

California State Board of Pharmacy 2720 Gateway Oaks Drive, Ste 100 Sacramento, CA 95833 Phone: (916) 518-3100 Fax: (916) 574-8618 www.pharmacy.ca.gov



To: Board Members

Subject: Agenda Item V - Strategic Plan

a. Discussion and Consideration of Board's Strategic Plan

Background

During its October 26-27, 2016, meeting, the Board approved its current strategic plan. Historically, the Board has conducted an annual review of its plan. The strategic plan is intended to be living document and updated to reflect changes in Board priorities that may result from changes in the marketplace, legislation, etc. Strategic plans are typically a five-year plan. It is anticipated that Board will engage in the strategic planning process during its September 2021 meeting.

For Board Discussion and Consideration

In preparation for this annual review staff have provided updates to the strategic goals. Several of the Committee's recently reviewed these updates. During the meeting the Chairperson from the respective committee will provide a summary of the goals and where appropriate will offer recommendations consistent with its committee discussion.

Goal 1: Licensing

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

Goal 2: Enforcement

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

Goal 3: Legislation and Regulation

The Board pursues statutes, regulations, and procedures that strengthen and support the Board's mandate and mission.

Goal 4: Communication and Public Education The Board educates consumers, licensees, and stakeholders about the practice and regulation of the profession.

Goal 5: Organizational Development

The Board provides excellent customer service, effective leadership, and responsible management.

The Board's <u>plan</u> is published on its website. Following this memo are the goals for each Committee, including status updates. Where recommendations are offered by a committee, the recommendation is included following status updates.

b. Overview of Process for Strategic Planning Session

In preparation for the development of a new strategic plan, an environmental scan survey was released in April 2021. Over 2,200 stakeholders responded to the survey as well as 31 staff. In addition, members were interviewed. During the September 2021 meeting, members will participate in a strategic planning session that will be facilitated by staff from the Department of Consumer Affairs, Strategic Organization, Leadership and Individual Development (SOLID) office. During the session members will have opportunity to discuss the results of the environmental scan, review trends identified and established goals and objectives for the new plan.

Given the significant number of responses, it may be appropriate for the Board to delegate to the President authority to work with staff to evaluate the information and provide recommendations that could be used to guide the discussion during the planning session.

UPDATE - Licensing Committee Strategic Goals

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

May 2020 Status:

- The Board implemented online license renewal payment to accept credit card payment for the individual licenses beginning in 2018. The board is continuing to work with the department to establish online license renewal payment for facility licenses.
- The Board implemented the ability to complete the application for issuance of a pharmacist license online and accepting online credit card payment for the initial license fee in December 2019. This has significantly improved the issuance process for pharmacist licenses.
- Board staff has continued the Business Modernization process, including analyzing the process used to assess business processes and determine how best to meet the needs of the organization and stakeholders.
 July 2021 Status
- The Board's online license renewal and collection of payments was expanded to include pharmacy renewals.
- Business Modernization efforts ceased while staff efforts were redirected to respond to the COVID-19 pandemic.

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

May 2020 Status:

- Post implementation review of the Advanced Practice Pharmacist is ongoing. Amendments to Business and Professions Code section 4211 went into effect January 1, 2020, which aligned the continuing education renewal requirements during the initial renewal cycle as well as the ability for an advanced practice pharmacist to have an inactive license to align with the pharmacist requirements.
- Occupation Analysis has been completed for both the recognized pharmacy technician certification examinations and regulation changes are pending to update the training requirements.
- Review of hospital pharmacy practice was evaluated, and legislative changes secured to established satellite compounding pharmacies. The board is continuing to receive hospital satellite compounding applications for licensure.
- Post implementation review of the Automated Drug Delivery Systems (ADDS) remains ongoing. The Board approved action to pursue legislative authority to expand Business and Professions Code section 4427.3 and add a new section to include authority to license ADDS to be used in all facilities listed in Health and Safety Code section 1250 as well as other

locations licensed by the State that, as a function of licensure, are authorized to offer medication services. The Board continues to work with DCA in implementing the application and license process in its applicant tracking and licensing database system. Staff continues to process the applications and license renewals manually.

