



Arizona State Board of Pharmacy

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Ms. Lindsey Perry, Auditor General
Office of the Auditor General
2910 N. 44th St., Suite 410
Phoenix, AZ 85018

Dear Ms. Perry,

The Arizona State Board of Pharmacy enjoyed the opportunity to discuss the activity of our Board with your team, led by Dale Chapman. It was a pleasure meeting with them and sharing what we do.

The Board of Pharmacy respectfully submits its response to the performance audit and sunset review.

The Board of Pharmacy continually strives to perform at our best and operate to uphold the mission of the Board. We concur with the recommendation and we will ensure they are addressed appropriately.

We would like to thank you and your team for the guidance to improve our operation.

Sincerely,

Dr. Kam Gandhi, PharmD
Executive Director

Enclosure

c: Board Members

Finding 1: Board did not ensure licensees and facilities we reviewed were qualified to practice and operating safely

Recommendation 1: The Board should ensure that initial pharmacist license applicants possess a valid fingerprint clearance card before it issues a license by developing and implementing policies and procedures requiring Board staff to check the validity of fingerprint clearance cards on the DPS website.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: Initially, the Board did not verify the Fingerprint Clearance Card (FCC) of initial pharmacist applicants. Interns are required to have an FCC to attend pharmacy school. The expiration date of an FCC is six years. Therefore, the Board would have been notified if there was a denied or suspended FCC for that intern or initial pharmacist applicant. The intent was to be efficient and eliminate redundancy without compromising standards. Today, verification of the FCC with the DPS website is conducted for all applicants, including initial pharmacist applicants, to ensure validity of the FCC.

Recommendation 2: The Board should work with the Legislature to amend statute to require licensees to maintain a valid fingerprint clearance card and submit them at renewal.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will review and discuss the implementation of requiring fingerprint clearance cards to be maintained and submitted at renewal at the upcoming Board meeting. In addition, the Board will hold stakeholder meetings to discuss the proposed legislative change. Should the Board move forward with the statutory change to require a fingerprint clearance card at renewal, an increase in staff in the next budgetary cycle would be required.

Recommendation 3: After statute is amended (see Recommendation 2), develop and implement written policies and procedures that require Board staff to check the DPS website to ensure the validity of fingerprint clearance cards submitted by all renewal licensure applicants.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: If given the statutory authority to require fingerprint clearance cards at renewal, the Board will develop and implement policies and procedures for verifying the validity of the fingerprint clearance card.

Recommendation 4: The Board should ensure that renewal applicants meet continuing education requirements by continuing to develop and implement written policies and procedures for conducting continuing education audits after each renewal cycle.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The licensee's renewal application requires the licensee to attest that they have completed the continuing education (CE) requirements for that renewal period. The Board recognized that the current CE audit process needed to extend to involve more licensees. Therefore, the Board has implemented a more robust CE audit policy and procedure. The Board is now conducting CE audits in conjunction with inspections which will increase the amount of CE audits to ensure licensees meet the CE requirements.

Recommendation 5: The Board should consistently determine complaint jurisdiction by developing and implementing guidance, such as types of violations that would not be within the Board's jurisdiction, to help ensure its lead compliance officer and executive director consistently and appropriately determine complaint jurisdiction.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: After a statute change that occurred in August 2019, the Board gave the Executive Director authority to dismiss or take no action on complaints without violations or complaints not within the Board's jurisdiction. Today, all complaints are reviewed by one to two compliance officers who are also pharmacists. If no violation of statute or rule is found, the compliance officers will refer it to the Deputy Director and Executive Director for dismissal. The complaint is reviewed by at least three pharmacists prior to dismissal. In addition, the Board will create a substantive policy that will outline the types of complaints that do not fall in the Board's jurisdiction.

Recommendation 6: The Board should document the rationale for its complaint jurisdiction determinations.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has implemented a process to better document complaint jurisdiction determination. The Board changed its policy and procedure on how

to determine and document complaints without violations or complaints not within the Board's jurisdiction.

Recommendation 7: The Board should consistently meet established inspection time frames by developing and implementing processes for tracking and monitoring the completion of facility inspections.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has developed and implemented a process for tracking and monitoring the completion of facility inspections. In addition to tracking and monitoring inspections, the established inspection time frames will be reevaluated. The Board has been implementing a risk based inspection process to ensure the safety of Arizonians. However, the pandemic has delayed the full implementation of this recommendation.

