were updated.

Passage of Board-Sponsored Legislation

The following legislative changes occurred as a result of the Board's sponsorship and advocacy:

- "Purpose" was added as a prescription container label element, if it is entered onto the prescription document by the prescriber.
- A designated representative at wholesaler premises must sign for all deliveries of drugs.
- Mobile pharmacies may be used in times of emergency response, or for temporary use nearby a licensed pharmacy that has been destroyed.
- The Board may convert a pharmacist's license to inactive status for failure to provide proof of completion of pharmacy continuing education.

2009-2010

Improvements to the Drug Recall System

The Board undertook an in-depth review of the 2008 heparin contamination crisis, which killed at least 81 patients nationwide despite widespread recalls. In 2008, the Board performed site inspections of all 533 California hospitals pharmacies and identified recalled heparin in nearly 20 percent of the hospitals, where recalled heparin was still in use on patients. In 2009, the Board completed a comprehensive review of the recall system with key stakeholders and developed guidelines for recalls in hospitals to prevent reoccurrence of recall failures in California.

Additionally, to ensure that all pharmacies are aware of recalls, and to facilitate immediate communication by the Board to its licensees, the Board secured a statutory amendment to require all facilities to maintain registration with the Board's e-mail "subscriber alert" system. A principal use of this system is to share recalls at the pharmacy or patient level. In 2010/11, 161 recall alerts were distributed by the Board.

Such alerts provide an important notification to ensure all pharmacies and wholesalers are aware of manufacturer recalls of dangerous drugs and devices, and that they take necessary action to quarantine and remove them from the market.

Criminal Conviction Unit

The Board established a criminal complaint unit in July 2009 to investigate Board licensees and applicants who have arrests and convictions. During the year, over 1,900 cases were completed, resulting in:

- 10 percent of the cases being referred for formal discipline (license revocation or restriction).
- 14 percent of the investigations resulting in issuance of a citation and fine or letter of admonition.

Regulation Activity

In 2009-10, the Board succeeded in securing the following regulatory changes:

- Pharmacists must certify at time of renewal that they have not been arrested or convicted of any crime.
- Applicants who compromise the pharmacist licensure examinations are prohibited from licensure and retaking the examination for three years in California.

Passage of Board-Sponsored Legislation

The following legislative changes occurred as a result of the Board's sponsorship and advocacy:

- A restored provision that requires pharmacist applicants to take 16 units of remedial education in a school of pharmacy if they fail either licensure examination four times.

2010-2011

Development of Standardized Patient-Centered Prescription Container Labels

Pursuant to legislation enacted to improve patient understanding and compliance with prescribed medication therapy, the Board promulgated the nation's first patient-centered prescription container labeling requirements that dedicate at least 50 percent of any label to the information most important to a patient. This patient-centered information must be in a specific order and enlarged type face size. The regulation also requires oral interpreter services in pharmacies for any patient with limited

English speaking skills. The Board is continuing its efforts in this area and will be posting online translations of standard directions for use in the future. New notice to consumer posters are also being developed to ensure the public has knowledge of these components.

Consumer Protection Enforcement Initiative

In response to an increase in the number and complexity of investigations, the Board partnered with the Department of Consumer Affairs (DCA) to develop and implement a multi-pronged solution to significantly reduce investigation times. The Board secured additional resources to perform investigations. The Board sponsored and secured legislative changes to remove barriers in its investigative process. The Board is providing significant staff resources to implement a new computer system for the department, replacing a legacy system developed in the early 1980s.

Consumer Education Videos

The Board developed two consumer education videos - - "Avoiding Medication Errors" and "Purchasing Drugs over the Internet." These educational videos empower consumers to make better choices when considering purchases of drugs over the internet, and outline steps patients can take to avoid becoming a victim of a medication error. In addition to posting these videos on the Board's website, they are also available on the California Consumer Protection Channel.

Educational Efforts to Curb Thefts from Pharmacies

The Board worked with the Drug Enforcement Administration (DEA) to host three day-long workshops on steps pharmacies can take to stop prescription drug thefts and diversion from their facilities. The Board awarded five hours of continuing education credit for attending these events.

Regulation Activity

In 2010-11, the Board succeeded in securing the following regulatory changes:

- Revised the "notice to consumers" postings that must be displayed in pharmacies, which includes information to promote better patient understanding of

drug therapy, the right to lawfully prescribed medication, and the right to consultation with a pharmacist, larger font on patient prescription container labels, and interpreter services.

- Updated the self-assessment forms that are required for use by pharmacies, including pharmacies that compound, and drug wholesalers.
- Added requirements that applicants for licensure as pharmacists, intern pharmacists and pharmacy technicians submit a self-query report from the Health Information Practitioner Data Bank to ensure there is no prior disciplinary action taken against these applicants by other states' regulators.

