

Arizona State Board of Pharmacy 36-Month Follow-Up Report

The September 2020 Arizona State Board of Pharmacy (Board) performance audit and sunset review found that the Board did not fulfill several regulatory responsibilities, base its fees on the cost of providing services, enforce compliance with State Controlled Substances Prescription Monitoring Program (CSPMP) requirements, and provide accurate and complete information to the public. We made 42 recommendations to the Board, and its status in implementing the recommendations is as follows:¹

Status of 42 recommendations

| Implemented | 18 |
|---|----|
| Implemented in a different manner | 5 |
| Partially Implemented | 1 |
| Implementation in process | 3 |
| Implementation in process in a different manner | 1 |
| No longer applicable | 1 |
| Not yet applicable | 3 |
| Not implemented | 10 |

We will follow up with the Board on the status of the recommendations from the September 2020 report that it has not implemented during the Board's next performance audit and sunset review, which we plan to initiate later in 2024.

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

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.

Implemented at 18 months

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.

Not implemented—As reported in the 18-month followup, in March 2021, the Board convened a task force consisting of Board members and stakeholders that recommended the Board not require licensees to maintain a valid fingerprint clearance card and submit them at renewal because statute already requires licensees to report certain misdemeanors and felonies to the Board. The Board voted to accept the task force's recommendation during its March 2021 regular Board meeting. However, fingerprint clearance cards rely on information from law enforcement agencies, which provides better assurance that an applicant has not been arrested for or convicted of a criminal offense that would preclude their ability to have their license renewed. Therefore, by not requiring licensees to maintain a valid fingerprint clearance card and submit them at renewal, and relying solely on renewal applicants to self-disclose, the Board cannot independently ensure that its licensees have not been arrested or convicted of an offense that would preclude them from renewing their license.

¹ In previous follow-up reports, we noted that there were 41 recommendations; however, for this follow-up report, we split recommendation 18 into 2 subrecommendations, resulting in 42 recommendations.

- **3.** The Board should, 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.
 - **No longer applicable**—This recommendation is no longer applicable because the Board has determined to not pursue a statutory amendment to require licensees to maintain a valid fingerprint clearance card and submit them at renewal (see explanation for Recommendation 2).
- **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.
 - **Implemented in a different manner at 12 months**—The Board has developed and implemented policies and procedures for conducting continuing education audits monthly instead of after each renewal cycle.
- 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.

Implemented at 18 months

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

Implemented at 18 months

- 7. The Board should consistently meet established inspection time frames by developing and implementing processes for tracking and monitoring the completion of facility inspections.
 - Implementation in process—Board policy specifies time frames for inspecting compounding pharmacies and outsourcing facilities and for conducting routine compliance inspections. All permitted facilities are subject to routine compliance inspections. According to Board policy, routine compliance inspections are to be completed within an 18-month cycle for each permitted facility, while compounding pharmacies and outsourcing facilities that compound sterile or nonsterile products including hazardous compounds may be placed on a 12-month inspection cycle. The Board's most recent 18-month inspection cycle concluded on December 31,2023, and according to the Board's inspection log, it inspected 1,182 of 1,728 pharmacies. According to the Board's inspection log, the Board inspected 68 of 198 compounding facilities during its calendar year 2023 12-month inspection cycle. The Board attributed its inability to inspect all pharmacies within its established time frames to inspection staff turnover, the need to hire and train new inspection staff, and the complexity of inspections. We will further assess the Board's compliance with its inspection time frames during the Board's next sunset review, which we plan to initiate later in 2024.

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

- **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:
 - **a.** 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.
 - **Implementation in process in a different manner**—In February 2023, the Board partnered with the Arizona Governor's Transformation Office (GTO) for assistance with evaluating its regulatory processes, such as its inspection, complaint-handling, and licensing processes. This assistance included conducting observations of some field inspections and recommending that the Board track the time it spends on various compliance-

- related activities, including travel time. However, the Board has not developed policies and procedures for determining its regulatory costs or conducting periodic review of its fees. We will further assess the Board's implementation of this recommendation during its next sunset review, which we plan to initiate later in 2024.
- **b.** After implementing this cost methodology, determine the appropriate license and permit fees.
 - Not yet applicable—See explanation for Recommendation 8a.
- **c.** Consider the effect of proposed fee changes on applicants, licensees, and permit holders and obtain their input when reviewing the fees.
 - Not yet applicable—See explanation for Recommendation 8a.
- d. Adjust its fees in its rules, as necessary.
 - Not yet applicable—See explanation for Recommendation 8a.
- **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.
 - Implemented in a different manner at 36 months—As reported in our initial followup, the Board has not worked with the Legislature to revise statute to eliminate the reciprocity fee and instead approved plans to revise its rules to lower the reciprocity fee from \$300 to \$150. The Board completed the revision to its rules, which became effective in March 2024, and although this rule change still requires reciprocity applicants to pay more than nonreciprocity applicants for an initial license, it more closely aligns the reciprocity fee with the nonreciprocity application fee.