Finding 2: Board's license and permit fees are not based on the cost of providing services, resulting in large and growing fund balance

Recommendation 8: The Board should conduct a review of its license and permit fees consistent with government fee-setting standards and guidelines, including ensuring the fees are based on actual costs and promote service efficiency, and then adjust its fees, accordingly. Specifically, the Board should:

Recommendation 8a: Develop and implement a method for determining and tracking the direct and indirect costs for its regulatory processes and establish policies and procedures for using this method. The policies and procedures should also require the periodic review of the Board's fees, including tracking and reassessing actual costs and assessing if costs are necessary for providing services.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will work to develop and implement a method to review the direct and indirect costs for its regulatory processes. Once this method is established, policies and procedures will be developed and implemented as necessary.

Recommendation 8b: After implementing this cost methodology, determine the appropriate license and permit fees.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: Once the cost methodology is complete, the Board will review and determine if the license and permit fees should be increased or decreased.

Recommendation 8c: Consider the effect of proposed fee changes on applicants, licensees, and permit holders and obtain their input when reviewing the fees.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will conduct open meetings and public forums to consider the effect of the proposed fee change on licensees and permit holders. Through these meetings, the Board will obtain the input from the licensee and permit holder on the proposed fee change.

Recommendation 8d: Adjust its fees in its rules, as necessary.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will adjust its fees in its rules as necessary.

Recommendation 9: The Board should work with the Legislature, as needed, to revise statute to eliminate the reciprocity fee and charge the same application fee to all initial pharmacist applicants.

Board Response: The finding of the Auditor General is agreed to and a different method of dealing with the finding will be implemented.

Response explanation: The Board will review the reciprocity fee and perform a cost analysis including direct and indirect costs associated with a reciprocity application. Once this cost analysis is complete, the Board will review the results and work with Legislature, as needed, to revise statute if the analysis shows that the reciprocity fee should be eliminated.

Finding 3: State may not be receiving full benefits of the CSPMP because the Board has not enforced or helped to enforce compliance with CSPMP requirements

Recommendation 10: The Board should enforce licensed pharmacist and permitted pharmacy compliance with State CSPMP statutes.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will modify the compliance officer checklist to include verification of each licensed pharmacist's registration with the CSPMP when conducting

inspections. Additionally, a rule change to require the currently available ASAP standard field to collect Pharmacist State License Number on all controlled substance dispensations would assist in monitoring which pharmacists should be checking the CSPMP. The field is currently optional, not required, and without it, the Board does not have an accurate determination of pharmacists who should be performing lookups.

Recommendation 11: The Board should develop and implement processes to identify licensed pharmacists who have not registered for and are not checking the CSPMP database as required and take enforcement action, as appropriate.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will modify the compliance officer checklist to include verification of each licensed pharmacist's registration with the CSPMP when conducting inspections. Additionally, a rule change to require the currently available ASAP standard field to collect Pharmacist State License Number on all controlled substance dispensations would assist in monitoring which pharmacists should be checking the CSPMP. The field is currently optional, not required, and without it, the Board does not have an accurate determination of pharmacists who should be performing lookups.

Recommendation 12: The Board should continue its newly developed process to identify permitted pharmacies with an Arizona address that should have, but are not, registered to submit information accessible through the CSPMP database.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will continue its process to identify permitted pharmacies with an Arizona address that should have, but are not, registered for the PMP Clearinghouse as required to report.

Recommendation 13: The Board should develop and implement a process to identify permitted pharmacies that are outside of Arizona that should have, but are not, registered to submit information accessible through the CSPMP database.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will continue to develop its process to identify permitted pharmacies that are outside of Arizona that should have, but are not, registered for the PMP Clearinghouse as required to report.

Recommendation 14: The Board should ensure that all permitted pharmacies that should be submitting information accessible through the CSPMP database, including those identified as a result of the Board's processes (see Recommendations 12 and 13), are doing so and follow up with any pharmacies that are delinquent in reporting.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has addressed this matter and will continue to monitor and follow up with the permitted pharmacies as required.