Passage of Board-Sponsored Legislation

The following legislative changes occurred as a result of the Board's sponsorship and advocacy:

- Strengthened reporting dead- lines to secure earlier mandatory reporting of drug thefts or firings of pharmacy staff for self use, diversion, or mental or physical impairment.
- Established time frames for providing copies of requested records to the Board.
- Prohibited a California revoked pharmacist from dispensing medication to patients in California from a nonresident pharmacy.

IV. STRATEGIC ISSUES AND PRIORITIES

The Board of Pharmacy regularly re-affirms ongoing strategic issues and identifies new issues to focus and prioritize Board activities and initiatives. These issues are summarized below.

Changing Demographics of California Consumers

California's senior population is growing, and that population is living longer. Aging consumers often have decreased cognitive skills, eyesight and mobility, and typically take more medication. Consequently, as the senior population increases so will the volume of prescriptions and the impact on pharmacists and pharmacy personnel to meet the demand.

California's population is also becoming more diverse with respect to race, ethnicity and primary language. This requires that pharmacists exhibit greater cultural awareness, and a broader range of communication skills than traditionally required of the profession. The increasing diversity of patients is coupled with a greater diversity of cultural beliefs related to healing and medicine, which may lead to purchase of prescriptions from non-traditional locations and providers.

Evolving Role of the Pharmacist

Pharmacist care is moving away from its role as a product-oriented profession to become more service-oriented, with a greater focus on patient care and outcomes. Maintaining the core competencies of the pharmacist profession as the role of the pharmacist evolves will be essential to improving health outcomes for Californians. A renewed emphasis on patient consultation and education will improve patient knowledge about their drug therapy and thus improve their overall health care.

Increasing Cost of Medical and Pharmaceutical Care

Demand for affordable health care services is increasing. At the same time, spiraling medical care and prescription drug costs may encourage people to take shortcuts in their drug therapy or seek medications from non-traditional pharmacy sources. With the increasing prevalence of the internet and web-based trade and services, patients can access drugs at different prices, worldwide. Patients seek lower cost medications from these sources assuming that these medications are the same quality they are accustomed to obtaining from their neighborhood pharmacies.

Drug shortages due to recalls, manufacturing delays, supply chain disruptions and/or outright market manipulation increase pressure on well-meaning pharmacists to obtain needed medications from questionable sources.

In addition, the high cost of drugs attracts unscrupulous individuals motivated by profit that can be made through illegal activities such as drug counterfeiting and drug diversion. This results in a flood of weak, ineffective or dangerous substances, thereby weakening public confidence in the present drug delivery system.

Increasing Online Drug Sales and Distribution

In addition to these many challenges ensuring a safe drug delivery system is the growing availability of prescription drugs over the internet. Easy access to drugs without authorized prescribers to evaluate patients or pharmacist participation places Californians at great risk. Entities promoting illegal drug distribution schemes have taken advantage of the internet, and the quality and authenticity of products and devices sold online is not verified. The State's ability to monitor and protect the public from improper drug distribution online is severely impaired due to continued resource constraints at the federal and State level.

Increasing Level of Prescription Drug Abuse

Prescription drug abuse is a growing problem among youth, young adults and older adults in California and throughout the nation. Frequently abused classes of prescription drugs include pain relievers, tranquilizers and sedatives, and stimulants prescribed to treat common conditions such as obesity, asthma and, most notably, attention deficit hyperactivity disorder (ADHD). Pain reliever prescriptions are now far more readily available on the internet, and consumers are able to fill multiple prescriptions at different pharmacies. Also, drug abuse among pharmacy staff continues, resulting in a growing need for data to help better understand the nature of this problem.

Lastly, California has not developed policy or systems to destroy unwanted and unneeded medication dispersed to patients. New laws are needed to deal with this problem

affordably without impact to the environment, and to provide reintroduction or diversion opportunities.

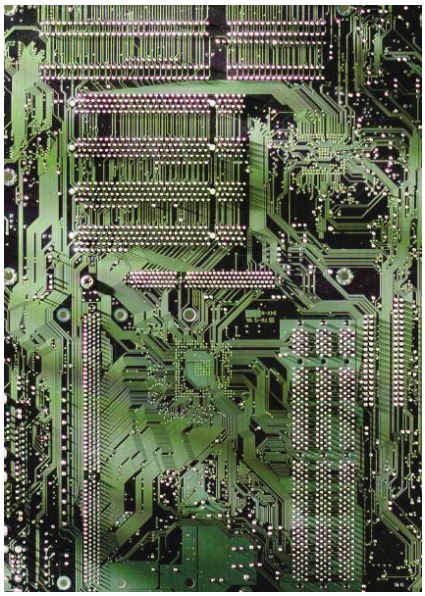
Increasing Prevalence of Counterfeit Drugs

There is an increasing prevalence of counterfeit prescription drugs bought and sold in the US as part of the legitimate drug supply. Counterfeit prescription drugs are a worldwide problem, reaching as high as 30 percent of the supply in some countries. The World Health Organization estimates that in developed countries, counterfeit drugs are less than one percent of the market.