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

- 10. The Board should enforce licensed pharmacist and permitted pharmacy compliance with State CSPMP statutes.
 - Implementation in process—Although the Board has taken some steps to enforce licensed pharmacist and permitted pharmacy compliance with CSPMP statutory requirements, it has not implemented all recommendations to help ensure compliance with these requirements. For example, as explained in Recommendation 11, although the Board reported that statutory changes, such as defining a "new course of treatment," are needed to help it determine whether pharmacists check the CSPMP database as required and discussed potential statutory changes at an August 31, 2022, CSPMP task force meeting, it decided not to pursue statutory changes, explaining that changes would be too costly to implement. However, the Board was unable to provide documentation supporting an analysis of or the costs it estimated to implement these changes. Additionally, as explained in Recommendations 13 and 14, the Board has not developed processes for identifying and following up with permitted pharmacies that are outside of Arizona that should have, but are not, registered to submit information accessible through the CSPMP database. We will further assess the Board's implementation of this recommendation during its next sunset review, which we plan to initiate later in 2024.
- **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.
 - Partially implemented at 36 months—As reported in our 18-month followup, the Board has developed and implemented processes to identify licensed pharmacists who have not registered with the CSPMP database as required and to remind these pharmacists of their responsibility to register with and check the CSPMP database. The Board also developed a process to enforce compliance with this registration requirement. For 1 licensed pharmacist we reviewed, this included the Board sending this licensee an advisory letter and nondisciplinary order requiring the licensee to take continuing education related to pharmacy law. Although the Board reported that statutory changes, such as defining a "new course of treatment," are needed to assist it in determining whether pharmacists check the CSPMP database as required and discussed potential statutory changes at an August 31, 2022, CSPMP taskforce meeting, it decided not to pursue statutory changes, explaining that changes would be

too costly to implement. However, the Board was unable to provide documentation supporting an analysis of or the costs it estimated to implement these changes.

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.

Implemented at 18 months

- **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.
 - Not implemented—During our 18-month followup, the Board reported that it was in the process of developing a procedure using its licensing database and the Drug Enforcement Administration (DEA) numbers of permitted pharmacies it collects to identify those pharmacies that are outside of Arizona that should be, but have not registered to submit information accessible through the CSPMP database. However, the Board indicated that its licensing database vendor is not able to generate a usable report for Board staff to identify nonresident pharmacies not reporting into the CSPMP. The Board reported that it is in the process of switching to a new licensing database, which it anticipates implementing by the end of calendar year 2024. The Board further reported that the new database should be able to furnish a usable report, and anticipates that the data and information needed for this report will be available in its new database by July 2025. We will assess the Board's implementation of this recommendation during its next sunset review, which we plan to initiate later in 2024.
- **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.
 - Implementation in process—As reported in our 18-month followup, the Board has implemented a process to identify permitted pharmacies with an Arizona address that should have, but are not, registered to submit information accessible through the CSPMP database and to open a complaint against delinquent pharmacies. However, as explained in Recommendation 13, the Board has not developed a process for identifying permitted pharmacies that are outside of Arizona that should have, but are not, registered to submit information accessible through the CSPMP database. Lacking this information, the Board would not be able to follow up with out-of-State pharmacies that are not reporting or are delinquent in reporting to the CSPMP database. We will further assess the Board's implementation of this recommendation during its next sunset review, which we plan to initiate later in 2024.
- **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.

Implemented at 12 months

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

Implemented at 18 months

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

Implemented at 18 months

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

- 18. The Board should provide required information on its website by updating it to include:
 - a. All required information about licensees and permit holders, including nondisciplinary actions.
 Not implemented—The Board's website does not include all required information about licensees and permit holders. For example, the Board had not made available on its website the record of final nondisciplinary action for 6 licensees we reviewed during the audit.
 - b. A statement informing the public that they can contact the Board for more information as required by statute.
 Implemented at 18 months—The Board posted the statutorily required statement on its website informing the public that they can contact the Board for more information about its licensees and permit holders.
- **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.
 - Not implemented—As reported in the 18-month followup, the Board developed policies and procedures to guide Board staff on providing information related to disciplinary and nondisciplinary actions to the public over the phone. The policy also allows Board staff to require a caller to file a public records request when inquiring about nondisciplinary actions because information about these actions may be difficult for Board staff to locate. Callers must make a written request for complaint history rather than receiving this information over the phone, and we noted that these practices can make it more challenging for callers to obtain publicly available information from the Board, especially those that may not have reliable internet access. However, the Board has not further updated or revised its policies and procedures. Additionally, in response to an anonymous phone call we made to the Board, Board staff reported that it could not provide information about a licensed pharmacy technician who received a disciplinary action over the phone; referred us to the Board's website and said we should submit a public information request. We will further assess the Board's provision of complete and accurate information to the public over the phone during its next sunset review, which we plan to initiate later in 2024.
- **20.** The Board should develop and provide training for its staff once it has developed the policies and procedures outlined in Recommendation 19.
 - Not implemented—As reported in the 18-month followup, the Board has provided training to its staff on its policies and procedures for providing information to the public. However, as explained in Recommendation 19, the Board's policies do not require its staff to provide complete complaint information over the phone, and in response to an anonymous phone call we made to the Board's office requesting information about a licensed pharmacy technician who had received a disciplinary action, its staff was unable to provide any information (see explanation for Recommendation 19). We will further assess the Board's implementation of this recommendation during its next sunset review, which we plan to initiate later in 2024.

