A REPORT
TO THE
ARIZONA LEGISLATURE

Performance Audit Division

Performance Audit and Sunset Review

Arizona State Board of Pharmacy

September • 2013
REPORT NO. 13-07

STATE OF ARIZONA
OFFICE OF THE
AUDITOR GENERAL

Debra K. Davenport
Auditor General

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STATE OF ARIZONA
OFFICE OF THE
AUDITOR GENERAL

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September 5, 2013

Members of the Arizona Legislature

The Honorable Janice K. Brewer, Governor

Mr. Thomas Van Hassel, President
Arizona State Board of Pharmacy

Mr. Hal Wand, Executive Director
Arizona State Board of Pharmacy

Transmitted herewith is a report of the Auditor General, *A Performance Audit and Sunset Review of the Arizona State Board of Pharmacy*. This report is in response to an October 26, 2010, resolution of the Joint Legislative Audit Committee. The performance audit was conducted as part of the sunset review process prescribed in Arizona Revised Statutes §41-2951 et seq. I am also transmitting within this report a copy of the Report Highlights for this audit to provide a quick summary for your convenience.

As outlined in its response, the Arizona State Board of Pharmacy agrees with all of the findings and plans to implement all of the recommendations.

My staff and I will be pleased to discuss or clarify items in the report.

Sincerely,

Debbie Davenport
Auditor General

Attachment

cc: Arizona State Board of Pharmacy Members

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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.

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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.

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Introduction

Audit scope and objectives

The Office of the Auditor General has conducted a performance audit and sunset review of the Arizona State Board of Pharmacy (Board) pursuant to an October 26, 2010, resolution of the Joint Legislative Audit Committee. This audit was conducted as part of the sunset review process prescribed in Arizona Revised Statues (A.R.S.) §41-2951 et seq and addresses the Board's licensing and permitting processes, permitted facility inspection program, complaint resolution process, and provision of information to the public. It also includes responses to the statutory sunset factors.

Mission and responsibilities

The Board was established in 1903 by the Arizona Territorial Government to regulate the practice of pharmacy. Its mission is to protect the health, safety, and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale, and storage of prescription medications, prescription devices, and nonprescription medications. The Board's responsibilities include:

- **Licensing professionals—**The Board licenses pharmacists and pharmacy interns, technicians, and trainees who work under the supervision of licensed pharmacists. According to board records, the Board issued, on average, about 5,000 initial licenses annually during fiscal years 2011 and 2012. In addition, the Board issues certifications to pharmacists and interns who administer immunizations. As of April 2013, the Board had 29,789 licensees and had issued 2,791 immunization certifications.

- **Permitting pharmacy- and drug-related facilities—**The Board issues permits to in-state and out-of-state facilities, including pharmacies, manufacturers, wholesalers, nonprescription drug retailers, and compressed medical gas distributors and suppliers.[1] According to board records, the Board issued, on average, about 900 initial permits annually during fiscal years 2011 and 2012. As of April 2013, the Board had 8,037 permitted facilities.

[1] The Board issues permits to facilities that are located outside of Arizona but sell various pharmaceutical products/devices or nonprescription drugs in the State.

- **Conducting inspections—**The Board inspects permitted facilities located in Arizona.[1] According to board records, the Board conducted 4,387 inspections between December 2010 and November 2012.

- **Resolving complaints—**The Board investigates complaints against licensees and permitted facilities and takes statutorily authorized nondisciplinary or disciplinary action, as needed. According to board records, in fiscal year 2012, the Board received 140 complaints and resolved 172 complaints, some of which were received during a prior fiscal year.

- **Providing information to the public—**The Board provides information about licensees and permitted facilities, including disciplinary history, on its Web site. In addition, the Board publishes agendas and minutes of its public meetings, a newsletter, and substantive policy statements on its Web site. Finally, board staff also respond to public requests for information.

- **Administering the Controlled Substances Prescription Monitoring Program (Monitoring Program)—**The Board maintains a computerized central database of all prescriptions for some types of controlled substances, such as opiates, depressants, and barbiturates, that are dispensed in Arizona. Because medical practitioners and pharmacies are required to report controlled substance prescription information weekly, the database improves the State's ability to identify controlled substance abusers and theft by tracking the prescribing, dispensing, and consumption of controlled substances. According to A.R.S. §36-2604, medical practitioners may request information from the database to treat patients. Such treatment may include identifying drug abuse and referring drug abusers and misusers for treatment. For example, medical practitioners or pharmacists may request a report on a patient's history with controlled substances in this State or in other states for a specified time frame, which can range from the past 30 days to more than 3 years. In addition, according to A.R.S. §36-2604, law enforcement may also request information related to an open investigation. The Board reported that during fiscal year 2012, the Monitoring Program monitored more than 34,000 medical practitioners' and pharmacists' weekly reported prescription activity and provided more than 841,000 reports regarding controlled substance use to medical practitioners, patients, professional boards, various state agencies, and law enforcement.

Organization and staffing

The Board consists of nine governor-appointed members: six pharmacists, with at least one employed by a licensed hospital and at least one employed by a community pharmacy and engaged in the day-to-day practice of pharmacy; one pharmacy technician; and two public members. Board members are appointed for 5-year terms. The Board was authorized 18 full-time equivalent staff positions for fiscal year 2013, all of which were filled as of May 2013.

[1] With the exception of nonprescription drug retailers, out-of-state permitted facilities are regulated by the local state board of pharmacy in each state. According to the National Association of Boards of Pharmacy, only three states—Arizona, Kansas, and Oregon—issue permits to nonprescription drug retailers.

Budget

The Board does not receive any State General Fund appropriations. Rather, its revenues consist primarily of license and permit fees. A.R.S. §32-1907 requires the Board to remit to the State General Fund 100 percent of all collected penalties and 10 percent of all other revenues, except for intergovernmental revenue and private grants. The Board's fiscal year 2013 net revenues totaled approximately $3.2 million (see Table 1). Personnel costs account for the majority of the Board's expenditures, which totaled more than $2.1 million in fiscal year 2012 and nearly $1.7 million in fiscal year 2013. However, the Board's fiscal year 2013 expenditures, which totaled more than $3.3 million, also included a $1 million transfer to the Arizona Poison and Drug Information Center as permitted by A.R.S. §32-1907 for the purpose of poison prevention, data collection, education, management of poisoned persons, and drug information services.[1] The Board's fiscal year 2013 ending fund balance was more than $2.5 million.

Table 1: Schedule of revenues, expenditures, and changes in fund balance
Fiscal years 2011 through 2013
(Unaudited)

	2011	2012	2013
Revenues, net of credit card fees[1]	$ 3,039,452	$ 3,263,908	$ 3,604,432
Remittances to the State General Fund[2]	(346,500)	(366,171)	(371,106)
Net revenues	2,692,952	2,897,737	3,233,326
Expenditures	1,886,984	2,136,625	3,349,453[3]
Transfers[4]	54,034	33,400	
Total expenditures and transfers	1,941,018	2,170,025	3,349,453
Net change in fund balance	751,934	727,712	(116,127)
Fund balance, beginning of year	1,203,176	1,955,110	2,682,822
Fund balance, end of year	$ 1,955,110	$ 2,682,822	$ 2,566,695

[1] Amount consists primarily of licenses and permit fees.