The State of California has passed a series of anti-counterfeiting and anti-diversion laws to prevent counterfeit medicine from entering the legitimate supply. Legislative requirements include provisions pertaining to the licensure and qualifications of wholesalers, restrictions on furnishing, and the requirement of an electronic pedigree to accompany and validate drug distributions. Implementation of this legislation began in 2005 and continues today. The e-pedigree for prescription drugs will reduce the growing incidence of counterfeit, damaged, adulterated or misbranded medications in California's pharmacies, a critical part of ensuring the integrity of the drug delivery system. However, creating new strategies and adapting existing tools and systems to prevent counterfeit prescription drugs will remain a great challenge and high priority for the Board.

Expanding the Use of Information Technology

Technology will continue to impact the processing and dispensing of medication. Electronic prescribing and "channeling" to locations other than a traditional pharmacy may become the business model. Creation, maintenance and transfer of electronic, "paperless" patient records and prescription orders will be the norm in the future, resulting in new challenges ensuring that patient records remain confidential and secure. New and innovative tools to manage records will be required. Automated pharmacy systems and electronic prescribing will also impact pharmacies. New methods of dispensing medications raise additional issues with ensuring patient safety.



Prescription drug monitoring programs are being used by all states to prevent dispensing of controlled substances to "doctor-shopping" or drug abusing patients. In California, the future of the CURES program (California's prescription monitoring program) is in question due to funding issues. Maintaining this program is a priority for the Board.

V. STRATEGIC PLAN FRAMEWORK

The Board of Pharmacy's strategic plan serves as a blueprint for decision-making for the upcoming years. This plan framework includes the Board's vision and mission statements, shared values and strategic plan goals. The Board revisits the plan framework on a regular basis to re-affirm its primary roles and responsibilities, and the core principles by which it operates.

Vision, Mission and Values

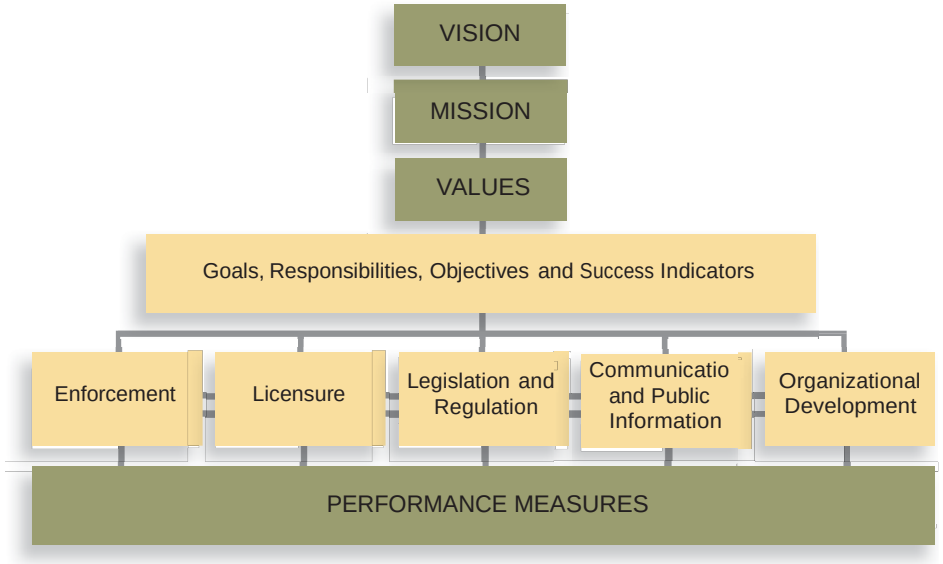
Vision Statement

Healthy Californians through safe, quality pharmacist care.

Mission Statement

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.

Figure 1: Strategic Plan Framework



Shared Values

Board members and staff adhere to the following values when considering all matters affecting the consumers of California and the profession of pharmacy.

Integrity: The Board exhibits integrity in all its actions to ensure the integrity of California's drug delivery system.

Transparency: Transparency in communications is central to all Board operations, oversight and enforcement activities.

Responsiveness: The Board takes timely action in response to strategic issues, and responds proactively to the changing needs of California consumers and licensees.

