December 30, 2019

Alexis Podesta, Secretary
California Business, Consumer Services and Housing Agency
915 Capitol Mall, Suite 350-A
Sacramento, CA 95814

Dear Ms. Alexis Podesta,

In accordance with the State Leadership Accountability Act (Leadership Accountability), the California State Board of Pharmacy submits this report on the review of our internal control and monitoring systems for the biennial period ending December 31, 2019.

Should you have any questions please contact Julia Ansel, Chief of Enforcement, at (916) 518-3108, Julia.ansel@dca.ca.gov.

GOVERNANCE

Mission and Strategic Plan

Mission Statement

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

Strategic Goals:

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.

LEGISLATION AND REGULATION

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

COMMUNICATION AND PUBLIC EDUCATION

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

ORGANIZATIONAL DEVELOPMENT

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

Control Environment

Management establishes and demonstrates integrity and ethical values

The Board of Pharmacy has established Workplace Guidelines and Staff Expectations that are reviewed and acknowledged by each employee. These guidelines and expectations are intended to communicate to Board of Pharmacy (Board) staff how they shall conduct themselves in the workplace. Any changes to the guidelines or expectations must be preapproved by management. Board management and staff should have the same understanding concerning these expectations. If staff have any questions concerning these guidelines, they can consult with their immediate supervisor.

Oversight is provided by a board, outside entity, or top executive

The Board of Pharmacy consists of 13 members who are appointed to four-year terms. Members can serve only two terms. The governor appoints seven registered pharmacists who reside in different parts of the state and four public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. Public members are not licensed by this Board.

Members of the Board appoint the executive officer who directs the Board's (agency's) operations and oversees staff, including field inspectors who are registered pharmacists.

The Board maintains an up to date organizational chart that clearly identifies the chain of command for each component of the Board. Each managerial position has a specific Duty Statement that outlines the level of responsibility, authority, and duties.

Every four years the board submits a Sunset Review Report to the California State Legislature. This reports outlines various recommendations from the appointed Board members and Executive Officer.

The entity ensures appropriate levels of responsibility and authority, and documentation of internal control systems

The DCA, the parent agency of the board makes available the services of the Internal Audit Office to all boards, bureaus, commissions, programs and committees of the DCA. The DCA Internal Audit Office can assist in the following ways:

The Internal Audit Office will identify and evaluate significant exposures to risk by:

    a. Reviewing policies and procedures as well as any laws or regulations applicable to an operation;
    b. Interviewing management and staff;
    c. Conducting attribute sampling of transactions performed in an organization; and
    d. Providing meaningful feedback to management on strengths within the organization as well as any deficiencies noted

Establishing and maintaining a competent workforce

The efficiency of the organization requires establishing and maintaining a competent workforce. This is done through recruitment and training of staff to maintain the skill level and knowledge to sustain high performances.

- Utilize internal and external training resources
- Address significant changes with staff
- Provide training when there are changes in workforce skills needed to accomplish the job
- Provide training in line with job requirements

Personnel need to possess and maintain a level of competency that allows them to accomplish their assigned responsibilities, as well as understand the importance of effective internal controls. Holding individuals accountable to established policies by evaluating personnel's competence is integral to attracting, developing, and retaining individuals.

Management evaluates competence of personnel across the entity in relation to established policies. Management acts as necessary to address any deviations from the established policies.

The Board maintains morale through team building activities, staff appreciation and acknowledgment. Additionally Mangement cross-trains, coached and fosters upward mobility through mentoring. Also, retaining funding and requesting additional funding to support additional positions to reduce backlog while also continuing to share the mission and vision with staff. Management continues to lead by example.

Management evaluates performance and enforces accountability

The Board utilizes a performance appraisal process that assesses an employee's job performance and productivity in relation to established criteria and organizational objectives. The manager/supervisor may consider other factors, including, but not limited to: behavior, accomplishments, potential for future improvement, strengths and weaknesses, etc. The performance appraisal should reflect the employee's performance for the previous 12 months, inform them of the managers'/supervisors' expectations, and advise them if the expectations are met.

The Individual Development Plan (IDP) is used for permanent employees who have passed their probationary period to establish personal objectives and develop a plan for achieving professional growth, career mobility, and/or future career changes.