- The Board voted to pursue legislative authority to amend Business and Professions Code section 4161(h) to provide an alternative pathway for licensure of a nonresident third-party logistics provider.
- The Board approved action to pursue legislative authority to align the requirements for the designative representative license types across various practice settings where appropriate.
- The Committee is developing the creation of advanced pharmacy technician proposal.

July 2021 Status

- AB 1533 (Assembly Committee on Business and Professions) includes statutory changes to implement changes stemming from program reviews, including expanding locations for ADDS licensure, changes to Advanced Practice Pharmacist requirements for license, alignment for designated representative licensure requirements, and an alternative pathway to licensure for nonresident third-party logistics providers.
- Committee continues review of Authorized Functions of a Pharmacy Technician.

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

May 2020 Status:

- To comply with The Americans with Disability Act (ADA), the applications for licensure have been made ADA accessible and as such, the instructions have been reformatted, if necessary, to simplify the requirements in assisting applicants in understanding what makes an application complete.
- Staff will continue to monitor and identify the most common deficiency items to clarify application instructions.
- Board staff continues with the evaluating the Business Modernization process, including the process used to assess business processes and determine how best to meet the needs of the organization and stakeholders.

<u>July 2021 Status</u>

• Applications updated to include provisions of Assembly Bill 2113 (Chapter 186, Statutes of 2020)

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

May 2020 Status:

- The passage of AB 2037 became effective on September 21, 2018 as well as SB 1447 became effective on July 1, 2019 to operate a licensed ADDS.
- AB 690 includes the requirements for pharmacy technicians to work in a remote dispensing site pharmacy. On October 9, 2019, this bill was chaptered and approved by the Governor which amended Business and Professions Code sections 4062 and 4132. The remote dispensing site pharmacy application is available on the Board's website, which includes the requirements for the pharmacy technician to work in a remote dispensing site pharmacy.
- July 2021 Status: In response to the COVID-19 pandemic, Board approved a temporary waiver to Business and Professions Code section 4071.1, expanding the provisions for remote order entry for pharmacists and pharmacy technicians. This general waiver has since expired and the Board will consider site-specific waivers going forward as the State begins the process of completely reopening consistent with the Governor's amendment of various executive orders.

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

May 2020 Status:

- The Board is continuing to work on Business Modernization.
- Online renewal is available for several license renewals.
- The Board recently implemented electronic notification via email to individuals at the time the Board issues their license. This provides immediate notification to the licensee.
- The Board recently implemented emailing exam pharmacist applicant's notification of eligibility for the examinations. This provides immediate notification to the applicant allowing for timely scheduling of upcoming exam dates.

<u>July 2021 Status:</u>

- Board implements online transcript verification process with the National Association of Boards of Pharmacy.
- The Board's online license renewal and collection of payments is expanded to include pharmacy renewals.

1.6 Implementing New Licensing Programs

- May 2020 Status: The Board implemented the following licenses within FY 2018/2019:
- Designated Representative-Reverse Distributor
- Designated Paramedic
- Clinic Co-location
- Correctional Clinics
- ADDS licensure

<u>July 2021 Status</u>: The Board currently does not have new licenses to implement.

1.7 Annual Benchmarking with National Practice Standard

May 2020 Status:

- As part of the Board's assessment and development of the advanced pharmacy technician proposal, the Board reviewed and considered pharmacy technician requirements at the national level, including education, authorized duties and staffing considerations.
- As additional licensing programs are evaluated (consistent with strategic goal 1.2), national benchmarking will be performed. <u>July 2020 Status:</u>
- Board staff monitor actions taken by other jurisdictions in response to COVID-19 pandemic.
- Board considers actions taken by other states in response to the FDA MOU Addressing Certain Interstate Distributors of Compounded Drugs.

Committee Recommendation: Recommend to the Board include in its next strategic plan, incorporation of a future strategic plan to focus on evaluation of various pharmacy practices and determination if changes in the law to reflect the variances in the practice are appropriate.

Update - Enforcement and Compounding Committee Strategic Goals

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.

Status May 2020:

- Investigation processing times are reported at meetings. Case priorities are reviewed and a team approach to case assignments and case outcomes has been implemented.
- The Committee is considering parameters for an alternative enforcement model.