Recommendation 15: The Board should work with the other 9 Arizona professional licensing boards listed in A.R.S. §36-2606(B)(1) to determine the information they need to investigate and enforce licensed prescriber noncompliance with State CSPMP statutory requirements.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: After receiving clarification regarding the 9 professional licensing boards' statutory authority for disciplinary action for failing to consult the CSPMP as required by law (see Recommendation 10), the Board will collaborate with the professional licensing boards of prescribers with the intent of proactively providing information about potential licensed prescriber noncompliance with State CSPMP statutory requirements.

Recommendation 16: The Board should follow State CSPMP statutes and provide other Arizona professional licensing boards with information they need to investigate and enforce non-compliance with these statutes.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: In January of 2018, legislation was passed allowing the other Arizona professional licensing boards access to have full access to the database, removing the requirement to state in writing that the information is necessary for an open investigation or complaint. The licensing boards must still request prescriber query histories, as they are not available for direct download. The Board will participate in meetings with the other licensing boards to allow for dialogue and sharing of aggregate data to help establish thresholds for noncompliance.

Recommendation 17: The Board should develop and implement processes for identifying licensed prescriber potential noncompliance with State CSPMP statutory requirements.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: On a per request basis, the Board provides AHCCCS and other healthcare entities information on their prescribers' registration status in the CSPMP. The Board also currently generates an aggregated report that examines licensed prescriber compliance with patient query requirements. The Board is hopefully going to purchase a new enhancement to help track compliance more accurately and effectively. The Board will continue to refine its processes for identifying licensed prescriber potential noncompliance as the enhancement allows. This enhancement will also assist with determining the level of noncompliance discussed in Recommendation 16.

Finding 4: Board did not provide required public information on its website or in response to our anonymous phone calls

Recommendation 18: The Board should provide required information on its website by updating it to include (1) all required information about licensees and permit holders, including nondisciplinary actions, and (2) a statement informing the public that they can contact the Board for more information as required by statute.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will update its website with the appropriate information.

Recommendation 19: The Board should ensure that it provides complete and accurate information to the public over the phone by revising and implementing its policies and procedures for providing public information to include how staff should respond to phone calls requesting complaint information.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board staff does meet regularly to discuss information and processes. Board staff has discussed and implemented a process on how to direct calls to the appropriate person.

Recommendation 20: The Board should develop and provide training for its staff once it has developed the policies and procedures outlined in Recommendation 19.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has implemented weekly calls to share new information and policies and procedures that will be rolled out.

Sunset Factor 2: The extent to which the Board has met its statutory objective and purpose and the efficiency with which it has operated.

Recommendation 21: The Board should ensure pharmacy technicians meet training requirements by either requiring pharmacy technician applicants to submit documentation showing they meet training requirements or revising its rule to rely on the national boards' training attestation requirements.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will revise its rule to rely on the national boards' training attestation requirements.

Recommendation 22: The Board should protect its cash receipts by developing and implementing written cash-handling policies and procedures that adhere to SAAM requirements, such as:

Recommendation 22a: Opening mail with at least 2 staff members present.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will adjust its policy and procedure to have at least 2 staff members present to open mail. However, implementation of this may be delayed because of COVID-19 as we have minimal staff in the office. We are looking to possibly implement this process virtually.

Recommendation 22b: Separating the duties of logging cash receipts from licensing functions.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will change its policy and procedure to separate the duties of logging cash receipts from any licensing functions. However, implementation of this may be delayed because of COVID-19 as we have minimal staff in the office. We are looking to possibly implement this process virtually.

Recommendation 22c: Depositing cash receipts exceeding \$1,000 on a daily basis.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: Currently, COVID-19 restrictions have prevented the implementation of daily deposits. Once the COVID-19 restrictions are lifted, the Board will conduct daily deposits.

Recommendation 22d: Processing cash transactions and depositing cash rather than returning it to the sender through the mail.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will change its current policy and procedures to process cash transactions and deposit the cash.

Recommendation 23: The Board should train staff on these updated policies and procedures and review staff work periodically for compliance.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Executive Director and Deputy Director of the Board conduct weekly meetings with the Board staff to share the latest information and changes impacting the Board. The directors also engage with staff members on a daily basis to answer any questions they may have regarding the provided information. In addition, the Executive Director, Deputy Director, or a Compliance Officer will review applications periodically to ensure compliance.

Sunset Factor 3: The extent to which the Board serves the entire State rather than specific interests.