Managers/supervisors are required to notify eligible employees of the opportunity to submit an IDP at least on an annual basis

The IDP identifies specific methods by which the employee can accomplish the performance objectives.

Information and Communication

Information requirements are established and met with reliable and relevant sources

Management at Board and DCA disseminates information about the operational processes to personnel to help them achieve the Board's objectives. Additionally, management receives information about the operational processes that flows up the reporting lines from personnel to help management achieve and determine if the Board's objectives are being met. As information reaches each level, both going up and down the chain of command it is evaluated for its reliability and

relevance to the appropriate units within the Board.

Finally, the appointed 13 member oversight body receives information that flows up the reporting lines from management and personnel. Information relating to internal controls communicated to the oversight body include significant matters about adherence to, changes in, or issues arising from the internal control system.

Quality information is communicated to internal parties within the entity

Internal communication is established through senior managers meetings, all staff meetings and one-on-one meetings to provide feedback.

Management obtains statistical data obtained from internal systems and disseminates it to senior and mid-level managers on a monthly and quarterly basis to identify trends, both positive and negative.

If a staff member has information that they believe is related to inefficiencies or inappropriateness within the Board, they are able to report it to the EEO office within the department, providing them protection.

Quality information is communicated to external parties

The Board, through its Public Information Officer, currently uses its Website, an email alert system, and social media (Twitter) to communicate reliable and relevant information to the licensee population and general public.

The Board hosts Public Meetings, through various committees and the full Board. Licensees and the general public are able to comment on agenda items and request items/topics to be discussed at future meetings. Also, a quarterly newsletter is published and distributed to the licensee population.

Board staff provides training seminars, conducts presentations, and briefings to the licensee population throughout the year.

MONITORING

The information included here discusses the entity-wide, continuous process to ensure internal control systems are working as intended. The role of the executive monitoring sponsor includes facilitating and verifying that the California State Board of Pharmacy monitoring practices are implemented and functioning. The responsibilities as the executive monitoring sponsor(s) have been given to:
Julia Ansel, Chief of Enforcement; Tom Lenox, Chief of Enforcement; Maryjo Tobola, SSMII; and
Debi Mitchell, SSMII.

Monitoring activities are performed, documented, and measured against a baseline.

Management has established monitoring activities to monitor the internal control system and evaluate the results. An example of this is the volume of work. For the Board, some of our prime areas of focus include, the number of licensing applications, processing times, issuance of licenses and completion times of investigations. Through the establishment of timelines for completion of workload in most units, management is able to evaluate the efficiency of the unit, the need to increase the workforce and review the workflow process to determine if the action system that has been established is the most efficient and accurate.

Some baseline goals are adopted from DCA's performance measures. As an example, the DCA's target time for intake is the number of days from complaint receipt to the date the complaint is closed or assigned to an investigator is 20 days. The DCA's target time for case investigations not transmitted to the Attorney General is 210 days, which includes both intake and investigation.

Management evaluates results and ensures appropriate corrective actions are implemented and documented

Investigative data is available for review. Internally, management reviews various data and internal operations on a monthly basis to evaluate for successes or changes needed. Management provides the Board with quarterly and yearly statistical data for review and recommendations at committee and full Board meetings. Analysis is conducted to identify upward or downward trends. Senior management meets weekly and routinely evaluates that data to make adjustments if necessary in an attempt to meet the established baseline goals. Performance measures are available through the department's public website for certain areas of operations. This documentation allows for full transparency.

RISK ASSESSMENT PROCESS

The following personnel were involved in the California State Board of Pharmacy risk assessment process: executive management, and middle management.

The following methods were used to identify risks: brainstorming meetings, ongoing monitoring activities, audit/review results, other/prior risk assessments, external stakeholders, and performance metrics.

The following criteria were used to rank risks: likelihood of occurrence, potential impact to mission/ goals/objectives, and tolerance level for the type of risk.

Management identifies, analyzes and responds to risks

Senior management and middle management at the Board meets and reviews Board operations on a weekly and monthly basis. These meetings are part of our ongoing monitoring of activities across the Board. If managers or staff (through reporting to their respective manager) become aware of risks, challenges or issues that need to be addressed to ensure optimal functioning across the organization, these issues are addressed in these meetings and discussed as a group by the management staff. There are times when risks or issues are identified at the staff level and then brought to management. In other instances, risks are identified by management and then management discusses the risks openly with staff in unit meetings.

