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Missouri State Auditor

INSURANCE, FINANCIAL INSTITUTIONS, AND PROFESSIONAL REGISTRATION

Division of Professional Registration

State Board of Pharmacy



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CITIZENS SUMMARY

Findings in the audit of the Division of Professional Registration, State Board of Pharmacy

Inspections	The Board has inspectors on staff that perform inspections of pharmacies/drug distributors, but inspectors do not maintain documentation supporting requirements reviewed, and checklists are not used to ensure critical requirements are considered during inspections. Inspectors began using an electronic observation report, but this has prevented them from obtaining a signature from either the pharmacist-on-duty or permit holder acknowledging the completion of the inspection and any observations noted.
Board Appointments	As of June 30, 2014, the Board had three vacancies, dating from January 2011, January 2012, and April 2013. If any current member is absent from a Board meeting, the Board would not have a quorum and could not conduct business.
Board Meetings	The Board did not follow the Sunshine Law for email meetings held. The Board's policy is that meeting minutes be approved before being made available for public inspection, but our review noted Board meeting minutes were not approved for up to 12 months after the meeting was held. As such, documentation of business conducted was not available for inspection and review by the general public within a reasonable amount of time.

In the areas audited, the overall performance of this entity was **Good**.*

*The rating(s) cover only audited areas and do not reflect an opinion on the overall operation of the entity. Within that context, the rating scale indicates the following:

- Excellent:** The audit results indicate this entity is very well managed. The report contains no findings. In addition, if applicable, prior recommendations have been implemented.
- Good:** The audit results indicate this entity is well managed. The report contains few findings, and the entity has indicated most or all recommendations have already been, or will be, implemented. In addition, if applicable, many of the prior recommendations have been implemented.
- Fair:** The audit results indicate this entity needs to improve operations in several areas. The report contains several findings, or one or more findings that require management's immediate attention, and/or the entity has indicated several recommendations will not be implemented. In addition, if applicable, several prior recommendations have not been implemented.
- Poor:** The audit results indicate this entity needs to significantly improve operations. The report contains numerous findings that require management's immediate attention, and/or the entity has indicated most recommendations will not be implemented. In addition, if applicable, most prior recommendations have not been implemented.

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Division of Professional Registration

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THOMAS A. SCHWEICH

Missouri State Auditor

Honorable Jeremiah W. (Jay) Nixon, Governor
and
John M. Huff, Director
Department of Insurance, Financial Institutions, and Professional Registration
and
Jane A. Rackers, Director
Division of Professional Registration
and
State Board of Pharmacy
Jefferson City, Missouri

We have audited certain operations of the Department of Insurance, Financial Institutions, and Professional Registration, Division of Professional Registration, State Board of Pharmacy, in fulfillment of our duties under Chapter 29, RSMo. The scope of our audit included, but was not necessarily limited to, the years ended June 30, 2014 and 2013. The objectives of our audit were to:

1. Evaluate the board's internal controls over significant management and financial functions.
2. Evaluate the board's compliance with certain legal provisions.
3. Evaluate the economy and efficiency of certain management practices and operations, including certain financial transactions.

Our methodology included reviewing minutes of meetings, written policies and procedures, financial records, and other pertinent documents; interviewing various personnel of the board, and testing selected transactions. We obtained an understanding of internal controls that are significant within the context of the audit objectives and assessed whether such controls have been properly designed and placed in operation. We tested certain of those controls to obtain evidence regarding the effectiveness of their design and operation. We also obtained an understanding of legal provisions that are significant within the context of the audit objectives, and we assessed the risk that illegal acts, including fraud, and violations of contract, grant agreement, or other legal provisions could occur. Based on that risk assessment, we designed and performed procedures to provide reasonable assurance of detecting instances of noncompliance significant to those provisions.

We conducted our audit in accordance with the standards applicable to performance audits contained in *Government Auditing Standards*, issued by the Comptroller General of the United States. Those standards require that we plan and perform our 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 such a basis.

The accompanying Organization and Statistical Information is presented for informational purposes. This information was obtained from the board's management and was not subjected to the procedures applied in our audit of the board.

For the areas audited, we identified (1) deficiencies in internal control, (2) noncompliance with legal provisions, and (3) no significant deficiencies in management practices and procedures. The accompanying Management Advisory Report presents our findings arising from our audit of the Department of Insurance, Financial Institutions, and Professional Registration, Division of Professional Registration, State Board of Pharmacy.

A handwritten signature in black ink, reading "Thomas A. Schweich". The signature is fluid and cursive, with the first name "Thomas" and last name "Schweich" clearly legible.