Status July 2021:

• Committee and Board approve development of a pre-filing conference to achieve policy goal of reducing case resolution time and cost.

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

<u>Status May 2020:</u>

- Inspectors continue to include in their routine inspections, pharmacy staff's compliance with consultation laws. Where noncompliance is noted, inspectors provide education as part of the inspection process and findings are included in investigation reports. As part of investigations into allegations of medication errors, consumers are contacted to determine if consultation was provided.
- Annual reporting on compliance observed through inspections will be provided.

Status July 2021:

- Inspectors continue to include as part of the inspection process, assessment of compliance for patient consultation requirements. Fortyfour violations of failure to provide consultation were identified during inspections conducted in FY 2020/21. In addition, 60 citations were issued.
- Effective October 1, 2021, the Board updated Duty to Consult regulations. Updated regulations establish minimum consultation requirements for prescriptions mailed or otherwise delivered to patients.
- In response to COVID-19, the Board's waiver to provide for alternative method of consultation remained in effect during FY 2020/21.

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.

<u>Status May 2020:</u> Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the common violations resulting in the issuance of citations. Further, information on top violations are reported in *The Script* and were reported in the Board's Sunset Report. <u>Status July 2021:</u> Multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the common violations resulting in the issuance of citations and common violations are reported in *The Script*.

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

<u>Status 2020:</u> The board convened a technology summit on the use of automated drug delivery systems (ADDS) and evaluated the findings of a pilot project to expand the use of ADDS. The board secured statutory changes to expand the use of ADDS in Senate Bill 1447 (Hernandez, Chapter 666, Statutes of 2018.)

<u>Status 2021:</u>

- In response to COVID-19 pandemic, the Board approved a waiver to expand conditions for remote order entry as well as remote supervision that expired in June 2021. The Board is now considering only site-specific waivers in this area.
- Committee considered provisions of Assembly Bill 2789 (Wood, Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission and recommends development of Frequently Asked Questions to assist licensees with compliance.
- Committee received presentation by the National Association of Boards of Pharmacy on the development of a Compounding Pharmacy Information-Sharing Project to help implement the FDA MOU on interstate compounding pharmacies.

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

Status May 2020:

• In coordination with the Office of the Attorney General, the board

initiated a review to improve the efficiency of the disciplinary process. The overall goal with the cooperation of the Attorney General's Office is to process all cases through the office of the Attorney General within one year.

• The Committee continued its consideration of an alternative enforcement model.

<u>Status 2021:</u>

- Committee approved educational materials intended to assist respondents with an understanding of the administrative case process.
- Committee and Board approve development of a pre-filing conference as part of the disciplinary process.
- Committee received a presentation by the Office of the Attorney General on its Annual Report to the Legislature including disciplinary case comparison data from FY 2018-19 and FY 2019/20.

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

<u>Status May 2020:</u> Assembly Bill 1751 (Low, Chapter 478, Statutes of 2018) established the authority for the Department of Justice to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information. The Department of Justice is in the process of implementing these provisions.

<u>Status July 2021:</u> The Department of Justice continues its efforts to implement information sharing across state lines.

2.7 Develop a process to submit complaints about inspectors anonymously and report back to the board.

<u>Status May 2020:</u> The board developed a brochure to be distributed to licensees at the time of inspection. Included in the brochure is information on filing a comment or complaint with the board's parent agency, the Department of Consumer Affairs. The brochure is also posted on the board's website. **Completed.**

2.8 Assess the collateral consequences of post discipline and research options.

<u>Status May 2020:</u> The Enforcement Committee initiated a review of the Board's Disciplinary

Guidelines during the March 2019 Board Meeting. Further work did not occur as the Committee focused on other competing priorities.

<u>Status July 2021</u>: Committee will resume its discussion and evaluation of the Board's Disciplinary Guidelines.

2.9 Evaluation of the Board's Citation and Fine program.

<u>Status May 2020:</u> The Committee has received several presentations on the citation and fine program and will continue to receive annual updates. The Committee completed its review of policy direction provided by the president and vice-president. Assessment and feedback by Board leadership continues including discussion on priorities and other factors that should be considered when issuing citations and fines. Annual review of the program will continue to assess trends and educational opportunities.