During Board and committee meetings, external stakeholders and Board members have the opportunity to discuss potential risks to the organization in an open, transparent public forum. In these settings, if a change needs to be made within the operations of the Board, staff takes direction from the 13 member board on how to proceed and possibly implement new activities, processes or procedures to mitigate the risk that has been brought to the Board's attention.

Significant changes are considered when identifying, analyzing and responding to risks

If the Board believes a risk jeopardizes our vision, mission, strategic plan, goals or objectives, it will be addressed. If the risk is in our control to manage, the Board will consider changes to operations,

procedures and processes to mitigate that risk. The Board's manadate is to protect the public and if a risk is evident that may have a potential impact to that mandate, the Board will act on it, as our tolerance level for risk is low when it comes to protecting the citizens of California.

RISKS AND CONTROLS

Risk: Outdated Technology System

The Board has been managing licensing and enforcement operations with an outdated system for many years and has been awaiting the implementation of a new system. This impacts the Board in a multitude of areas; system limitations cause the board to have additional workaround databases and modifications to legacy systems have a lengthy approval process from the department. This can impact the board's ability to process applications and establish timely requirements. Time is spent realigning and training staff on the use of workarounds. A new system will have an impact on the Board's budget and a possible financial burden to implement. There is risk that a new system may not be able to meet all of the board's licensing and enforcement needs. There could be loss of information during conversion and full implementation may take a very long time.

Control: Business Modernization

This control is in the infancy stages and as such the board is not in the position yet to comment on whether the control that is being initiated through Business Modernization is reducing the risk as expected, but we are hopeful and excited about the possibilities for the organization overall. With assistance from the Office of Information Services (OIS), the Board has begun Business Mapping for various units within the organization. The Board will work with the DCA and vendors to implement and meet timelines to insure licensing and enforcement system requirements are met. In the interim, Board staff continues to receive training on legacy systems and the Board works with DCA OIS to meet current licensing and enforcement needs of the organization.

Risk: Funding - Sources & Levels

The Board licenses and regulates approximately 140,000 licensees. The Board has experienced significant growth in expenditures over the past several years. Sources of increased expenditures include staff salaries/ benefits and enforcement related costs. The Board's expenditures are not fully offset by the revenue it generates, creating a structural imbalance. The Board has struggled to close the gap between revenue and its authorized expenditures. Board costs exist that are outside of the its control, including statewide ProRata and Attorney General costs.

Control: Fee Increases

The Board is a self-funded organization. Revenue origins include, license fees, cost recovery and citation and fines. The Board initiated a fee increase on July 1, 2017. The Board is seeking to secure another fee increase and has submitted a regulation proposal to the Office of Administrative Law (OAL). The requested date to implement the new fee schedule is April 1, 2020, pending approval from OAL. Continual evaluation of Board fees and revenue intake is necessary as expenditures continue to increase.

Risk: Recruiting and Retention

The Board is a dynamic, challenging and fast paced organization. Over the last several years, the Board has grown quickly in a short amount of time. Workload has increased over the past several years and staffing levels must be at 100% to handle the increased demand. The Board's inability to recruit and retain staffing levels at times can compromise the organization's ability to fulfill its mandate. Recruitment and retention functions are vital to the success of the organization.

Control: Retention Activities and Continued Focus on Recruitment

Executive management keeps abreast of changes in policies/recruitment processes through monthly mtgs with DCA-HR liaisons and continues to receive ongoing HR training. Management communicates and ensures clear, consistent priorities, procedures and expectations of staff. Management will focus on succession planning, cross-training, and foster upward mobility through coaching and mentoring. The Board hopes to obtain additional funding through a BCP for an additional Board personnel liaison to help with recruitments and other HR functions. The Board shall maintain morale and aid new staff to integrate into the organization through team building activities, staff appreciation and acknowledgment. Increased communication may be achieved throughout the organization by holding all staff meetings (mtgs) multiple times per year and 1-on-1's to provide individual feedback. A Halloween decorating contest/potluck and a winter staff party is held annually. The Board will hold a Thanksgiving Potluck Feast with staff this year. Each unit holds monthly/quarterly mtgs and celebrates co-workers' birthdays. Upper management continues to lead by example and shares the board's vision/mission with staff at these events.

