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CALIFORNIA BOARD OF PHARMACY

BOARD MEMBERS

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DEAN GRAFILO, DIRECTOR, DEPARTMENT OF CONSUMER AFFAIRS
VIRGINIA HEROLD, EXECUTIVE OFFICER, BOARD OF PHARMACY
MESSAGE FROM THE BOARD PRESIDENT

The strategic planning process of the California State Board of Pharmacy (board) is an annual activity involving board members, staff, and the public, all in an effort to anticipate and plan for events and issues for the coming years. In building its future strategic plan, the board focuses on pending changes in pharmacy practice, consumer needs and demands, and health care trends that impact the profession. After a lengthy discussion of potential and existing issues, the participants go through a process that categorizes, consolidates, and prioritizes the issues. This leads to the development of specific goals for the coming years. The resulting strategic plan is utilized by the board to ensure focus on established goals while allowing for flexibility in addressing new issues and challenges as they arise.

Board activity is organized through five policy committees: Enforcement and Compounding, 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 in conjunction with public input. Each board committee considers its individual strategic plan goals at meetings, and progress on the goals is periodically reviewed at full board meetings. The careful planning and continuous monitoring of the strategic plan assures that the board achieves its planned objectives and provides consumer protection in a manner that promotes optimal efficiency.

The board publishes advance notice of each strategic planning meeting, and participation and contribution are encouraged. Active involvement of the board, its staff, and the public results in the development of a strategic plan that truly represents the board’s mission and promotes public-focused actions for Californians.
ABOUT THE BOARD OF PHARMACY

The Board of Pharmacy (board) is an active consumer protection agency responsible for regulating a dynamic pharmacy health care profession. The board provides regulatory oversight to those who dispense, compound, store and transport prescription drugs and devices, as well as those who provide professional services that are focused on medication management and pharmaceutical care. As a national leader in consumer protection and pharmacy regulation, the board has developed and implemented a number of policies to ensure the quality and safety of medications provided to California’s consumers, in addition to monitoring the services provided by its licensees.

Today, the board oversees all aspects of the practice of pharmacy in California: the practitioner (the pharmacist), the practice site (the pharmacy), and the product (prescription or compounded drugs and devices). Additionally, the board regulates drug wholesalers, other practitioners and specialized facilities that store and furnish prescription drugs or handle and remove outdated medication from the drug supply.

With an annual budget exceeding $20 million and more than 100 staff, the board licenses over 140,000 individuals and firms and enforces 25 distinct and varied regulatory programs.

Much of the board’s work is carried out by committees. These committees develop recommended policies that advance mission-related goals in line with the board’s strategic plan. Committee recommendations are then discussed, modified, or acted upon by the board at public board meetings. The board and its committees are organized as follows:
POLICY BOARD
13 Members
(7 Pharmacists, 6 Public Members)
2012 – 2016 ACCOMPLISHMENTS

- The board has strengthened its regulatory framework for pharmacies that compound sterile drug products. These actions were taken in large part in response to a national public health emergency identified in Massachusetts that resulted in an impact to patients across the United States. Actions include an increase in the frequency and quality of inspections performed by the board, including annual inspections of out-of-state pharmacies that ship sterile products into California.

- The board refined patient-centered labeling requirements to improve readability of the standardized prescription label for consumers. Additional actions include development of translated directions for use on labels and a requirement that oral interpreters are available within pharmacies for patients with limited English proficiency. The board’s standards have been recognized by three national organizations as standards for prescription label design.

