Arizona State Board of Pharmacy

Board did not fulfill several regulatory responsibilities, base its fees on the cost of providing services, enforce compliance with State Controlled Substances Prescription Monitoring Program (CSPMP) requirements, and provide accurate and complete information to the public

Performance Audit and
Sunset Review

September 2020
Report 20-106

A Report to the Arizona Legislature

Lindsey A. Perry
Auditor General

ARIZONA Auditor General
Making a Positive Difference

ARIZONA Auditor General

Making a Positive Difference

The Arizona Office of the Auditor General's mission is to provide independent and impartial information and specific recommendations to improve the operations of State and local government entities. To this end, the Office provides financial audits and accounting services to the State and political subdivisions, investigates possible misuse of public monies, and conducts performance audits and special reviews of school districts, State agencies, and the programs they administer.

The Joint Legislative Audit Committee

Representative **Anthony T. Kern**, Chair
Representative **John Allen**
Representative **Timothy M. Dunn**
Representative **Mitzi Epstein**
Representative **Jennifer Pawlik**
Representative **Rusty Bowers** (ex officio)

Senator **Rick Gray**, Vice Chair
Senator **Lupe Contreras**
Senator **Andrea Dalessandro**
Senator **David C. Farnsworth**
Senator **David Livingston**
Senator **Karen Fann** (ex officio)

Audit Staff

Dale Chapman, Director
Cheya Wilson, Manager
Kaylee Arteaga, Graphics Coordinator

Stephanie Hamilton, Team Leader
Kristel Nielsen
Tanner Weigel

Contact Information

Arizona Office of the Auditor General
2910 N. 44th St., Ste. 410
Phoenix, AZ 85018-7271

(602) 553-0333

contact@azauditor.gov

www.azauditor.gov

LINDSEY A. PERRY
AUDITOR GENERAL

ARIZONA
AUDITOR GENERAL

MELANIE M. CHESNEY
DEPUTY AUDITOR GENERAL

September 16, 2020

Members of the Arizona Legislature

The Honorable Doug Ducey, Governor

Dr. Kam Gandhi, Executive Director
Arizona State Board of Pharmacy

Transmitted herewith is the Auditor General's report, *A Performance Audit and Sunset Review of the Arizona State Board of Pharmacy*. This report is in response to a September 19, 2018, 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 to provide a quick summary for your convenience.

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

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

Sincerely,

Lindsey Perry, CPA, CFE
Auditor General

cc: Arizona State Board of Pharmacy members

Arizona State Board of Pharmacy

Board did not fulfill several regulatory responsibilities, base its fees on the cost of providing services, enforce compliance with State Controlled Substances Prescription Monitoring Program (CSPMP) requirements, and provide accurate and complete information to the public

Audit purpose

To determine if the Board issued licenses and permits to qualified applicants in a timely manner, followed its procedures for investigating and resolving complaints and doing so in a timely manner, based its license and permit fees on the cost of providing services, enforced compliance with State CSPMP requirements, and provided required information to the public about licensees and permit holders.

Key findings

- Board did not verify the validity of fingerprint clearance cards for all but 1 of the pharmacist license applicants we reviewed; did not ensure that licensees met continuing education requirements; has not always investigated complaints with similar allegations; and did not meet required inspection time frames.
- Board's license and permit fees are not based on the cost of providing services, resulting in a large and growing fund balance.
- State may not be receiving the full benefits of the CSPMP because the Board has not enforced or helped to enforce compliance with CSPMP requirements.
- Board did not provide required public information on its website or in response to our anonymous phone calls.

Key recommendations

The Board should:

- Ensure that initial pharmacist license applicants possess valid fingerprint clearance cards before issuing licenses.
- Ensure license renewal applicants meet continuing education requirements by conducting continuing education audits.
- Consistently determine complaint jurisdiction and document these determinations.
- Consistently meet established inspection time frames by developing and implementing processes for tracking and monitoring the completion of facility inspections.
- Conduct a review of its license and permit fees consistent with government fee-setting standards and guidelines and adjust its fees accordingly.
- Ensure that its licensees and permit holders follow State CSPMP requirements and provide other Arizona professional licensing boards with the information they need to investigate and enforce noncompliance with these requirements.
- Provide complete and accurate information to the public on its website and over the phone.

TABLE OF CONTENTS

TABLE OF CONTENTS

Figure

Tables

ARIZONA Auditor General
Making a Positive Difference

Arizona State Board of Pharmacy Performance Audit and Sunset Review
September 2020

Board overview

The Arizona State Board of Pharmacy (Board) regulates the practice of pharmacy through issuing licenses and permits, investigating and resolving complaints, and providing information to the public about the status of licenses and permit holders. The Board consists of 9 members appointed by the Governor for 5-year terms, and it was appropriated 22.4 full-time equivalent positions for fiscal year 2020. The Board does not receive any State General Fund appropriations. Instead, the Board's revenues consist primarily of license and permit fees and revenues to operate the Controlled Substances Prescription Monitoring Program.

Active licenses as of January 2020	Active permits as of January 2020
32,546	5,251

Facility inspections conducted in fiscal year 2019
2,193

Complaints received in fiscal year 2019
Approximately 570

Audit results summary

Key regulatory areas reviewed		
Pharmacist licenses—Key qualifications include a pharmacy degree, passing score on a national exam, and a valid fingerprint clearance card.	Ensured qualifications met ✓	Verified fingerprint clearance card ✗
Pharmacy technician licenses—Key qualifications include passing a national exam, proof of training completion, and a valid fingerprint clearance card.	Ensured qualifications met ✗	Verified fingerprint clearance card ✓
Pharmacy and manufacturer permits—Board must process permits within 180 days. Permit applicant must provide information on their facility and activities.	Issued timely ✓	Assessed adequacy of submitted documentation ✗
Continuing education audits—Audits help ensure compliance with statutory and rule continuing education requirements.	Performed regularly ✗	Disciplined licensees ✓
Facility inspections—Facilities should be inspected at least once every 18 months.	Conducted every 18 months ✗	Followed up on violations ✗
Complaint handling—Complaints should be investigated and adjudicated within 180 days. Board should consistently determine complaint jurisdiction.	Investigated and adjudicated in 180 days ✗	Consistently determined jurisdiction ✗
Public information—Statute specifies the complaint and license status information that should be provided to the public.	Correctly provided on website ✗	Correctly provided via phone ✗
Fee setting—Board should establish fees based on the actual costs of providing services.	Based fees on actual costs ✗	Periodically reviewed ✗
Other responsibilities reviewed		
Controlled Substances Prescription Monitoring Program (CSPMP)—Statute requires prescribers and dispensers to review CSPMP information.	Ensured licensee or permit holder compliance ✗	Provided information to other licensing boards ✗
Cash handling—Requirements include appropriate segregation of cash-handling and recording duties and depositing cash as soon as practical.	Adequately protected cash receipts ✗	Followed State cash-handling policies ✗
Conflicts of interest—Requirements and best practices include signing a statement annually and recusing from decisions involving substantial interests.	Recused Board members refrained from participating in decision ✗	Board members and staff signed annual conflict-of-interest statement ✗
Open meeting law—Requirements include citing reasons for executive session and making meeting minutes publicly available within 3 working days.	Correctly cited reasons for executive sessions ✗	Meeting minutes available within required time frame ✗

INTRODUCTION

The Office of the Auditor General has completed a performance audit and sunset review of the Arizona State Board of Pharmacy (Board). This report addresses the Board's processes for issuing initial pharmacist and pharmacy technician licenses in accordance with statute and rule, ensuring renewal applicants meet continuing education requirements, consistently determining its complaint jurisdiction, and inspecting permitted facilities within established time frames. It also addresses the Board's processes for ensuring that its license and permit fees are consistent with the cost of its regulatory activities, its responsibilities for ensuring compliance with the Controlled Substances Prescription Monitoring Program (CSPMP) statutory requirements, and providing information to the public in accordance with statute. Finally, the report provides responses to the statutory sunset factors.

Mission and regulatory responsibilities

The Board's mission is to oversee the practice of pharmacy (see textbox) and includes the following regulatory responsibilities:

Board's mission statement

To protect the health, safety, and welfare of Arizona citizens by regulating the practice of pharmacy and the manufacturing, distribution, sale, and storage of prescription medications and devices, and nonprescription medications.

- Issuing licenses to pharmacists and pharmacy technicians that must be renewed every 2 years and one-time nonrenewable licenses to pharmacy technician trainees and pharmacy interns (see Table 1, page 3, for more information on these professions).[1] As of January 2020, the Board reported that it had more than 32,000 licensees.
- Permitting pharmacies and drug-related facilities, such as manufacturers and wholesalers, both in and out of the State, and renewing these permits every 2 years (see Table 1, page 3, for more information on these facilities). As of January 2020, the Board reported it had more than 5,200 permit holders.
- Inspecting permitted facilities at the time of initial application and periodically throughout the life of the permit.[2] According to Board records, it inspected 2,193 permit holders in fiscal year 2019.
- Investigating and adjudicating complaints against licensees and permit holders. According to Board records, it received approximately 570 complaints against licensees and permit holders in fiscal year 2019 (see Appendix A, page a-1, footnote 58, for more information about the number of complaints the Board received).
- Providing information about licensed individuals and permitted facilities to the public.
- Operating, monitoring, maintaining, and staffing the CSPMP, which was established in 2007.

[1] Pursuant to Arizona Administrative Code (AAC) R4-23-1103(C)(5), pharmacy technician trainee licenses are valid for 2 years and are not renewable, unless the Board allows for re-application. As established in Arizona Revised Statutes (A.R.S.) §32-1923(E), pharmacy intern licenses are valid for 6 years and are not renewable, unless the Board grants an exception.

[2] The Board issues permits to facilities located out-of-state that distribute or sell prescription-only drugs/devices or nonprescription drugs in Arizona. The Board does not inspect these facilities.

Table 1
Licenses and permits issued by the Board

License type	General description of responsibilities and examples of qualifications[1]	Licenses issued fiscal year 2019	Total active licenses as of January 2020
Pharmacist	• Dispense prescription medication and counsel patients about the use of their medication. • Must graduate from a college of pharmacy recognized by the Board.	699	11,848
Pharmacy intern	• Work under a pharmacist's supervision. • Must be enrolled in a Board-approved college of pharmacy.	555	1,768
Pharmacy technician	• Fill prescriptions and complete administrative tasks under a pharmacist's supervision. • Must complete a training program in a pharmacy. • Must pass a national examination.	1,167	11,772
Pharmacy technician trainee	• Fill prescriptions and complete administrative tasks under a pharmacist's supervision. • Must have at least a high school diploma or equivalent. • Must be completing a technician training program.	2,858	7,158
Total		**5,279**	**32,546**

Permit type	General description of responsibilities and examples of qualifications	Permits issued fiscal year 2019[2]	Total active permits as of January 2020
Compressed medical gas distributor/Durable medical equipment and compressed medical gas supplier	Manufacture, distribute and/or sell: • Compressed gases, such as liquid oxygen. • Prescription-only medical devices, such as electronic wheelchairs, blood glucose monitors, and hospital beds.	152	689
Drug manufacturer	Manufacture, compound, produce, or package any drug in a facility other than a pharmacy.	209	797
Drug wholesaler	Possess and distribute drug products to manufacturers, medical practitioners, pharmacies, and other wholesalers.	187	1,066
Pharmacy	• Dispense medication and devices for retail sale under a pharmacist's supervision. • May compound and dispense prescriptions.	520	2,473
Remote dispensing site pharmacy/ Automated prescription-dispensing kiosk	• Dispense medication with pharmacy technician onsite and pharmacist supervising remotely. • Dispense medication from a machine that operates as an extension of a pharmacy. • Must be owned/operated by a pharmacy with an active Arizona pharmacy permit.	9	15
Third-party logistics provider	Store and ship drug products on behalf of facilities such as wholesalers and manufacturers.	88	211
Total		**1,165**	**5,251**

[1] The description of responsibilities and qualifications does not include all qualifications required or allowed by statute and rule.

[2] Reported numbers may be higher than the number of permits actually issued because some permit applications were still in process but were considered "issued" by the Board's licensing database when we compiled this data.

Source: Auditor General staff analysis of A.R.S. Title 32, AAC Title 4, Ch. 23, Board licensing data, Board-provided information, and explanations from Board staff.

CSPMP helps support access to legitimate uses of controlled substances

Statute requires licensed prescribers and dispensers to register with the CSPMP and review a patient's profile in the CSPMP database prior to prescribing or dispensing certain controlled substances.[3,4] Statute also requires pharmacies and dispensing medical practitioners to report information to the CSPMP about certain controlled substances dispensed to individuals.[5] According to the U.S. Drug Enforcement Administration (DEA), state prescription drug monitoring programs, such as the CSPMP, benefit states by supporting access to legitimate medical use of controlled substances; identifying and deterring or preventing drug abuse and diversion; facilitating the identification, intervention with, and treatment of persons addicted to prescription drugs; and informing public health initiatives through outlining of use and abuse trends.[6] Additionally, a Johns Hopkins Bloomberg School of Public Health report on the opioid epidemic makes several recommendations for effectively using prescription drug monitoring programs as a tool for combating the epidemic.[7] In June 2017, Governor Doug Ducey declared a State-wide emergency in response to the opioid overdose epidemic and according to an Arizona Department of Health Services report, CSPMP data showed opioid prescriptions filled per month in Arizona declined by 23 percent between July 2017 and November 2019.

Pursuant to A.R.S. §36-2603, the Board must appoint a task force of public and private stakeholders to help administer the CSPMP database. The CSPMP task force is required to identify educational, outreach, and support services to medical practitioners and to consult and recommend exceptions to electronic prescribing requirements. The task force met annually in calendar years 2017 through 2019 and has discussed topics such as updates and enhancements to the CSPMP, including prescriber reporting improvements and updates on CSPMP compliance by prescribers and dispensers.

To operate the CSPMP, the Board contracts with a vendor to provide the State with a centralized database tracking system (CSPMP database) to track the prescribing, dispensing, and consumption of certain controlled substances. The Board grants licensed medical practitioners (prescribers) and licensed pharmacists (dispensers) and their delegates, such as medical assistants and pharmacy technicians, access to the CSPMP database so they may review information for patients who receive certain dispensed controlled substances, such as narcotics like hydrocodone, depressants like diazepam, and stimulants like methylphenidate. The Board is also responsible for providing patient information related to the CSPMP to authorized individuals and organizations, such as other Arizona professional licensing boards. Specifically, Board CSPMP responsibilities include:

- **Providing access to the CSPMP database—**Prior to accessing the CSPMP database directly, prescribers and dispensers who are licensed under applicable Arizona professional licensing boards (see textbox, page 5) must register with the CSPMP. Registration may be requested at no cost by submitting required information to the Board through its CSPMP webpage, such as their professional license number and license type. The Board reviews registration submissions for qualifications before authorizing the registration and allowing access to the CSPMP database. Statute specifies that patient data in the CSPMP database is confidential

---

[3] A.R.S. §36-2606(A)(F)(G).