Risk: Implementation of New Laws and Regulations

Many times new legislation impacts the Board and its operations. Implementation of new mandates and regulations could result in decreased protections for consumers, impacting the drug supply chain for California citizens. This may impact the Board's regulatory capabilities within its jurisdiction and adversely affect Board operations. There are times when new programs, as mandated by law, must be implemented by the Board where the effective date has approached, but resources, funding and staffing to implement the new program and accommodate increased workload are not in place. Resources, staffing and funding may not be available at the same time a new law or regulation goes into effect. This puts a significant strain on the Board and staff to uphold its mandate to protect the public. The balance of workload throughout the organization becomes extremely challenging in these instances.

The Department of Consumer Affairs issues licenses, certificates, registrations, and permits in over 250 business and professional categories through 37 regulatory entities comprised of boards, bureaus, committees, a program, and a commission. These 37 entities set and enforce minimum qualifications for the professions and vocations they regulate, which requires them to promulgate regulations.

Prompted by an increase in the number of regulations disapproved by the Office of Administrative Law, in late 2016, the Department and the Business, Consumer Services and Housing Agency (Agency) changed the process for reviewing regulations. The resulting enhanced scrutiny from the Department and Agency successfully reduced the number of disapproved regulations because it led to a more thorough examination of regulation packages. But while disapproval rates plummeted, a consequence

was lengthened timelines to adopt regulations.

Control: Management of New Laws and Regulations

Board staff will work with DCA budgets to identify a long-term solution to this issue. The Board will attempt to provide timely policy directives to licensees, staff and the public as necessary. Proactive and early communication with internal staff and education of the public regarding new mandates and laws is vital. Management will proactively align resources, training, policies and procedures to implement new laws and regulations. Staff needs to effectuate regulations in a timely manner. Applications must be processed timely and issued so that California's drug supply is not interrupted or adversely impacted. The Board will collaborate with other agencies whenever possible to make transitions as seamless as possible. Staff will continue to advocate for necessary resources to implement new regulations and programs.

Control: Increase in legal Staffing

The Department was authorized in the 2019 Budget Act to hire six attorneys, a senior legal analyst, and a research program specialist II to increase its capacity for developing, reviewing and issuing regulations. The Department's attorneys are being trained by the Office of Administrative Law to review regulations. The Department is also conducting training of all participants in the regulations process to improve regulation packages and timelines. In addition, the Department is developing a department-wide computerized regulation management and tracking system to better track and streamline the review of regulations.

Risk: Fi$cal Impacts to Operations and Decision Making

Accurate and timely revenue and expenditure reports are not currently available from the Fi$Cal system and this ultimately results in DCA being unable to produce timely reconciled monthly and year-end financial statements to Boards. Specifically, the Board is unable to access timely reports and readily validate the accuracy of data postings. This results in information lags as well as in poor, and inaccurate, real-time reporting to the Board. Further, reports generated from the system often track awkward reconciliation points or contain incomplete or not user-friendly data. Accurate and usable reports are needed to make prudent budget and operational decisions. Special funds often have structural funding concerns, so understanding cash balances and expenditure status is essential. Board staff, as a result, often manually track unresolved Fi$Cal issues in hopes of providing better real time data to executive level managers. This adds significant staff time, and the manual preparation of reports outside of the system opens the Board up to a larger opportunity for making unintended errors.

Control: Elevating Issues to DCA

The Board is in communication with DCA on a regular basis to resolve open items which include posting corrections, programming concerns, and report suggestions within the system.

Control: Independently Tracking Data

The Board relies on data tracking outside of the Fi$cal system and regularly works with budget, accounting, and business services staff at DCA to track issues and make forecasting projections. This information is often utilized for meeting materials. Additionally, the Board requests information

as needed from DCA to try to identify and fix errors.

CONCLUSION

The California State Board of Pharmacy strives to reduce the risks inherent in our work and accepts the responsibility to continuously improve by addressing newly recognized risks and revising risk mitigation strategies as appropriate. I certify our internal control and monitoring systems are adequate to identify and address current and potential risks facing the organization.

Anne Sodergren, Interim Executive Officer

CC: California Legislature [Senate (2), Assembly (1)]
    California State Auditor
    California State Library
    California State Controller
    Director of California Department of Finance
    Secretary of California Government Operations Agency