[2] As required by A.R.S. §32-1907, the Board remits to the State General Fund 100 percent of all collected penalties and 10 percent of all other revenues except for intergovernmental revenue and private grants.

[3] Amount increased greatly in fiscal year 2013 because the Board provided $1 million to the Arizona Poison and Drug Information Center as permitted in A.R.S. §32-1907.

[4] Amount primarily consists of transfers to the State General Fund in accordance with Laws 2010, 7th S.S., Ch. 1, §148 and Laws 2011, Ch. 24, §§108, 129, and 138 to provide support for state agencies.

Source: Auditor General staff analysis of the Arizona Financial Information System (AFIS) *Accounting Event Transaction File* for fiscal years 2011 and 2012; the AFIS Management Information System *Status of General Ledger-Trial Balance* screen for fiscal years 2011 through 2013.

[1] Board management reported the Board had a sufficient fund balance to make the $1 million transfer to the Arizona Poison and Drug Information Center in fiscal year 2013, but does not expect to have the monies to do so in fiscal year 2014.

Licensing and permitting

The Board should ensure that it issues licenses and permits only to qualified applicants and tracks its compliance with statutorily required time frames for processing applications.

Board did not ensure that applicants met all requirements before it issued them a license or permit

The Arizona State Board of Pharmacy (Board) should ensure that applicants meet all licensure and permitting requirements before it issues them a license or permit. The Board issues various licenses and permits to individuals and facilities in the pharmacy industry. Board statutes and rules outline specific requirements for licensure and permitting, which vary according to the 16 different types of licenses or permits the Board issues (see textbox for examples).

Example license and permit requirements

- **Pharmacist license**—Must have a pharmacy degree, complete at least 1,500 certified practice hours, and pass pharmacist licensure and state pharmacy law exams.
- **Pharmacy trainee license (works under the supervision of a licensed pharmacist)**—Must be 18 years old and have a high school diploma or equivalent to qualify for a license.
- **In-state pharmacy permit**—Must be overseen by an Arizona licensed pharmacist, provide facility plans or construction drawings that demonstrate compliance with size and security features required by rules, provide proof of compliance with local zoning laws that demonstrate the business is located in a nonresidential area, and receive an initial inspection.
- **In-state nonprescription drug retailer permit**—Must complete an application specifying the amount of nonprescription drug product it will stock and provide documentation of compliance with local zoning laws.

Source: Auditor General staff review of board license and permit requirements.

However, the Board issued 12 of 40 licenses and permits from fiscal years 2011 and 2012, or 30 percent of those that auditors reviewed, without ensuring that applicants met all requirements. By doing so, the Board was at risk for issuing licenses and permits to nonqualified applicants. A lack of policies and procedures and applications that do not require sufficient information contributed to the Board's issuance of these licenses and permits without first ensuring all requirements were met. Although the Board has taken some steps to try to mitigate this problem for the pharmacist license, the Board has not yet developed a process to ensure that all applicants meet all licensure and permit requirements. Therefore, 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. Specifically:

- **For 4 of 30 approved licenses reviewed, Board did not ensure that applicants met all licensure qualifications**—Auditors reviewed a random sample of 30 license applications that the Board approved in fiscal years 2011 and 2012 and found that the Board issued 4 of these licenses without determining that the applicants met all statutory and rule requirements for licensure.[1] Specifically, for these 4 applications, the

[1] The 30 applications reviewed included all license types—pharmacists, interns, technicians, and trainees.

Board did not obtain the necessary documentation to determine that the applicant met all requirements prior to issuing the license. Licensure requirements that the Board did not ensure these applicants met included proof of attendance at pharmacy school, completion of 1,500 certified practice hours, official court documents for self-disclosed misdemeanor violations, and proof of foreign pharmacy certification—which demonstrates that a foreign applicant has sufficient knowledge of safe pharmacy practice in the U.S. and can communicate information in English. As of June 2013, the Board had obtained the missing documentation showing that three of the four licensees met all statutory and rule licensure requirements. For the fourth applicant, the Board did not obtain a copy of official court documents on a misdemeanor conviction that the applicant self-reported. According to board management, this documentation helps board staff to determine whether the applicant is of good moral character, a requirement for licensure.

The Board has taken some steps to help verify that one of its four license types was issued only to applicants who met all licensure requirements. In addition to a review that occurs prior to issuing the license, board staff reported that in September 2012 a staff member began to audit pharmacist application files after the licenses were issued and prior to preparing the files to be scanned into the Board's database. The purpose of the file audit is to help ensure that the licensing files are organized and contain documentation that all licensure requirements were met. According to staff, due to the large workloads resulting from most pharmacist applications being submitted around pharmacy school graduation dates and only one staff member processing the licenses, there is not time to perform the file audit before issuing the license. According to staff, there have been instances where they have determined that a license had been issued without the file containing all of the required documentation. Staff then contacted the licensee to request the required documentation. According to staff, although some licensees did not respond, possibly due to out-of-date contact information, those who did respond provided the requested documentation. However, this audit approach has not been applied to the other three license types that the Board issues, and the Board still needs to ensure that applicants meet all licensure requirements prior to issuing a license.

- **For eight of ten approved permit applications reviewed, Board did not ensure that applicants met all permit qualifications—**Auditors reviewed a random sample of ten permit applications the Board approved in fiscal years 2011 and 2012 and found that the Board approved and issued eight of these permits without ensuring that the applicants met all statutory and rule requirements.[1]

  Deficiencies in the Board's permit applications explain most of the problems for seven of the eight permits. Specifically, the Board's permit applications do not require the applicant to submit information or documentation demonstrating compliance with some statutory and rule requirements. For example, for various permits, board rules require applicants to provide fingerprints, lease agreements, or documentation showing compliance with local zoning laws, but some of the Board's applications do not request information or documentation from applicants regarding these requirements. This problem could potentially affect many applicants. Auditors reviewed the statute and rule requirements for each of the Board's 12 permit types and

[1] The ten permit applications reviewed included five permit types—in-state and out-of-state pharmacies and nonprescription drug retailers, as well as out-of-state wholesalers.

found that 9 of the permit applications did not request that the applicant submit documentation to demonstrate compliance with one or more statutory or rule requirements.

In addition, for two of the eight permits, one of which was also included in the seven permits previously mentioned, board staff did not obtain and review all documentation required by the application. Specifically, in May 2010, the Board approved one applicant for a manufacturer permit, but nearly 18 months later, after further review, determined that the company was not manufacturing products and therefore should be classified as a wholesaler. However, board staff merely switched the permit type and did not require the applicant to submit the proper wholesaler application and associated wholesaler documentation, such as proof of a $100,000 surety bond. Also, for the other application, which was for an out-of-state pharmacy permit, the Board did not obtain a copy of the applicant's business license in the state where the permitted facility operates. According to board staff, this helps to ensure that the applicant's license from the other state was in good standing before issuing an Arizona license. As of June 2013, the Board obtained documentation to show that both of these permittees met these missing permit requirements. However, one of these two permittees was still missing two other requirements and, as a result, still has not met all statutory and rule requirements to obtain a permit.

