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STATE OF ARIZONA
OFFICE OF THE
AUDITOR GENERAL

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DEPUTY AUDITOR GENERAL

November 17, 2016

The Honorable John Allen, Chair
Joint Legislative Audit Committee

The Honorable Judy Burges, Vice Chair
Joint Legislative Audit Committee

Dear Representative Allen and Senator Burges:

Our Office has recently completed a 36-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:

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- 1 is no longer applicable.

Unless otherwise directed by the Joint Legislative Audit Committee, this concludes our follow-up work on the Board's efforts to implement the recommendations from the September 2013 report.

Sincerely,

Dale Chapman, Director
Performance Audit Division

DC:ka
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

36-Month Follow-Up Report

Recommendation

Status/Additional Explanation

Licensing and Permitting

<p>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.</p>	<p>Implemented at 36 months</p>
<p>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.</p>	<p>Implemented at 36 months</p>
<p>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.</p>	<p>Implemented at 6 months</p>
<p>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.</p>	<p>Implementation in process Although the Board's policies require staff to track its compliance with license/permit time frames, the Board reported that it plans to fully implement this recommendation by implementing a new database in February 2017 that will automate this tracking. In the interim, staff have begun to develop and use manual processes for tracking some of the time frames and are still refining these manual processes.</p>
<p>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.</p>	<p>Implementation in process The Board's 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 its new database for tracking time frames (see Licensing Recommendation 4).</p>
<p>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.</p>	<p>Implementation in process Although board staff have been trained on some of the Board's policies and procedures, the Board cannot fully implement this recommendation until it implements Licensing Recommendations 4 and 5.</p>

Recommendation

Status/Additional Explanation

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. | Implemented at 36 months |
| 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. | Implemented at 36 months |
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Sunset factor #2 The extent to which the Board has met its statutory objective and purpose and the efficiency with which it has operated.

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| 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
The Board's database does not provide the information needed to allow it to correctly assign pharmacist licensees to their biennial renewal groups prior to issuing an initial license. The Board is in the process of developing a new database that will be able to assign all licensees/permittees to their biennial renewal groups prior to issuing an initial license/permit. According to the Board, the new database will be implemented in February 2017. |

Recommendation**Status/Additional Explanation**

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 provided 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.

Partially implemented at 36 months

The Board has adopted new rules for both in-state and out-of-state compressed medical gas distributors and suppliers. However, the Board cannot adopt a new rule clarifying that, to obtain a permit, out-of-state drug manufacturers should provide a resume from the manager or responsible person until the Governor's rule moratorium is removed. According to the Board, it plans to seek this rule change once the moratorium is removed.