Compassion: The Board understands the diversity of Californians and their health care needs and advocates for strong consumer protection.

Goals

The Board of Pharmacy has established five goals that provide the framework for defining and implementing strategic objectives and monitoring Board progress:

Goal One: Enforcement

Exercise oversight on all pharmacy activities.

Goal Two: Licensure

Ensure the qualifications of licensees.

Goal Three: Legislation and Regulation

Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

Goal Four: Communication and Public Information

Provide relevant information to consumers and licensees.

Goal Five: Organizational Development

Achieve regulatory efficiency, customer service and consumer protection.

VI. CONSTITUENCIES OF THE BOARD

Meeting all constituency needs is central to the Board's mission and day-to-day operations. The following table provides an overview of Board of Pharmacy constituencies.

The Board reviews and updates its list of constituencies and their needs when updating the strategic plan to ensure that plan actions are designed to fulfill all related Board responsibilities.

Consituency	Consituency Needs
Consumers	A safe, affordable and high quality drug delivery system; qualified pharmacists; and positive health outcomes.
Applicants	Timely and fair access to licensure; and support and information.
Licensees	Regulation of practice; technical support and information; and enforcement of laws and regulations.
State Regulatory Agencies	Protection of the public interest and efficient administration of the program; and information and support.
Office of the Attorney General	Protection of the public interest and fair and efficient administration of all Board of Pharmacy programs.
Legislators	Consumer protection; responsiveness to enforcement of laws.
Professional Associations	Collaboration, support and information.

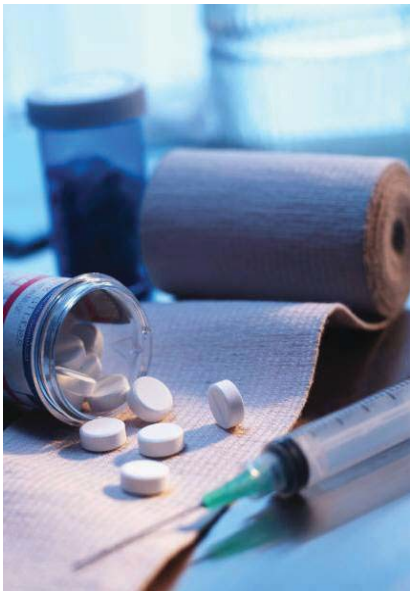
VII. PERFORMANCE MEASUREMENT

The Board of Pharmacy measures performance based on its ability to provide timely and efficient oversight and enforcement of all pharmacy activities, ensure the professional qualifications of all licensed pharmacists, and protect and engender the confidence of consumers in the safety and integrity of California's drug delivery system.

The Board has identified the following broad performance measures to help monitor and gauge Board performance and implementation of the strategic plan.

- Consumer Protection [CP]*
- Positive Health Outcomes [HE]
- Consumer Education [CE]
- Consumer Confidence [CC]
- Professional Competencies [PC]
- Efficiency in Operations [EF]
- Quality Enforcement [QE]
- Promulgation of Best Practices [BP]
- Regulatory Compliance [RC]

The Board has identified specific success indicators to measure progress towards achieving each strategic plan goal. Indicators are presented in the following section. Each indicator relates to one or more of the performance measures introduced above.



*Letters in brackets are abbreviations used later in this document.

VIII. IMPLEMENTATION AND ACTION PLAN

The Board's implementation and action plan includes the ongoing actions, strategic objectives, performance measures and success indicators to guide attainment of each of the plan's goals and to achieve the Board's vision and mission. Responsibilities, objectives and measures are organized according to the five strategic plan goals (each of which also refers to a Board strategic committee):

- **Enforcement**
- **Licensure**
- **Legislation and Regulation**
- **Communication and Public Information**
- **Organizational Development**

GOAL ONE: ENFORCEMENT

Exercise oversight on all pharmacy and drug distribution activities.

The following responsibilities of the Enforcement Committee support achievement of Goal One:

- Increase regulatory compliance through the use of targeted outreach and education. (new)
- Increase inter-agency partnerships to strengthen enforcement and consumer protection. (1.5/8)
- Administer the Pharmacists Recovery Program. (1.2/1)
- Administer the probation monitoring program. (1.2/2)
- Obtain immediate public protection sanctions for egregious violations. 1.2/5)
- Inspect licensed premises to educate licensees proactively about legal requirements and practice standards to prevent serious violations that could harm the public. (1.4/1)
- Initiate investigations based upon violations discovered during routine inspections. (1.4/3)
- Foster the implementation of e-pedigree on all prescription medications sold in California. (1.5/1)
- Collaborate with and monitor the efforts of the Drug Enforcement Administration, Department of Health and Human Services and other entities to implement e-prescribing for controlled substances. (1.5/3)
- Participate in emerging issues at the State and national levels affecting the health of Californians regarding their prescription medicine. (1.5/5)
- Work with other California agencies to implement requirements for model programs to take back unwanted prescription medicine from the public. (1.5/9)
- Use the Healthcare Integrity and Protections Data Bank (HIPDB). (1.5/17)
- Address extra-jurisdictional issues that impact the safety and integrity of California's drug delivery system, including web-based pharmaceutical prescriptions and trade, out of State activities, etc. (new)
- Conduct annual comprehensive review of investigative and enforcement activities to identify and implement process improvements. (1.5/15)
- Secure the continuation of CURES, enhance use of this prescription monitoring program by dispensaries, and include access to data across state lines. (new)