[4] Statute requires prescribers to obtain a patient utilization report prior to prescribing an opioid analgesic or benzodiazepine controlled substance listed in schedule II, III, or IV at the beginning of a new course of treatment and at least quarterly while the prescription remains part of treatment. Drugs are assigned to a schedule based on their potential for abuse. For example, schedule II drugs, such as Vicodin or oxycodone, have a high potential for abuse whereas schedule IV drugs, such as Valium, have a low potential for abuse. Dispensers are required to obtain a patient utilization report at the beginning of each new course of treatment prior to dispensing a schedule II controlled substance and must also submit information about all dispensed controlled substances that are listed in schedules II through V.

[5] A.R.S. §36-2608(A).

[6] Drug Enforcement Administration. (2016). *State prescription drug monitoring programs*. Washington, DC: U.S. Department of Justice. Retrieved 3/31/2020 from https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm.

[7] Alexander, G.C., Frattaroli, S., & Gielen, A.C., eds. (2017). *The opioid epidemic: From evidence to impact*. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. Retrieved 6/29/2020 from https://www.jhsph.edu/events/2017/americas-opioid-epidemic/report/2017-JohnsHopkins-Opioid-digital.pdf.

and unauthorized use of the information is a class 6 felony.[8] Registration applicants must agree to use the CSPMP data only for evaluating or providing medical treatment to a patient and acknowledge that any other use may result in disciplinary action, civil penalties, or criminal action.

- **Providing information from the CSPMP database—**The Board is required to notify other Arizona professional licensing boards if a licensed or permitted prescriber fails to comply with the CSPMP requirements.[9] Additionally, the Board is allowed to process requests for CSPMP database information when allowed by statute. For example, when law enforcement agencies subpoena information as part of an ongoing case, the Board will review the request and provide information, as appropriate (see Table 2 for more information on data requests). In addition, the Board produces a monthly scorecard report containing aggregate information about the number of controlled substance prescriptions dispensed and the number of lookups performed by registered prescribers. The Board provides this scorecard to the Arizona Department of Health Services to be published on its Opioid Epidemic website, which includes information about Arizona's opioid crisis. The Board also provides a quarterly prescriber report to each registered prescriber showing them how their prescribing behavior compares to other prescribers with the same medical specialty.

Arizona professional licensing boards whose licensees are statutorily required to register with and access the CSPMP database if prescribing or dispensing certain controlled substances

- Arizona Board of Homeopathic and Integrated Medicine Examiners
- Arizona Board of Osteopathic Examiners in Medicine and Surgery
- Arizona Medical Board
- Arizona Naturopathic Physicians Medical Board
- Arizona Regulatory Board of Physician Assistants
- Arizona State Board of Dental Examiners
- Arizona State Board of Nursing
- Arizona State Board of Optometry
- Arizona State Board of Pharmacy
- Arizona State Board of Podiatry Examiners

Source: Auditor General staff review of A.R.S. §36-2606 and A.R.S. Title 32.

Table 2
CSPMP data requests received by Board
Fiscal year 2019

Requesting agency	Number of requests
Law enforcement	1,722
Court orders	204
Licensing boards	70
Arizona Health Care Cost Containment System	34
Total	**2,030**

Source: Board-provided information.

The Board also encourages CSPMP database use by reminding new pharmacists to register with the CSPMP database and by providing online training videos and in-person training.

Organization and staffing

As required by A.R.S. §32-1902, the Board consists of 9 members appointed by the Governor for 5-year terms. Membership includes 6 pharmacists, with at least 1 employed by a licensed hospital and another employed as a practicing pharmacist in a community pharmacy; 1 pharmacy technician; and 2 public members. As of January 2020, 3 Board members were serving without reappointment because the Governor had not yet appointed new Board members since these 3 members' terms had expired in January 2020.

The Board was appropriated 22.4 full-time equivalent (FTE) positions for fiscal year 2020, and as of June 2020, had the following 17 positions filled: 6 compliance officers, 5 administration/operations staff, including the executive

[8] A.R.S. §§36-2604 and 36-2610.

[9] A.R.S. §36-2607.

director, 4 licensing staff, 1 inspector, and 1 CSPMP director. In addition, the Board reported that as of March 2020, it had hired 7 additional staff to operate the CSPMP, which it pays for using nonappropriated monies from a federal grant and an agreement with the Arizona Department of Health Services. These 7 staff are not included in its appropriation of 22.4 FTE positions.

Budget

The Board does not receive any State General Fund appropriations. Instead, the Board's revenues consist primarily of license and permit fees, which it deposits into the Board of Pharmacy Fund (Pharmacy Fund). Statute requires the Board to remit all monies collected from civil penalties and 10 percent of other monies, including license and permit fees, to the State General Fund, with the Board retaining the remaining 90 percent of these monies. The Board also receives revenues to operate the CSPMP consisting of grants, gifts, or donations and up to $500,000 annually transferred from the Board's operating monies, which are deposited into the Board's CSPMP Fund.[10] Additionally, in fiscal year 2019, the CSPMP Fund received more than $2 million in revenues from other sources, including from the Arizona Department of Health Services Medical Marijuana Fund, which paid for more than 80 percent of the CSPMP expenditures (see Table 3, page 7). The Board estimated that in fiscal year 2020, it would receive more than $5.3 million in net revenues.

In fiscal years 2017 through 2020, most of the Board's expenditures were or are estimated to be for Board staffing and maintenance and support of the CSPMP database (see Table 3 for additional information).

[10] A.R.S. §36-2605 allows the CSPMP Fund to receive legislative appropriations, but it has not received any legislative appropriations between fiscal years 2017 and 2019. In addition, the Board transferred nearly $400,000 in fiscal year 2017 and $500,000 in each of fiscal years 2018 and 2019 from the Pharmacy Fund to the CSPMP Fund. However, these transfers are not reflected in Table 3 because it would overstate the Board's revenues and expenditures.

Table 3[1]
Schedule of revenues, expenditures, transfers, and changes in fund balances
Fiscal years 2017 through 2020
(Unaudited)

	2017 Actual	2018 Actual	2019 Actual	2020 Estimate
Revenues				
Licensing and related fees[2]	$3,748,074	$4,174,489	$4,374,629	$3,713,181
Intergovernmental revenue				
Arizona Department of Health Services – Medical Marijuana Fund[3]	644,849	802,527	1,359,944	1,497,173
Arizona Department of Health Services – Prescription Drug Overdose Prevention Program[4]	213,705	116,902	154,470	229,106
Other		209,469	122,280	152,520
Examination fees	123,154	108,850	126,900	100,980
Fines, forfeits, and penalties	68,404	147,748	63,872	51,283
Other[5]	168,850	33,063	550,959	32,162
Total gross revenues	4,967,036	5,593,048	6,753,054	5,776,405
Net credit card transaction fees	(66,208)	(67,771)	(123,890)	(61,463)
Remittances to the State General Fund[6]	(546,354)	(472,546)	(576,372)	(389,760)
Total net revenues	**4,354,474**	**5,052,731**	**6,052,792**	**5,325,182**
Expenditures and transfers				
Payroll and related benefits	2,039,951	2,101,661	2,137,295	2,279,857
Professional and outside services	97,461	91,933	103,131	240,469
Travel	62,399	69,301	49,244	74,132
Aid to organizations[7]	292,600	292,600	207,717	200,000
Other operating				
Database access, support, and maintenance[8]	602,998	1,103,380	1,084,913	1,138,289
Other[9]	331,692	311,080	337,580	506,513
Furniture, equipment, and software	3,953	26,800	24,253	108,801
Total expenditures	3,431,054	3,996,755	3,944,133	4,548,061
Transfers out to the Arizona Department of Administration[10]	500		38,608	
Total expenditures	**3,431,554**	**3,996,755**	**3,982,741**	**4,548,061**
Net change in combined fund balances	922,920	1,055,976	2,070,051	777,121
Combined fund balances, beginning of year	4,693,000	5,615,920	6,671,896	8,741,947
Combined fund balances, end of year	**$5,615,920**	**$6,671,896**	**$8,741,947**	**$9,519,068**

[1] Table 3 includes financial activity related to the Pharmacy and CSPMP Funds.

[2] Beginning in August 2019, statutory changes discontinued the Board's regulation of nonprescription retailers which, according to the Board, decreased the amount of revenue received.

[3] Revenues received from the Arizona Department of Health Services Medical Marijuana Fund were used to pay for access to the CSPMP database (see footnote 8).

[4] The Arizona Department of Health Services provided these revenues pursuant to an agreement with the Board for enhancing and maximizing the CSPMP.

[5] In fiscal year 2019, the Board received a one-time payment of more than $380,000 of unclaimed licensing fees from the Treasurer's Office. These monies were a result of online application fees from previous years that were not recorded to the Pharmacy Fund.

[6] As required by A.R.S. §32-1907(A), the Board is required to remit 100 percent of civil penalties and 10 percent of all its other monies to the State General Fund, except monies related to the CSPMP Fund.

[7] Aid to organizations includes $200,000 in each fiscal year that was paid to the University of Arizona for the Arizona Poison Control and Drug Information Center as allowed by A.R.S. §32-1907(D). In fiscal years 2017 and 2018, aid to organizations also included $92,600 to a program for substance abuse treatment for pharmacists.

[8] The database access, support, and maintenance expenditures are payments to the CSPMP database vendor to allow prescribers and dispensers across the State to more easily access the CSPMP database and to provide support and maintenance of this access.

[9] Other operating expenditures include rent, insurance, telecommunications, postage, software and computer-related maintenance and support, data processing, and office supplies.

[10] Transfers to the Arizona Department of Administration in fiscal year 2019 are primarily for tenant improvements to the Board's offices.

Source: Auditor General staff analysis of the Arizona Financial Information System *Accounting Event Transaction File* for fiscal years 2017 through 2019, the State of Arizona Annual Financial Report for fiscal years 2017 through 2019, and Board-provided estimates for fiscal year 2020.

Board did not ensure licensees and facilities we reviewed were qualified to practice and operating safely

The Board performs several regulatory activities that are meant to help ensure the safe and qualified practice of pharmacy (see textbox). However, we identified several instances in which the Board did not adequately fulfill its regulatory responsibilities, which may put the public's health and safety at risk. Specifically:

Key Board regulatory activities[1]

Licensing—Review applicant qualifications, such as education, training, and fingerprint clearance card validity.

Continuing education—Audit a sample of renewed licenses to ensure compliance with continuing education requirements.

Complaint handling—Investigate and adjudicate complaints against its licensees and permit holders.

Inspecting facilities—Conduct periodic inspections at pharmacies and manufacturers to help ensure continued compliance with statute and rule.

[1] See Sunset Factors, pages 21 through 23, for additional regulatory responsibilities we reviewed.

- **Board did not verify the validity of fingerprint clearance cards for all but 1 of the pharmacist license applicants we reviewed, nor do they have the statutory authority to require a valid fingerprint clearance card at renewal—**The Board did not confirm the validity of fingerprint clearance cards for 29 of 30 randomly selected initial pharmacist licenses issued by the Board in fiscal year 2019 that we reviewed (see textbox, page 9, for information about fingerprint clearance cards).[11] According to DPS, fingerprint clearance card validity can only be confirmed by checking the DPS website or contacting DPS directly. Although statute requires applicants to submit fingerprint clearance cards to the Board, according to the Board, it did not confirm the validity of these applicants' fingerprint clearance cards because many of the applicants were recent graduates from pharmacy schools and possessed a pharmacy intern license, which also requires a fingerprint clearance card. The Board further reported that it assumed pharmacy schools would notify it of any problems with the fingerprint clearance card, despite the Board having the responsibility to ensure applicants meet this requirement.

  Confirming the validity of the fingerprint clearance card is important because a fingerprint clearance card may become suspended if a cardholder is arrested for a precluding offense. We used the DPS website to determine whether the fingerprint clearance cards were valid for all 30 pharmacist applicants and were able to confirm that as of August 2019, all but 1 of the 30 had a valid fingerprint clearance card.[12] However, by not confirming the validity of these applicants' fingerprint

[11] The sample was selected from the 699 initial pharmacist licenses the Board issued to applicants in fiscal year 2019.

[12] We could not confirm whether the remaining fingerprint clearance card was valid when the applicant applied for a pharmacist license because it expired approximately 8 months after the Board issued the license and had not been renewed at the time of our review. Although statute requires a valid fingerprint clearance card for licensure, it does not require licensees to maintain a valid fingerprint clearance card (see page 9 for more information).

clearance cards, the Board did not ensure that it was issuing licenses to only qualified applicants as required by statute.[13]

Further, the Board does not require any of its applicants to maintain a valid fingerprint clearance card at license renewal because it lacks the statutory authority to do so. Absent this authority, the Board instead requires that renewal applicants self-disclose whether they have been arrested for, charged with, or convicted of a misdemeanor or felony since their last renewal, including those arrests or convictions that have been expunged or dismissed. However, fingerprint clearance cards rely on information from law enforcement agencies, which provides better assurance that an applicant has not been arrested for or convicted of a criminal offense that would preclude their ability to have their license renewed.

Fingerprint clearance card—A card that the Arizona Department of Public Safety (DPS) issues indicating that the cardholder is not awaiting trial for or has not been convicted of committing only certain precluding criminal offenses, such as sexual assault, forgery, and concealed weapon violations. DPS issues this card based on its review of an applicant's criminal history record information. The card is valid for 6 years; however, if a cardholder is arrested for a precluding offense during this time period, DPS is authorized to suspend the card. DPS is also required to notify the cardholder and the entity if the cardholder is employed or licensed by an entity that is statutorily authorized to receive notification that the card is suspended pending the outcome of the arrest.

Source: Auditor General staff review of A.R.S. §41-1758 et seq and communication with DPS staff.

- **Board did not ensure that licensees met continuing education requirements—**Despite statutory and rule requirements that pharmacy technicians and pharmacists complete 20 and 30 hours, respectively, of continuing education biennially prior to renewing their license, the Board did not ensure that these requirements were met. Although the Board's renewal application requires licensees to attest to completing required continuing education hours, the Board did not regularly verify that licensees met these requirements. Further, even when the Board conducted a continuing education audit after its 2018 renewal cycle that identified a substantial amount of licensee noncompliance with continuing education requirements, it did not establish a regular continuing education verification process.[14] Specifically, the Board audited the continuing education for 50 randomly selected licensees it renewed in calendar year 2018.[15] Seven of the 50 licensees, or 14 percent, had not complied with the continuing education requirements despite these licensees asserting their compliance. For example, the Board determined that 2 licensees had not completed any continuing education hours in the 2-year renewal cycle, while the other 5 licensees were deficient in the number of continuing education hours they obtained.[16] Because the Board selected the renewal applicants at random for its continuing education audit, it is likely that this identified noncompliance was not isolated to the audited population.