Thomas A. Schweich
State Auditor

The following auditors participated in the preparation of this report:

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Division of Professional Registration

State Board of Pharmacy

Management Advisory Report - State Auditor's Findings

1. Inspections

Controls and procedures over pharmacy and drug distributor inspections need improvement. As of June 30, 2014, the Board of Pharmacy (Board) had 2,421 licensed pharmacies and 1,387 licensed drug distributors. The Board inspected a total of 2,081 pharmacies and drug distributors during the 2 years ended June 30, 2014.

Section 338.360, RSMo, authorizes the Board to inspect pharmacies and drug distributors in Missouri. Inspections are completed for any pharmacy/drug distributor that is new, has not had an inspection in the past 18 months, and did not have a clean inspection from the Federal Drug Administration (FDA) in the past 2 years. Pharmacies/drug distributors may be exempt from any inspection if they received an inspection from the FDA in the past 2 years that resulted in no significant issues.

Board inspections consist of a review of various statutory requirements based on an inspector's general review of a pharmacy/drug distributor through a limited sampling of records. At the end of the inspection, the inspector typically issues an observation report and/or a compliance notice, depending on the significance of issues found. An observation report is issued if no compliance issues or less than significant compliance issues are noted, and a compliance notice is issued when significant compliance concerns are noted and require immediate corrective measures.

1.1 Documentation

Inspectors do not maintain documentation supporting requirements reviewed during inspections, and checklists are not used to ensure critical requirements are considered at each inspection. According to personnel, the chief inspector reviews weekly summaries, compliance notices, and some observation reports; however, these reviews are not documented.

The Board has 8 inspectors on staff that perform inspections throughout the state, including a chief inspector who oversees inspections completed. Weekly summaries are submitted to the chief inspector along with any resulting reports of issues noted. Both weekly summaries and resulting inspection reports, such as the observation report and the compliance notice, only address issues or noncompliance found. Documentation relating to what specific requirements were reviewed during inspections is not prepared or maintained. According to personnel, inspectors are licensed pharmacists that operate in a professional capacity. They are extensively trained and are provided guidance for performing their inspections, including a citation inspection guide that lists out all critical compliance requirements. The Executive Director indicated that documenting everything reviewed would be time consuming and inefficient.

Adequately documenting the requirements reviewed, periodically reviewing the documentation to ensure critical requirements are reviewed, and documenting the chief inspector's supervisory reviews of weekly summaries



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and inspection reports would provide additional assurance inspections are properly completed.

1.2 Pharmacist acknowledgment

The Board does not ensure observation reports are signed by the pharmacist on duty or the permit holder during inspections. Observation reports include a signature line for the pharmacy to acknowledge the completion of the inspection and any observations noted. Our review found observation reports submitted electronically did not include a signature from a representative of the pharmacy/drug distributor. According to personnel, during 2013, inspectors began using electronic versions of the observation report, preventing inspectors from being able to obtain a signature.

Without obtaining a signature of the pharmacist or permit holder on observation reports, the Board has less assurance the inspection was completed as required and any observations were discussed and acknowledged by the pharmacy/drug distributor. According to personnel, the Board is currently developing a method to obtain signatures electronically.

Recommendations

The State Board of Pharmacy:

- 1.1 Maintain adequate supporting documentation of requirements reviewed during inspections. Supporting documentation should be periodically reviewed, and reviews of supporting documentation and resulting inspection reports should be documented.
- 1.2 Ensure all observation reports are signed by the pharmacy/drug distributor.

Auditee's Response

- 1.1 *The Board utilizes an Inspection Cite Guide that identifies over 420 individualized inspection standards in addition to compliance standards set forth in statutes and regulations. Under these circumstances, risk focused inspections effectively and efficiently produce results superior to those that could be achieved with inspection checklists. The chief inspector reviews all compliance notices and initials the compliance notice to document his review. The Board will continue to review its inspection procedures and requirements for efficiency and effectiveness.*
- 1.2 *In 2013, the Missouri General Assembly appropriated funds to purchase a new licensure system for all boards within the Division of Professional Registration, including the Missouri Board of Pharmacy. The Board requested that the new licensing system include the capability of capturing electronic signatures during an inspection. It is anticipated that electronic signature capture will be*



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available in mid-2015. The Board will promptly implement electronic signature requirements once available.

2. Board Appointments

The Division of Professional Registration should improve procedures to ensure Board vacancies are filled timely. As of June 30, 2014, the Board had three vacancies. The positions became vacant in January 2011, January 2012, and April 2013.