Strategic Objectives		Completion Date
1.1	Perform a trend analysis on violations of all types by type of licensee. (new)	January 2013
1.2	Establish a continuing education program on enforcement issues including security and drug abuse. (new)	January 2013 - Completed
1.3	Promulgate regulations required by SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) for recovery programs administered by Department of Consumer Affairs health care boards. (1.5/11)	July 2015 – Completed
1.4	Evaluate the effectiveness of the ethics course as an enforcement option. (1.5/4)	June 2014
1.5	Implement drug audits template for use by pharmacies. (5.4/7)	January 2014 - Completed
1.6	Develop regulations to implement e-pedigree. (new)	November 2013 – Pre-empted by Federal Legislation
1.7	Implementation of Sterile Compounding Inspections (new)	July 2015 - Completed
1.8	Develop New Compounding Regulations (new)	April 2016
1.9	Medicine Disposal (new)	April 2016
1.10	Reduce Loss of Controlled Substances and Maintain Inventory (new)	April 2016
1.11	Development and Implementation of CURES 2.0 (new)	July 2016
1.12	HR 3204 – DQSA – Drug Product Training Implementation (new)	July 2016
1.13	SB 1441 Uniform Standards Implementation Committee (new)	July 2016

Performance Measures and Success Indicators

The Board will assess the quality of its enforcement programs using the following performance measures and success indicators.

Performance Measures:

- Consumer Protection [CP]
- Consumer Confidence [CC]
- Efficiency in Operations [EF]
- Quality Enforcement [QE]
- Regulatory Compliance [RC]

Success Indicators		Related Performance Measures
1A	Complete all desk investigations within 90 days. (1.1/1)	[CP, CC, EF, QE, RC]
1B	Complete all field investigations within 120 days. (1.1/2)	[CP, CC, EF, QE, RC]
1C	Close all Board investigations and mediations within 180 days. (1.1/3)	[CP, CC, EF, QE, RC]
1D	Issue citations and fines within 30 days. (1.2/3)	[CP, CC, EF, QE, RC]
1E	Issue letters of admonition within 30 days. (1.2/4)	[CP, CC, EF, QE, RC]
IF	Complete all field investigation for cases involving drug abuse within 60 days. (new)	[CP, HE, QE, RC]
1G	Refer all cases to the AG's office within 10 days. (new)	[CP, QE, RC]
1H	Secure pleadings from AG's office within 90 days after referral. (new)	[CP, QE, RC]
1I	Inspect 100 percent of all licensed facilities once every three years by June 20, 2011. (1.4)	[CP, QE, RC]
1J	Review draft pleadings within 10 days. (new)	[CP, QE, RC]
IK	Perform quarterly status reports or for all referral cases pending. (new)	[CP, QE, RC]
IL	Protest proposed decisions and stipulations within 30 days. (new)	[CP, QE, RC]
IM	Evaluate the Pharmacists Recovery Program. (new)	[CP, QE, RC]

GOAL TWO: LICENSURE

Ensure the qualifications of applicants and licensees.

The following responsibilities of the Licensing Committee support achievement of Goal Two:

- Issue professional and occupational licenses to those individuals and firms that meet minimum requirements. (2.1/4)
- Deny licenses to applicants not meeting Board requirements. (2.1/5)
- Deny applications to those who do not meet California standards. (2.1/6)
- Respond to e-mail status requests and inquiries to designated e-mail addresses. (2.1/7)
- Respond to telephone status request and inquiries. (2.1/8)
- Make address and name changes. (2.3/1)
- Process off-site storage applications. (2.3/2)
- Transfer intern hours and license verification to other states. (2.3/3)
- Work with local and State officials on emergency preparedness and planning for pandemics and disasters, including the storage and distribution of drugs to assure patient access and safety. (2.4/4)
- Participate in ACPE reviews of California Schools of Pharmacy. (2.4/11)
- Improve reporting and accounting procedures for intern hours. (2.4/14)
- Evaluate continuing education requirement for pharmacists. (2.4/24)
- Inspect sterile compounding pharmacies initially before licensure and annually before renewal. (1.4/2)