- **Board has not reviewed and approved all permit applications as required by statute, but has allowed staff to do so—**The Board has allowed its staff to issue some permits without board review. Board statutes require the Board to review and approve permit applications before staff issue permits for some permit types, including pharmacy, wholesaler, and manufacturer in-state and out-of-state permits. Although it was the Board's practice to review in-state and out-of-state pharmacy and in-state manufacturer and wholesaler permits, the Board did not review and approve any of the three out-of-state wholesaler permit applications included in the sample of permit applications auditors reviewed. In addition, board staff reported that they issue out-of-state wholesaler and manufacturer permits without board review unless the applicant has disclosed a prior felony conviction or drug-related offense/charge or has had a permit disciplined in Arizona or another state. In response to the audit, as of June 27, 2013, the Board started reviewing and approving permit applications for in-state and out-of-state pharmacies, wholesalers, and manufacturers as required by statute.

The Board lacks written policies and procedures regarding steps its staff should take to ensure an applicant has met each statute and rule requirement prior to issuing a license or permit. As of April 2013, the Board had begun to develop some policies and procedures regarding some license application requirements and some license application processing procedures. However, additional policies and procedures are needed. Therefore, 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. The policies and procedures the Board develops should outline the specific documentation that staff should accept as proof that each license and permit requirement has been met. Additionally, once the new policies and procedures have been developed and implemented, the Board should ensure that its staff are trained on the policies and procedures. The Board should also 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. Finally, as required by statute, the

Board, rather than its staff, should continue to review and approve all pharmacy, wholesaler, and manufacturer in-state and out-of-state permit applications.

Board should track its compliance with time frames for issuing licenses and permits

The Board should track its compliance with statutorily required time frames for issuing licenses and permits. Specifically, statute requires the Board to establish time frames for issuing licenses and permits in rule. These time frames are important because they provide information and an assurance to the public about what to expect in regard to having a license approved or denied, and increase the Board's accountability when time frames are not met. If the Board does not meet its time frames for processing licenses and permits, statute requires it to refund licensing fees to applicants and pay a penalty of 2.5 percent of the applicant's fees to the State General Fund for each month that licenses and permits are not issued or denied within the established time frames.

Although the Board has established time frames in rule, the Board does not track its compliance with these time frames and, prior to April 2013, did not retain sufficient documentation to allow it to track these time frames. Specifically, auditors' review of the random sample of 30 approved license applications the Board issued in fiscal years 2011 and 2012 found that for 9 of these applications, the Board did not retain sufficient documentation to determine whether it processed these applications within required time frames. For example, board staff did not date stamp all application documents received and did not retain all documents needed to track timeliness, such as application checklists used by board staff that document several processing dates. Additionally, board staff did not use a database or other method to track the time frames. Similarly, board staff did not retain sufficient documentation to determine whether the permit processing time frame was met for 1 of the random sample of 10 permit applications auditors reviewed.

Because it does not track compliance with its established time frames, the Board does not know whether time frames are being met, whether it should identify and address any problems that may be causing any untimely processing of licenses, and whether fees should be refunded to an applicant and/or penalties should be paid to the State General Fund. Prior to April 2013, the Board lacked policies and procedures for processing license and permit applications within statutorily required time frames and for tracking its compliance with these time frames. As of April 2013, in response to the audit, the Board began to develop policies and procedures that outline steps its staff should take to process licenses within the statutorily required time frames. However, these policies and procedures still do not require staff to track compliance with the time frames. Therefore, 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. Finally, once policies and procedures have been developed and implemented, the Board should ensure all appropriate staff are trained on them.

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 should accept as proof that each requirement has been met.

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.

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.

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.

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.

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.

Inspections

Board inspections help to ensure permitted facilities' compliance with laws and regulations. Although inspections reviewed were thorough and consistent, the Board can improve its inspection process by performing sufficient followup to ensure violations are corrected and improving its method for tracking inspections of nonprescription retailers.

Inspections help ensure compliance with applicable laws and regulations

Arizona Revised Statutes §32-1904(A)(1) and (4) require the Arizona State Board of Pharmacy (Board) to inspect in-state permitted facilities, and board staff conduct routine inspections to help ensure that permitted facilities comply with applicable state and federal laws and regulations (see textbox).[1] The Board's inspection process is generally appropriate. Specifically:

- **Inspection checklists guide staff—**The Board has developed checklists to guide inspections of permitted facilities. Inspection checklists for pharmacies and nonprescription drug retailers—the largest categories of permitted facilities—help to guide inspectors' review of requirements based on all applicable state and federal laws and regulations, which generally focus on patient safety and confidentiality.

- **Inspections reviewed appeared thorough and consistent—**Auditors observed 22 inspections of permitted facilities and reviewed 37 inspection files and determined that staff used appropriate inspection checklists, which help to ensure that inspections are thorough and consistent. In addition, based on both the auditors' observations

Types of board inspections

Pharmacy—Inspect records, observe and interview staff, check for outdated medication, verify staff are licensed, perform controlled substance audits, and evaluate the pharmacy's environment, i.e., temperature, cleanliness, and security.

Nonprescription drug retailer—Check expiration dates on all nonprescription products that make a medical claim (such as that a product relieves pain or kills germs) and evaluate the retailer's stock rotation and environment, i.e., temperature and cleanliness.

Wholesaler—Review recordkeeping for tracking drugs that arrive at and leave the facility and condition of the merchandise, and evaluate the facility, i.e., lighting, ventilation, temperature, cleanliness, and security.

Manufacturer—Review procedures for several facility processes, including the quarantine and testing of raw ingredients, retention of product samples, and maintenance of logs related to equipment maintenance and product strength/purity; and evaluate the facility, i.e., cleanliness, security, and environment, including how temperature and humidity are monitored.

Compressed medical gas supplier/distributor—Assess processes for filling, labeling, testing, and storing canisters; maintaining customer records; and handling complaints; and evaluate the facility, i.e., cleanliness, security, and environment, including how temperature is monitored.

Source: Auditor General staff observation of board inspection staff and review of board inspection checklists.

[1] In addition to routine inspections, the Board also conducts inspections prior to granting permits and after a permitted facility has been remodeled, relocated, or changed ownership. These inspections are required by board rules and ensure that permitted facilities remain in compliance with regulations pertaining to staffing, physical layout, procedures, equipment, and environment.

and file review, board staff consistently identified violations based on permitted facilities' noncompliance with laws and regulations.

- **Board takes action when violations are found—**When a permitted facility has violated statute or rule, board management may either require the facility to submit a corrective action plan or, if the violation could have a serious impact on public health, refer the matter to the Board's complaint-resolution process. Auditors' review of inspection files showed that board management required corrective action plans for violations such as having an excessive amount of expired medication on store shelves, not updating equipment maintenance logs, and failing to perform inventories of controlled substances. For example, auditors reviewed one complaint that began as a routine board inspection but was appropriately escalated to the opening of a complaint. In this case, staff identified a potential violation by a pharmacy for selling prescription-only drugs obtained from another country as over-the-counter medicine. In cases such as this, where board management determines that a violation poses a threat to public health, it will open a complaint against the permitted facility in order to take disciplinary action. After reviewing this complaint, the Board disciplined the pharmacy by imposing a $10,000 civil penalty, placing the pharmacy on probation, and requiring its staff to conduct two inspections during the probation period to help ensure continued compliance.

