

California State Board of Pharmacy

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To: Board Members

Subject: Agenda Item IX. Discussion and Consideration of Adoption of the Board's Strategic Plan

Business, Consumer Services and Housing Agency

Department of Consumer Affairs

Gavin Newsom, Governor

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 next year the board will engage in the strategic planning process.

For Board Discussion and Consideration

In preparation for this annual review, staff have prepared status updates to the strategic goal areas. During the meeting members will have the opportunity to review the status of the plan, provide suggestions on areas of focus for the next fiscal year, and recommend changes.

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 plan is published on its website. Also, attached are the goals for each Committee, including status updates.

UPDATE - Licensing Committee Strategic Goals (Rev. May 2020)

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

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 continues with the Business Modernization process the process used to assess business processes and determine how best to meet the needs of the organization and stakeholders.

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.

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 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 the department 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 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.
- 1.3 Improve the application process for new licensees, including providing informational resources directed toward applicants to offer more guidance about the application process. 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 and application complete.
- Staff will continue to monitor and identify the most common deficiency items to clarify application instructions.
- Board staff continues with the Business Modernization process the process used to assess business processes and determine how best to meet the needs of the organization and stakeholders.

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.

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.

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

Status:

- The board is continuing to work the department 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.

1.6 Implementing New Licensing Programs

Status: The board implemented the following licenses within FY 2018/2019:

- Designated Representative-Reverse Distributor
- Designated Paramedic
- Clinic Colocation
- Correctional Clinics
- ADDS licensure

The board currently does not have new licenses to implement.

1.7 Annual Benchmarking with National Practice Standard 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.

UPDATE - Enforcement Committee Strategic Goals (Rev. May 2020)

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:

- 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.

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

Status:

- 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.

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:</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.

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

<u>Status:</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 expanding 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.)

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

Status:

• In coordination with the Office of the Attorney General, the board has initiated process 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 continues its consideration of an alternative enforcement model.

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

<u>Status:</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.

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

<u>Status:</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.

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

<u>Status:</u> The enforcement committee has initiated a review of the board's Disciplinary Guidelines.

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

<u>Status:</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 discussion priority 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.

2.10 Review the role and responsibility of the PIC.

Status: 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.

UPDATE - Legislation and Regulation Committee Strategic Goals (Rev. May 2020)

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.

<u>Status</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 NABP.

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

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

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

<u>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.

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

<u>Status</u>: Board staff and counsel continue to collaborate to improve the quality of regulation packages including ensuring regulation language is clear, consistent, and necessary. Further, the DCA has established a regulations unit to perform pre-review of regulation packages.

UPDATE - Communication and Public Education Strategic Goals (Rev. May 2020)

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

<u>Status</u>: Although the Board has expanded its communications to both consumers and licensees, these efforts do not follow a written communication plan.

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

<u>Status</u>: The Board has expanded into social media to communicate with the public and licensees, in addition to relying on its website, newsletter and subscriber alerts. The Board has hosted live CE training events throughout the state and produced three online CE webinars for licensees. The Board has moved its meeting locations throughout the state, increasing public exposure and awareness of the Board's activities.

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 implemented regulations requiring pharmacists, intern pharmacists, pharmacy technicians and designated representatives to register their email addresses to receive subscriber alerts.

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 information on major laws and policies, including inventory reconciliation, compounding matters and changes to security prescription forms.

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>: The Board is creating an informational brochure and provides information in The Script to improve communication between inspectors and licensees during inspections. Inspector staff are performing routine inspections. Common discussion points are shared among inspector staff to facilitate more standardized communication.

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. In addition, staff is developing a search tools to help consumers find pharmacies providing special 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 has updated a consumer brochure about the risks of buying drugs online. Staff is working to review and update additional consumer materials as needed.

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

<u>Status</u>: Prior to the pandemic, Board staff was working to attend more outreach events targeting consumers as well as licensees. Recently staff worked with DCA to publish an online article with consumer tips on filling opioid prescriptions and talking to their pharmacist.

UPDATE - Organizational Development Committee Strategic Goals (Rev. May 2020)

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

<u>Status</u>: The Board's Strategic Plan was updated October 2016, 2018, and 2019. The next review of the Board's Strategic Plan is scheduled for the May 2020 Board Meeting.

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

<u>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.

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

<u>Status</u>: Approximately 3 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.)

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>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.

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

Status:

- The inspector training manual was revised in February 2020.
- Standardized training plans were developed and are used to onboard new staff.

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

<u>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.

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

<u>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.

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

<u>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.