Strategic Objectives		Completion Date
2.1	Work with the Department of Corrections on the licensure of pharmacies in prisons. Develop a regulation process to define licensure and drug distribution for prison pharmacists (2.4/3)	January 2013
2.2	Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians. (2.4/6)	June 2013
2.3	Evaluate licensing requirements for businesses seeking licensure that are under common ownership. (2.4/23)	June 2013
2.4	Implement the Department of Consumer Affairs BreEZe system to allow on-line licensing renewal application submission and enforcement tracking. (2.4/8)	January 2014 – Delayed
2.5	Expand background checks to include review of federal and other state records, arrest reports and prior convictions. (new)	July 2016
2.6	Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training. (2.4/12)	January 2016
2.7	Develop 4 State Protocols for Advanced Practice Pharmacist (new)	April 2016
2.8	Develop 2 Regulations for Advanced Practice Pharmacist including Travel Medications and Immunization (new)	April 2016
2.9	Develop and Implement Advanced Practice Pharmacist Licensure (new)	April 2016
2.10	Develop and Implement Third- Party Logistics Providers (3PL) Licensure (new)	July 2015 - Completed
2.11	Develop and Implement Automation Delivery Devices Licensure (new)	January 2017
2.12	Streamline Pharmacist Examination Application Requirements (new)	January 2016
2.13	Develop and Implement Centralized Hospital Packaging Pharmacies License (new)	January 2014 - Completed

Performance Measures and Success Indicators

The Board will assess the quality of its licensing program using the following performance measures and success indicators.

Performance Measures:

- Consumer Confidence [CC]
- Professional Competencies [PC]
- Efficiency in Operations [EF]
- Promulgation of Best Practices [BP]
- Regulatory Compliance [RC]

Success Indicators		Related Performance Measures
2A	Review initial applications within 30 days.	[PC, EF]
2B	Issue licenses within three working days of a completed application. (2.1)	[PC, EF]
2C	Review 100 percent of all applications within seven work days of receipt. (2.1/1)	[PC, EF]
2D	Process 100 percent of all deficiency documents within five work days of receipt. (2.1/2)	[PC, EF, RC]
2E	Cashier 100 percent of all revenue received within two working days. (2.2)	[EF]
2F	Update 100 percent of all information changes to licensing records within five working days. (2.3)	[EF]

GOAL THREE: LEGISLATION AND REGULATION

Advocate legislation and promulgate regulations that advance the vision and mission of the Board of Pharmacy.

The following responsibilities of the Legislation and Regulation Committee support achievement of Goal Three:

- Identify and advocate for legislative changes to keep pharmacy laws current and consistent with the Board's mission. (3.1)
- Identify and promulgate regulatory changes to keep pharmacy regulations current and consistent with the Board's mission. (3.2)
- Evaluate and secure statutory fee increase to ensure sufficient funding to fulfill all of the Boards statutory obligations as a consumer protection agency. (3.1/9)

Strategic Objectives		Completion Date
3.1	Produce new notice to consumers posters and produce video regarding patient-centered prescription labels. (3.2/19)	June 2012 - Completed
3.2	Update references to USP Standards (§1780). (3.2/20)	December 2012
3.3	Promulgate regulations for accreditation agencies for pharmacies that compound (§1751.x). (3.2/22)	December 2012 – Enactment of SB 294 removed the need to pursue this regulation
3.4	Revise and update the Board's Disciplinary Guidelines (section 1760). (3.2/5)	December 2012 – Completed – new revisions are underway
3.5	Prepare and participate in the 2012 sunset review. (new)	January 2013 - Completed
3.6	Evaluate regulations specifying container labels.	January 2014 - Completed
3.7	Update protocol for pharmacists furnishing emergency contraception (EC). (3.2/17)	July 2013 – Completed
3.8	Promulgate Board issued continuing education (CE) credit. (3.2/18)	December 2013
3.9	Strengthen renewal requirements for pharmacy technicians and designated representatives.	October 2015 – Completed
3.10	Implement e-pedigrees on prescription drugs dispensed in California. (3.1/7)	November 2013 – Pre-empted by Federal Legislation