- **Board largely meets inspection frequency goal—**Although statute does not require specific frequencies for conducting routine inspections, board management has developed a goal to inspect every pharmacy and nonprescription drug retailer once every 18 months to 2 years, depending on board staffing levels. Auditors' analysis of inspection data showed that the Board largely met its goal. Specifically, approximately 91 percent of pharmacies and 88 percent of nonprescription drug retailers that were permitted as of December 2010 were inspected in the 2-year period from December 1, 2010 through November 30, 2012 (see Table 2, page 13). According to board management, inspections of the other types of permitted facilities are a lower priority, and the Board does not have an inspection frequency goal for these facilities because they are also regulated and inspected by either the U.S. Food and Drug Administration or the U.S. Drug Enforcement Agency. As shown in Table 2, the Board conducted inspections of fewer of these facilities.

Board can improve its inspection process

Although the Board's inspection process is generally appropriate, it could improve this process by conducting sufficient follow-up work to ensure inspection violations are corrected and by improving its tracking of nonprescription drug retailer inspections. Specifically:

- **Board should perform sufficient follow-up work to ensure violations are corrected—**Although the Board requires permitted facilities to submit corrective action plans to address violations, it does not always ensure that the plans are implemented or verify that violations were corrected. For example, board staff issued a violation to a pharmacy because a pharmacist administered immunizations without being certified by the Board to do so. The pharmacy submitted a corrective action plan and some supporting documentation to show that the

Table 2: Number of permitted facilities inspected between December 1, 2010 and November 30, 2012, by permit type As of December 2012 (Unaudited)

Permit type	Number of permitted facilities[1]	Number of facilities inspected[2]	Percent of facilities inspected
Pharmacy	1,179	1,075	91.2%
Nonprescription retailer	3,724	3,261	87.6
Manufacturer[3]	19	11	57.9
Wholesaler[3]	113	32	28.3
Compressed medical gas distributor/supplier	166	8	4.8
Total	5,201	4,387	

1 Because the Board has a goal to inspect pharmacies and nonprescription retailers every 18 months to 2 years depending on staffing levels, only facilities with active permits that were permitted prior to the 2-year analysis period of December 1, 2010 to November 30, 2012, were included. In addition, only permitted facilities located in Arizona were included because the Board does not inspect out-of-state facilities.

2 Data entry for some inspections conducted during this time frame was still in process as of December 3, 2012. Therefore, the actual number and percent of facilities inspected may be higher.

3 According to board management, inspections for these permit types are a lower priority and the Board does not have an inspection frequency goal for these facilities because they are also regulated and inspected by either the U.S. Food and Drug Administration or the U.S. Drug Enforcement Agency.

Source: Auditor General staff analysis of inspection data from the Board's licensing database.

pharmacist was in the process of obtaining the required certification and had already completed some required courses. Although auditors verified that the pharmacist eventually obtained the certification, board staff did not verify that the certification was obtained or reinspect pharmacy records to ensure the pharmacist did not give additional immunizations prior to being certified.

Board management reported that violations found during inspections tend to be low risk and are not generally a threat to public health. Management also reported that following up on these low-risk violations would strain staff resources and that following up on prior violations at the next routine inspection seemed sufficient. However, seven of eight western states' pharmacy regulatory boards that auditors contacted reported conducting some type of follow-up work to ensure that violations are corrected, such as requesting appropriate supporting documentation of the corrective action taken, making phone calls, or reinspecting facilities, as appropriate.[1]

In response to the audit, board management has developed two new follow-up procedures to help ensure that some types of violations are corrected. Specifically, these procedures require staff to (1) reinspect permitted facilities where environmental violations are found, such as sanitation issues or lack of hot water, and (2) verify that licensees giving immunizations who have not obtained the Board's required immunization certification complete the certification process. The Board should implement these follow-up procedures. In addition, the Board

1 Auditors contacted state pharmacy board officials and staff in eight western states—California, Montana, Nevada, New Mexico, Oregon, Texas, Utah, and Washington.

should develop and implement follow-up procedures that require some type of follow-up work for all the violations its inspectors identify, such as requiring permittees to submit documentation showing the corrective actions taken, reinspecting permitted facilities, or using other methods to ensure that all violations found through inspections are corrected, based on the level of risk the violations pose and available staff resources.

- **Board should better track its nonprescription drug retailer inspections—**As previously mentioned, the Board has established a goal to inspect every pharmacy and nonprescription drug retailer once every 18 months to 2 years depending on board staffing levels. Although the Board inspected about 90 percent of its pharmacy and nonprescription drug retailer permits according to its goals, the processes for tracking each are different. Specifically, although the Board's method for tracking pharmacy inspections appears to be sufficient, auditors determined the Board had an insufficient process for tracking nonprescription drug retailer inspections. As shown in Table 2 (see page 13), the Board had not inspected 463 of the 3,724 permitted nonprescription drug retailers between December 2010 and November 2012.

  In response to auditors' findings, board management reviewed all nonprescription drug retailer permits in April 2013 to understand why so many nonprescription drug retailers had not been inspected. Board management identified the following factors:

  - **Database lacks some functionality**—The Board's licensing database lacks the functionality required to ensure that nonprescription retailers are inspected on a regular basis. Specifically, it does not have a feature that allows board staff to sort and generate a list of permits by their last date of inspection to determine which permits have gone the longest without an inspection and, therefore, should be a priority for inspection.

  - **Inspection staff made some errors**—Inspection staff errors have also contributed to some permittees not receiving an inspection. Specifically, the Board developed a method to conduct inspections according to zip code, and the database can generate a list of permittees by zip code. Although this list did not include when the permittees were last inspected, inspection staff used this list to look up a permittee individually in the database to determine when it was last inspected. However, according to board management, some permittees had data entry errors in the zip code field, which caused these permits to be inappropriately excluded from the list and not identified for inspection. Finally, one inspector did not obtain lists of permittees by zip code and instead obtained lists of permittees by city or town, which caused some permittees in rural areas of the State to not be identified for inspection.

  - **Staff had difficulty gaining access to some nonprescription drug retailers**—Board management also noted that some nonprescription drug retailer inspections had not been conducted because its staff had difficulty gaining access to these retailers. For example, some airport gift shops are not accessible because they are located in areas behind federal Transportation Safety Administration checkpoints and, thus, require special permission or a paid airline ticket to gain access. According to board management, inspection staff are working with airport security officials to access these nonprescription retailers.

During the audit, the Board developed a manual method of tracking nonprescription drug retailer inspections that is similar to its method for tracking pharmacy inspections. Board management reported that this manual tracking method will be used until improvements can be made to its database. According to board management, it expects to transition to new database vendors beginning in June 2013 and plans to work with these vendors to make changes to the database that will allow it to track the frequency of inspections (see page 23 for more information on the Board's database). The Board should ensure that it continues to improve its tracking of nonprescription drug retailer permits to ensure that they are inspected every 18 months to 2 years in accordance with the Board's inspection frequency goal. In addition, the Board should continue its efforts to gain access to nonprescription drug retailers that are in restricted areas.

Recommendations:

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

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.

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.

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

Complaint resolution

The Board resolves complaints in an appropriate and timely manner and monitors licensees' and permitted facilities' compliance with assigned discipline.