Recommendation 24: The Board should ensure it complies with all State conflict-of-interest requirements.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board takes this matter seriously and does focus on the State vs specific interests.

Recommendation 25: The Board should develop and implement comprehensive policies and procedures for addressing potential conflicts of interest in accordance with State laws, including:

Recommendation 25a: Requiring Board members and staff to refrain from voting or otherwise participating in matters related to the disclosed interest.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will develop and implement a policy and procedure to address potential conflicts of interest for Board members and staff in accordance with State laws.

Recommendation 25b: Requiring Board members and staff to complete an annual conflict-of-interest disclosure form.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has implemented an annual conflict-of-interest disclosure form. This will be addressed at every January Board meeting.

Recommendation 25c: Defining a process for ensuring that completed conflict-of-interest disclosure forms are maintained in a separate special disclosure file available for public inspection.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has implemented a process to maintain the completed annual conflict-of-interest forms in a separate disclosure file. This is maintained by the Executive Secretary.

Recommendation 25d: Implementing a process for managing and monitoring any disclosed potential conflicts of interest to ensure the conflict will not interfere with the performance of Board member and staff duties.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will develop and implement a process for managing and monitoring any disclosed potential conflicts of interests to ensure the conflict will not interfere with the performance of a Board member or staff duties.

Recommendation 25e: Documenting reasons for Board member recusal in Board meeting minutes and maintaining a copy of these minutes in the special disclosure file.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board has revised its process to have each Board member sign and complete a disclosure or recusal form developed by the Board's attorney(s). The form will also include the reasons for the recusal. These forms will be maintained in a special disclosure file.

Sunset Factor 5: The extent to which the Board has encouraged input from the public before adopting its rules and the extent to which it has informed the public as to its actions and their expected impact on the public.

Recommendation 26: The Board should ensure it complies with all open meeting law requirements.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board developed a checklist that the Executive Secretary or Board staff completes for each meeting to ensure it complies with open meeting law requirements.

Recommendation 27: The Board should develop and implement policies and procedures to guide its staff in complying with the State's open meeting law, including appropriately citing executive sessions on Board meeting agendas and making its public meeting minutes available as required by law.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will develop policies and procedures to guide its staff in complying with the State's open meeting law. The Board is currently working on adjusting its Board meeting agenda to appropriately cite executive sessions. In addition, the Board has developed a process to ensure the meeting minutes are available, or a notice, within 3 working days and/or that the recorded meeting minutes are available, or a notice, within 5 working days.

Sunset Factor 6: The extent to which the Board has been able to investigate and resolve complaints that are within its jurisdiction.

Recommendation 28: The Board should investigate and adjudicate complaints in 180 days or less.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The complaints the Board receives range from complex to relatively straightforward. The Board investigates and adjudicates the majority of its complaints within the 180 day time frame. The Board strives to swiftly complete the complaints and has developed a process to ensure that the complaints are completed in an efficient manner. However, this process does take into account that some complaints take longer because of the complexity or circumstances of the case.

Recommendation 29: The Board should develop and implement time frames for the steps in its complaint-handling process to help ensure complaints are investigated and adjudicated in 180 days or less.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: Currently the Board is reviewing the complaint process to distinguish what the time frames are appropriate for the steps in the complaint-handling process. Within the next 6 months, the Board plans to develop and implement time frames for the steps in its complaint-handling process with the goal of completing the cases within 180 days.

Recommendation 30: The Board should track complaints in accordance with its complaint-handling process steps.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will continue to use its database to track complaints and evaluate the steps taken to process the complaint as discussed in the response explanation to Recommendation 30.

Recommendation 31: The Board should continue with its newly implemented process for issuing subpoenas to licensees/permit holders who do not respond to requests for information in a timely manner and take action, where appropriate, against licensees/permit holders who do not respond to subpoenas.

Board Response: The finding of the Auditor General is agreed to and the audit recommendation will be implemented.

Response explanation: The Board will continue issuing subpoenas to licensees and permit holders in order to take action in a timely manner. In addition, if a licensee or permit holder fails to comply with the subpoena, which will be noted in the investigation and presented to the Board to decide whether or not to take action for the failure to comply with the Board's subpoena. The Board will also look at running legislation that requires a license holder or permit holder to cooperate with the Board without the need for a subpoena.