  The Board renewing licenses without taking steps to ensure applicants have completed the required continuing education puts public safety at risk because licensees may not be aware of the newest research and best practices in the pharmacy profession. The National Association of Boards of Pharmacy (NABP) recommends that state boards of pharmacy require license renewal applicants to complete continuing education as a requirement for license renewal, enforce this requirement, and ensure the continued competence of its regulated licensees. Additionally, other Arizona regulatory boards are required by statute or rule to conduct continuing education audits. For example, the Arizona Medical Board and the Arizona Naturopathic Physicians Medical Board are required to audit at least 10 percent of physicians to verify compliance with continuing

[13] A.R.S. §32-1904(A)(6).

[14] According to the Board, as of March 2020, it was in the process of conducting a continuing education audit of 50 licensees who renewed their license during the 2017 or 2019 renewal cycle, which represents less than 1 percent of license renewal applications it received during those 2 years.

[15] The Board audited 25 pharmacy technicians and 25 pharmacists, which comprised less than 1 percent of the 7,815 licenses it renewed in calendar year 2018.

[16] The Board took action to address the noncompliance by issuing consent agreements to all 7 licensees. The consent agreements included a civil monetary penalty based on the number of hours missing and a requirement to complete 1.5 times the continuing education hours in the next renewal cycle. One of the 7 licensees agreed to voluntarily surrender her license rather than sign the consent agreement.

education requirements on an annual or biennial basis, respectively.[17] According to Board staff, conducting the continuing education audits was time-consuming and overwhelming and as such, the Board had not required its staff to regularly perform these audits. As of April 2020, the Board had begun to establish policies and procedures for auditing continuing education compliance after each renewal cycle.

- **Board has not always investigated complaints alleging prescriptions were not filled—**We reviewed 7 complaints from the March and May 2019 Board meeting agendas that alleged a prescription was not filled by a pharmacy.[18] These complaints were placed on the Board meeting agendas for the Board to determine whether these complaints were within its jurisdiction and if it should open the complaints for investigation. Although the Board opened 1 of these complaints for investigation, it determined that the other 6 complaints were outside of its jurisdiction. The Board did not explain its rationale for opening the 1 complaint for investigation but not the other 6 complaints despite all 7 complaints containing similar allegations. In addition, our review of a random sample of 30 complaints against licensees/permit holders that the Board received in fiscal year 2019 identified 3 complaints with allegations that prescriptions were not being filled.[19] The Board opened and investigated these 3 complaints. Although Board members determine whether or not to open some complaints for investigation, the Board had not established guidance for Board staff to ensure it received sufficient complaint information on which to base its decisions and had not documented the rationale of its decisions.

  During the audit, the Board revised its complaint-handling process to require its lead compliance officer to review all complaints and assess whether the complaint is within the Board's jurisdiction and, for those that are not, forward a recommendation to the Board's executive director to close the complaint. The Board has delegated authority to its executive director to close complaints that are not within the Board's jurisdiction.[20] However, the Board has not developed guidance, such as types of violations that would not be within the Board's jurisdiction, to help ensure its lead compliance officer and executive director consistently and appropriately determine complaint jurisdiction.

- **Board did not meet required inspection time frames—**Our review of a sample of inspections performed at 13 of the Board's 1,373 permitted pharmacies and manufacturers (facilities) with an active permit as of September 2019 found that the Board did not meet its time frame to conduct an inspection once every 18 months for 9 of the 13 permitted facilities, including 2 sterile compounding facilities.[21] The Board is also required to conduct inspections of sterile compounding facilities once every 18 months as a member of the NABP Multistate Pharmacy Inspection Blueprint Program (Blueprint Program) because these facilities may perform tasks that are higher risk (see textbox, page 11, for risks associated with compounding).[22] Further,

---

[17] A.R.S. §32-1434(D) and AAC R4-18-205(E).

[18] We judgmentally selected 10 complaints for review—5 of the 7 complaints that were placed on the meeting agenda for Board members to determine jurisdiction in the March 2019 Board meeting agenda and all 5 complaints that were placed on the meeting agenda for Board members to determine jurisdiction in the May 2019 Board meeting agenda. Seven of these complaints had similar allegations.

[19] We reviewed a random sample of 30 of the 570 complaints against licensees/permit holders that the Board received in fiscal year 2019. Although the Board's data showed that it received 570 complaints in fiscal year 2019, this number is likely inaccurate because the Board did not sufficiently track this data. For example, the Board's data included complaint allegations that were not in the Board's jurisdiction and were not opened for investigation and the Board did not differentiate these complaints from complaints that it determined were within its jurisdiction. In addition, when the Board opens complaints against several licensees/permit holders for the same allegation, the Board assigns each complaint the same complaint number.

[20] Laws 2019, Ch. 257, allows the Board to delegate authority to its executive director to take no action or dismiss a complaint that has insufficient evidence that a violation has occurred. It also requires the executive director to provide Board members with a list of these actions at each regularly scheduled Board meeting.

[21] We reviewed a random sample of 7 of the 1,323 pharmacies and 3 of the 50 manufacturers that had an active permit as of September 2019. Because none of the 7 pharmacies initially reviewed engaged in sterile compounding, we judgmentally selected an additional 3 pharmacies that would be more likely to engage in sterile compounding and found 2 of these 3 did so.

[22] According to NABP, the Blueprint Program provides pharmacy boards with the tools to inspect sterile compounding pharmacies that ship across state lines. States that participate in the Blueprint Program can rely on other states' inspections, rather than performing their own inspections.

as of February 2020, 2 of the 13 facilities had operated nearly 3 and more than 5 years, respectively, without an inspection.

Risks of compounding

Compounding is the process of combining, mixing, or altering ingredients to create a medication tailored to the needs of an individual patient. Some of the risks associated with compounding include:

- FDA does not verify the safety, effectiveness, or quality of compounded drugs and poor compounding practices can result in serious drug quality issues.
- Sterile compounding requires the maintenance of sterile conditions, such as air quality, disinfected surfaces, and use of protective clothing because the contamination of sterile compounds poses the greatest probability of risk to patients.
- Contaminated sterile products are potentially the most harmful when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues.
- In 2012, a Massachusetts pharmacy shipped contaminated compounded drugs that were ultimately used by 14,000 patients, leading to more than 750 fungal infections and 60 patient deaths.

Source: U.S. Food and Drug Administration (FDA) website and U.S. Pharmacopeia and the National Formulary. (2008). *USP general chapter <797> pharmaceutical compounding—sterile preparations*. Rockville, MD.

Although each of the Board's compliance officers separately track the inspections they perform, Board management does not centrally track or monitor inspection frequency. Therefore, Board management is not aware when inspection time frames are not met and this inadequate oversight has contributed to some permitted facilities operating more than 18 months without an inspection.

Recommendations

The Board should:

1. Ensure that initial pharmacist license applicants possess a valid fingerprint clearance card before it issues a license by developing and implementing policies and procedures requiring Board staff to check the validity of fingerprint clearance cards on the DPS website.

2. Work with the Legislature to amend statute to require licensees to maintain a valid fingerprint clearance card and submit them at renewal.

3. After statute is amended (see Recommendation 2), develop and implement written policies and procedures that require Board staff to check the DPS website to ensure the validity of fingerprint clearance cards submitted by all renewal licensure applicants.

4. Ensure that renewal applicants meet continuing education requirements by continuing to develop and implement written policies and procedures for conducting continuing education audits after each renewal cycle.

5. Consistently determine complaint jurisdiction by developing and implementing guidance, such as types of violations that would not be within the Board's jurisdiction, to help ensure its lead compliance officer and executive director consistently and appropriately determine complaint jurisdiction.

6. Document the rationale for its complaint jurisdiction determinations.

7. Consistently meet established inspection time frames by developing and implementing processes for tracking and monitoring the completion of facility inspections.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

Board's license and permit fees are not based on cost of providing services, resulting in large and growing fund balance

Board has not based licensing and permit fees on actual costs of providing services

The Board's primary revenue source is its licensing and permit fees, but it has not established these fees based on the costs to perform its regulatory processes, and it reported that it does not know when it last reviewed its fees. For the most part, the Board's fees have remained unchanged since 2009. For example:

- As allowed by statute, in 2019, the Board established 2 new permit types and their associated permit application fees—a $480 application fee for an automated prescription-dispensing kiosk permit and a $1,000 application fee for a third-party logistics provider permit (see Table 1, page 3, for more information about the purposes of these permits).[23] According to a Board official, the Board did not perform a cost analysis of its process to review and approve these permits or any other related regulatory processes to determine the application fees for these new permits. Instead, because these permits are a type of pharmacy and wholesaler, respectively, the Board established the fees based on the fee amount that it was already charging for existing pharmacy and wholesaler permits.

- The Board charges the same $480 pharmacy permit application fee to both in-state and out-of-state applicants even though it does not inspect out-of-state pharmacy permit applicants prior to issuing the permit.[24]

- The Board charges pharmacists who apply for licensure by reciprocity a $300 "reciprocity fee" (see Table 4).[25] According to statute, the reciprocity fee is to cover the expense of investigating the applicant's character, general reputation, and pharmaceutical standing in the jurisdictions in which the applicant is licensed.[26] The Board relies on NABP's license transfer application, which provides information on the applicant's disciplinary history and license status in other states and according

Table 4
Initial pharmacist license application fees as of March 2020

Application and fee type	Fee amount
Licensure by exam	
Licensure fee	$180
Application fee	50
Wall license	20
Total	**$250**
Licensure by reciprocity	
Reciprocity fee	$300
Licensure fee	180
Wall license	20
Total	**$500**

Source: AAC R4-23-205.

[23] A.R.S. §32-1931.

[24] The Board requires out-of-state permit applicants to possess a valid license or permit in their home state and relies on this to ensure the applicant is in good standing.

[25] AAC R4-23-205.

[26] A.R.S. §32-1924(D) requires that the Board charge a fee for reciprocal licensure that is not more than $500.

to the Board, it has done so since 1998. If the license transfer application does not reveal any concerns, the Board does not conduct an investigation. However, if an applicant has disciplinary or criminal history, the Board requests and reviews the information, regardless of whether they are seeking licensure by reciprocity or by exam. Therefore, the Board's investigative costs for reviewing and issuing reciprocity licenses may not justify the $300 fee because it is the same investigative work that it conducts for all applicants.

The Board has approved nearly 7,000 pharmacist licenses by reciprocity between 1998 and March 2020.[27] As a result, the Board received nearly $2.1 million in revenue for work that may have cost it less to perform.

Fee-setting standards and guidelines for user fees:[1]	
	Based on the cost of providing a service.
	Reviewed periodically to align with actual cost and adjust for inflation.
	Considered impact on stakeholders and obtained input for fee changes.

[1] See Appendix A, page a-2, for more information on the sources reviewed.

Standards and guidelines for government fee setting developed by several government and professional organizations state that user fees should be set and reviewed periodically to ensure they are based on the costs of providing a service.[28] When an agency sets fees that are not based on the cost of providing a service, there is an increased risk that the agency's fee revenues may be greater or less than the costs of the services it provides. Standards and guidelines for fee setting also indicate that when setting fees to cover the cost of operations, agencies should ensure that their operations are as efficient as possible. Further, agencies should develop a method to identify both direct and indirect costs to help accurately determine their costs for providing a service or good and then set their fees accordingly. Finally, the guidelines indicate that agencies should consider the effect the proposed fee changes may have on stakeholders and obtain their input when reviewing and setting the fees.

According to the Board, it has not established its fees based on the direct and indirect costs of its regulatory activities or periodically reviewed the appropriateness of its fees based on changes to these costs because it was not aware of these fee-setting guidelines or that fees should align with its actual costs.

Board's fund balance is large and growing

As shown in Table 5, page 14, from fiscal years 2017 to 2019, the Board's Pharmacy Fund balance—which represents the accumulated difference between revenues and expenditures—increased by more than $2.7 million. As of fiscal year 2019, the Board's more than $8 million Pharmacy Fund balance was nearly 3 times its expenditures for that year. The Board projects its Pharmacy Fund balance will continue to increase as its revenues exceed its expenditures and reach approximately $8.4 million at the end of fiscal year 2020.

[27] Although Laws 2019, Ch. 55, requires Arizona State regulating entities to issue reciprocal occupational or professional licenses under certain circumstances to individuals that establish Arizona residency, according to the Board, it was already providing out-of-state pharmacists the ability to reciprocate their license in compliance with these requirements and therefore, it has not changed its process.

[28] We reviewed fee-setting guidelines from the Arizona State Agency Fee Commission, the Government Finance Officers Association, the Mississippi Joint Legislative Committee on Performance Evaluation and Expenditure Review, the U.S. Government Accountability Office, and the U.S. Office of Management and Budget (see Appendix A, page a-2, for more information).

Table 5
Board of Pharmacy Fund
Summary of revenues, expenditures, transfers, and fund balance
Fiscal years 2017 through 2019
(Unaudited)

	2017	2018	2019[1]	Increase between 2017 and 2019
Revenues and transfers in	$3,495,920	$3,923,832	$4,436,830	**$ 940,910**
Expenditures and transfers out[2]	2,679,295	2,785,977	2,846,042	**166,747**
Fund balance	$5,428,258	$6,566,113	$8,156,902	**$2,728,644**

[1] In fiscal year 2019, the Board received a one-time payment for unclaimed license fees. See Table 3, footnote 5, on page 7 for more information.

[2] Expenditures and transfers out for all fiscal years include transfers to the CSPMP Fund. Specifically, the Board transferred nearly $400,000 in fiscal year 2017 and $500,000 in each of fiscal years 2018 and 2019 from the Pharmacy Fund to the CSPMP Fund.

Source: Auditor General staff analysis of the Arizona Financial Information System *Accounting Event Transaction File* and the State of Arizona *Annual Financial Report* for fiscal years 2017 through 2019.

Recommendations

The Board should:

8. Conduct a review of its license and permit fees consistent with government fee-setting standards and guidelines, including ensuring the fees are based on actual costs and promote service efficiency, and then adjust its fees accordingly. Specifically, the Board should:

    a. Develop and implement a method for determining and tracking the direct and indirect costs for its regulatory processes and establish policies and procedures for using this method. The policies and procedures should also require the periodic review of the Board's fees, including tracking and reassessing actual costs and assessing if costs are necessary for providing services.

    b. After implementing this cost methodology, determine the appropriate license and permit fees.

    c. Consider the effect of proposed fee changes on applicants, licensees, and permit holders and obtain their input when reviewing the fees.

    d. Adjust its fees in its rules, as necessary.

9. Work with the Legislature, as needed, to revise statute to eliminate the reciprocity fee and charge the same application fee to all initial pharmacist applicants.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement or implement in a different manner the recommendations.