Board appropriately resolves complaints in a timely manner

The Arizona State Board of Pharmacy (Board) is responsible for investigating complaints against licensees and permitted facilities and taking appropriate nondisciplinary or disciplinary action, as necessary. Statute authorizes the Board to investigate complaints alleging violations of statute and/or board rules, including professional incompetence, unprofessional or unethical conduct, and mental or physical inability to engage in the practice of pharmacy. Complaints may be submitted by the public or opened by the Board and are investigated by board staff. Based on its review of investigative reports, the Board may dismiss complaints or take nondisciplinary or disciplinary action as appropriate. Nondisciplinary and disciplinary options include advisory letters, civil penalties, drug and alcohol treatment, probation, suspension, and revocation. In fiscal year 2012, the Board received 140 complaints.

Auditors found that the Board appropriately investigated and adjudicated the complaints it reviewed, resolved complaints in a timely manner, and monitored compliance with assigned discipline. Specifically, the Board:

- **Thoroughly investigated reviewed complaints**—Auditors reviewed 30 complaints the Board received in fiscal years 2011 and 2012 and found that board staff conducted appropriate and thorough investigations, including performing unannounced investigations, interviewing involved parties, and collecting and reviewing evidence and written statements from pharmacy professionals who were responsible for the premises and/or were on site at the time of the incidents. Board staff prepared thorough investigative reports that summarized allegations, evidence, and potential violations. Additionally, according to board management, investigative reports are reviewed prior to sending them to the Board, which helps to ensure the quality and completeness of the reports.

- **Issued discipline when violations were substantiated and appeared to avoid bias**—Based on auditors' review of the 30 complaints, observation of board meetings, and review of board meeting minutes, the Board dismissed unsubstantiated complaints and took action when it found violations. For example, the Board dismissed some complaints that were based on customer service issues that did not involve a violation of statute or rule. However, when the Board determined that a licensee or permitted facility violated statute or rule, it issued discipline.

  The Board also takes steps to avoid the appearance of bias while adjudicating complaints. Auditors observed board members recusing themselves from decision-

making during board meetings in matters where there was a potential conflict of interest. In addition, auditors observed that the Board received and considered a licensee's or permittee's prior complaint history only after it made a determination that there was a violation of statute or rule.

- **Resolved complaints in a timely manner—**The Office of the Auditor General has found that Arizona health regulatory boards should resolve complaints within 180 days of receiving them, which includes the time to both investigate and adjudicate the complaints. Auditors analyzed 423 complaints the Board received in fiscal years 2010 through 2012 and found that it resolved approximately 98 percent of these complaints within the 180-day standard. Only 8 of the 423 cases were not resolved in 180 days. Seven of the 8 cases took between 197 and 204 days to resolve and, therefore, exceeded the standard by 24 days or less. The eighth complaint, which involved the revocation of a pharmacist's license, took 482 days to resolve. Auditors attributed the length of time to resolve this case to a complex investigation and the licensee's refusal to respond to the Board's notices or appear before the Board when ordered to do so.

- **Monitors compliance with assigned discipline—**The Board issues discipline through consent agreements that are monitored by board staff. When the Board finds a licensee or permitted facility in violation of a statute or rule, it negotiates the terms of discipline through consent agreements with guidance from its assistant attorney general. The consent agreements generally outline the rights and responsibilities of the licensee/permitted facility, findings of facts in the case, the specific violations of law, and the discipline assigned by the Board. In addition, board staff monitor licensees' and permitted facilities' compliance with the consent agreement terms to ensure compliance with board discipline.

Public information

Although the Board provides appropriate and accurate information regarding disciplinary history on its Web site, it should implement its newly developed policies and procedures to help ensure that staff provide complete and timely information requested by phone.

Board should improve its provision of information to public

The Arizona State Board of Pharmacy (Board) provides appropriate public information on its Web site but not over the phone. The Board's Web site provides appropriate information about licensees and permitted facilities, including disciplinary history. Auditors reviewed Web site information for a sample of licensees and permitted facilities against hard copy files and found it to be accurate. The information also complied with Arizona Revised Statutes §32-3214, which prohibits state agencies from providing information on their Web sites regarding dismissed complaints or complaints that resulted in nondisciplinary action. In accordance with this statute, the Board's Web site includes a statement that members of the public may request information about dismissed complaints and complaints that resulted in nondisciplinary action by contacting the Board directly. However, board staff did not provide this information over the phone when requested. Specifically:

- Auditors placed three phone calls to board staff in October 2012 to request complaint history for three licensees. Although staff provided disciplinary information that could be obtained on the Web site during one call, staff did not disclose that the licensee also had a dismissed complaint. For the other two calls, board staff reported that the two licensees had no complaint history although one received an advisory letter and the other had an open complaint. According to board management, the staff members who provided incomplete information for these three calls either did not have access to or did not use the Board's complaint database, which contains information on open complaints and board actions taken.

  In response to these findings, board management reported that they would revise their procedures so that only staff who have access to complaint history would take these calls. However, when auditors placed three additional calls to request complaint history for three licensees in January and February 2013, board staff who did not have access to information about open complaints, dismissed complaints, or complaints that resulted in nondisciplinary action still took the calls. As a result, board staff did not provide complete information.

- In addition, in January 2013, auditors placed a call to request copies of all inspection reports for one pharmacy. Of the 12 inspections performed at this pharmacy, board staff provided only 2 inspection reports, and it took staff 42 calendar days to respond. Because the public does not have access to inspection data, a member of the public would not have information on the number of inspections a permitted facility has received, including the 12 inspections that this pharmacy received, most of which reported unsatisfactory results. Board management attributed the delayed response

and incomplete information to staff inaction, poor filing practices, and a lack of policies and procedures regarding responding to public information requests for inspection information.

The public should have access to complete and timely information about licensees and permitted facilities to make informed decisions. In response to the audit, board management developed policies and procedures in April 2013 to help ensure that staff provide complete and timely information in response to public requests. Based on these new policies and procedures, board management reported that appropriate board staff will provide information about licensees over the phone in response to phone inquiries for licensee information. In addition, board management reported that information requests regarding permittee inspections will be researched, reviewed by appropriate staff, and returned to requestors within 48 hours. The Board should implement these policies and procedures to ensure that staff provide complete and timely information in response to public requests and train staff accordingly.

Recommendation:

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.

Sunset factor analysis

The analysis of the sunset factors includes recommendations for the Board to improve its practices regarding cash receipts, comply with statute when assigning license and permit applicants to renewal groups, and open a complaint when licensees fail to meet continuing education requirements (see pages 21 through 23). In addition, the Board should develop various rules as indicated in sunset factor 4 (see page 24).

In accordance with Arizona Revised Statutes (A.R.S.) §41-2954, the Legislature should consider the factors included in this report in determining whether the Arizona State Board of Pharmacy (Board) should be continued or terminated.

