



**DEBRA K. DAVENPORT, CPA**  
AUDITOR GENERAL

**STATE OF ARIZONA**  
OFFICE OF THE  
**AUDITOR GENERAL**

**MELANIE M. CHESNEY**  
DEPUTY AUDITOR GENERAL

January 5, 2016

The Honorable Judy Burges, Chair  
Joint Legislative Audit Committee

The Honorable John Allen, Vice Chair  
Joint Legislative Audit Committee

Dear Senator Burges and Representative Allen:

Our Office has recently completed a 24-month followup of the Arizona State Board of Pharmacy regarding the implementation status of the 16 audit recommendations (including sub-parts of the recommendations) presented in the performance audit report released in September 2013 (Auditor General Report No. 13-07). As the attached grid indicates:

- 6 have been implemented;
- 8 are in the process of being implemented;
- 1 is not yet applicable; and
- 1 is no longer applicable.

Our Office will conduct a 36-month followup with the Board on the status of those recommendations that have not yet been fully implemented.

Sincerely,

Dale Chapman, Director  
Performance Audit Division

DC:kf  
Attachment

cc: Dennis McAllister, President  
Arizona State Board of Pharmacy

Kam Gandhi, Executive Director  
Arizona State Board of Pharmacy

# Arizona State Board of Pharmacy

## Auditor General Report No. 13-07

### 24-Month Follow-Up Report

#### Recommendation

#### Status/Additional Explanation

#### Licensing and Permitting

- |  |   |
|--|---|
| 1. The Board should develop and implement policies and procedures that direct its staff to obtain and review all necessary documentation to ensure that license and permit applicants meet all statutory and rule requirements prior to issuing a license or permit. These policies and procedures should outline the specific documentation that staff should accept as proof that each requirement has been met. | <b>Implementation in process</b><br>The Board has developed policies and procedures that direct its staff to obtain and review all necessary documentation to ensure that license and permit applicants meet all statutory and rule requirements prior to issuing a license or permit. However, the Board is in the process of revising these policies and procedures to ensure that all requirements are included and that the policies are consistent with its other application documents. |
| 2. The Board should revise its license and permit applications to require applicants to submit all necessary information and documentation with their applications so the Board can determine whether the applicants meet all statutory and rule requirements to receive a license or permit.  | <b>Implementation in process</b><br>The Board has revised its license and permit applications and other application documents to require applicants to submit most of the necessary information and documentation with their applications. The Board reported that it will continue to revise these documents to ensure that they request all required information and documentation and that they are consistent with board policies and procedures.   |
| 3. The Board should continue to review and approve all applications for in-state and out-of-state pharmacy, wholesaler, and manufacturer permits as required by statute.   | <b>Implemented at 6 months</b>  |
| 4. The Board should develop and implement policies and procedures that require its staff to track the Board's compliance with all licensing and permitting time frames. These policies and procedures should also specify either an electronic method for tracking compliance with the time frames or the documentation that staff should retain to allow them to manually do so.                                  | <b>Implementation in process</b><br>The Board has developed policies that require its staff to track the time frames for issuing licenses and permits. Staff have begun to track the time frames for some of the licenses and are developing an in-house system to track the time frames for permits. In addition, the Board reported that it is seeking additional resources, such as new software or additional staff, to help it to fully track all license and permit time frames.        |
| 5. As required by A.R.S. §41-1073, for those license and permit applications that are processed outside of the Board's time frames, the Board should ensure it refunds all application fees to applicants and pays required penalties to the State General Fund.   | <b>Implementation in process</b><br>The Board's new policy requires it to review whether licenses and permits are issued within required time frames on a quarterly basis and, for untimely issuances, refund all application fees to applicants and pay any required penalties to the State General Fund. However, the Board will not be able to implement this new policy until it has developed a system for tracking timeliness (see Licensing Recommendation 4).                         |

## Recommendation

## Status/Additional Explanation

6. Once all of the policies and procedures have been developed and implemented, the Board should ensure appropriate staff are trained on and follow them.

### Implementation in process

Although the Board's staff have been trained on some of the policies and procedures, the Board cannot fully implement this recommendation until it finalizes the revision of its policies and procedures according to Licensing Recommendations 1, 2, and 4.