State may not be receiving full benefits of the CSPMP because Board has not enforced or helped to enforce compliance with CSPMP requirements

Board has not ensured its licensees/permit holders use the CSPMP database when required or provided information to other Arizona professional licensing boards to help them identify noncompliance among their licensees

As discussed in the Introduction (see pages 4 through 5), prescribers' and dispensers' use of the CSPMP is important to support access to and legitimate medical use of controlled substances; identify and deter or prevent drug abuse and diversion; facilitate the identification, intervention with, and treatment of persons addicted to prescription drugs; and inform public health initiatives through outlining of use and abuse trends.[29] Figure 1 (see page 16), shows how prescribers, dispensers, and pharmacies should use the CSPMP database to help achieve these purposes. For example, the CSPMP database works most effectively as a tool for prescribers and dispensers when pharmacies have submitted complete information on controlled substances they dispensed so it is available in the CSPMP database. In addition, according to the Arizona Department of Health Services 2018 Arizona Opioid Prescribing Guidelines, using the CSPMP database helps prescribers develop a plan of care for a patient and avoid fatal drug-to-drug interactions by identifying harmful medical interactions and can provide evidence of multiple providers prescribing controlled substances. Finally, because pharmacists are not required to dispense a controlled substance if it would be potentially harmful to the patient's health, CSPMP database information can help them exercise professional judgment to determine whether or not to dispense a controlled substance.

However, the Board has not taken the steps needed to ensure that all permitted pharmacies that can dispense controlled substances are reporting information into the CSPMP database vendor's clearinghouse or that licensed prescribers and dispensers use CSPMP database information as required by statute to help the State and Arizona residents realize these benefits.[30] Specifically, the Board:

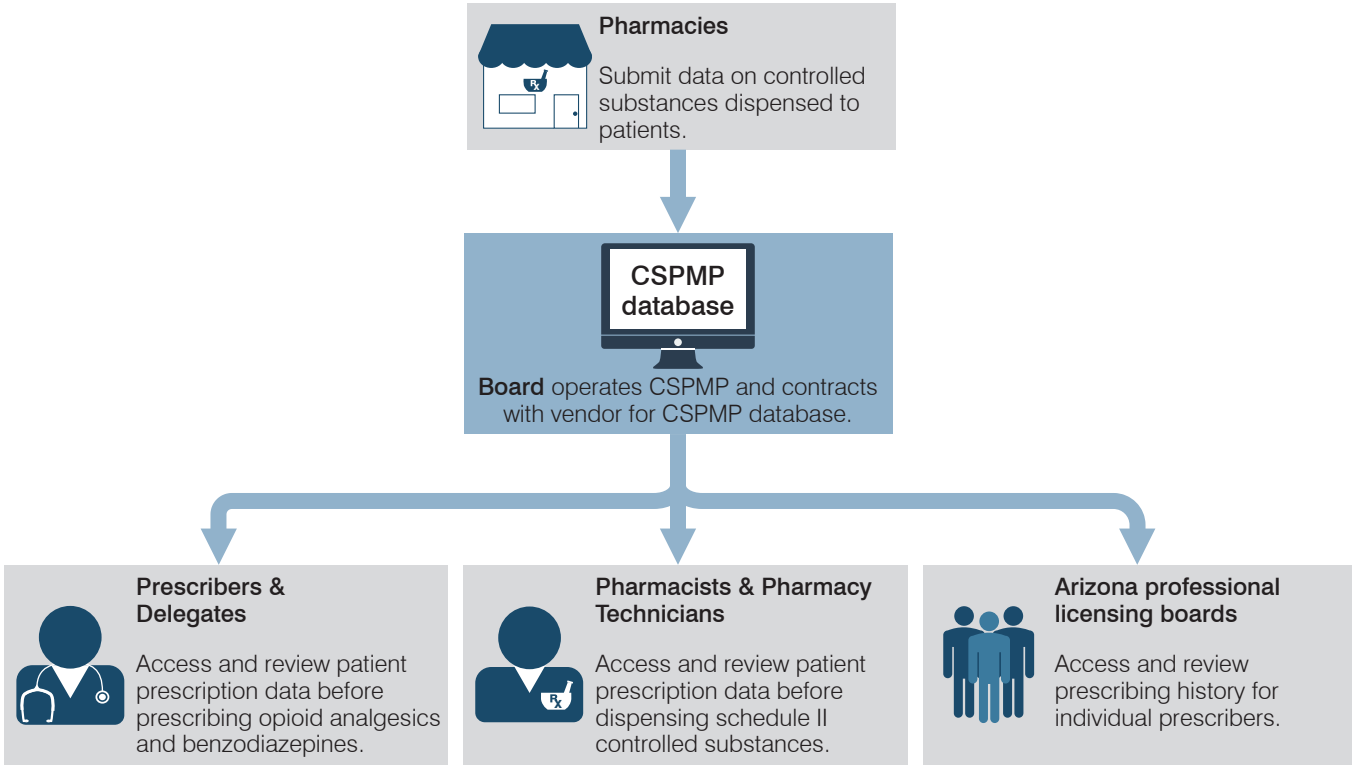
- **Has not assessed whether all permitted pharmacies that can dispense controlled substances are submitting dispensing information to the CSPMP database vendor's clearinghouse to help ensure that the CSPMP database includes complete information for prescribers and dispensers who are required to review it—**The Board reviews a bi-weekly report generated by the CSPMP database that identifies pharmacies that did not submit dispensing information to the CSPMP as required so that the Board can notify those pharmacies that they are delinquent in reporting; however, the Board does not know

[29] Drug Enforcement Administration. (2016). *State prescription drug monitoring programs*. Washington, DC: U.S. Department of Justice. Retrieved 3/31/2020 from https://www.deadiversion.usdoj.gov/faq/rx_monitor.htm.

[30] Pharmacies and medical practitioners who dispense controlled substances register with the CSPMP database vendor's clearinghouse to submit information about dispensed controlled substances. This information then becomes available to search in the CSPMP database.

whether all permitted pharmacies that can dispense controlled substances are included in this report.[31] Therefore, the CSPMP database may be missing key information about controlled substances that were dispensed to patients, which potentially places those who rely on CSPMP database information at risk of making misinformed prescribing and dispensing decisions. After we inquired about the Board's practices for assessing whether all permitted pharmacies were reporting information as required, the Board reported that it took action to improve its process.

Figure 1
Key users of State's CSPMP database



Source: Auditor General staff review and summary of A.R.S. §§36-2601 et seq and interviews with Board staff.

Specifically, it reported that it began comparing the pharmacies that were submitting dispensing information to the CSPMP database vendor's clearinghouse to the list of all permitted pharmacies with an Arizona address that can dispense controlled substances to determine if any of those pharmacies were not submitting dispensing information as required.[32] The Board found that the CSPMP database did not include 177 of the 1,230 permitted pharmacies with Arizona addresses that can dispense controlled substances. The Board reported that, although it could not determine whether or not these pharmacies had previously submitted the required information, as of March 2020, it had added 137 of those 177 pharmacies to the CSPMP database so that it could begin tracking these pharmacies.[33] In addition, the Board reported that it planned to develop a similar process for identifying and tracking permitted pharmacies that have a non-Arizona address.

[31] A.R.S. §36-2608(A) requires pharmacies to report to the CSPMP controlled substance dispensation information, such as the prescriber's DEA number and patient's name.

[32] Similar to licensed pharmacists, if a permitted pharmacy does not dispense controlled substances, it does not have to submit information to the CSPMP database vendor's clearinghouse. According to the Board, it can make this determination by searching its permitted pharmacies for those with a DEA number—an identifier assigned by the DEA that allows them to dispense controlled substances.

[33] The remaining 40 permitted pharmacies were closed as of March 2020.

- **Has not assessed whether licensed pharmacists are registered for and check patient information in the CSPMP database prior to dispensing controlled substances to help deter or prevent drug abuse—**The Board has not identified which of its licensed pharmacists are registered for and check patient information in the CSPMP database prior to dispensing schedule II controlled substances when required by statute.[34] Licensed pharmacists that are not registered for the CSPMP are unable to check patient information to determine whether a prescription could be potentially harmful and should not be dispensed. According to Board information, as of March 2020, it had nearly 8,000 licensed pharmacists with a physical address in Arizona but only 5,005 were registered for the CSPMP database, which provides them with access to conduct required checks in the database.[35] Although not all licensed pharmacists must register for the CSPMP database, such as pharmacists working in pharmacies that do not dispense controlled substances, without any assessment of whether licensed pharmacists have registered for and are checking the CSPMP database as required, the Board cannot determine which of its licensees have complied with these statutory requirements and take necessary action to address any instances of noncompliance. According to the Board, during the audit, it began identifying Arizona pharmacists who were not registered for the CSPMP database and notifying them that they need to register if they are employed by a facility that dispenses controlled substances.

- **Has not provided information to other Arizona professional licensing boards to enable them to enforce licensee compliance with State CSPMP statutes—**The Board has not provided other Arizona professional licensing boards with the information they would need to help identify and address which of their licensees did not obtain a patient utilization report from the CSPMP database prior to prescribing an opioid analgesic or benzodiazepine as required by statute (see the Introduction, page 5, for the list of Arizona professional licensing boards).[36] According to Board information, nearly 4,300 of the nearly 18,800 licensed prescribers, or approximately 23 percent, who wrote opioid analgesic or benzodiazepine prescriptions that were filled in January 2020 were not registered for CSPMP database access and would not have been able to check a patient's utilization report prior to prescribing these medications or at least quarterly while the prescription remained a part of the treatment.[37] However, the Board did not provide any of this information to the licensed prescribers' respective professional licensing boards. By not doing so, these boards, which have statutory authority to enforce their licensees' compliance with State CSPMP statutes, cannot address noncompliance among their licensees and hold those licensees accountable for following State CSPMP statutes. Although other Arizona professional licensing boards can access the CSPMP database to research individual patients, they must rely on the Board for aggregate information that they can use to more quickly identify potential noncompliance among their licensed prescribers.

Board has taken educational rather than enforcement approach to CSPMP compliance and does not think other boards would want to enforce licensee compliance with State CSPMP statutes

The Board reported that it has taken an educational rather than an enforcement approach to help ensure compliance with State CSPMP statutes and a belief that other Arizona professional licensing boards would not be interested in enforcing their licensees' compliance with these statutes. Specifically:

- **Board reported it has taken an educational rather than enforcement approach to ensure CSPMP compliance—**The Board reported a preference for educating licensees and permit holders regarding State CSPMP statutory requirements rather than pursuing any enforcement remedies to address instances

[34] A.R.S. §36-2606(G) requires that before a pharmacist dispenses a schedule II controlled substance, they shall obtain a patient utilization report regarding the patient for the preceding 12 months at the beginning of each new course of treatment.

[35] The Board assessed only Arizona pharmacists and did not include those licensed by the Board but working outside of the State.

[36] A.R.S. §36-2606(F) requires that medical practitioners, before prescribing an opioid analgesic or benzodiazepine controlled substance listed in schedule II, III, or IV for a patient, obtain a patient utilization report regarding the patient for the preceding 12 months from the CSPMP database at the beginning of each new course of treatment and at least quarterly while that prescription remains a part of the treatment.

[37] According to the Board's data, more than 500,000 opioid analgesic and benzodiazepine prescriptions were filled in Arizona in January 2020.

of noncompliance. Specifically, the Board provides online training videos about how to access and use the CSPMP database and directly notifies pharmacists about the requirement to register for the CSPMP database. Although providing this educational assistance is beneficial, it does not relieve the Board of its statutory responsibility to enforce CSPMP statutory compliance with its licensees and inform other Arizona professional licensing boards of potential noncompliance when necessary.

- **Board has not provided CSPMP information to other Arizona professional licensing boards because Board staff do not think the boards would use it to enforce compliance with the CSPMP—**Although other Arizona professional licensing boards have statutory authority to enforce their licensees' compliance with State CSPMP statutes, according to Board staff, these boards are not interested in enforcing these statutes and may not use noncompliance information if it were provided by the Board. Additionally, according to the Board, it does not know if noncompliance with State CSPMP statutes is considered "unprofessional conduct" by these other boards' statutes. However, as of June 2020, the Board has not worked with other Arizona professional licensing boards to determine whether they would use CSPMP information or reports or the type of information they would need to enforce CSPMP compliance. According to Board staff, identifying potential noncompliance would likely be a time-consuming, manual process. As a result, the Board has not established processes for identifying licensed prescriber potential noncompliance with CSPMP requirements and notifying the appropriate Arizona professional licensing board of this potential noncompliance. However, after we inquired about processes for providing information to these boards, the Board reported that it requested information from the CSPMP database vendor about potentially adding reporting functionalities that would assist in identifying and reporting potential noncompliance.

Recommendations

The Board should:

10. Enforce licensed pharmacist and permitted pharmacy compliance with State CSPMP statutes.

11. Develop and implement processes to identify licensed pharmacists who have not registered for and are not checking the CSPMP database as required and take enforcement action, as appropriate.

12. Continue its newly developed process to identify permitted pharmacies with an Arizona address that should have, but are not, registered to submit information accessible through the CSPMP database.

13. Develop and implement a process to identify permitted pharmacies that are outside of Arizona that should have, but are not, registered to submit information accessible through the CSPMP database.

14. Ensure that all permitted pharmacies that should be submitting information accessible through the CSPMP database, including those identified as a result of the Board's processes (see Recommendations 12 and 13), are doing so and follow up with any pharmacies that are delinquent in reporting.

15. Work with the other 9 Arizona professional licensing boards listed in A.R.S. §36-2606(B)(1) to determine the information they need to investigate and enforce licensed prescriber noncompliance with State CSPMP statutory requirements.

16. Follow State CSPMP statutes and provide other Arizona professional licensing boards with information they need to investigate and enforce noncompliance with these statutes.

17. Develop and implement processes for identifying licensed prescriber potential noncompliance with State CSPMP statutory requirements.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

Board did not provide required public information on its website or in response to our anonymous phone calls

Board did not provide required complaint information on its website and provided inaccurate and incomplete complaint information over the phone

Although the Board is statutorily required to provide certain information about its licensees and permit holders to the public (see Table 6), its website did not include required complaint information and it provided inaccurate and incomplete information over the phone. The Board's provision of inaccurate and incomplete information about licensees, such as pharmacists and pharmacy technicians, and permitted facilities, such as pharmacies, prevents the public from making accurately informed decisions about which pharmacies they will use to obtain prescription medication. Specifically:

Table 6
Statutorily required/allowed ways Board should provide public information about complaints

	Phone	Website	Office
Dismissed complaint	✓	✗	✓
Open complaint investigation	✗	✗	✗
Nondisciplinary action	✓	✓	✓
Disciplinary action	✓	✓	✓

Source: Auditor General staff review of A.R.S. §§ 32-3209, 32-3214, and 39-121.

- **Board's website did not have all required complaint information—**Our comparison of complaint information from our random sample of 30 complaints to information available on the Board's website found that the website did not include complete information (see Sunset Factor 6, pages 25 through 26, for more information on our complaints review).[38] Specifically, for 6 of the 30 complaints, the website lacked information about nondisciplinary actions the Board issued. For example, the Board issued an advisory letter and 3 hours of nondisciplinary continuing education in medication error prevention and patient safety to a pharmacy technician who dispensed a higher dose of fentanyl than had been prescribed. However, contrary to statute, the Board's website did not reflect this information.