1. **The objective and purpose in establishing the Board and the extent to which the objective and purpose are met by private enterprises in other states.**

   Established in 1903, the Board's mission is to protect the health, safety, and welfare of the citizens of Arizona by regulating the practice of pharmacy and the distribution, sale, and storage of prescription medications, prescription devices, and nonprescription medications. It accomplishes this mission by licensing pharmacists and pharmacy interns, technicians, and trainees; issuing permits to in-state and out-of-state pharmacies, manufacturers, wholesalers, nonprescription drug retailers, and compressed medical gas distributors and suppliers; inspecting in-state permitted facilities; investigating and adjudicating complaints against licensees and permitted facilities and taking appropriate disciplinary action; providing information to the public and promulgating state rules and regulations regarding the practice of pharmacy (see pages 1 through 2 for additional information regarding board responsibilities).

   Auditors did not identify any states that met the objective and purpose of the Board through private enterprises.

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

   The Board has generally met its statutory objective and purpose by inspecting most in-state permitted facilities that dispense and/or distribute prescription drugs, appropriately resolving complaints against licensees and permitted facilities in a timely manner, and taking appropriate disciplinary action when necessary. However, as discussed in the report, the Board should ensure that it issues licenses and permits only to qualified applicants and tracks its compliance with time frames for issuing licenses and permits (see pages 5 through 9), develops and implements inspection follow-up procedures and better tracks its nonprescription drug retailer inspections (see pages 12 through 15), and provides appropriate information to the public (see pages 19 through 20). Further, auditors identified additional areas in which the Board should improve its operations:

- **Board's cash receipt practices have some deficiencies—**According to an Office of the Auditor General August 2013 procedural review, the Board's cash receipt responsibilities were not adequately separated and board staff did not have sufficient reconciliation procedures.[1] Specifically, board staff who received and recorded cash receipts also had the ability to process and issue licenses and permits within the Board's licensing system. Additionally, board staff did not reconcile daily cash receipts to the licenses and permits issued and recorded in its licensing system. These inadequate practices increased the risk of theft and misappropriation for the Board's license and permit revenues, which totaled approximately $3.1 million between July 1, 2012 and March 31, 2013. As a result, 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.

- **Board does not adhere to statutory requirements for assigning licensees and permittees to renewal groups—**The August 2013 procedural review also found that the Board's process for assigning licensees and permittees to one of two biennial renewal groups did not fully comply with statute. Specifically, statute requires the Board to assign an applicant to one of its two biennial renewal groups prior to issuing an initial license. Additionally the Board is required to prorate the initial license or permit fee based on the assigned renewal group. However, because of limitations in both the Board's licensing system and the process it uses to assign applicants to renewal groups, the Board did not comply with statute. Instead, the Board issues initial licenses and permits that are effective until they expire at the end of October of the current year and, at renewal, assigns the applicant to one of the two biennial renewal groups. However, this results in initial licenses and permits being issued for shorter periods of time than required by statute, and subsequently results in the issuance of 1-year renewals, instead of the 2-year renewals required by statute. 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.

- **Board staff do not open a complaint when a licensee fails to meet continuing education requirements—**Because it is a statutory violation for a pharmacist or technician to fail to meet continuing education requirements, board staff should open a complaint and give the Board the opportunity to address the violation. Statute requires pharmacists and pharmacy technicians to take continuing education classes during each biennial renewal period. These licensees are then required to certify that they met the continuing education requirements by signing their license renewal applications. Specifically, every 2 years, pharmacists are required to take 30 hours of continuing education, with at least 3 hours in pharmacy law, and pharmacy technicians are required to take 20 hours of continuing education, with at least 2 hours in pharmacy law. According to board staff, the Board audits between 15 and 30 licensees each month to verify that the continuing education reported on the license renewal applications was completed. Board staff also indicated that, if

[1] Procedural Review of the Arizona State Board of Pharmacy as of March 31, 2013, issued August 19, 2013.

licensees are deficient in meeting these requirements, they are permitted to address the deficiencies by taking the necessary continuing education courses, and staff will then follow up to ensure the courses were taken. Board staff further indicated that the decision to allow licensees an opportunity to address deficiencies by taking courses was made several years ago in consultation with a previous board staff supervisor, but was not directed by the Board.

However, according to A.R.S. §32-1901.01(B)(7), it is unprofessional conduct for a pharmacist to fail to comply with continuing education requirements, and if the Board substantiates a violation, it may impose a civil penalty, issue a letter of reprimand or a decree of censure, place a licensee on probation, or suspend or revoke the license. Similarly, the Board may use the same options to discipline a technician who fails to meet the continuing education requirements according to A.R.S. §32-1927.01. By not opening a complaint for these violations of statute, board staff have not provided the Board the opportunity to review these potential violations and superseded the Board's authority to take action regarding the potential violations. Therefore, 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.

- **Board's database does not provide meaningful information for management purposes—**The Board's database lacks the ability to provide meaningful management reports, such as reports regarding how long it takes to issue a license/permit or how frequently inspections are performed on permitted facilities. In addition, the database does not have enough fields to collect all of the information needed to create meaningful reports. For example, the database has only three date fields for a pharmacist license record when approximately nine date fields would be needed to track the amount of time the Board takes to process the license. The Board is aware that the database does not meet its needs. As of May 2013, the Arizona Department of Administration has entered into a new multi-vendor, multi-year information technology contract to provide database and information management services, such as Web design, application development, and professional services to several state agencies, including the Board. The Arizona Department of Administration reported it will begin to transition agencies from their current database vendor to the new database vendors beginning in June 2013 and expects the transition period will take between 9 and 12 months. According to board management, the Board hopes to work closely with the new database vendors to ensure its database has better reporting capabilities and can capture the information needed to track various board activities and responsibilities.

3. **The extent to which the Board serves the entire State rather than specific interests.**

The Board serves licensees, permitted facilities, their clients, and the public throughout the State by issuing licenses and permits to individuals and facilities. In addition, it receives and investigates complaints filed by the public against licensees and permitted facilities and also disciplines licensees and permitted facilities that violate board laws and rules. Further, the Board conducts inspections of permitted facilities throughout the State to help ensure their compliance

with applicable laws and regulations. Finally, the Board provides the public with information through its Web site regarding licensees' and permitted facilities' licensing and permit status and disciplinary history. The Web site also informs the public that it may contact the board office to obtain information about dismissed complaints and nondisciplinary actions taken against licensees and permitted facilities. However, auditors found that the Board can do more to provide complete information to the public by telephone (for more information, see pages 19 through 20).

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

General Counsel for the Auditor General has analyzed the Board's rule-making statutes and believes the Board has established nearly all of the rules required by statute and that established rules are consistent with statute. However, auditors found that the Board lacks rules required by statute that govern when substitution for prescription drugs is not allowable and rules regarding prescription drug identification information. The Board should develop rules that conform to the practice of referring to federally provided information in these two areas.

In addition, auditors found that the Board lacks three rules that govern requested documentation for its compressed medical gas distributor/supplier and drug manufacturer permits. Specifically, 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. Based on auditors' review of board application requirements as compared to statute and rules, the Board already requests this information in its applications, but has not yet established these requirements in its rules to allow it to do so.

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.**

Auditors found that the Board has encouraged input from the public before adopting its rules. Specifically, in 2012, the Board revised its rules regarding various requirements for long-term care pharmacies. As part of its process to determine needed revisions, the Board assembled a task force that included pharmacists working in pharmacies that cater to long-term care facilities. The task force met in three public sessions to propose revisions to the long-term care pharmacy rules and submitted the resulting proposed rules for inclusion in the Arizona Administrative Register.