Section 338.110, RSMo, requires the State Board of Pharmacy to be composed of seven members appointed by the Governor with the advice and consent of the senate, with six licensed pharmacists actively engaged in the practice of pharmacy, and one voting public member. At least one member must be a person who provides pharmaceutical services to a hospital, skilled nursing facility, or intermediate care facility on a full-time basis. The term of office for Board members is 5 years and members serve until a replacement is appointed and qualified.

The day-to-day operations of the Board are overseen by the Executive Director; however, Board vacancies could negatively impact the operations of the Board. In order to have a quorum and hold Board meetings, four members must be present, which is the current level of Board membership. If any member is absent for a meeting, the Board would not have a quorum, and a meeting could not be held to conduct business. Section 338.140, RSMo, indicates a majority of the State Board of Pharmacy will constitute a quorum for the transaction of business.

Recommendation

The Division of Professional Registration work with the Governor's office to fill Board vacancies timely.

Auditee's Response

The Board will continue to cooperate with the Governor's office.

3. Board Meetings

Policies and procedures over Board meetings need improvement.

3.1 Closed meetings

The Board was not in compliance with the Sunshine Law for email meetings held. Periodically, the Board holds closed meetings through email to vote on specific issues. Agendas for these meetings were posted; however, the Board did not motion to close and/or take a roll call vote in open meeting to close email meetings held, as required. As a result, the Board was conducting business outside of regular board meetings.

Section 610.022, RSMo, provides that a public governmental body planning to hold a closed meeting should follow the notice procedures for an open meeting, include notice that a closed meeting will be held, and cite the specific provision of the law that allows the meeting to be closed. Further, a



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meeting may not be closed without the affirmative public vote of the majority of a quorum.

3.2 Approvals

The Board did not approve meeting minutes timely. It is the Board's policy that meeting minutes be approved before the minutes become available for public inspection. As a result, documentation of business conducted was not available for inspection and review by the general public within a reasonable amount of time.

Our review noted Board meeting minutes were approved up to 12 months after the meeting was held, including 11 Board meeting minutes that were not approved for at least 6 months after the meeting was held. For example, the Board did not approve the October 9, 2013 Board meeting minutes until October 16, 2014, over 12 months later. According to the Executive Director, approvals of meeting minutes got delayed due to significant turnover of Board personnel that shifted their priorities.

Section 610.020.7, RSMo, states minutes of open and closed meetings shall be taken and retained by the Board and Section 610.023.2, RSMo, requires the Board to make records available to the public for inspection and copying. Without timely approving Board meeting minutes, the public records of open Board meetings are not made available to the public for inspection within a reasonable amount of time.

Recommendations

The State Board of Pharmacy:

- 3.1 Ensure meetings are closed by an affirmative vote by each Board member during open session.
- 3.2 Approve Board meeting minutes and make such records available to the public timely.

Auditee's Response

- 3.1 *Missouri law is unclear as to the handling of closed session e-mail ballots. The Board's current process was adopted after consultation with legal counsel and will be reviewed to assess continued compliance with Missouri's Sunshine Law.*
- 3.2 *The Board historically approves minutes during its regularly scheduled in-person meetings (which occur approximately every three (3) months) when public participation is at its highest. The Board will continue to monitor its processes to ensure timely completion of minutes.*

Division of Professional Registration

State Board of Pharmacy

Organization and Statistical Information

The State Board of Pharmacy was established in 1909 under House Bill 87 by an act of the Missouri General Assembly. The Omnibus State Reorganization Act of 1974 transferred the Board to the Division of Professional Registration. By Executive Order 06-04, the division moved from the Department of Economic Development to the reorganized Department of Insurance, Financial Institutions, and Professional Registration on August 28, 2006.

The Board has superintending control over the practice of pharmacy in the State of Missouri, and its primary duties consist of examining and licensing pharmacists, pharmacy technicians, intern pharmacists, pharmacies, and drug distributors; investigating complaints; disciplining licensees; and inspecting pharmacies and drug distributors. At June 30, 2014, there were approximately 34,700 licensed pharmacists, pharmacy technicians, intern pharmacists, pharmacies, and drug distributors. Pharmacist initial license fee is \$150 with a biennial renewal license fee of \$200; pharmacy technician license fee is \$35 with an annual renewal fee of \$35; intern pharmacist license fee is \$50 with a biennial renewal license fee of \$80; and pharmacy and drug distributor license fees are \$300 with a biennial renewal fee of \$450.