- The board developed a multi-pronged approach to combat the prescription drug abuse epidemic. These actions include education to consumers and licensees, aggressive enforcement of errant licensees, and the designation of a precedential decision involving a pharmacist’s corresponding responsibility. The board also created a state protocol for use by pharmacists that allows the dispensing of an antidote (naloxone) without a prescription for use in opioid overdose. The board also has advocated for the much-needed upgrade to California’s prescription drug monitoring program (CURES) and widely promoted and facilitated pharmacist access to the CURES system in order to increase review of a patient history prior to the dispensing of controlled substances prescriptions by a pharmacist.
PHARMACY ACCOMPLISHMENTS

• On August 9, 2013, the board voted to create its first precedential decision. This decision involved the revocation of a pharmacist’s and pharmacy’s licenses for excessive dispensing of controlled substances to patients. The decision defines “red flags” that pharmacists and pharmacies should recognize when dispensing controlled substances and after a pharmacist evaluates the prescription to make certain it is valid and legitimate on its face. There is also a duty to evaluate the patient, the prescriber, and the medication therapy.

• The board created several statewide protocols that permit pharmacists to provide specific consumer health care services such as smoking cessation, self-administered hormonal contraception, and naloxone. Additionally, the board has developed the framework to license advanced practice pharmacists, an important change in professional scope that will result in improved health care access for consumers across the state.

• The board responded during state wildfire emergencies declared by the Governor to ensure consumer access to pharmaceuticals.

• The board has collaborated with other state, federal, and local agencies in pursuing pharmacy law violations to achieve more complete consumer protection. For example, three county district attorney offices have collected over $1.5 million in fines from CVS, Rite Aid, and Walgreen pharmacies for violations of California’s unfair business practices statute for failure to provide patients with oral pharmacist consultation as required by state law.

• The board has represented California at a 2015 CDC (Centers for Disease Control and Prevention) International Conference on Emerging Infectious Diseases and provided a presentation on medication contamination and counterfeiting. The board participated on a PEW Charitable Trust committee that developed best national practices for sterile compounding pharmacies and outsourcing facilities, recognizing California’s national leadership and prominence in this focus area.

• The board has provided presentations at three FDA national meetings on topics such as sterile compounding and regulation of drug wholesalers/third-party logistics providers. It has also participated in forums convened by the DEA and National Association of Boards of Pharmacy in developing national policy. The board’s multiple statewide joint educational forums with the DEA on prescription drug abuse and corresponding responsibility are well-attended, and pharmacists who attend can earn continuing education in a subject area advocated by the board.

• Beginning in 2014, the board conducted a study on the practice of pharmacy as a way to validate the California Pharmacist Licensure Examination (CPJE). This study was done consistent with the provisions of Business and Professions Code section 139. The results of this survey were used to update the content outline for the CPJE for future examinations.
CURRENT BOARD AND INDUSTRY ISSUES

• PRESCRIPTION DRUG ABUSE

Most people who abuse prescription opioid drugs initially get them for free from a friend or relative. However, those at highest risk of overdose are more likely to get them from a doctor's prescription. This finding underscores the need for continued prevention efforts that focus on physicians’ prescribing behaviors and pharmacies’ dispensing practices. As the agency responsible for regulating the practice of pharmacy, the board must be a leader in combating the prescription drug abuse problem.

In California, the board has taken a comprehensive approach to addressing this problem. It developed a protocol to allow pharmacists to furnish naloxone, a medication that when administered in a timely manner can save a patient from an opioid overdose. In ongoing efforts, the board has taken both an educational approach as well as an enforcement approach to address this issue. California has the greatest number of opioid overdose related deaths in the US; the board’s efforts in this area must expand and continue.

Further, recognizing that many individuals first start abusing medications by gaining access to opioid medications that remain in the home, the board also established regulations for taking back prescription drugs. These regulations serve as a complement to the regulations established by the Drug Enforcement Administration and ensure that consumers have a safe and convenient way to dispose of unwanted and unused medications.
• **PHARMACY WORKFORCE**

The role of a pharmacist continues to evolve. The implementation of the Affordable Care Act and creation of the new licensure category of advanced practice pharmacist focus on collaborative practice with other health care providers. Pharmacists are recognized as underused health care providers given their education and training and are well positioned and accessible to the public to provide patient care. The board will continue to evaluate opportunities for expanded practice areas where pharmacists can provide services to patients that otherwise would have barriers to such care.