## Inspections

1. The Board should implement its new follow-up procedures that help ensure that some types of violations are corrected.

### Implemented at 24 months

2. The Board should develop and implement follow-up procedures that require some type of follow-up work to ensure that all violations found through inspections are corrected, such as requiring staff to review submitted documentation, reinspect, or perform other follow-up methods, as appropriate.

### Implementation in process

Overall the Board has improved its inspection follow-up policies and practices. The Board requires licensees to send a corrective action plan that explains how violations found through inspections have been corrected. Board policy requires inspectors to determine whether the corrective action plan is sufficient to address the violations but does not require licensees to submit evidence of the corrective action along with the corrective action plan. In addition, auditors found five of six inspections reviewed resulted in appropriate board followup. In the inspection that did not result in appropriate followup, the Board's follow-up policies required a re-inspection of the facility, but the inspector did not perform one. Auditors will assess the Board's continued implementation of this recommendation at the next followup.

3. The Board should continue to improve its tracking of nonprescription drug retailer inspections to ensure that they are inspected every 18 months to 2 years in accordance with the Board's inspection frequency goal.

### Implemented at 6 months

4. The Board should continue its efforts to gain access to nonprescription drug retailers that are in restricted areas.

### Implemented at 6 months

## Public Information

1. The Board should implement its April 2013 policies and procedures to ensure that staff provide complete and timely information in response to public requests and ensure that all staff are trained on them.

### Implementation in process

As of May 2014, the Board had implemented its policies, trained its staff, and had demonstrated that it provided accurate and timely public information over the phone. However, the Board's policies require it to provide information, such as copies of inspection reports, within 48 hours, and the Board has not yet complied with this policy. Specifically, auditors made one anonymous request for inspection reports for one pharmacy but did not receive them for more than 20 business days and did not receive all available reports. Auditors will again evaluate the implementation of this recommendation at the next followup.

**Recommendation****Status/Additional Explanation****Sunset factor #2 The extent to which the Board has met its statutory objective and purpose and the efficiency with which it has operated.**

1. The Board should strengthen controls over cash receipts by adequately separating responsibilities to the extent possible. In addition, the Board should reconcile cash receipts to the numbers of licenses and permits issued and recorded in the Board's licensing system. This reconciliation should be prepared, or at least reviewed, by a person independent of cash receipt collection.

**Implemented at 6 months**

2. To comply with statutory requirements for assigning licensees and permittees to their biennial renewal groups prior to issuing an initial license or permit, the Board should consider modifying its licensing system to provide the information the Board needs to make these assignments as required.

**Not yet applicable**

According to the Board, its database needs to be recoded to allow it to correctly assign licensees and permittees to their biennial renewal groups prior to issuing an initial license or permit. The Board has been working with the Arizona Department of Administration to transition to a new database vendor; however, this transition has not taken place. The Board has requested funding through the state budget process for fiscal year 2017 to obtain its own database vendor.

3. The Board should ensure that its staff open a complaint when licensees do not comply with continuing education requirements and forward the complaint to the Board for review and possible disciplinary action.

**Implemented at 24 months**

**Sunset factor #4 The extent to which rules adopted by the Board are consistent with the legislative mandate**

1. The Board should develop rules that govern when substitution for prescription drugs is not allowable and rules regarding prescription drug identification information. These rules should conform to the practice of referring to federally provides information in these two areas.

**No longer applicable**

Laws 2014, Ch. 102, removed the requirements to establish these rules. Therefore, this recommendation is no longer applicable.

2. The Board should develop rules clarifying that, in order to obtain a permit, in-state compressed medical gas distributors and suppliers should provide proof of compliance with local zoning laws and that out-of-state compressed medical gas distributors and suppliers should provide proof of a state license or permit from the jurisdiction in which the facility operates. In addition, the Board should develop a rule clarifying that, in order to obtain a permit, out-of-state drug manufacturers should provide a resume from the manager or responsible person.

**Implementation in process**

The Board has adopted new rules for both in-state and out-of-state compressed medical gas distributors and suppliers. However, the Board has not adopted a rule clarifying that, in order to obtain a permit, out-of-state drug manufacturers should provide a resume from the manager or responsible person. According to the Board, it plans to seek this rule change the next time it opens a rule-making docket.