STATE OF ARIZONA
OFFICE OF THE
AUDITOR GENERAL

Arizona State Board of Pharmacy

REPORT HIGHLIGHTS
PERFORMANCE AUDIT

Board should ensure that applicants meet all licensing and permit requirements

Our Conclusion

The Arizona State Board of Pharmacy (Board) issues licenses to professionals, such as pharmacists, interns, technicians, and trainees; and permits to drug-related facilities, such as pharmacies and nonprescription drug retailers. The Board should ensure that licenses and permits are issued only to applicants who meet all statute and rule requirements. In addition, although the Board conducts thorough and consistent inspections of pharmacies, it needs to follow up to ensure that violations are corrected and improve its tracking of nonprescription drug retailer inspections. Finally, the Board appropriately resolves complaints in a timely manner, but should improve its procedures for providing timely and complete public information about licensees and permit holders.

Board did not ensure that all applicants met licensing requirements—The Board issues licenses to pharmacists, interns, technicians, and trainees. We reviewed a random sample of 30 licenses approved in fiscal years 2011 and 2012 and found that the Board issued licenses to four applicants without obtaining all necessary documentation to show that the applicants met statutory and rule requirements. The missing documentation included proof of attendance at pharmacy school, proof of 1,500 certified practice hours, and proof of foreign pharmacy certification.

The Board has taken some steps to help verify that it issued one of its four license types only to applicants who met all licensure requirements. In September 2012, a board staff member began auditing the pharmacist application files, in part, to determine that all necessary documentation was obtained. However, this audit procedure is applied only to the pharmacist license and performed after a license is issued.

Board did not ensure that all applicants met permitting requirements—The Board also issues permits to facilities such as pharmacies and nonprescription drug retailers. We reviewed a random sample of ten permits and found that eight were issued without complete documentation of compliance with statutes and rules. For example, board rules require applicants to provide fingerprints, lease agreements, or proof of compliance with zoning laws, but some of the Board's permit applications do not request information or documentation regarding these requirements. In addition, for two of the eight permits, board staff did not review all documentation the permit application required. For example, when the Board learned that a drug-manufacturing permit holder was actually a wholesaler, the permit was changed, but no application or wholesaler documentation was required, such as proof of a $100,000 surety bond.

The Board lacks written policies and procedures regarding steps its staff should take to ensure that license and permit requirements are met. The Board has begun to develop some policies and procedures, but additional policies and procedures are needed.

Board should track compliance with licensing and permitting time frames—The Board also does not track its compliance with statutorily required time frames. If a state agency fails to issue licenses and permits in a timely manner, it must refund the license fees and may pay a penalty to the State General Fund. Because the Board does not track how long it takes to issue a license or permit, it does not know whether it is in compliance with its time frames. Although the Board has now outlined steps for processing license and permit applications within the required time frames, the steps do not require staff to track compliance with these time frames.

Recommendations

The Board should:

- Develop and implement policies and procedures that direct its staff to ensure that license and permit applicants meet all requirements;
- Revise applications to request all necessary documentation; and
- Track compliance with licensing and permitting time frames.

2013

September • Report No. 13-07

Board's inspection process is generally appropriate, but can be improved in two areas

Board inspections of permitted facilities are thorough and consistent. When inspectors find violations, board management requires a corrective action plan or, if violations are more serious, refers the matter to the Board's complaint-resolution process.

Board should perform sufficient follow-up work—The Board requires permitted facilities to address violations through a corrective action plan. However, the Board does not always follow up to ensure that violations were corrected, citing limited staff resources and the practice of waiting until the next inspection to verify that violations were addressed. Of the eight western states' pharmacy boards we surveyed, seven indicated that they conduct some type of follow-up work by calling facilities, inspecting the facilities, or asking for documentation.

In response to the audit, the Board developed two new follow-up procedures that require followup for some types of violations, but should also develop and implement additional follow-up procedures for all violations.

Board should improve its tracking of nonprescription drug retailer inspections—In addition, the Board comes close to meeting its goal of inspecting all pharmacies and nonprescription drug retailers every 18 to 24 months, having inspected about 90 percent between December 2010 and November 2012. However, although the Board has a sufficient process for tracking pharmacy inspections, it does not have a sufficient process for tracking nonprescription drug retailer inspections. Between December 2010 and November 2012, the Board did not inspect 463 of its 3,724 permitted nonprescription drug retailers. Board management cited several factors for not performing these inspections, including problems with its database, inspection staff errors, and difficulty in gaining access to some retailers. During the audit, the Board made improvements to its manual method of tracking nonprescription drug retailers that it will use until the database can be improved.

Recommendations

The Board should:

- Implement its new follow-up procedures and develop and implement procedures for following up on all violations, and
- Continue to improve its tracking of nonprescription drug retailer inspections.

Board should improve its provision of information to public

Although the Board provides appropriate public information on its Web site, it did not do so over the phone. We placed calls to the Board asking about complaint information for six licensees. Although staff provided some correct information regarding disciplinary actions, they failed to disclose complete or accurate information, including information on nondisciplinary actions, open complaints, and dismissed complaints. We also called asking for all the inspection reports for one pharmacy. The Board had performed 12 inspections of this pharmacy, but after waiting 42 calendar days, we received only 2 inspection reports. In response to this audit, the Board adopted policies and procedures in April 2013 to ensure that its staff provide timely and complete information in response to public requests.

Recommendation

The Board should implement its April 2013 policies and procedures to ensure timely and complete information is provided to the public and train its staff on these policies and procedures.