  In addition, the Board's website does not include the statutorily required statement that a person may obtain public records related to any licensee or permit holder, including dismissed complaints, by contacting the Board directly.[39]

[38] We randomly selected 30 of the 570 complaints the Board's data showed that it received in fiscal year 2019. However, this number is likely inaccurate because the Board did not sufficiently track this data. For example, the Board's data included complaint allegations that were not in the Board's jurisdiction and were not opened for investigation and the Board did not differentiate these complaints from complaints that it determined were within its jurisdiction. In addition, when the Board opens complaints against several licensees/permit holders for the same allegation, the Board assigns each complaint the same complaint number.

[39] A.R.S. §32-3214(C).

- **Board staff provided inaccurate and incomplete complaint information over the phone—**In response to our 2 anonymous phone calls to the Board's office regarding 1 licensed pharmacist and 1 permitted pharmacy, Board staff provided inaccurate complaint information.[40] In both instances, Board staff referred us to the Board's website to obtain information. However, the licensed pharmacist and permitted pharmacy both had complaint information that was not available on the Board's website. Regarding the licensed pharmacist, after we obtained information about 1 complaint from the website, we inquired about any additional complaints. Board staff told us the licensee did not have any other complaints and did not tell us about a closed complaint that resulted in an advisory letter and a nondisciplinary order to complete continuing education. This information is not available on the website and can only be obtained by contacting the Board.

  Regarding the permitted pharmacy, Board staff did not tell us about a dismissed complaint. Statute requires that a record of the dismissed complaint be available to the public upon request but does not allow this information to be provided on the Board's website.[41] However, when we asked Board staff to provide us with the information over the phone, Board staff responded that they would not provide the information over the phone.

  In both calls, Board staff did not take reasonable steps to provide us with other options for obtaining the public information, such as transferring us to Board management.

Board's policies lack guidance to help staff with provision of accurate and complete public information

The Board did not ensure that its staff or its website provided public information in compliance with statutory provisions. For example, although Board management indicated they were aware that the Board's website lacked information about complaints that resulted in nondisciplinary actions and the statutorily required statement that a person may obtain public records by contacting the Board directly, the Board had not updated the website or developed and implemented a plan to do so. Additionally, although Board management verbally reported that staff are to refer callers to the executive director or deputy director to obtain complaint information, the policies and procedures do not guide staff to do so. Rather, Board policy states that complaint information should not be provided by Board staff over the phone. Therefore, Board staff responsible for answering the phone reported that they would direct the caller to the website.

Recommendations

The Board should:

18. Provide required information on its website by updating it to include (1) all required information about licensees and permit holders, including nondisciplinary actions, and (2) a statement informing the public that they can contact the Board for more information as required by statute.

19. Ensure that it provides complete and accurate information to the public over the phone by revising and implementing its policies and procedures for providing public information to include how staff should respond to phone calls requesting complaint information.

20. Develop and provide training for its staff once it has developed the policies and procedures outlined in Recommendation 19.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

[40] We made 2 calls in September 2019 to request complaint history information about a licensed pharmacist who had an advisory letter, a nondisciplinary continuing education order, and a consent agreement; and a permitted pharmacy that had a dismissed complaint.

[41] A.R.S. §32-3214.

In accordance with A.R.S. §41-2954, the legislative committees of reference shall consider but not be limited to the following factors in determining the need for continuation or termination of the Board. The sunset factor analysis includes additional findings and recommendations not discussed earlier in the report.

Sunset factor 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.

The Board was established in 1903, and its mission is to protect the health, safety, and welfare of the public through the regulation of the practice of pharmacy and the manufacturing, distribution, sale, and storage of prescription medications and devices, and nonprescription medications. The Board is responsible for issuing licenses to qualified professionals and permits to qualified facilities engaged in activities related to the practice of pharmacy and for investigating and adjudicating complaints against licensees and permit holders. The Board is also responsible for providing information to the public regarding licensees' disciplinary history and license status, conducting inspections of permitted facilities located in Arizona, and administering the CSPMP, a prescription drug monitoring program, which includes a database to help facilitate the appropriate prescribing, dispensing, and use of controlled substances.

According to NABP, all 50 states and the District of Columbia regulate the practice of pharmacy and have a functioning board of pharmacy. Additionally, 49 states administer a prescription drug monitoring program (PDMP) (see Sunset Factor 11, page 28, for more information on PDMPs in other states). We did not identify any states that met the Board's objective and purpose through private enterprise. However, the Board relies on NABP for some services, such as providing information on reciprocal license applicants, including the status of their license in other states and any discipline they have received.

Sunset factor 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 met some of its statutory objective and purpose. Specifically, our review of 30 initial pharmacist licenses and 30 initial pharmacy technician licenses the Board issued to applicants in fiscal year 2019 found that all 60 were issued within the time frames established in rule.[42,43] Additionally, the Board had determined that all 30 initial pharmacist license applicants had met the statutory education and examination requirements.[44]

However, we identified several areas in which the Board has not fully met its statutory objective and purpose or fulfilled other responsibilities. Specifically, the Board:

- **Did not ensure pharmacy technician applicants met training requirements prior to issuing licenses, but a January 2020 change to requirements for taking national pharmacy technician exam may mitigate need for Board to ensure applicants meet training requirements—**Our review of 30 initial pharmacy technician licenses issued in fiscal year 2019 found that the Board did not ensure that applicants had completed required training. Although rule requires pharmacy technician applicants to provide proof that they either (1) complete training in a pharmacy while working as a licensed technician trainee, or (2) complete

[42] AAC R4-23-202, R4-23-203, and R4-23-1103.

[43] We reviewed a random sample of 30 of the 699 initial pharmacist licenses and 30 of the 1,167 initial pharmacy technician licenses the Board issued to applicants in fiscal year 2019.

[44] A.R.S. §32-1922.

an on-the-job training program immediately after becoming licensed as a technician, Board staff did not require applicants to submit training information.[45] According to Board staff, they do not check this requirement because they believe applicants demonstrate sufficient training by passing 1 of the national certification exams that is required prior to receiving a license in Arizona. All 30 applicants we reviewed passed 1 of the national certification exams. Additionally, as of January 2020, both national certifying organizations that offer the exams accepted by the Board require exam applicants to attest that they have completed a qualifying pharmacy technician education/training program or other qualifying work experience before taking the national exam (see Sunset Factor 11, pages 27 through 28, for more information on licensing requirements). However, as of May 2020, the Board had yet to require its applicants to demonstrate compliance with its rule requirement or revise its rule to rely on the national certifying organizations' attestation requirements.

- **Did not adequately protect cash receipts, placing public monies at risk of loss or theft—**The Board has not adequately protected the monies it receives either through the mail or in-person at the Board office, such as renewal fees and civil penalties. Our review of the Board's cash-handling processes identified the following:

    - One staff member opens the mail alone, logs checks and money orders received into an internal database, and performs some licensing functions, such as issuing a copy of a license to a licensee.

    - Board staff do not always deposit amounts over $1,000 at the end of each business day as required and leave the money in an unlocked drawer overnight.

    - Board staff receive some cash in the mail, but return cash to the sender rather than processing the transaction and depositing it.

    The *State of Arizona Accounting Manual* (SAAM) cash-handling requirements include maintaining an appropriate segregation of cash-handling and cash-recording functions, such as opening the mail in the presence of another person and not authorizing staff who handle cash to also issue licenses. Further, SAAM requires monies, including cash, to be deposited as soon as it is practical but no later than the end of the business day after totaling $1,000 or more. Because cash receipts are susceptible to loss or theft, it is critical that State agencies adequately control and safeguard these monies.

Finally, as discussed in Findings 1 through 3, the Board had not ensured licensees were qualified to practice and facilities were operating safely, established licensing and permit fees consistent with the cost of its regulatory activities, or enforced CSPMP statutes. To address these issues, we recommended that the Board:

- Ensure pharmacist license applicants possess a valid fingerprint clearance card by checking the validity of fingerprint clearance cards on the DPS website and working with the Legislature to amend statute to require licensees to maintain a valid fingerprint clearance card at license renewal; ensure that renewal applicants meet continuing education requirements by conducting continuing education audits after each renewal cycle; consistently determine complaint jurisdiction and document the rationale for its determination; and track, monitor, and timely perform facility inspections (see Finding 1, pages 8 through 11).

- Review and adjust its license and permit fees based on the costs of its regulatory activities (see Finding 2, pages 12 through 14).

- Enforce State CSPMP statutes for its permitted pharmacies and licensed pharmacists and take steps to provide information to other Arizona professional licensing boards to assist them with enforcing these statutes (see Finding 3, pages 15 through 18).

[45] AAC R4-23-1102 and R4-23-1105.

Recommendations

The Board should:

21. Ensure pharmacy technicians meet training requirements by either requiring pharmacy technician applicants to submit documentation showing they meet training requirements or revising its rule to rely on the national boards' training attestation requirements.

22. Protect its cash receipts by developing and implementing written cash-handling policies and procedures that adhere to SAAM requirements, such as

    a. Opening mail with at least 2 staff members present.

    b. Separating the duties of logging cash receipts from licensing functions.

    c. Depositing cash receipts exceeding $1,000 on a daily basis.

    d. Processing cash transactions and depositing cash rather than returning it to the sender through the mail.

23. Train staff on these updated policies and procedures and review staff work periodically for compliance.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

Sunset factor 3: The extent to which the Board serves the entire State rather than specific interests.

The Board serves the entire State by licensing and permitting applicants, inspecting permitted facilities throughout Arizona, and investigating and adjudicating complaints (see Finding 1, pages 8 through 11, for more information).

However, the Board has not complied with several of the State's conflict-of-interest requirements. Statutes require (1) public officers and employees to make known any substantial interests, such as through a conflict-of-interest disclosure form, and refrain from voting on decisions in which they have a substantial interest, and (2) agencies to maintain a special file that contains all disclosures of substantial interest that is available for public inspection.[46] Further, best practices indicate that the conflict-of-interest disclosure form should be signed annually and require Board members and staff to affirm that they have no conflicts of interest, if applicable. Signing a conflict-of-interest disclosure form annually reminds employees/public officers of the importance of complying with conflict-of-interest laws and helps ensure that potential conflicts of interest are disclosed if an employee's or public officer's circumstances change. A completed conflict-of-interest disclosure form also enables Board members and staff to disclose any potential financial and/or personal interests that the Board could then make available for public inspection.

The Board has taken some steps to ensure its decisions are free of conflicts of interest. Specifically, the Board has a policy that requires Board members to declare conflicts of interest during Board meetings. In addition, the Board reported it provides training to all newly appointed Board members regarding conflicts of interest and the process for refraining from participating in Board business if there is a conflict. Further, we observed 2 Board meetings during which Board members formally recused themselves from various agenda items.

However, for both of these Board meetings, the Board did not document the reason(s) for Board members' recusals in the meeting minutes. Further, we identified 2 complaints for which a Board member voted even though she had recused herself from the associated agenda items. Board staff also reported that the Board does not require its members or staff to sign an annual conflict-of-interest disclosure form. Additionally, the Board lacks the statutorily required special file to document disclosures of substantial interest. Finally, the Board lacks policies and procedures for disclosing conflicts of interest in writing, requiring or maintaining a special file, and managing any disclosed potential conflicts of interest.

[46] A.R.S. §§38-503 and 38-509.

Recommendations

The Board should:

24. Ensure it complies with all State conflict-of-interest requirements.

25. Develop and implement comprehensive policies and procedures for addressing potential conflicts of interest in accordance with State laws, including:

    a. Requiring Board members and staff to refrain from voting or otherwise participating in matters related to the disclosed interest.

    b. Requiring Board members and staff to complete an annual conflict-of-interest disclosure form.

    c. Defining a process for ensuring that completed conflict-of-interest disclosure forms are maintained in a separate special disclosure file available for public inspection.

    d. Implementing a process for managing and monitoring any disclosed potential conflicts of interest to ensure the conflict will not interfere with the performance of Board member and staff duties.

    e. Documenting reasons for Board member recusal in Board meeting minutes and maintaining a copy of these minutes in the special disclosure file.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

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

Our review of 9 Board statutes that require it to make rules found that the Board had adopted the specified rules for all but 1 of these statutes. Specifically, the Board has not adopted the following rules pertaining to prescription medication donation programs, as required by A.R.S. §32-1909(G):

- An identification card or other method for people to prove they are eligible to receive donation prescription medication through the prescription medication donation program.
- A list of prescription medications, organized by drug type or category, that the prescription medication donation program may accept from individuals and health care institutions.
- A list of prescription medications, organized by drug type or category, that the prescription medication donation program may not accept from a health care institution. This list will include a statement as to why the drug is ineligible for donation.

According to the Board, since 2006 when the statute was established, no pharmacies have initiated prescription medication donation programs. As a result, the Board has not developed the required rules for these programs. According to the Board, it intends to work with the Governor's Office to seek statutory changes to eliminate the requirement for the Board to adopt these rules.

Sunset factor 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.

The Board has encouraged input from the public and informed the public of its actions and their expected impact by involving the public in rulemaking. Specifically, the Board provided opportunities for public input as part of its rulemaking between September 2016 and January 2019 by publishing notices of proposed rulemaking in the Arizona Administrative Register, allowing for 30 days of public comment after it published the notice, indicating the date and time when a meeting for public input would take place at the Board office, and providing contact information for Board staff who could receive input about the proposed rulemaking. In addition, the Board incorporated feedback and suggestions received through public comments in its final rulemaking when possible.

However, the Board did not comply with 2 open meeting law provisions. Specifically, the Board did not correctly cite the statutory reasons for entering into executive session on 4 Board meeting agendas—2 Board meetings and 2 complaint committee meetings—we observed between July and September 2019. In addition, for 2 of these 4 meetings, the Board did not make its public meeting minutes available within 3 working days nor did it post its recorded meeting minutes, or a notice about the recorded meeting minutes, within 5 business days of the meeting. The Board does not have policies and procedures that provide staff with the necessary guidance to comply with the State's open meeting law.

Finally, as discussed in Finding 4, the Board did not provide required public information on its website or in response to anonymous phone calls we made. We recommended that the Board update its website to provide the required information, revise and implement its policies and procedures to help ensure staff provide complete and accurate information to the public, and train Board staff on these policies and procedures (see Finding 4, pages 19 through 20).

Recommendations

The Board should:

26. Ensure it complies with all open meeting law requirements.

27. Develop and implement policies and procedures to guide its staff in complying with the State's open meeting law, including appropriately citing executive sessions on Board meeting agendas and making its public meeting minutes available as required by law.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

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

Although the Board has statutory authority to investigate and adjudicate complaints within its jurisdiction, it did not do so in a timely manner for 9 complaints we reviewed. Our review of a random sample of 30 complaints against licensees and permit holders that the Board received in fiscal year 2019 found that the Board followed its complaint investigation policies and procedures (see Appendix A, page a-1, for more information about this sample).[47] Also, for the meetings we observed and the complaints we reviewed, the Board appropriately followed a violations outcome grid that it developed to promote consistent adjudication when imposing discipline (see textbox, page 26, for disciplinary and nondisciplinary options the Board has available to address statute and/or rule violations).

