



Arizona Board of Pharmacy
1616 W. Adams Street, Room 120
Phoenix, AZ 85007
MAIL TO: P O Box 18520,
Phoenix, AZ 85005

August 21, 2013

Debra Davenport, CPA
Auditor General
Office of the Auditor General
2910 N. 44th St., Suite 410
Phoenix, AZ 85018

Dear Ms. Davenport,

The Arizona Board of Pharmacy (Board) appreciates the opportunity to respond to the findings of the Audit Report which was received from your office on August 20, 2013. We would also like to express our appreciation to your staff for their professionalism while conducting the review.

The Board and staff also appreciate the time and resources committed by your office.

The Board and staff are cognizant of the recommendations in the report and we assure you that we have either implemented corrective action or are in the process of doing so. It is our intent to comply with all of the recommendation.

Please call me if you have any questions or concerns.

Thank you for your consideration,

Hal Wand
Executive Director

cc: Arizona State Board of Pharmacy members

Licensing and Permitting Recommendations:

- 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 may accept as proof that each requirement has been met.**

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

The application documents and policy and procedures have been or are being reviewed and many appropriate revisions have been started already.

Also, outdated policies (guidelines) have been removed from the board's webpage and replaced with new policies or a notice that the policy (guideline) is under revision.

- 2. The Board should revise its permit applications to require applicants to submit all the 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.**

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

The license and permit application documents have been reviewed and revisions are being made.

- 3. The Board should continue to review and approve all applications for in-state and out of wholesaler, and manufacturer permits as required by statute.**

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

- 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.**

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

Policies and procedures have been reviewed and identified for revision; the revision process is ongoing and several rules change packages have been opened which will make the time frames (which were determined several years ago) more consistent with actual work flow in our offices. Electric time stamp machines have been purchased.

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.**

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

Policies and procedures have been reviewed, revisions have been made and revisions will be ongoing depending on the progress of the rules changes in process.

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.**

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

It is our goal to have all revisions as well as training complete by the end of this calendar year (December 30, 2013).

Inspections / Recommendations:

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

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

The board staff have been receiving and reviewing the letters that were sent back from the persons responsible for complying with pharmacy rules and/or statutes after non-compliant inspection findings.

It is clear that the respondents attest that the appropriate remediation has been done. We will increase our re-inspections at the sites that have responded to alleged violations to verify that the corrective action has in fact been done. This may result in a significant increase in travel expenses and thus becomes an important budgetary consideration.

- 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, re-inspect, or perform other follow-up methods, as appropriate.**

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

It is my understanding that appropriate staff review is being conducted on the overwhelming majority of the responses to violations noted on inspection. Re-inspections for verification will be increased.

- 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.**

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

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

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

Complaint Resolutions

None reported.

Public Information Resolutions

- 1. The Board should implement its April 2013 policy and procedure to ensure that staff provide complete and timely information in response to public requests and ensure that staff is trained on them.**

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

Compliance/Inspection staff will be utilized as public information resources one day per week beginning September 1, 2013 as an added resource to answer inquiries not related to items in the revised policy/ices and to cover for the expected increase of public records requests being processed by the personnel identified in the revised policy. These staff members were already in the office one day a week for briefings, discussions with supervisors and post inspection follow-up activities.

Sunset Factor Analysis

Sunset Factor 2 Bullet 1

As indicated in the Office of the Auditor General's August 2013 procedural review, the Board agrees to and will implement the recommendations.

Sunset Factor 2 Bullet 2

The board has been renewing licenses and permits since 1976 under the statutes mentioned in the report from the auditors without notice or any complaint that it was not in compliance.

The board does agree with the auditors to make the changes as recommended, however the board staff feels that it will be unable to make the necessary changes to accommodate renewals of the licenses and permits that will expire on October 31, 2013, which is less than 60 days away. Those permits and licenses will therefore be processed the same way as they have been the previous 37 years because it is too late to modify the processes in question this close to the upcoming renewal period. If no changes to the statutes are made to accommodate the current renewal processes, board staff will make every effort to be sure that the October 31, 2014 renewal period will have been modified to comply with the auditors recommendations.

Sunset Factor 2 Bullet 3

The board agrees with the auditors findings and will open a complaint whenever a licensee is known to have been deficient in the required CE hours unless the board instructs the staff not do so pursuant to A.R.S. § 32-1927 (D).

Sunset Factor 2 Bullet 4

The board's database was designed by IBM engineers who were responsible for the design of the database that the state of Arizona used in the 1990's (and which it still uses) to allow Arizona drivers to renew their registrations for motor vehicle license tags online. The Government Information & Technology Agency (GITA) was attempting to design a common database for all boards and commissions at no charge to the agencies. This goal would be accomplished by using the excess funds available in the motor vehicle license renewal fund as a consequence of the state's contract with IBM. The board was approached by staff from GITA and asked to be the "guinea pig" or model agency in this endeavor and the board agreed. Unfortunately, the contract with IBM was cancelled before the design work was completed and the board became just one of the many agencies using what came to be known as the "web portal" administered by NIC. Design changes now cost money and some necessary "source code" from IBM is not available to NIC, so some changes could not be accommodated. The board has been utilizing the unfinished system with minor changes since September, 2006. The web portal was designed to process credit cards for online transactions for a variety of state agencies not as a licensing database. A new vendor has replaced NIC and we will work with them to design and implement appropriate changes or look to obtain a new system either from existing state contracts or in the retail market.

Sunset Factor 3

A new policy and procedure for public information requests has been developed.

Sunset Factor 4

The board agrees to and will implement the recommendations. The board is in the process of revising the compressed medical gas distributor/supplier permits due to new legislation regarding durable medical equipment. It is our intention to remove the requirement for proof of compliance with local zoning laws from all categories of permits. The manufacturer rules will also be reviewed and revised as recommended. Rules that refer to the federal agencies that provide lists of approved generic substitutions and prescription drug information/codes will also be drafted.

I am disappointed to admit that our 5 year rules revision is late this year but an extension has been granted for an extra three months. Part of the reason for the backlog here is that there was a rather long moratorium on new rules being promulgated by state agencies; it was in effect since early calendar year 2010 until late 2012. This has resulted in a rather substantial backup of proposed rules packages which we are currently attempting to “triage” or prioritize. We have placed a second compliance officer into service as a part time rules writer. This individual, who is both a pharmacist and a lawyer, has been a tremendous help in this important area and in our efforts to catch up.

The Board will develop a rule to require out-of-state compressed medical gas distributors and suppliers to provide proof of a state license or permit from the jurisdiction in which the facility operates.