As the role of pharmacists changes, the board is initiating an evaluation of the role that pharmacy technicians will play in this emerging practice environment. The board started this evaluation in the fall of 2015, with the goal of identifying optimal practice standards for multiple pharmacy personnel. The board’s Licensing Committee is conducting this evaluation, which will continue in 2017 and possibly beyond.

Additionally, as pharmacies look for ways to automate functions, the board needs to be heavily involved in the expanded use of automation technology to ensure patients retain ready access to pharmacists.

• **LICENSING SYSTEM**

For a number of years, the Department of Consumer Affairs (DCA) has worked to replace and/or enhance its legacy licensing and enforcement tracking systems used by most DCA agencies. The system selected was a commercial off-the-shelf product (COTS) that was intended to streamline processes, provide better access for consumers and licensees, and help programs within the department gain better reporting tools. The board needs to continue its efforts to work with the department to identify a replacement system (either the COTS system previously identified or another system) that will better serve applicants, licensees, and consumers with more robust functionality and ease of use.

• **PHARMACY COMPOUNDING**

Pharmacy compounding is developing into a more frequent practice of pharmacies. The board has worked to strengthen California’s regulatory framework for pharmacies to improve the quality of compounded medication made by pharmacists. After promulgating regulations, the board must now focus on implementing these requirements, educating pharmacists and pharmacies about compliance, and promoting the construction of compliant modifications to pharmacies. As the practice of compounding continues to evolve, the board must continue to expand its efforts in this area as well as respond to changes in the marketplace and the evolution of new business models such as outsourcing facilities.
STRATEGIC PLANNING PROCESS

To understand the environment in which the board operates and identify factors that could impact the board’s success, the California Department of Consumer Affairs’ SOLID Unit facilitated the development of the board’s strategic plan. SOLID worked with the board to identify strategic goal areas, which act as stems for the board’s strategic objectives. The illustration below details how the board’s strategic plan is constructed by determining (1) the strategic goal areas, (2) objectives under each goal area, and (3) creation of success indicators in the board’s subsequent action plan.

SOLID conducted an environmental scan of the internal and external environments respective to the board’s goal areas by collecting information through the following methods:

- An online survey sent to board stakeholders in February 2016. The online survey received 320 responses.
- An online survey sent to all board employees in February 2016. This survey received responses from 50 employees.
- A focus group conducted with board managers in March 2016.
- Interviews with nine board members, the executive officer, and the assistant executive officer in April 2016.

Themes and trends identified from the environmental scan and future board initiatives were discussed by board members and board executive staff during a public strategic planning session facilitated by SOLID on June 7, 2016. This information guided the board in the development of its strategic objectives outlined in this 2017 – 2018 strategic plan.

The board also considered its mission statement, vision statement, and internal values as driving forces behind the development of its strategic objectives.
STRATEGIC GOAL AREAS

- Licensing
- Enforcement
- Legislation and Regulation
- Communication and Public Education
- Organizational Development

- Create Objectives for each goal area
- Determine action steps and success measures for each objective
MISSION, VISION, AND VALUES

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

VISION
Healthy Californians through quality pharmacists’ care.

VALUES
Integrity
Transparency
Responsiveness
Compassion
STRATEGIC GOAL AREAS

1 LICENSING
The board promotes licensing standards to protect consumers and allow reasonable access to the profession.

ENFORCEMENT
The board protects consumers by effectively enforcing laws, codes, and standards when violations occur.

2 LEGISLATION AND REGULATION
The board pursues statutes, regulations, and procedures that strengthen and support the board’s mandate and mission.

3 COMMUNICATION AND PUBLIC EDUCATION
The board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

4 ORGANIZATIONAL DEVELOPMENT
The board provides excellent customer service, effective leadership, and responsible management.
GOAL

LICENSING

The board promotes licensing standards to protect consumers and allow reasonable access to the profession.

1.1 Research and identify issues that result from unlicensed vendors in the marketplace to proactively maintain patient safety and health.