Auditors also assessed the Board's compliance with various provisions of the State's open meeting law for board meetings and board task force meetings held between November 2012 and February 2013 and found the Board to be in compliance. For example, as required by open meeting law, the Board posted meeting notices and agendas on its Web site at least 24 hours

in advance and posted the notices and agendas at the physical locations indicated on its Web site.[1] In addition, in compliance with statute, board management made meeting minutes or an audio recording of the meeting available 3 business days after the meeting dates.[2]

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

The Board has statutory authority to investigate and resolve complaints within its jurisdiction and has various nondisciplinary and disciplinary options available to use to address violations of statute and/or rule, such as issuing an advisory letter, probation, and revocation of a license or permit. Auditors found that the Board resolved complaints appropriately and in a timely manner for the time periods auditors reviewed (see pages 17 through 18 for additional information).

7. The extent to which the Attorney General or any other applicable agency of state government has the authority to prosecute actions under the enabling legislation.

The Attorney General is the Board's attorney according to A.R.S. §41-192(A). As such, the Board can bring violations by a licensee or permitted facility to the attention of the Attorney General or county attorney according to A.R.S. §32-1904(B)(8).

8. The extent to which the Board has addressed deficiencies in its enabling statutes that prevent it from fulfilling its statutory mandate.

The Board reported that it has sought statutory changes to address deficiencies in statutes. These include the following:

- Laws 2013, Ch. 43, amended A.R.S. §§32-1927, 32-1927.01, and 32-1927.02 to prescribe the Board's process for ordering a summary suspension of a license or permit and to add continuing education as an option the Board may exercise when issuing disciplinary and nondisciplinary action.

- Laws 2012, Ch. 330, added a section to A.R.S. §32-1977 regarding requirements for the sale of some active ingredients in methamphetamine. The legislation addressed concerns that purchasers of sufficient quantities of products containing ephedrine or pseudoephedrine could convert them into methamphetamine.

- Laws 2011, Ch. 103, amended A.R.S. §32-1970 to allow pharmacists to monitor a drug therapy prescribed by a medical provider, such as a licensed physician or nurse practitioner. The amendment more specifically describes the pharmacist's duties in monitoring a drug therapy.

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[1] In addition to complying with these open meeting law requirements, the Board must also comply with A.R.S. §32-1905, which requires it to designate a time and place for its meetings 30 days in advance. Although the Board did not meet this 30-day requirement for its November 2012 meeting, as of November 2012, the Board came into compliance by posting the meeting time and place for all of its 2013 public meetings.

[2] The Board did not need to enter into an executive session at any of the board meetings that auditors attended; therefore, auditors cannot comment on the Board's use of executive session.

- Laws 2010, Ch. 92, amended A.R.S. §32-1968 to provide for additional methods of presenting a prescription to a pharmacist, including through electronic transmission of a prescription by a patient or practitioner.

- Laws 2009, Ch. 41, added A.R.S. §32-1974 to allow pharmacists to administer immunizations or vaccines and prescribe the duties associated with such service.

9. The extent to which changes are necessary in the laws of the Board to adequately comply with the factors listed in this sunset law.

The audit did not identify any needed changes to board statutes.

10. The extent to which the termination of the Board would significantly affect the public health, safety, or welfare.

Terminating the Board would affect the public's health, safety, and welfare if its regulatory responsibilities were not transferred to another entity. The Board's role is to protect the public by licensing individuals and permitting facilities that meet Arizona's qualifications to practice pharmacy, inspecting in-state permitted facilities to help ensure they operate in compliance with state and federal laws and rules, receiving and investigating complaints against licensees and permitted facilities, and taking nondisciplinary or disciplinary action when allegations are substantiated. The Board is also responsible for providing information to the public about license and permit status and complaint and disciplinary history. These functions help protect the public from potential harm. For example, auditors reviewed complaints investigated by the Board alleging actions by pharmacy professionals that posed a threat to the public, including dispensing errors, theft of controlled substances, fraud, and substance abuse.

11. The extent to which the level of regulation exercised by the Board compares to other states and is appropriate and whether less or more stringent levels of regulation would be appropriate.

The audit found that the level of regulation exercised by the Board is generally similar to that in other states and appears appropriate. According to a 2013 National Association of Boards of Pharmacy state survey, all 50 states regulated pharmacists and 41 states, including Arizona, regulated pharmacy technicians.[1]

The audit did not identify areas where more or less stringent levels of regulation would be appropriate. However, as of May 2013, the Board was in the process of researching more stringent levels of regulation with respect to adopting or implementing additional parts of United States Pharmacopeia Chapters 795 and 797 for the compounding of sterile preparations.[2] Specifically, the Board is reviewing rules that guide compounding practices in Arizona as a result of a national fungal meningitis outbreak that occurred in late 2012. According to

[1] National Association of Boards of Pharmacy. (2012). *Survey of pharmacy law*—2013. Mount Prospect, IL: Author.

[2] According to A.R.S. §32-1901, compounding is the preparing, mixing, assembling, packaging, or labeling of a drug by a pharmacist or pharmacist technician under the pharmacist's supervision for the purpose of dispensing to a patient based on a valid prescription order. However, compounding does not include the preparation of commercially available products from bulk compounds or the preparation of drugs for sale to pharmacies, practitioners, or entities for the purpose of dispensing or distribution.

congressional testimony of the Commissioner of the U.S. Food and Drug Administration, this outbreak was attributed to unsterile injectable steroids compounded by the New England Compounding Center.[1] As of April 2013, the outbreak had resulted in 51 deaths and over 730 infectious illness cases in 20 states. The U.S. Food and Drug Administration continues to investigate the incident and has established an agency-wide steering committee to coordinate its efforts, which include inspecting high-risk pharmacies involved in the production of sterile drug products. In response to the outbreak, the Board established a Compounding Task Force in January 2013 that meets monthly and whose main charge is to discuss, review, and recommend changes and additions to Arizona's compounding rules. In addition, the Compounding Task Force is considering recommending that the Legislature consider revising statute to require a compounding certificate for pharmacists and technicians, as well as specifying space/safety requirements within a pharmacy used for compounding purposes.

12. The extent to which the Board has used private contractors in the performance of its duties as compared to other states and how more effective use of private contractors could be accomplished.

The Board uses private contractors for four types of services, including staff training, court reporters, temporary employees, and design and maintenance of its Controlled Substance Prescription Monitoring Program (see page 2 for additional information about this program). Auditors found that the Board used private contractors to perform duties to a similar extent as other western states' pharmacy boards that used private contractors. Auditors contacted eight western states' pharmacy boards to determine if they used private contractors to design or maintain a prescription monitoring database, design or maintain a licensing database, review licensing credentials, train staff, provide temporary employees, perform inspections or investigations, provide legal services, or any other services.[2] According to the executive directors and staff of these boards, five of the eight states used private contractors to a similar extent as Arizona, and three states did not use private contractors. Executive directors and staff from the five states that use contracts reported they contracted for services that included design or maintenance of a prescription monitoring or licensing database, provision of temporary employees, legal services, or other services, such as laboratory or licensing exam review services.

The audit did not identify any additional areas where the Board should consider using private contractors.

