

December 29, 2023

Melinda Grant, Undersecretary
California Business, Consumer Services and Housing Agency
500 Capitol Mall, Suite 1850
Sacramento, CA 95814

Dear Undersecretary Melinda Grant,

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, 2023.

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 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.

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

Control Environment

The Board 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 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.

The Board follows the policies and procedures implemented by the Department of Consumer Affairs (Department or DCA) including Information Security, Conflict of Interest, and Sexual Harassment Prevention policies.

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

The Board 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 the Board.

Members of the Board appoint the Executive Officer (EO) who directs the Board'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.

As determined by law, the Board submits a Sunset Review Report to the California State Legislature. This report outlines various recommendations from the appointed Board members and EO.

The Board is a quasi-autonomous entity with budget and personnel oversight provided by DCA; Business, Consumer Services and Housing Agency; and the Department of Finance.

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

The Internal Audit Office is available to all programs within DCA. DCA's Internal Audit Office assists in the following ways:

1. Reviews policies and procedures as well as any laws and regulations applicable to the operations.
2. Interviews management and staff.

3. Conducts attribute sampling of transactions performed by the Board.
4. Provides meaningful feedback to management on strengths and deficiencies with the Board.

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. The Board must:

- Utilize internal and external training resources including training plans for newly hired staff.
- 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.
- Announce staff achievements, including new staff, staff promotions and milestones reached in state service.
- Provide staff with opportunities for cross-training and upward mobility.

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 the 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 meetings and team-building activities. Management coaches and fosters upward mobility through mentoring. The Board uses detailed onboarding plans and provides feedback both informally and formally through probation and annual performance appraisals. Management leads 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. IDPs are encouraged but not required. Annual performance appraisals are required to review staff's performance and provide input to staff.

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 through the identification of training opportunities and goals.

Information and Communication

Information requirements are established and met with reliable and relevant sources

Management at the 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 Board receives information on the operations of the Board from the EO on an as needed basis. Information is also reported as part of quarterly meetings. Information relating to internal controls communicated to the Board members 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 manager meetings, all staff meetings, team meetings, and one-on-one meetings to provide feedback and allow for staff input.

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 encouraged to share with managers or during team meetings. Further, policies of the DCA detail the appropriate means to report violations or other issues to the appropriate DCA office as applicable.

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 the public.

As part of its licensee education efforts, the Board maintains an "Ask an Inspector" program, where a Board Inspector and/or Board staff are available to respond to verbal and written inquiries from the public and licensees relating to inquiries of pharmacy law or regulations.

The Board hosts public meetings, through various Committees and the Board meetings. Licensees and the public are able to comment on agenda items and request items/topics be discussed at future meetings. The Board publishes a newsletter and develops informational material for consumers and licensees. Such information is made available on the Board's website.

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, Assistant Executive Officer; Anne Sodergren, Executive Officer.

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The EO is ultimately responsible for management of the plan with responsibilities as the executive monitoring sponsors delegated in part to: Julia Ansel, Assistant Executive Officer

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, 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 evaluates the efficiency of the unit and the need to increase the workforce and review the workflow process to determine if the system that has been established is the most efficient and accurate.

Some baseline goals are adopted from DCA's performance measures. As an example, pursuant to Business and Professions Code section 129, DCA has a 10-day target timeframe from the date the complaint is received until the matter is assigned for investigation or otherwise closed. DCA's target time for case investigations not transmitted to the Attorney General is 210 days, which includes both intake and investigation.

The Board has a 2022-2026 Strategic Plan in place that includes action plans to achieve strategic objectives.

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 routinely to evaluate the data to adjust assigned workload if necessary, in an attempt to meet the established baseline goals. Lessons learned are integrated into processes as appropriate and norming sessions are held regularly to ensure standardization across the organization.

Performance measures are available through the Department's public website for certain areas of operations and licensing and investigation processing times are reported quarterly and posted on the Board's website. 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, middle management, and front line management.

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

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

Management identifies, analyzes and responds to risks

Executive and management staff meet and review Board operations on a weekly and monthly basis through team meetings and one-on-one meetings. These meetings are part of 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. Risks are discussed 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. Such actions could include implementation of 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 its vision, mission, strategic plan, goals or objectives, it

will be addressed. If the risk is in the Board's control to manage, the Board will consider changes to operations, procedures and processes to mitigate that risk. The Board's mandate is protection of the public and if a risk is evident that may have a potential impact to that mandate, the Board will act on it, as the tolerance level for risk is low when it comes to protecting the citizens of California.