1.2 Implement online application, license renewal, and fee payment for applicants and licensees to improve licensing conveniences.

1.3 Complete a comprehensive review of at least five licensure categories and update requirements to ensure relevancy and keep licensing requirements current with professional practices.

1.4 Explore, and possibly implement, opportunities to use contracted organizations to administer the board’s California Practice Standards and Jurisprudence Examination to increase access to the examination.

1.5 Improve the application process for new licensees, including providing informational resources directed toward applicants to offer more guidance about the application process.

1.6 Establish requirements to form a licensing process for alternate work sites and vendors in the pharmacy marketplace to advance patient safety and health.

1.7 Identify opportunities to expand electronic interfaces with licensees to allow for online application and renewal.
ENFORCEMENT

The board protects consumers by effectively enforcing laws, codes, and standards when violations occur.

2.1 Implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.

2.3 Collect data and report to board members about enforcement trends that are presented at case closures so the board can better educate licensees about board priorities.

2.4 Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.

2.5 Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

2.6 Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.

2.7 Investigate options on the interoperability with a National Prescription Drug Monitoring Program.
GOAL

3

LEGISLATION AND REGULATION

The board pursues statutes, regulations, and procedures that strengthen and support the board’s mandate and mission.

3.1 Educate the board on national pharmacy initiatives impacting consumers and the future of pharmacy (e.g., pharmacists, pharmacy, technicians, distributors, etc.) to strategize the board’s efforts in alignment with where the profession is going to be in 2020.

3.2 Support legislative and regulation proposals from board approval to enactment to effectuate the goals of the board.

3.3 Advocate for or against legislation that impacts the board’s mandate for consumer protection.

3.4 Establish a systemized, ongoing review process for board regulations to improve and maintain clear and relevant regulations.
COMMUNICATION AND PUBLIC EDUCATION

The board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

4.1 Develop and implement a communication plan for licensees and consumers to improve communication and keep these stakeholders better informed.

4.2 Identify and use additional resources for public and licensee outreach services to implement the communication plan.

4.3 Establish a process to collect e-mail addresses and mobile numbers for text messaging from all licensees for better ability to improve communication.

4.4 Provide implementation guidance on newly enacted changes to Pharmacy Law by publishing summaries and explaining implementation tactics.

4.5 Inspect pharmacies at least once every four years to provide a forum for licensee-inspector communication and education in practice settings.

4.6 Communicate the availability of new or specified pharmacy services and locations so that the public is aware of pharmacies that can meet their needs.

4.7 Revise consumer-facing materials (e.g., posters, point-to-your-language notices, television messages) to achieve better consumer understanding of their rights and optimal use of medications.

4.8 Promote board initiatives to improve patient knowledge, medication adherence, and medication safety.
ORGANIZATIONAL DEVELOPMENT
The board provides excellent customer service, effective leadership, and responsible management.

5.1 Conduct a full annual review of the board’s strategic plan to monitor progress.

5.2 Provide leadership training opportunities to managers to expand skills and improve performance.

5.3 Expand annual individual development plans for staff to promote growth and development.

5.4 Collaborate with the Department of Consumer Affairs to explore the feasibility of procuring electronic management tools to increase efficiencies and reduce reliance on paper.

5.5 Maintain procedure manuals to capture institutional knowledge and enable consistent operations.

5.6 Establish customer service metrics to track board efforts to meet customer expectations.

5.7 Evaluate options for improvement of licensing renewal processes to allow for online renewal.

5.8 In collaboration with the executive officer, ensure appropriate resources for board issues relating to staff activities and development.
CALIFORNIA STATE BOARD OF PHARMACY

For information about the board, Board meetings, consumer and licensee education material, applications for licensing, as well as information on other public forums vital to pharmacy services, visit the board’s website, www.pharmacy.ca.gov.
This strategic plan is based on stakeholder information and discussions facilitated by SOLID for the California Board of Pharmacy during 2016.