However, the Board took between 189 and 699 days, nearly 2 years, to investigate and adjudicate 9 complaints—most of which alleged that licensees failed to report required information about arrests, such as a DUI or disorderly conduct, to the Board within 10 days of the arrest or at the time of application.[48] We have determined that Arizona health regulatory boards should investigate and adjudicate complaints within 180 days of receiving them. Most of these complaints were delayed because the licensee did not respond to the Board's requests for information. In addition, according to Board staff, it did not have enough staff to timely investigate all complaints and it did not focus on these complaints because the complaint allegations were determined to be low risk. As of September 2019, the Board reported it had established a new step in its complaint-handling process for subpoenaing licensees/permit holders to compel them to provide requested information. Additionally, according to the Board,

[47] Although the Board's data showed that it received 570 complaints in fiscal year 2019, this number is likely inaccurate because the Board did not sufficiently track this data. For example, the Board's data included complaint allegations that were not in the Board's jurisdiction and were not opened for investigation and the Board did not differentiate these complaints from complaints that it determined were within its jurisdiction. In addition, when the Board opens complaints against several licensees/permit holders for the same allegation, the Board assigns each complaint the same complaint number.

[48] Of the 9 complaints, 1 was dismissed; 1 received an advisory letter; 1 received a nondisciplinary continuing education order; 1 voluntarily surrendered their license; 1 had their license revoked; and 2 resulted in a consent agreement with a civil penalty. The remaining 2 complaints were still open as of February 2020 for a total of 267 and 601 days, respectively.

as of April 2020, it was taking steps to hire an additional investigator to help manage its complaint-investigation workload.

Lengthy investigations and/or adjudications may put the public at risk because licensees/permit holders can continue to practice/operate during the time the complaint is being investigated and adjudicated, even though they may be unfit to do so. According to the Board, it has not developed time frames for specific steps in its complaint-handling process or for completing the overall complaint-handling process, which would help ensure that it completes complaint investigations and adjudications in a timely manner.

Examples of the Board's disciplinary and nondisciplinary options

Disciplinary actions:
- Letter of reprimand[1]
- Decree of censure[2]
- Continuing education
- Civil penalty (not to exceed $1,000)
- Probation
- Suspension of license or permit
- Revocation of license or permit

Nondisciplinary actions:
- Advisory letter
- Continuing education

[1] A letter of reprimand is a disciplinary letter from the Board informing the licensee or permit holder that their conduct violates State or federal law and may require the Board to monitor them.

[2] A decree of censure is an official Board action and may require restitution of fees to a patient or consumer.

Source: Auditor General staff analysis of A.R.S. §§32-1927 to 32-1927.03.

Recommendations

The Board should:

28. Investigate and adjudicate complaints in 180 days or less.

29. Develop and implement time frames for the steps in its complaint-handling process to help ensure complaints are investigated and adjudicated in 180 days or less.

30. Track complaints in accordance with its complaint-handling process steps.

31. Continue with its newly implemented process for issuing subpoenas to licensees/permit holders who do not respond to requests for information in a timely manner and take action, where appropriate, against licensees/permit holders who do not respond to subpoenas.

Board response: As outlined in its **response**, the Board agrees with the finding and will implement the recommendations.

Sunset factor 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 serves as the Board's legal advisor and provides legal services as the Board requires, according to A.R.S. §41-192(A)(1). Further, the Board's various enabling statutes provide the Attorney General's Office and the County Attorney with authority to pursue criminal and civil actions in superior court for violations of specified Board statutes and rules.

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

According to the Board, there are no deficiencies in its enabling statutes that prevent it from fulfilling its statutory mandate.

Sunset factor 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.

We identified 1 statutory change that will enable the Board to better protect public health, safety, and welfare. As indicated in Finding 1 (see page 9), the Board should pursue changes to its enabling statutes so that it has the authority to require licensees to maintain a valid fingerprint clearance card and submit these upon license renewal. For licensees that have listed the Board on their fingerprint clearance card application, DPS is statutorily

required to notify the Board if the licensee's fingerprint clearance card is suspended, revoked, or has a driving restriction placed on it. This would allow the Board to continue to receive notifications from DPS rather than relying on self-reported information. Specifically, fingerprint clearance cards expire after 6 years and without a requirement for the continued maintenance of a fingerprint clearance card, the Board may not continue to stay informed and receive DPS notifications.

Sunset factor 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 regulations help protect the public by licensing individuals who practice pharmacy and permitting facilities that manufacture, distribute, sell, and store prescription medications and devices and nonprescription medications. Additionally, the Board helps protect the public by receiving and investigating complaints against licensees and permit holders within its jurisdiction, and taking appropriate disciplinary action upon substantiating complaints. For example, the Board summarily suspended a pharmacy technician's license after learning that the licensee had diverted controlled substances. The Board later revoked the license. The Board also inspects permitted facilities to ensure compliance with statute and rule, including pharmacies that compound sterile pharmaceuticals, which may perform tasks that present a higher level of risk to public safety. Finally, the Board administers the State's CSPMP, which enables prescribers and dispensers of controlled substances to make informed decisions prior to prescribing and dispensing these substances. Terminating the Board without transferring responsibility for the CSPMP to another agency would remove a tool for helping to combat controlled substance abuse.

Sunset factor 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.

We found that the level of regulation the Board exercises appears appropriate and is similar to the level of regulation in other states we reviewed. Specifically, we judgmentally selected 4 states for review—California, Colorado, New Mexico, and Utah—and found that regulatory requirements for licensure in these states are similar to Arizona's. For example:

- **National examination—**Arizona and all 4 states require pharmacist license applicants to pass the North American Pharmacist Licensure Examination national exam and a jurisprudence exam to obtain licensure.[49] To obtain a pharmacy technician license, Arizona, Colorado, New Mexico, and Utah require pharmacy technician applicants to pass a national exam as a requirement for licensure.[50] Applicants for pharmacy technician licensure in California may obtain licensure in multiple ways, including by passing the national exam.

- **Education—**Arizona and all 4 states require pharmacy license applicants to graduate from a school of pharmacy that is accredited by the Accreditation Council for Pharmacy Education. To obtain a pharmacy technician license, Arizona, California, and Utah require applicants to complete education and training prior to licensure.[51] For example, Arizona requires pharmacy technician applicants to complete a training program in a pharmacy setting. Utah requires applicants to complete an approved education program that includes a 180-hour supervised practical training component.

- **Fingerprint-based background checks—**Arizona and all 4 states require both pharmacist and pharmacy technician license applicants to disclose certain charges, arrests, and convictions, and other relevant

[49] California requires its own California Practice Standards and Jurisprudence Examination, while Arizona and the other 3 states reviewed require applicants to pass NABP's Multistate Pharmacy Jurisprudence Examination.

[50] Colorado requires applicants to be nationally certified, which includes passing a national exam. New Mexico has an option for applicants who are completing a training program and have not yet passed the national exam to be licensed as a provisional pharmacy technician for 1 year.

[51] Colorado does not explicitly require formal education or training for pharmacy technician applicants, but requires applicants to be nationally certified, which requires applicants to complete an approved course of education and training unless they meet an exception, such as having obtained at least 500 hours equivalent work experience; New Mexico allows applicants to either obtain the national certification or to work as a pharmacy technician while receiving on-the-job training.

disciplinary history on their application. Additionally, Arizona requires both pharmacist and pharmacy technician applicants to obtain a fingerprint clearance card whereas California and Utah require these applicants to submit fingerprints for the purpose of a criminal background check to qualify for licensure. Colorado requires only pharmacy technician applicants to attest to having undergone a criminal history background check.[52] New Mexico does not require pharmacist or pharmacy technician applicants to undergo a fingerprint-based background check.

- **Continuing education—**Arizona and all 4 states require pharmacist licensees to complete continuing education hours as part of renewing their license. For pharmacy technicians, Arizona and 3 states reviewed require pharmacy technician licensees to complete continuing education hours as part of renewing their license.[53] California does not have continuing education requirements for pharmacy technicians.

- **Reciprocal pharmacist licensure—**Arizona and all 4 states require pharmacists applying for a reciprocal license to submit a license transfer application through NABP.[54] Arizona is the only state that charges an additional fee for reciprocity and the 4 states we reviewed do not charge an additional fee to process a reciprocal application compared with an application for initial licensure as a pharmacist.

Additionally, we compared Arizona's facility permits to permitting in the 4 states reviewed and found that although each state differs in how it categorizes and defines its facilities, all generally regulate pharmacies, wholesalers, and manufacturers. For example, Arizona and all 4 states have statutory authority to inspect licensed, permitted, or registered facilities periodically to ensure compliance with state laws. In addition, Arizona, California, New Mexico, and Utah require facilities to apply for a new permit or license when undergoing change of ownership, whereas facilities in Colorado must apply to transfer their existing registration to the new owner when changing ownership.

Finally, we compared the Board's administration of the CSPMP to other states. Forty-nine states administer a PDMP to help states with appropriate prescribing efforts, such as the reduction of controlled substance diversion and abuse, although a variety of state agencies are responsible for PDMP administration in their respective states (see Table 7).[55]

Sunset factor 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 does not use private contractors in the performance of most of its regulatory duties. We contacted boards of pharmacy in 4 states—California, Colorado, New Mexico, and Utah—to obtain information regarding their use of contractors for regulatory functions and found that they similarly do not contract for most of their services, with 3 exceptions. First, California and Colorado reported using a private vendor to administer programs for evaluating and helping licensees in

Table 7
Number and types of state agencies administering a PDMP

Agency type administering PDMP	Number of states
Pharmacy board	20
Department of health	15
Professional licensing agency	6
Law enforcement	4
Substance abuse agency	3
Consumer protection agency	1
Total	**49**

Source: Institute for Intergovernmental Research, Prescription Drug Monitoring Program Training and Technical Assistance Center. (2019). *PDMP by operating state agency type*. Retrieved 7/7/2019 from https://www.pdmpassist.org/pdf/PDMP_Agency_Type_20190701.pdf.

[52] Colorado also allows pharmacy technician applicants to provide proof that they have undergone a background check for other reasons, such as a condition of employment at a pharmacy.

[53] Colorado and New Mexico do not outline specific continuing education hour requirements in statute or rule for pharmacy technicians, but require licensees to maintain national certification, which requires completion of continuing education as a condition for national certification renewal.

[54] California indicated that it only retrieves an applicant's test score from the NABP transfer application, and otherwise treats these applications just like an initial applicant for pharmacist licensure in the state of California.

[55] Missouri does not have a state-wide PDMP, but the St. Louis County Department of Public Health operates a PDMP and has made it available to other Missouri counties. Additionally, the District of Columbia has a PDMP.

substance abuse recovery.[56] Second, California also reported using private vendors to develop its licensure exams. Finally, Colorado reported contracting with NABP to process reciprocal pharmacist licensure applications.

The Board contracts for 1 of its duties—maintaining the CSPMP central database tracking system. As mentioned in Sunset Factor 11, various types of state agencies oversee their respective PDMPs. Three of the 4 states we contacted contract for their PDMP database services. Specifically, the California Department of Justice, Colorado State Board of Pharmacy, and New Mexico Board of Pharmacy contract with private entities to run their PDMP data tracking systems. Utah's Division of Occupational and Professional Licensing operates its PDMP, but contracts with a private vendor for pharmacy data submissions and validation.

[56] The Colorado contract was entered into by the Colorado board's umbrella agency, and multiple boards have access to the same contracted services.

Auditor General makes 31 recommendations to the Board

The Board should:

1. Ensure that initial pharmacist license applicants possess a valid fingerprint clearance card before it issues a license by developing and implementing policies and procedures requiring Board staff to check the validity of fingerprint clearance cards on the DPS website (see Finding 1, pages 8 through 11, for more information).

2. Work with the Legislature to amend statute to require licensees to maintain a valid fingerprint clearance card and submit them at renewal (see Finding 1, pages 8 through 11, for more information).

3. After statute is amended (see Recommendation 2), develop and implement written policies and procedures that require Board staff to check the DPS website to ensure the validity of fingerprint clearance cards submitted by all renewal licensure applicants(see Finding 1, pages 8 through 11, for more information).

4. Ensure that renewal applicants meet continuing education requirements by continuing to develop and implement written policies and procedures for conducting continuing education audits after each renewal cycle (see Finding 1, pages 8 through 11, for more information).

5. Consistently determine complaint jurisdiction by developing and implementing guidance, such as types of violations that would not be within the Board's jurisdiction, to help ensure its lead compliance officer and executive director consistently and appropriately determine complaint jurisdiction (see Finding 1, pages 8 through 11, for more information).

6. Document the rationale for its complaint jurisdiction determinations (see Finding 1, pages 8 through 11, for more information).

7. Consistently meet established inspection time frames by developing and implementing processes for tracking and monitoring the completion of facility inspections (see Finding 1, pages 8 through 11, for more information).

8. Conduct a review of its license and permit fees consistent with government fee-setting standards and guidelines, including ensuring the fees are based on actual costs and promote service efficiency, and then adjust its fees accordingly. Specifically, the Board should:

    a. Develop and implement a method for determining and tracking the direct and indirect costs for its regulatory processes and establish policies and procedures for using this method. The policies and procedures should also require the periodic review of the Board's fees, including tracking and reassessing actual costs and assessing if costs are necessary for providing services.

    b. After implementing this cost methodology, determine the appropriate license and permit fees.

    c. Consider the effect of proposed fee changes on applicants, licensees, and permit holders and obtain their input when reviewing the fees.

    d. Adjust its fees in its rules, as necessary (see Finding 2, pages 12 through 14, for more information).

9. Work with the Legislature, as needed, to revise statute to eliminate the reciprocity fee and charge the same application fee to all initial pharmacist applicants (see Finding 2, pages 12 through 14, for more information).

10. Enforce licensed pharmacist and permitted pharmacy compliance with State CSPMP statutes (see Finding 3, pages 15 through 18, for more information).

11. Develop and implement processes to identify licensed pharmacists who have not registered for and are not checking the CSPMP database as required and take enforcement action, as appropriate (see Finding 3, pages 15 through 18, for more information).

12. Continue its newly developed process to identify permitted pharmacies with an Arizona address that should have, but are not, registered to submit information accessible through the CSPMP database (see Finding 3, pages 15 through 18, for more information).

13. Develop and implement a process to identify permitted pharmacies that are outside of Arizona that should have, but are not, registered to submit information accessible through the CSPMP database (see Finding 3, pages 15 through 18, for more information).

14. Ensure that all permitted pharmacies that should be submitting information accessible through the CSPMP database, including those identified as a result of the Board's processes (see Recommendations 12 and 13), are doing so and follow up with any pharmacies that are delinquent in reporting (see Finding 3, pages 15 through 18, for more information).

15. Work with the other 9 Arizona professional licensing boards listed in A.R.S. §36-2606(B)(1) to determine the information they need to investigate and enforce licensed prescriber noncompliance with State CSPMP statutory requirements (see Finding 3, pages 15 through 18, for more information).