	Strategic Objectives (Continued)	Completion Date
3.11	Add Self Query Report from the National Practitioner Data Bank –Healthcare Integrity and Protection Data Bank (NPDB- HIPDB) to the Pharmacist Intern Application & Pharmacist Examination Application (new)	July 2012 - Completed
3.12	Update Compounding Drug Product Regulation (new)	April 2013 - Completed
3.13	Update Emergency Contraception Regulation (new)	July 2013 - Completed
3.14	Update Partial Filling of Schedule II Prescriptions; Unprofessional Conduct Defined; and Criteria for Rehabilitation Regulations (new)	April 2014 - Completed
3.15	Update Fees to Statutory Maximums in Regulation (new)	July 2014 - Completed
3.16	Update Patient-Centered Label Requirement in Regulation (new)	April 2015 - Completed
3.17	Updated Requirements to Pharmacy Technician Application Regulation (new)	April 2016
3.18	Update Self-Assessment forms for Community Pharmacy, Hospital Pharmacy, and Wholesaler in Regulation (new)	April 2016
3.19	Develop and Adopt Emergency Regulations for the Protocol for Pharmacists to Furnish Naloxone Hydrochloride ("naloxone") without a Prescription (new)	April 2015 - Completed
3.20	Update Requirements for Compounded Drug Products in Regulation (new)	April 2016
3.21	Adopt Self-Administered Hormonal Contraceptive Protocol in Regulation (new)	April 2016
3.22	Adopt Nicotine Replacement Product Protocol in Regulation (new)	April 2016
3.23	Permanently Adopt Regulations for the Protocol for Pharmacists to Furnish Naloxone Hydrochloride ("naloxone") without a Prescription (new)	April 2016
3.24	Adopt Standards for Pharmacists to Initiate and/or Administer Vaccinations in Regulation (new)	April 2016
3.25	Adopt Licensing Regulations for the Advanced Practice Pharmacist (new)	April 2016

	Strategic Objectives (Continued)	Completion Date
3.26	Update Disciplinary Guidelines in Regulation (new)	April 2016
3.27	Require Drug Warning Labels in Regulation (new)	April 2016
3.28	Develop and Adopt Standards in Regulation for Pharmacists to Furnish Travel Medications (new)	April 2016
3.29	Require Reconciliation and Inventory Reporting of Controlled Substances in Regulation (new)	April 2016
3.30	Prepare and participate in the 2015 sunset review. (new)	January 2017
3.31	Develop and Implement Outsourcing Regulations (new)	January 2017

Performance Measures and Success Indicators

The Board will assess the quality of its legislation and regulation programs using the following performance measures and success indicators.

Performance Measures:

- Consumer Protection [CP]
- Consumer Confidence [CC]
- Promulgation of Best Practices [BP]

Success Indicators		Related Performance Measures
3A	Successful enactment of promoted legislative changes. (3.1/measure)	[CP, CC]
3B	Successful enactment of promoted regulatory changes. (3.2/measure)	[CP, CC]

GOAL FOUR: COMMUNICATION AND PUBLIC EDUCATION

Provide relevant information to consumers and licensees.

The following responsibilities of the Communication and Public Education Committee support achievement of Goal Four:

- Educate the public, licensees and health care professionals about critical health care issues. (4.1/4.2/4.3)
- Participate in forums, conferences and public education events. (4.4/1)
- Publish The Script. (4.2/1)
- Develop and conduct Board-sponsored continuing education programs. (4.2/2)
- Provide important and timely information on website. (4.2/3)
- Educate consumers about steps they can take to prevent medication errors. (4.1/10)

Strategic Objectives		Completion Date
4.1	Develop notice to consumers posters and video to comply with new regulations.	June 2012 - Completed
4.2	Restructure the Board's website to make it more user friendly. (4.1/2)	January 2016
4.3	Develop a communications plan. (new)	January 2013
4.4	Assess the effectiveness of the Board's educational materials and outreach: survey consumers to identify whether Board-produced materials are valued and what new materials are desired. (4.1/1)	June 2013
4.5	Collaborate with schools of pharmacy for pharmacist interns to develop consumer fact sheets on health topics. (4.1/4)	June 2014
4.6	Implement e-prescribing and educate consumers and licensees on related issues. (new)	September 2015
4.7	Use social media to reach key constituencies. (new)	January 2017
4.8	Produce Consumer Education Materials About Buying Prescription Drugs From the Internet (new)	January 2015 - Completed
4.9	Produce a Public Service Announcement About Prescription Drug Abuse (new)	April 2014 – Completed

	Strategic Objectives (Continued)	Completion Date
4.10	Develop a Prescription Drug Abuse Committee to Address National Epidemic (new)	September 2015 – Completed
4.11	Address Patient Consultation in Pharmacies	January 2017
4.12	Secure Legislation Regarding Label Translations	January 2016 – Completed
4.13	Refine Requirements for Patient-Centered Labels	April 2015 – Completed

Performance Measures and Success Indicators

The Board will assess the quality of its communication and education programs using the following performance measures and success indicators.