The Board consists of seven members, with six members actively engaged in the practice of pharmacy and one voting public member. At least one member must be a person who provides pharmaceutical services to a hospital, skilled nursing facility, or intermediate care facility on a full-time basis. Board members are appointed by the Governor with the advice and consent of the senate and serve a term of 5 years. Members whose terms expire may continue to serve until a replacement is appointed and qualified. Board members at June 30, 2014, were:

Member	Term Expires
Janine M. Burkett, President	April 18, 2015
Pamela L. Marshall, Vice-President	September 24, 2015
Barbara A. Bilek, Member	June 1, 2012
Anita K. Parran, Member	April 27, 2010
Vacant	
Vacant	
Vacant	

Board members receive a \$50 per diem compensation and expenses while performing their duties. The Board appoints an executive director to perform the administrative duties of the Board. Kimberly Grinston serves as Executive Director. Thirteen other employees perform administrative duties and responsibilities.

Appendix A

Division of Professional Registration

State Board of Pharmacy

Board of Pharmacy Fund

Comparative Statement of Receipts, Disbursements, and Changes in Cash and Investments

	Year Ended June 30,	
	2014	2013
RECEIPTS		
Professional license or permit fees	\$ 2,627,190	2,914,727
Penalties	9,000	49,005
Other fees	157,611	105,842
Occupational board exam	6,900	21,000
Overpayments	4,024	1,945
Total Receipts	2,804,725	3,092,519
DISBURSEMENTS		
Personal services	880,236	887,635
Employee fringe benefits	344,242	321,795
Expense and equipment	337,442	296,115
Licensure replacement system expense and equipment	73,900	0
State Central Services cost allocation	21,092	23,829
Total Disbursements	1,656,912	1,529,374
RECEIPTS OVER (UNDER) DISBURSEMENTS	1,147,813	1,563,145
TRANSFERS		
To Professional Registration Fees Fund (1)	258,430	203,956
To General Revenue Fund (2)	69,205	13,316
Total Transfers	327,635	217,272
RECEIPTS OVER (UNDER) DISBURSEMENTS AND TRANSFERS	820,178	1,345,873
CASH AND INVESTMENTS, JULY 1	7,247,443	5,901,570
CASH AND INVESTMENTS, JUNE 30	\$ 8,067,621	7,247,443

- (1) For reimbursement of personal services, employee benefits, and operating expenses paid from the Professional Registration Fees Fund.
- (2) For reimbursement of services provided by the Administrative Hearing Commission and the Attorney General's office totaling \$22,068 in fiscal year 2014 and \$13,316 in fiscal year 2013; and for transferring funds totaling \$47,137 in excess of the maximum fund balance allowed for the Board of Pharmacy Fund in fiscal year 2014.

Appendix B

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Comparative Statement of Appropriations and Expenditures

Year Ended June 30,						
2014			2013			
Appropriation Authority	Expenditures	Lapsed Balances	Appropriation Authority	Expenditures	Lapsed Balances	
BOARD OF PHARMACY FUND						
Personal Service	\$ 947,067	880,236	66,831	943,420	887,635	55,785
Expense and Equipment	680,217	337,335	342,882	666,448	295,279	371,169
Criminal history checks	5,000	107	4,893	5,000	70	4,930
For reimbursing the Division of Employment Security benefit account for claims paid to former state employees for unemployment insurance coverage and for related professional services	0	0	0	768	766	2
For a Professional Registration licensure system replacement from Professional Registration board funds	73,900	73,900	0	0	0	0
Total Board of Pharmacy Fund	\$ 1,706,184	1,291,578	414,606	1,615,636	1,183,750	431,886

Appendix C

Division of Professional Registration State Board of Pharmacy Comparative Statement of Expenditures (From Appropriations)

	Year Ended June 30,				
	2014	2013	2012	2011	2010
Salaries	\$ 880,236	887,635	872,562	858,813	875,050
Travel, in-state	21,377	15,874	18,471	16,795	23,217
Travel, out-of-state	8,333	3,412	4,131	1,789	4,228
Supplies	47,625	56,620	53,089	53,359	45,498
Professional development	18,628	7,218	5,449	4,269	5,131
Communication services and supplies	19,067	14,979	15,333	10,910	14,380
Services:					
Professional	251,542	178,749	170,014	203,251	164,429
Maintenance and repair	7,758	9,275	2,285	9,538	6,271
Equipment:					
Motorized	28,015	0	31,231	12,900	0
Office	43	85	0	29	0
Other	0	0	89	190	0
Building lease payments	2,555	255	0	540	992
Miscellaneous expenses	5,948	8,470	11,516	11,165	13,159
Program distributions	451	1,178	2,465	4,864	20,757
Total Expenditures	\$ 1,291,578	1,183,750	1,186,635	1,188,412	1,173,112