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

- **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.
 - **Not implemented**—As reported in the initial followup, the Board opted to revise its rules to allow it to rely on the national boards' training attestation requirements and has been in the process of revising its rules. However, the Board has yet to finalize these rules and reported anticipating doing so by the end of calendar year 2024.

- **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
 - **a.** Opening mail with at least 2 staff members present.

Implemented at 12 months

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

Implemented at 18 months

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

Implemented in a different manner at 36 months—As reported in the 18-month followup, the Board developed policies and procedures for depositing cash receipts exceeding \$1,000 by the end of the business day following receipt of the cash. However, the Board updated its policy in March 2023 to include language that permits extended overnight storage of cash receipts, stipulating that "adequate" staffing levels are needed to follow its written policy. The Board reported that when needed, cash receipts are stored in a locked cabinet with access restricted to 1 person in an office that is not accessible to the public. Based on our review of 5 Board deposit records from July 2023 that exceeded \$1,000, the Board adhered to its policies and procedures by depositing these cash receipts by the next business day for 4 of 5 deposits. The Board made 1 deposit 2 business days after it received the cash, attributing the delay to the lack of staff availability to make the deposit.

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

Implemented at 12 months

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

Not implemented—Although the Board provided training to its staff on topics that cover some of its cash-handling processes, it has not developed a specific cash-handling training, and documentation provided by the Board shows potential inadequacies in its training curriculum. For example, the Board administered a mail-processing quiz that contains questions related to cash-handling, and 4 of 6 staff members who took the quiz received a failing score of 50 percent. Additionally, the Board did not provide documentation showing that it has developed a process for periodic review of staff work to help ensure compliance with its policies and procedures. We will further assess the Board's implementation of this recommendation during its next sunset review, which we plan to initiate later in 2024.

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

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

Implemented at 12 months

- **25.** The Board should develop and implement comprehensive policies and procedures for addressing potential conflicts of interest in accordance with State laws, including:
 - **a.** Requiring Board members and staff to refrain from voting or otherwise participating in matters related to the disclosed interest.

Implemented at 12 months

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

Implemented at 12 months

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

Implemented at 12 months

d. 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.

Implemented at 36 months

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

Implemented in a different manner at 12 months—Although the Board's meeting minutes document when Board members recuse themselves from agenda items, the Board has implemented a different process for documenting the reasons for members' recusals. Specifically, Board members are required to complete a "Declaration of Conflict of Interest" form for each recusal, including the reason for the recusal. The Board maintains completed forms 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.

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

Implemented at 12 months

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.

Implemented at 12 months

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

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

Not implemented—As reported in our 18-month followup, the Board has not developed and implemented time frames for all the steps in its complaint-handling process to help ensure complaints are investigated and adjudicated within 180 days. The Board reported that it is working with a new database vendor to develop the capability in its database to track complaint-handling, and as of April 2024, reported that it anticipates implementing this capability by the end of calendar year 2024, at which time it will also update and implement policies for complaint processing, including developing time frames for the steps in its complaint-handling process. We will assess the Board's implementation of this recommendation and Recommendations 29 and 30 during its next sunset review, which we plan to initiate later in 2024.

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.

Not implemented—See explanation for Recommendation 28.

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

Not implemented—See explanation for Recommendation 28.

- **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.
 - Implemented in a different manner at 18 months—The Board has modified its approach to issuing subpoenas. Specifically, the Board has developed and implemented a policy that requires it to issue subpoenas with all complaint notices to licensees requiring licensees to respond to the complaint allegations rather than only when the licensee does not respond to the Board's requests. According to the Board, it issues subpoenas to permit holders as necessary. Further, the Board has implemented its policy to take action, where appropriate, against licensees/permit holders who do not respond to subpoenas. Specifically, if a licensee or permit holder does not respond to a subpoena, the complaint is presented to the Board for referral to a formal hearing.