<u>Status July 2021:</u> Committee receives annual presentation on citation and fine program. Assessment and feedback by Board leadership continues, providing policy direction considerations when issuing citations and fines.

2.10 Review the role and responsibility of the PIC.

<u>Status May 2020:</u> Senate Bill 476 (Stone) would have created a task force to study and submit a report to the Legislature on the prevalence of management interference upon the ability of pharmacists-in-charge to do their jobs and any legislative recommendations for improvement. SB 476 was held in committee and under submission on May 16, 2019. No further action has been taken on this strategic goal. The committee agreed during through discussion that the role and responsibility of the PIC will be discussed with the review of the Disciplinary Guidelines.

Status July 2021: No subsequent action has been taken on this item.

Committee Recommendation: Clarify Goal 2.10 - To review the current status to ensure the PIC has the authority to meet the legal needs to be the PIC.

UPDATE – Legislation and Regulation Committee Strategic Goals

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 was going to be in 2020.

<u>May 2020</u>: In the past, the former executive officer would provide updates from national meetings she attended. Since the retirement of the former executive officer, Board staff have not had the opportunity to attend the National Association of Boards of Pharmacy (NABP) meeting. The president and executive officer will attend the May 2020 virtual NABP annual meeting. Board provided a summary of the meeting during the July 2020 Board meeting.

<u>July 2021</u>: Vice-President and Executive Officer attend annual meeting. A summary of the meeting will be provided during the July 2021 Board meeting

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

<u>May 2020:</u>

- The Board submitted its Sunset Report in December 2019, which included several legislative priorities. Due to the COVID-19 pandemic, the Legislature has been in recess for a few months, delaying consideration of the Board's Sunset Report and legislative proposals.
- The Board currently has 17 regulation packages in various stages of promulgation.

<u>July 2021:</u>

- Assembly Bill 1533 (Assembly Business and Professions Committee) includes several Board-sponsored provisions and will extend the operations of the Board for four years.
- Assembly Bill 527 (Wood) includes Board-sponsored provisions to reschedule specified combination products.
- Senate Bill 409 (Caballero) includes Board-sponsored legislation to expand authority for pharmacists and pharmacies to provide specified CLIA waived testing.
- During FY 20/21, the board successfully promulgated 5 regulation packages and currently has an additional 10 regulation packages in various stages of promulgation.

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

<u>May 2020 Status</u>: Due to COVID-19 pandemic, the Legislature has been in recess for a few months. As such the Board has not considered legislation. <u>July 2021 Status</u>: The Board establishes positions on 14 measures.

3.4. Establish a systemized, ongoing review process for board regulation to improve and maintain clear and relevant regulations.

<u>May 2020 Status</u>: Board staff and counsel collaborate to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary.

<u>July 2021 Status</u>: With the establishment of DCA's regulations unit, the Board has been assigned counsel specific to regulations. Board staff and counsel continue to collaborate closely to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary. Specific focus has been on getting the older regulation packages moving through the various promulgation stages.

Communication and Public Education Strategic Goals

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

<u>Status</u>: This goal is incorporated into daily Board operations. Staff assesses Board activities to develop and implement communication plans tailored to specific policies and actions. These plans are executed through suitable channels, including website, subscriber alerts, publications, public outreach, licensee training, and social media. This approach provides flexibility and enables staff to effectively inform and communicate with stakeholders.

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

<u>Status</u>: The Board continues utilizing new resources to reach out to the public and licensees. Besides print materials, the Board communicates via multiple electronic media, including website, email alerts, social media. The Board also has set up a listserv for disseminating news, online webinars, live and teleconference training events, and teleconference meetings that enable widespread public participation.

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

<u>Status:</u> The Board has largely achieved this goal through regulations requiring pharmacists, intern pharmacists, pharmacy technicians and designated representatives to register their email addresses to receive subscriber alerts. It is likely that legislation would be needed to require licensees to provide mobile numbers for texts from the Board.

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

<u>Status:</u> The Board maintains a pharmacy lawbook online and publishes annual summaries of new laws online and in The Script. The Board also issues subscriber alerts and publishes FAQs and guidance on major laws and policies.