16. Follow State CSPMP statutes and provide other Arizona professional licensing boards with information they need to investigate and enforce noncompliance with these statutes (see Finding 3, pages 15 through 18, for more information).

17. Develop and implement processes for identifying licensed prescriber potential noncompliance with State CSPMP statutory requirements (see Finding 3, pages 15 through 18, for more information).

18. Provide required information on its website by updating it to include (1) all required information about licensees and permit holders, including nondisciplinary actions, and (2) a statement informing the public that they can contact the Board for more information as required by statute (see Finding 4, pages 19 through 20, for more information).

19. Ensure that it provides complete and accurate information to the public over the phone by revising and implementing its policies and procedures for providing public information to include how staff should respond to phone calls requesting complaint information (see Finding 4, pages 19 through 20, for more information).

20. Develop and provide training for its staff once it has developed the policies and procedures outlined in Recommendation 19 (see Finding 4, pages 19 through 20, for more information).

21. Ensure pharmacy technicians meet training requirements by either requiring pharmacy technician applicants to submit documentation showing they meet training requirements or revising its rule to rely on the national boards' training attestation requirements (see Sunset Factor 2, pages 21 through 23, for more information).

22. Protect its cash receipts by developing and implementing written cash-handling policies and procedures that adhere to SAAM requirements, such as:

    a. Opening mail with at least 2 staff members present.

    b. Separating the duties of logging cash receipts from licensing functions.

    c. Depositing cash receipts exceeding $1,000 on a daily basis.

    d. Processing cash transactions and depositing cash rather than returning it to the sender through the mail (see Sunset Factor 2, pages 21 through 23, for more information).

23. Train staff on these updated policies and procedures and review staff work periodically for compliance (see Sunset Factor 2, pages 21 through 23, for more information).

24. Ensure it complies with all State conflict-of-interest requirements (see Sunset Factor 3, pages 23 through 24, for more information).

25. Develop and implement comprehensive policies and procedures for addressing potential conflicts of interest in accordance with State laws, including:

    a. Requiring Board members and staff to refrain from voting or otherwise participating in matters related to the disclosed interest.

    b. Requiring Board members and staff to complete an annual conflict-of-interest disclosure form.

    c. Defining a process for ensuring that completed conflict-of-interest disclosure forms are maintained in a separate special disclosure file available for public inspection.

    d. Implementing a process for managing and monitoring any disclosed potential conflicts of interest to ensure the conflict will not interfere with the performance of Board member and staff duties.

    e. Documenting reasons for Board member recusal in Board meeting minutes and maintaining a copy of these minutes in the special disclosure file (see Sunset Factor 3, pages 23 through 24, for more information).

26. Ensure it complies with all open meeting law requirements (see Sunset Factor 5, pages 24 through 25, for more information).

27. Develop and implement policies and procedures to guide its staff in complying with the State's open meeting law, including appropriately citing executive sessions on Board meeting agendas and making its public meeting minutes available as required by law (see Sunset Factor 5, pages 24 through 25, for more information).

28. Investigate and adjudicate complaints in 180 days or less (see Sunset Factor 6, pages 25 through 26, for more information).

29. Develop and implement time frames for the steps in its complaint-handling process to help ensure complaints are investigated and adjudicated in 180 days or less (see Sunset Factor 6, pages 25 through 26, for more information).

30. Track complaints in accordance with its complaint-handling process steps (see Sunset Factor 6, pages 25 through 26, for more information).

31. Continue with its newly implemented process for issuing subpoenas to licensees/permit holders who do not respond to requests for information in a timely manner and take action, where appropriate, against licensees/permit holders who do not respond to subpoenas (see Sunset Factor 6, pages 25 through 26, for more information).

Objectives, scope, and methodology

The Office of the Auditor General conducted a performance audit and sunset review of the Board pursuant to a September 19, 2018, resolution of the Joint Legislative Audit Committee. This audit was conducted as part of the sunset review process prescribed in A.R.S. §41-2951. This audit addresses the Board's processes to issue licenses and permits to applicants, investigate and adjudicate complaints, conduct inspections of permitted facilities, provide information to the public, and administer the CSPMP. It also includes responses to the statutory sunset factors.

We used various methods to study the issues in this performance audit and sunset review of the Board. These methods included reviewing Board statutes, rules, and policies and procedures; interviewing Board members and staff; reviewing information on the Board's website; and reviewing best practices.[57] In addition, we used the following specific methods to meet the audit objectives:

- To determine whether the Board issued initial pharmacist and pharmacy technician licenses to qualified applicants in a timely manner, we randomly selected and reviewed a sample of 30 of the 699 pharmacist licenses and a sample of 30 of the 1,167 pharmacy technician licenses issued by the Board in fiscal year 2019. To assess the Board's compliance with ensuring that applicants submit a valid fingerprint clearance card for licensure, we compared fingerprint clearance card information from our sample of 30 initial pharmacist licenses to the DPS website. Additionally, to assess the Board's continuing education process, we reviewed 23 of the 50 licensees that the Board selected for its continuing education audit after the 2018 renewal cycle, 15 of which were judgmentally selected and 8 of which were randomly selected. Finally, to determine whether the Board issued initial pharmacy and manufacturer permits to qualified applicants in a timely manner, we randomly selected and reviewed a sample of 12 of the 209 manufacturer applications and 10 of the 520 pharmacy applications the Board issued in fiscal year 2019.

- To assess whether the Board investigated and adjudicated complaints in a timely manner, we randomly selected and reviewed a sample of 30 of the 570 complaints the Board received in fiscal year 2019.[58] Additionally, to assess whether the Board adequately determined its jurisdiction for investigating complaints, we judgmentally selected and reviewed 10 complaints—5 each from the March 2019 and May 2019 Board meeting agendas.

- To evaluate the Board's inspection frequency at permitted facilities, we randomly selected and reviewed the inspection history for 7 of the 1,323 permitted pharmacies and 3 of the 50 permitted manufacturers that were active as of September 2019. We also judgmentally selected 3 additional pharmacy permits from the 1,323 permitted pharmacies that were active as of September 2019 based on those we thought were more likely to

[57] National Association of Boards of Pharmacy (NABP). (2019). *Model state pharmacy act and model rules of the National Association of Boards of Pharmacy*. Retrieved 1/2/2020 from https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/; National State Auditors Association. (2004). *Carrying out a state regulatory program: A National State Auditors Association best practice document*. Lexington, KY. Retrieved 1/2/2020 from https://www.nasact.org/files/News_and_Publications/White_Papers_Reports/NSAA%20Best%20Practices%20Documents/2004_Carrying_Out_a_State_Regulatory_Program.pdf.

[58] Although the Board's data showed that it received 570 complaints in fiscal year 2019, this number is likely inaccurate because the Board inadequately tracked this data. For example, the Board's data included complaint allegations that were not in the Board's jurisdiction and were not opened for investigation and the Board did not differentiate these complaints from complaints that it determined were within its jurisdiction. In addition, when the Board opens complaints against several licensees/permit holders for the same allegation, the Board assigns each complaint the same complaint number, which may also affect the total number of complaints it actually received.

engage in sterile compounding. We also observed Board compliance officers inspect 4 different pharmacies in August and September 2019. Additionally, we reviewed information on drug compounding from the FDA and the U.S. Pharmacopeia.[59]

- To determine whether the Board appropriately established its fees, we interviewed Board management, reviewed Board rulemaking notices from 2009 to 2019, and reviewed best practices for government fee-setting developed by several government and professional organizations.[60] In addition, we compiled and analyzed unaudited information from the Arizona Financial Information System *Accounting Event Transaction File* and the State of Arizona *Annual Financial Report* for the Pharmacy Fund for fiscal years 2017 through 2019.

- To evaluate the Board's administration of the CSPMP database, we reviewed CSPMP database reports for January 2020 and interviewed CSPMP staff.

- To evaluate whether the Board provided appropriate information to the public, we compared the information found in our sample of 30 of the 570 complaints the Board received in fiscal year 2019 to the information provided on the Board's website for these complaints. Additionally, we placed 2 anonymous phone calls to the Board in September 2019 to request information about 1 licensed pharmacist and 1 permitted pharmacy that had received complaints to test the Board's compliance with statute and evaluate its procedures for providing information to the public.

- To obtain information for the Introduction, we reviewed the Board's licensing database to determine the number of licenses and permits issued during fiscal year 2019, reviewed information from the Board on the number of active licenses and permits as of January 2020, and compiled and analyzed unaudited information from the Arizona Financial Information System *Accounting Event Transaction File* and the State of Arizona *Annual Financial Report* for fiscal years 2017 through 2019, and Board-provided information for fiscal year 2020. Additionally, we reviewed information on the importance of states having and using PDMP and guidance from the Arizona Department of Health Services.[61]

- To obtain information for the Sunset Factors, we reviewed the Board's rulemaking notices in the Arizona Administrative Register from September 2016 through January 2019 and assessed the Board's compliance with various provisions of the State's open meeting law for 4 Board meetings held between July and September 2019. Further, we observed the Board's cash-handling procedures and compared these to best practices in the *State of Arizona Accounting Manual*, and assessed the Board's compliance with the State's conflict-of-interest laws by reviewing statute, Board policies and procedures, and best practices.[62] In addition, we judgmentally selected 4 states—California, Colorado, New Mexico, and Utah—and reviewed their regulation of pharmacists, pharmacy technicians, and other areas of the practice of pharmacy, including administering

---

[59] U.S. Pharmacopeia and the National Formulary. (2008). *USP general chapter <797> pharmaceutical compounding—sterile preparations*. Rockville, MD.

[60] We reviewed the following fee-setting best practices: Arizona State Agency Fee Commission. (2012). *Arizona State Agency Fee Commission report*. Phoenix, AZ; U.S. Government Accountability Office. (2008). *Federal user fees: A design guide*. Washington, DC. Retrieved 3/3/2020 from https://www.gao.gov/assets/210/203357.pdf; Michel, R.G. (2004). *Cost analysis and activity-based costing for government*. Chicago, IL: Government Finance Officers Association; Mississippi Joint Legislative Committee on Performance Evaluation and Expenditure Review. (2002). *State agency fees: FY 2001 collections and potential new fee revenues*. Jackson, MS. Retrieved 3/3/2020 from https://www.peer.ms.gov/Reports/reports/rpt442.pdf; and U.S. Office of Management and Budget. (1993). *OMB Circular No. A 25, revised*. Washington, DC. Retrieved 3/3/2020 from https://www.whitehouse.gov/wp-content/uploads/2017/11/Circular-025.pdf.

[61] Arizona Department of Health Services. (2020). *Opioid update & surveillance data summary*. Retrieved on 6/29/2020 from https://www.azdhs.gov/documents/prevention/health-systems-development/epidamic/update-adhs-opioid-response-2017-2019.pdf; Alexander, G.C., Frattaroli, S., & Gielen, A.C., eds. (2017). *The opioid epidemic: From evidence to impact*. Baltimore, MD: Johns Hopkins Bloomberg School of Public Health. Retrieved 6/29/2020 from https://www.jhsph.edu/events/2017/americas-opioid-epidemic/report/2017-JohnsHopkins-Opioid-digital.pdf.

[62] Ethics & Compliance Initiative (ECI). (2016). *Conflicts of Interest*. Retrieved 12/9/2019 from https://www.ethics.org/knowledge-center/conflicts-of-interest-report/; Controller and Auditor General of New Zealand. (2007). *Managing conflicts of interest: Guidance for public entities*. Wellington, New Zealand. Retrieved 12/9/2019 from https://oag.parliament.nz/2007/conflicts-public-entities/docs/oag-conflicts-public-entities.pdf; Organisation for Economic Co-operation and Development (OECD). (2003). *Recommendation of the council on guidelines for managing conflicts of interest in the public services*. Paris, France. Retrieved 12/9/2019 from https://legalinstruments.oecd.org/public/doc/130/130.en.pdf.

a PDMP. We also contacted staff from boards of pharmacy in these states to confirm our understanding of their regulations and to obtain information about their use of private contractors.

- Our 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. We reported our conclusions on these internal controls and, where applicable, Board efforts to improve its controls in Findings 1, 3, and 4, as well as Sunset Factors 2, 3, 5, and 6 of the report.

We selected our audit samples to provide sufficient evidence to support our findings, conclusions, and recommendations. Unless otherwise noted, the results of our testing using these samples were not intended to be projected to the entire population.

We conducted this performance audit of the 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.

We express our appreciation to the Board and its staff for its cooperation and assistance throughout the audit.

BOARD RESPONSE

Arizona State Board of Pharmacy

Physical Address: 1616 W. Adams, Suite 120, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
p) 602-771-2727 f) 602-771-2749 www.azpharmacy.gov

September 10, 2020

Ms. Lindsey Perry, Auditor General
Office of the Auditor General
2910 N. 44th St., Suite 410
Phoenix, AZ 85018

Dear Ms. Perry,

The Arizona State Board of Pharmacy enjoyed the opportunity to discuss the activity of our Board with your team, led by Dale Chapman. It was a pleasure meeting with them and sharing what we do.

The Board of Pharmacy respectfully submits its response to the performance audit and sunset review.

The Board of Pharmacy continually strives to perform at our best and operate to uphold the mission of the Board. We concur with the recommendation and we will ensure they are addressed appropriately.

We would like to thank you and your team for the guidance to improve our operation.

Sincerely,

Dr. Kam Gandhi, PharmD
Executive Director

Enclosure

c: Board Members

Finding 1: Board did not ensure licensees and facilities we reviewed were qualified to practice and operating safely

Recommendation 1: The Board should ensure that initial pharmacist license applicants possess a valid fingerprint clearance card before it issues a license by developing and implementing policies and procedures requiring Board staff to check the validity of fingerprint clearance cards on the DPS website.

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

Response explanation: Initially, the Board did not verify the Fingerprint Clearance Card (FCC) of initial pharmacist applicants. Interns are required to have an FCC to attend pharmacy school. The expiration date of an FCC is six years. Therefore, the Board would have been notified if there was a denied or suspended FCC for that intern or initial pharmacist applicant. The intent was to be efficient and eliminate redundancy without compromising standards. Today, verification of the FCC with the DPS website is conducted for all applicants, including initial pharmacist applicants, to ensure validity of the FCC.

Recommendation 2: The Board should work with the Legislature to amend statute to require licensees to maintain a valid fingerprint clearance card and submit them at renewal.

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

Response explanation: The Board will review and discuss the implementation of requiring fingerprint clearance cards to be maintained and submitted at renewal at the upcoming Board meeting. In addition, the Board will hold stakeholder meetings to discuss the proposed legislative change. Should the Board move forward with the statutory change to require a fingerprint clearance card at renewal, an increase in staff in the next budgetary cycle would be required.

Recommendation 3: After statute is amended (see Recommendation 2), develop and implement written policies and procedures that require Board staff to check the DPS website to ensure the validity of fingerprint clearance cards submitted by all renewal licensure applicants.