Performance Measures:

- Consumer Education [CE]
- Consumer Confidence [CC]
- Professional Competencies [PC]
- Promulgation of Best Practices [BP]
- Regulatory Compliance [RC]

Success Indicator		Related Performance Measures
4A	Increased access to Board educational materials.	[CE, CC]
4B	Publish The Script twice annually.	[BP, PC, RC]
4C	Evaluate requirements for patient-centered labels.	[CE, BP, RC]

GOAL FIVE: ORGANIZATIONAL DEVELOPMENT

Achieve regulatory efficiency, customer service and consumer protection.

The following responsibilities of the Organizational Development Committee support achievement of Goal Five:

- Streamline operations and maximize services. (5.1/1)
- Secure funding for high priority programs. (5.1/2)
- Use the strategic plan to guide all Board activities and committees. (new)
- Manage the Board's financial resources to ensure fiscal viability and program integrity. (5.1/4)
- Perform annual performance and training assessments of all staff. (5.2/3)
- Ensure that the Board has sufficient staff resources to carry out its mission. (new)
- Convene annual inspector meetings to ensure standardized investigation and inspection processes, and provide law and practice updates. (5.5/3)
- Perform succession planning to ensure continuity for Board operations. (5.7)
- Respond to subpoenas within the timeline specified. (5.8/2)
- Respond to specific requests for public information. (5.8/3)
- Analyze Board operations to identify potential process improvements. (new)
- Identify best practices and apply as appropriate. (new)

Strategic Objectives		Completion Date
5.1	Enhance the Board's orientation and training program for new Board members. (new)	January 2016
5.2	Develop a performance measurement framework for the Board that includes specific indicators, targets and data sources for each strategic plan goal. (new)	June 2012 - Completed
5.3	Implement BreEZe. (new)	January 2014 – Delayed
5.4	Secure Updated Fee Structure Allowing for Increased Costs of Services (new)	October 2015
5.5	Implementation of Organizational Change Reflecting Staff Growth and Management Structure (new)	January 2016

Performance Measures and Success Indicators

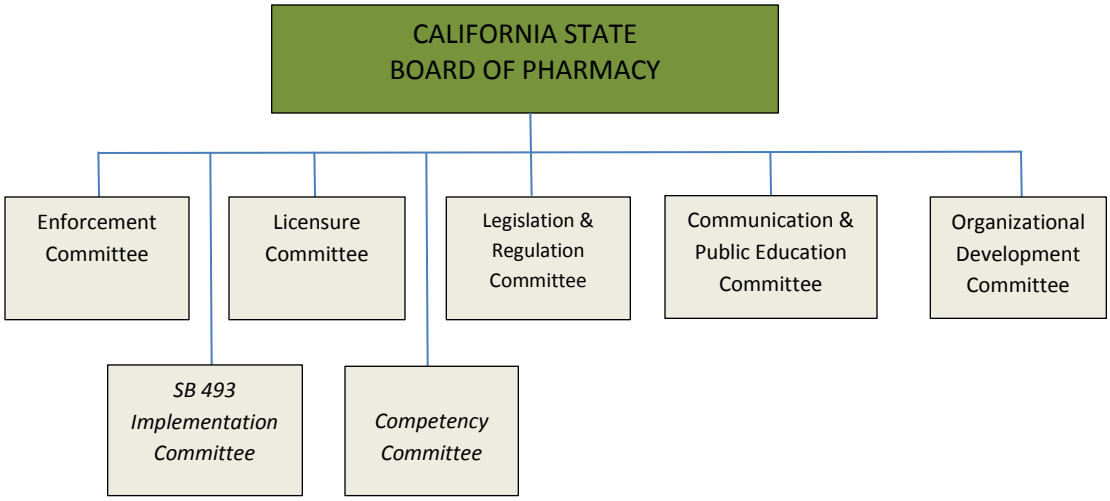
The Board will assess the quality of its organizational development programs using the following performance measures and success indicators.

Performance Measures:

- Consumer Protection [CP]
- Positive Health Outcomes [HE]
- Consumer Education [CE]
- Consumer Confidence [CC]
- Professional Competencies [PC]
- Efficiency in Operations [EF]
- Quality Enforcement [QE]
- Promulgation of Best Practices [BP]
- Regulatory Compliance [RC]

Success Indicators		Related Performance Measures
5A	Obtain approval for identified program needs each budget year. (5.1)	[EF, BP]
5B	Fill vacant Board positions in a timely manner. (5.2)	[CC, EF, QE]
5C	Number of staff trained for advanced duties and/or promoted (5.7/measure)	[PC, EF]
5D	Respond to all public record requests within 10 days. (5.8)	[CC, EF]

Appendix A | Board of Pharmacy Strategic Committee Structure



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BE AWARE & TAKE CARE: Talk to your pharmacist!