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

<u>Status</u>: Besides field visits, the Board continues to promote communications with licensees through brochures, a video, and information in the Script regarding inspections.

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.

<u>Status</u>: The Board has created an online search tool to help consumers find drug take-back locations and an online registry for pharmacies providing contraception, naloxone, HIV PrEP/PEP medications, vaccinations, and other authorized health care services.

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.

<u>Status</u>: The Board continues to develop and update consumer information materials, including a current proposal to revise the Notice to Consumers.

4.8. Promote board initiatives to improve patient knowledge, medication adherence, and medication safety.

<u>Status</u>: This goal is an ongoing priority for the Board. Efforts include updating the Notice to Consumers, promoting consumer messages on social media, and returning to community outreach events as conditions improve following the COVID-19 pandemic.

Committee Recommendation: Continue to pursue the Board's current communication and public education strategic goals.

UPDATE - Organizational Development Committee Strategic Goals

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

May 2020 Status: The Board's Strategic Plan was updated October 2016, 2018, 2019, and 2020.

July 2021 Status: Committee's offer recommendation as part of the annual review of the plan.

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

performance.

<u>May 2020 Status</u>: All management staff completed biennial Sexual Harassment Prevention training in 2019. Leadership Communication and Performance Management trainings were scheduled but subsequently cancelled due to Governor Gavin Newsom's Executive Order N-25-20, dated March 12, 2020. July 2021 Status:

- Management staff complete six-hour training, Beyond the Pandemic: The Hybrid Workforce.
- Management staff complete training in several areas including Implicit Bias, Effective Documentation for Performance Management, Effective Delegation, and Diversity and Inclusion.
- New management staff completed 80 hours of required leadership training.

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

<u>May 2020 Status</u>: Approximately three Individual Development Plans and 21 Performance Appraisals were provided to inspector and office staff. (Note: Because of changes to union contracts, annual individual development plans are no longer required. Rather, staff must elect to participate in the process.)

July 2021 Status: A total of 18 performance appraisal provided and five probation reports were provided to inspector and office staff.

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.

<u>May 2020 Status</u>: The Board continues to work with the Department of Consumer Affairs on Business Modernization which will replace legacy systems as well as include workflow design improvements and scanning management. <u>July 2021 Status</u>:

• The Board finalized an online Health Services Registry for licensees to selfidentify specified services provided to California consumers. • Regrettably with the COVID-19 pandemic requiring redirection of staff resources to other functions and unexpected leaves of absences, Business Modernization Efforts largely cease.

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

May 2020 Status:

• The inspector training manual was revised in February 2020.

• Standardized training plans were developed and are used to onboard new staff.

<u>July 2021 Status</u>: In response to the COVID -19 pandemic, Board develops and implements process changes and teleworking for office staff.

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

<u>May 2020 Status</u>: Approximately 40 post inspection surveys were conducted by Chiefs of Enforcement prior to Governor Gavin Newsom's Executive Order N-25-20, dated March 12, 2020.

July 2021 Status: Sixty-nine post inspection surveys were conducted.

5.7 Evaluation options for improvement of licensing renewal processes to allow for

online renewal.

<u>May 2020 Status</u>: In 2019, the Board implemented online license renewal payments for individual licenses and is working with the Department of Consumer Affairs to secure online renewal payment for facilities. <u>July 2021 Status</u>: Online license renewal payments expanded to include renewal payments for pharmacies.

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

<u>May 2020 Status</u>: Over the past 18 months field staff have completed USP training. In addition, several field staff cGMP training and limited staff participated in training provided by the FDA. In addition, field staff participated in board provided trainings covering new laws, inspections, and requirements for new licensing programs have also occurred. Office staff completed customer service training, and management staff received training the Budget Change Proposal process.

<u>July 2021 Status:</u>

- All staff complete sexual harassment prevention training and Information Security Awareness Fundamentals training.
- Inspector staff complete the Board's Prescription Drug Abuse Prevention Training.

- Additional trainings completed by some staff included Writing Excellent Letters, Memos and E-mails and Excel.
- Some staff complete USP 800 and USP 797 training.