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

Response explanation: If given the statutory authority to require fingerprint clearance cards at renewal, the Board will develop and implement policies and procedures for verifying the validity of the fingerprint clearance card.

Recommendation 4: The Board should ensure that renewal applicants meet continuing education requirements by continuing to develop and implement written policies and procedures for conducting continuing education audits after each renewal cycle.

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

Response explanation: The licensee's renewal application requires the licensee to attest that they have completed the continuing education (CE) requirements for that renewal period. The Board recognized that the current CE audit process needed to extend to involve more licensees. Therefore, the Board has implemented a more robust CE audit policy and procedure. The Board is now conducting CE audits in conjunction with inspections which will increase the amount of CE audits to ensure licensees meet the CE requirements.

Recommendation 5: The Board should consistently determine complaint jurisdiction by developing and implementing guidance, such as types of violations that would not be within the Board's jurisdiction, to help ensure its lead compliance officer and executive director consistently and appropriately determine complaint jurisdiction.

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

Response explanation: After a statute change that occurred in August 2019, the Board gave the Executive Director authority to dismiss or take no action on complaints without violations or complaints not within the Board's jurisdiction. Today, all complaints are reviewed by one to two compliance officers who are also pharmacists. If no violation of statute or rule is found, the compliance officers will refer it to the Deputy Director and Executive Director for dismissal. The complaint is reviewed by at least three pharmacists prior to dismissal. In addition, the Board will create a substantive policy that will outline the types of complaints that do not fall in the Board's jurisdiction.

Recommendation 6: The Board should document the rationale for its complaint jurisdiction determinations.

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

Response explanation: The Board has implemented a process to better document complaint jurisdiction determination. The Board changed its policy and procedure on how

to determine and document complaints without violations or complaints not within the Board's jurisdiction.

Recommendation 7: The Board should consistently meet established inspection time frames by developing and implementing processes for tracking and monitoring the completion of facility inspections.

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

Response explanation: The Board has developed and implemented a process for tracking and monitoring the completion of facility inspections. In addition to tracking and monitoring inspections, the established inspection time frames will be reevaluated. The Board has been implementing a risk based inspection process to ensure the safety of Arizonians. However, the pandemic has delayed the full implementation of this recommendation.

Finding 2: Board's license and permit fees are not based on the cost of providing services, resulting in large and growing fund balance

Recommendation 8: The Board should conduct a review of its license and permit fees consistent with government fee-setting standards and guidelines, including ensuring the fees are based on actual costs and promote service efficiency, and then adjust its fees, accordingly. Specifically, the Board should:

Recommendation 8a: Develop and implement a method for determining and tracking the direct and indirect costs for its regulatory processes and establish policies and procedures for using this method. The policies and procedures should also require the periodic review of the Board's fees, including tracking and reassessing actual costs and assessing if costs are necessary for providing services.

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

Response explanation: The Board will work to develop and implement a method to review the direct and indirect costs for its regulatory processes. Once this method is established, policies and procedures will be developed and implemented as necessary.

Recommendation 8b: After implementing this cost methodology, determine the appropriate license and permit fees.

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

Response explanation: Once the cost methodology is complete, the Board will review and determine if the license and permit fees should be increased or decreased.

Recommendation 8c: Consider the effect of proposed fee changes on applicants, licensees, and permit holders and obtain their input when reviewing the fees.

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

Response explanation: The Board will conduct open meetings and public forums to consider the effect of the proposed fee change on licensees and permit holders. Through these meetings, the Board will obtain the input from the licensee and permit holder on the proposed fee change.

Recommendation 8d: Adjust its fees in its rules, as necessary.

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

Response explanation: The Board will adjust its fees in its rules as necessary.

Recommendation 9: The Board should work with the Legislature, as needed, to revise statute to eliminate the reciprocity fee and charge the same application fee to all initial pharmacist applicants.

Board Response: The finding of the Auditor General is agreed to and a different method of dealing with the finding will be implemented.

Response explanation: The Board will review the reciprocity fee and perform a cost analysis including direct and indirect costs associated with a reciprocity application. Once this cost analysis is complete, the Board will review the results and work with Legislature, as needed, to revise statute if the analysis shows that the reciprocity fee should be eliminated.

Finding 3: State may not be receiving full benefits of the CSPMP because the Board has not enforced or helped to enforce compliance with CSPMP requirements

Recommendation 10: The Board should enforce licensed pharmacist and permitted pharmacy compliance with State CSPMP statutes.

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

Response explanation: The Board will modify the compliance officer checklist to include verification of each licensed pharmacist's registration with the CSPMP when conducting

inspections. Additionally, a rule change to require the currently available ASAP standard field to collect Pharmacist State License Number on all controlled substance dispensations would assist in monitoring which pharmacists should be checking the CSPMP. The field is currently optional, not required, and without it, the Board does not have an accurate determination of pharmacists who should be performing lookups.

Recommendation 11: The Board should develop and implement processes to identify licensed pharmacists who have not registered for and are not checking the CSPMP database as required and take enforcement action, as appropriate.

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

Response explanation: The Board will modify the compliance officer checklist to include verification of each licensed pharmacist's registration with the CSPMP when conducting inspections. Additionally, a rule change to require the currently available ASAP standard field to collect Pharmacist State License Number on all controlled substance dispensations would assist in monitoring which pharmacists should be checking the CSPMP. The field is currently optional, not required, and without it, the Board does not have an accurate determination of pharmacists who should be performing lookups.

Recommendation 12: The Board should continue its newly developed process to identify permitted pharmacies with an Arizona address that should have, but are not, registered to submit information accessible through the CSPMP database.

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

Response explanation: The Board will continue its process to identify permitted pharmacies with an Arizona address that should have, but are not, registered for the PMP Clearinghouse as required to report.

Recommendation 13: The Board should develop and implement a process to identify permitted pharmacies that are outside of Arizona that should have, but are not, registered to submit information accessible through the CSPMP database.

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

Response explanation: The Board will continue to develop its process to identify permitted pharmacies that are outside of Arizona that should have, but are not, registered for the PMP Clearinghouse as required to report.

Recommendation 14: The Board should ensure that all permitted pharmacies that should be submitting information accessible through the CSPMP database, including those identified as a result of the Board's processes (see Recommendations 12 and 13), are doing so and follow up with any pharmacies that are delinquent in reporting.

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

Response explanation: The Board has addressed this matter and will continue to monitor and follow up with the permitted pharmacies as required.

Recommendation 15: The Board should work with the other 9 Arizona professional licensing boards listed in A.R.S. §36-2606(B)(1) to determine the information they need to investigate and enforce licensed prescriber noncompliance with State CSPMP statutory requirements.

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

Response explanation: After receiving clarification regarding the 9 professional licensing boards' statutory authority for disciplinary action for failing to consult the CSPMP as required by law (see Recommendation 10), the Board will collaborate with the professional licensing boards of prescribers with the intent of proactively providing information about potential licensed prescriber noncompliance with State CSPMP statutory requirements.

Recommendation 16: The Board should follow State CSPMP statutes and provide other Arizona professional licensing boards with information they need to investigate and enforce non-compliance with these statutes.

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

Response explanation: In January of 2018, legislation was passed allowing the other Arizona professional licensing boards access to have full access to the database, removing the requirement to state in writing that the information is necessary for an open investigation or complaint. The licensing boards must still request prescriber query histories, as they are not available for direct download. The Board will participate in meetings with the other licensing boards to allow for dialogue and sharing of aggregate data to help establish thresholds for noncompliance.

Recommendation 17: The Board should develop and implement processes for identifying licensed prescriber potential noncompliance with State CSPMP statutory requirements.

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

Response explanation: On a per request basis, the Board provides AHCCCS and other healthcare entities information on their prescribers' registration status in the CSPMP. The Board also currently generates an aggregated report that examines licensed prescriber compliance with patient query requirements. The Board is hopefully going to purchase a new enhancement to help track compliance more accurately and effectively. The Board will continue to refine its processes for identifying licensed prescriber potential noncompliance as the enhancement allows. This enhancement will also assist with determining the level of noncompliance discussed in Recommendation 16.

Finding 4: Board did not provide required public information on its website or in response to our anonymous phone calls

Recommendation 18: The Board should provide required information on its website by updating it to include (1) all required information about licensees and permit holders, including nondisciplinary actions, and (2) a statement informing the public that they can contact the Board for more information as required by statute.

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

Response explanation: The Board will update its website with the appropriate information.

Recommendation 19: The Board should ensure that it provides complete and accurate information to the public over the phone by revising and implementing its policies and procedures for providing public information to include how staff should respond to phone calls requesting complaint information.

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

Response explanation: The Board staff does meet regularly to discuss information and processes. Board staff has discussed and implemented a process on how to direct calls to the appropriate person.

Recommendation 20: The Board should develop and provide training for its staff once it has developed the policies and procedures outlined in Recommendation 19.

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

Response explanation: The Board has implemented weekly calls to share new information and policies and procedures that will be rolled out.

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

Recommendation 21: The Board should ensure pharmacy technicians meet training requirements by either requiring pharmacy technician applicants to submit documentation showing they meet training requirements or revising its rule to rely on the national boards' training attestation requirements.

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

Response explanation: The Board will revise its rule to rely on the national boards' training attestation requirements.

Recommendation 22: The Board should protect its cash receipts by developing and implementing written cash-handling policies and procedures that adhere to SAAM requirements, such as:

Recommendation 22a: Opening mail with at least 2 staff members present.

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

Response explanation: The Board will adjust its policy and procedure to have at least 2 staff members present to open mail. However, implementation of this may be delayed because of COVID-19 as we have minimal staff in the office.We are looking to possibly implement this process virtually.

Recommendation 22b: Separating the duties of logging cash receipts from licensing functions.

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

Response explanation: The Board will change its policy and procedure to separate the duties of logging cash receipts from any licensing functions. However, implementation of this may be delayed because of COVID-19 as we have minimal staff in the office. We are looking to possibly implement this process virtually.

Recommendation 22c: Depositing cash receipts exceeding $1,000 on a daily basis.

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

Response explanation: Currently, COVID-19 restrictions have prevented the implementation of daily deposits. Once the COVID-19 restrictions are lifted, the Board will conduct daily deposits.

Recommendation 22d: Processing cash transactions and depositing cash rather than returning it to the sender through the mail.

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

Response explanation: The Board will change its current policy and procedures to process cash transactions and deposit the cash.

Recommendation 23: The Board should train staff on these updated policies and procedures and review staff work periodically for compliance.

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

Response explanation: The Executive Director and Deputy Director of the Board conduct weekly meetings with the Board staff to share the latest information and changes impacting the Board. The directors also engage with staff members on a daily basis to answer any questions they may have regarding the provided information. In addition, the Executive Director, Deputy Director, or a Compliance Officer will review applications periodically to ensure compliance.

Sunset Factor 3: The extent to which the Board serves the entire State rather than specific interests.

Recommendation 24: The Board should ensure it complies with all State conflict-of-interest requirements.

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

Response explanation: The Board takes this matter seriously and does focus on the State vs specific interests.

Recommendation 25: The Board should develop and implement comprehensive policies and procedures for addressing potential conflicts of interest in accordance with State laws, including:

Recommendation 25a: Requiring Board members and staff to refrain from voting or otherwise participating in matters related to the disclosed interest.

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

Response explanation: The Board will develop and implement a policy and procedure to address potential conflicts of interest for Board members and staff in accordance with State laws.

Recommendation 25b: Requiring Board members and staff to complete an annual conflict-of-interest disclosure form.

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

Response explanation: The Board has implemented an annual conflict-of-interest disclosure form. This will be addressed at every January Board meeting.

Recommendation 25c: Defining a process for ensuring that completed conflict-of-interest disclosure forms are maintained in a separate special disclosure file available for public inspection.

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

Response explanation: The Board has implemented a process to maintain the completed annual conflict-of-interest forms in a separate disclosure file. This is maintained by the Executive Secretary.

Recommendation 25d: Implementing a process for managing and monitoring any disclosed potential conflicts of interest to ensure the conflict will not interfere with the performance of Board member and staff duties.

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

Response explanation: The Board will develop and implement a process for managing and monitoring any disclosed potential conflicts of interests to ensure the conflict will not interfere with the performance of a Board member or staff duties.

Recommendation 25e: Documenting reasons for Board member recusal in Board meeting minutes and maintaining a copy of these minutes in the special disclosure file.

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

Response explanation: The Board has revised its process to have each Board member sign and complete a disclosure or recusal form developed by the Board's attorney(s). The form will also include the reasons for the recusal. These forms will be maintained in a special disclosure file.

Sunset Factor 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.

Recommendation 26: The Board should ensure it complies with all open meeting law requirements.

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

Response explanation: The Board developed a checklist that the Executive Secretary or Board staff completes for each meeting to ensure it complies with open meeting law requirements.

Recommendation 27: The Board should develop and implement policies and procedures to guide its staff in complying with the State's open meeting law, including appropriately citing executive sessions on Board meeting agendas and making its public meeting minutes available as required by law.

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

Response explanation: The Board will develop policies and procedures to guide its staff in complying with the State's open meeting law. The Board is currently working on adjusting its Board meeting agenda to appropriately cite executive sessions. In addition, the Board has developed a process to ensure the meeting minutes are available, or a notice, within 3 working days and/or that the recorded meeting minutes are available, or a notice, within 5 working days.

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

Recommendation 28: The Board should investigate and adjudicate complaints in 180 days or less.

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

Response explanation: The complaints the Board receives range from complex to relatively straightforward. The Board investigates and adjudicates the majority of its complaints within the 180 day time frame. The Board strives to swiftly complete the complaints and has developed a process to ensure that the complaints are completed in an efficient manner. However, this process does take into account that some complaints take longer because of the complexity or circumstances of the case.

Recommendation 29: The Board should develop and implement time frames for the steps in its complaint-handling process to help ensure complaints are investigated and adjudicated in 180 days or less.

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

Response explanation: Currently the Board is reviewing the complaint process to distinguish what the time frames are appropriate for the steps in the complaint-handling process. Within the next 6 months, the Board plans to develop and implement time frames for the steps in its complaint-handling process with the goal of completing the cases within 180 days.

Recommendation 30: The Board should track complaints in accordance with its complaint-handling process steps.

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

Response explanation: The Board will continue to use its database to track complaints and evaluate the steps taken to process the complaint as discussed in the response explanation to Recommendation 30.

Recommendation 31: The Board should continue with its newly implemented process for issuing subpoenas to licensees/permit holders who do not respond to requests for information in a timely manner and take action, where appropriate, against licensees/permit holders who do not respond to subpoenas.

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

Response explanation: The Board will continue issuing subpoenas to licensees and permit holders in order to take action in a timely manner. In addition, if a licensee or permit holder fails to comply with the subpoena, which will be noted in the investigation and presented to the Board to decide whether or not to take action for the failure to comply with the Board's subpoena. The Board will also look at running legislation that requires a license holder or permit holder to cooperate with the Board without the need for a subpoena.


ARIZONA
Auditor General
Making a Positive Difference