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[1] Hamburg, M.A. (Commissioner Food and Drugs, U.S. Food and Drug Administration). *A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented*: Hearing Before the Subcommittee on Oversight and Investigations of the U.S. House of Representatives. (Date 4/16/13). Witness testimony from Energy & Commerce Committee Web site.

[2] Auditors contacted state pharmacy board officials and staff in eight other western states—California, Montana, Nevada, New Mexico, Oregon, Texas, Utah, and Washington.

Appendix A

This appendix provides information on the methods auditors used to meet the audit objectives. The Auditor General and staff express appreciation to the Arizona State Board of Pharmacy, its Executive Director, and staff for their cooperation and assistance throughout the audit.

Methodology

Auditors conducted this performance audit of the Arizona State Board of Pharmacy (Board) in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Auditors used various methods to study the issues in the performance audit and sunset review. These methods included reviewing board statutes, rules, and policies and procedures; interviewing board members, staff, and stakeholders; and reviewing information from the Board's Web site. In addition, auditors reviewed minutes from and attended two board meetings and one task force meeting held between November 2012 and February 2013. In addition, auditors used the following specific methods to meet its audit objectives:

- To determine whether the Board's processes and practices helped ensure that licenses and permits are issued in a timely manner to qualified applicants, auditors reviewed random samples of 30 approved and 5 denied license applications and 10 approved and 2 denied permit applications that the Board issued in fiscal years 2011 and 2012.[1] In addition, auditors reviewed the Board's license and permit application materials and compared them to statutes and rules.

- To determine whether the Board's process and practices helped ensure that inspections are performed efficiently and effectively, auditors observed 22 inspections of permitted facilities between October 2012 and January 2013 and reviewed a random sample of 37 inspection files for inspections performed between January 2011 and December 2012. In addition, auditors reviewed inspection forms and checklists and compared them with statutes and rules; analyzed board inspection data from December 1, 2010 to November 30, 2012; and contacted eight western states to obtain information about their inspection programs.[2]

- To assess whether the Board processes complaints in an appropriate and timely manner, auditors analyzed the Board's complaint data for fiscal years 2010 through

[1] The license sample included all license types, including pharmacist, intern, technician, and trainee licenses. The permit sample consisted of 5 of the Board's 12 permit types, including in-state and out-of-state pharmacy and nonprescription drug retailer permits, as well as out-of-state wholesaler permits.

[2] Auditors contacted state pharmacy board officials and staff in eight western states—California, Montana, Nevada, New Mexico, Oregon, Texas, Utah, and Washington.

2012; and reviewed a sample of 30 complaints involving 50 licenses or permits received during fiscal years 2011 and 2012.[1]

- To assess whether the Board shares appropriate licensee information with the public, auditors placed six anonymous phone calls to board staff in October 2012 and January and February 2013 requesting information about six licensees and compared the information provided to the Board's database. Auditors also reviewed licensing and complaint history information about specific licensees and permittees on the Board's Web site and assessed whether the information provided was consistent with statutory requirements.

- To obtain information for the Introduction, auditors reviewed board records regarding the number of licenses, permits, and immunization certificates issued, as well as the number of inspections and complaint investigations performed. In addition, auditors reviewed information regarding the Board's Controlled Substance Prescription Monitoring Program. Lastly, auditors compiled and analyzed unaudited information from the Arizona Financial Information System (AFIS) *Accounting Event Transaction File* for fiscal years 2011 and 2012 and the AFIS Management Information System Status of *General Ledger-Trial Balance* screen for fiscal years 2011 through 2013.

- To obtain information for the Sunset Factors, auditors reviewed the Office of the Auditor General's August 2013 procedural review and information regarding the Board's continuing education audit process.[2] In addition, auditors reviewed updates from the Arizona Department of Administration regarding transition of the Board's database to new database vendors. Auditors also tested whether board staff posted public notices and agendas for board meetings in compliance with open meeting law. Further, auditors reviewed a 2013 state survey from the National Association of Boards of Pharmacy.[3] Auditors reviewed the Food and Drug Administration's April 2013 testimony to the U.S. House of Representatives regarding the compounding industry.[4] Finally, to obtain information regarding these states' use of private contractors, auditors contacted the eight western states previously mentioned (see footnote 2, page a-1).

- Auditors' work on internal controls included reviewing the Board's policies and procedures for ensuring compliance with board statutes and rules and, where applicable, testing its compliance with these policies and procedures. Auditors' conclusions on these internal controls and board efforts to improve their controls in response to audit findings during the audit are reported in the report chapters. In addition, auditors conducted data validation work to assess the reliability of the Board's database information used to assess complaint timeliness and pick various samples of licenses, permits, complaints, and inspections for further test work. Specifically, auditors compared information in the databases against scanned electronic or hard files. Auditors determined that the Board's databases were sufficiently reliable for the purposes of the audit.

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[1] For the 30 complaints that auditors reviewed involving 50 licensees and permittees, 19 were dismissed, 16 were given sanctions when violations were identified, 14 received nondisciplinary action, and one was referred to another state's board for review.

[2] Procedural Review of the Arizona State Board of Pharmacy as of March 31, 2013, issued August 19, 2013.

[3] National Association of Boards of Pharmacy. (2012). *Survey of pharmacy law—2013*. Mount Prospect, IL: Author.

[4] Hamburg, M.A. (Commissioner Food and Drugs, U.S. Food and Drug Administration). *A Continuing Investigation into the Fungal Meningitis Outbreak and Whether It Could Have Been Prevented*: Hearing Before the Subcommittee on Oversight and Investigations of the U.S. House of Representatives. (Date 4/16/13). Witness testimony from Energy & Commerce Committee Web site.

AGENCY RESPONSE

Arizona Board of Pharmacy
1616 W. Adams Street, Room 120
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MAIL TO: P O Box 18520,
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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. T**he 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.

Performance Audit Division reports issued within the last 24 months

11-07 Department of Corrections—Oversight of Security Operations
11-08 Department of Corrections—Sunset Factors
11-09 Arizona Department of Veterans' Services—Veterans' Donations and Military Family Relief Funds
11-10 Arizona Department of Veterans' Services and Arizona Veterans' Service Advisory Commission—Sunset Factors
11-11 Arizona Board of Regents—Tuition Setting for Arizona Universities
11-12 Arizona Board of Regents—Sunset Factors
11-13 Department of Fire, Building and Life Safety
11-14 Arizona Game and Fish Commission Heritage Fund
12-01 Arizona Health Care Cost Containment System—Coordination of Benefits
12-02 Arizona Health Care Cost Containment System—Medicaid Eligibility Determination
12-03 Arizona Board of Behavioral Health Examiners
12-04 Arizona State Parks Board
12-05 Arizona State Schools for the Deaf and the Blind
12-06 Arizona Health Care Cost Containment System—Medicaid Fraud and Abuse Prevention, Detection, Investigation, and Recovery Processes
12-07 Arizona Health Care Cost Containment System—Sunset Factors
13-01 Department of Environmental Quality—Compliance Management
13-02 Arizona Board of Appraisal
13-03 Arizona State Board of Physical Therapy
13-04 Registrar of Contractors
13-05 Arizona Department of Financial Institutions
13-06 Department of Environmental Quality—Underground Storage Tanks Financial Responsibility

Future Performance Audit Division reports

Arizona State Board of Cosmetology