RISKS AND CONTROLS

Risk: Dependence on Legacy Systems

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

Further, limitations on legacy systems' ability to create on-line file management for applications, licensee and investigation workloads results in the Board's reliance on paper. The Board struggles to meet rising expectations with aging infrastructure and more complex IT needs. With the pandemic came new hurdles including telework and significant need for increased online services. Some of these needs were difficult to realize in an efficient manner because of the legacy systems and patchwork of workaround systems.

Current operating systems are complex to manage and difficult to scale. The aging infrastructure makes it more challenging to adapt to changing conditions as highlighted with the COVID-19 pandemic. The Board notes that there have been several attempts to replace legacy systems that were unsuccessful in part due to a lack of resources.

Control: Business Modernization

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The Board's efforts for Business Modernization are underway and will serve as the pathway to determine the appropriate long-term IT solutions. The Board will continue to work with DCA and vendors to implement and meet timelines to ensure 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's Office of Information Services (OIS) to meet current licensing and enforcement needs of the organization.

In working with DCA OIS all Business Modernization Maps and Could-be Mapping are complete. Additionally, all Licensing and Administrative Units functional

requirements are complete. Enforcement unit functional requirements will be reviewed in the coming months.

The Board is also working with OIS and the Department to procure a new inspection program for field staff in the 2024 calendar year.

Control: Knowledge Transfer

The Board will continue to develop staff's understanding of workaround systems to minimize risk of failure to such systems.

Control: File Scanning

Licensing files are reliant on paper based document storage. Current legacy systems do not capture everything that exists in a paper file. The Board purchased high capacity scanners in 2023. The Board will research a storage solution for paper based files and develop a schedule and plan to scan paper-based files and convert to digital documents.

Control: Interim Solutions

Although the long-term solution should include replacement of legacy systems and inclusion of functionality offered by workaround systems, opportunities for interim solutions will continue to provide the Board with additional short-term solutions to improve stakeholder interaction with the Board and could serve to reduce, at least in part, some of the Board's current reliance on the submission of paper.

Risk: Workforce Development

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 percent to handle the increased demand. Staff development can be hindered by heavy volume, tight deadlines and complexity of work performed. Such a work environment can lead to burnout and staff turnover. The Board's inability to recruit and retain appropriate staffing levels at times can create inefficiencies, backlog, and compromise the organizations ability to fulfill it's mandate. Recruitment and retention functions are vital to the success of the organization. The state hiring process can be lengthy. Recruitments can be challenging with little or no interest in Board positions at certain classification levels.

Control: Set Expectations

Board management will work to ensure staff are aware of performance expectations and foster an environment that encourages staff to work together to achieve standards. Ongoing training is provided to reinforce the importance of timely processing of licensing applications.

Control: Retention Continued Focus on Recruitment

Executive management keeps abreast of changes in policies/recruitment processes through regular meetings with DCA Office of Human Resources (OHR) liaisons and continues to receive ongoing OHR training. Management communicates and ensures clear, consistent priorities, procedures and expectations of staff are consistent with the strategic objectives identified by the Board and consistent with established performance measures.

Management will focus on succession planning, cross-training, and fostering upward mobility through coaching and mentoring. Management ensures that staff understand their respective important roles in helping the Board achieve its consumer protection mandate and understand the culture of teamwork.

Control: Succession Plan

The Board is developing a long-term staffing plan to address operational challenges experienced by insufficient staff vacancies and limited IT resources. The plan will create growth opportunities for staff, increase staff retention, and ensure staff have appropriate tools to be successful.

Control: Ongoing Staff Development

Staff performance appraisals are completed annually by management. Through the IDP process, management will assist staff in identifying training opportunities primarily using the DCA SOLID training classes. Management will also provide options for on-the-job training and job shadowing. Managers meet weekly with staff to identify challenges, celebrate successes, and identify areas of improvement.

Risk: Excessive Leave Balances

Multiple staff members have leave balances that exceed the maximum vacation/ annual leave balance allowed and some are eligible and or nearing retirement in the next few years. These leave balances are an unfunded budgetary liability. Retirements can result in significant cash payouts for over ten staff members whose have leave balances exceed 640 hours.

Control: Require and Monitor Leave Reduction Plans for Staff

In compliance with CalHR rules, all employees who exceed the maximum number of leave hours complete an Excess Vacation/Annual Leave Use Plan each year. Management will continue to monitor all staff member's plans for adherence.

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, Executive Officer

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