



**STATE OF TENNESSEE
COMPTROLLER OF THE TREASURY**

**BOARD OF PHARMACY AND
CONTROLLED SUBSTANCE
DATABASE COMMITTEE**

Performance Audit Report

September 2017

Justin P. Wilson, Comptroller



**Division of State Audit
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September 5, 2017

The Honorable Randy McNally
Speaker of the Senate
The Honorable Beth Harwell
Speaker of the House of Representatives
The Honorable Mike Bell, Chair
Senate Committee on Government Operations
The Honorable Jeremy Faison, Chair
House Committee on Government Operations
and
Members of the General Assembly
State Capitol
Nashville, Tennessee 37243
and
Dr. Reginald Dilliard, Executive Director
Board of Pharmacy
665 Mainstream Dr.
Nashville, TN 37243

Ladies and Gentlemen:

Transmitted herewith is the sunset performance audit of the Board of Pharmacy and the Controlled Substance Database Committee. This audit was conducted pursuant to the requirements of Section 4-29-111, *Tennessee Code Annotated*, the Tennessee Governmental Entity Review Law.

This report is intended to aid the Joint Government Operations Committee in its review to determine whether the board and committee should be continued, restructured, or terminated.

Sincerely,

Deborah V. Loveless, CPA
Director

17264

State of Tennessee

Audit Highlights

Comptroller of the Treasury

Division of State Audit

Performance Audit
**Board of Pharmacy
and
Controlled Substance Database Committee**
September 2017

**PREVIOUS FINDINGS
OCTOBER 2015 AUDIT**

**CURRENT STATUS
2017**

- | | |
|---|--------------------|
| 1. While the Board of Pharmacy issues its licenses in a timely manner, with the exception of pharmacist licenses, the Health Related Boards' computer system could not track and monitor the licensing process to identify impediments (page 3) | PARTIALLY RESOLVED |
| 2. The Board of Pharmacy does not monitor disciplined licensees; has no formal, written policies and procedures for doing so; and has no formal relationship with its recommended peer assistance recovery network (page 5) | PARTIALLY RESOLVED |
| 3. Statutory and structural gaps may limit the effectiveness of the Controlled Substance Database monitoring program and the information it provides (page 6) | RESOLVED |
| 4. Staff of the Controlled Substance Database monitoring program and the Department of Health do not proactively analyze the database to provide information to health regulatory boards and law enforcement (page 7) | RESOLVED |
| 5. Program staff and the Department of Health do not monitor the vendor that provides and maintains the Controlled Substance Database for compliance with contract requirements regarding data controls for ensuring validity and reliability, though it appears the vendor does have such controls in place (page 8) | PARTIALLY RESOLVED |

6. The Board of Pharmacy has no written policies or procedures for licensing, inspection, investigations, or the imposition of disciplinary actions and penalties that ensure staff and board members conduct business in a timely, consistent, and equitable manner (page 9) PARTIALLY RESOLVED

7. Conflict-of-interest disclosure statements should be filed annually as required by the Health Related Boards' regulations and best practices (page 10) RESOLVED

**Performance Audit
Board of Pharmacy
and
Controlled Substance Database Committee**

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**Performance Audit
Board of Pharmacy
and
Controlled Substance Database Committee**

INTRODUCTION

PURPOSE AND AUTHORITY FOR THE AUDIT

This performance audit of the Board of Pharmacy and Controlled Substance Database Committee was conducted pursuant to the Tennessee Governmental Entity Review Law, Title 4, Chapter 29, *Tennessee Code Annotated*. Under Section 4-29-239, the Board of Pharmacy and Controlled Substance Database Committee are scheduled to terminate June 30, 2018. The Comptroller of the Treasury is authorized under Section 4-29-111 to conduct a limited program review audit of the board and committee and to report to the Joint Government Operations Committee of the General Assembly. This audit is intended to aid the committee in determining whether the Board of Pharmacy and Controlled Substance Database Committee should be continued, restructured, or terminated.

ORGANIZATION AND STATUTORY RESPONSIBILITIES

Board of Pharmacy

Created by Section 68-10-301 et seq., *Tennessee Code Annotated*, the Board of Pharmacy consists of seven members, one of whom is a consumer, all appointed by the Governor for one non-repeatable six-year term. The Governor appoints board members from graduates of a recognized school or college of pharmacy, ensuring that at least one board member is 60 years of age or older and that at least one board member is of a racial minority. Pharmacists must have lived and practiced in Tennessee at least five years to be eligible for nomination to the board. The consumer member must also have lived in the state for at least five years and have no financial or other interest in a health care facility or business. The Governor may remove members for misconduct at the recommendation of the remaining board members. Board members receive a per diem of \$100 per day for attending board meetings and other administrative functions of the board, as well as for necessary travel expenses.

**Board of Pharmacy Members
August 2017**

<i>Member</i>	<i>Term Expires</i>
Kevin K. Eidson, Pharm. D., President	7/15/2018
R. Michael Dickenson, D.Ph., Vice-President	7/16/2019
Will Bunch, D.Ph., serving until replaced	7/31/2017
Rissa H. Pryse, D.Ph.	7/31/2021
Debra Wilson, D.Ph.	7/31/2020
Katy Wright, D.Ph.	7/15/2021
Lisa Tittle, public member	12/31/2020

Controlled Substance Database Committee

Created by Section 53-10-303, *Tennessee Code Annotated*, the Controlled Substance Database Committee, previously only an “advisory” committee until that was changed by amendment effective January 1, 2013, consists of the following 11 members.

**Controlled Substance Database Committee Members
August 2017**

Governor-appointed, licensed board members

<i>Original Board</i>	<i>Member</i>
Board of Dentistry	Katherine N. Hall, DDS
Board of Medical Examiners	Melanie Blake, MD
Board of Medical Examiners’ Committee on Physician Assistants	Omar Nava
Board of Nursing	Brent Earwood, APN, CRNA
Board of Optometry	Brad Lindsey, O.D.
Board of Osteopathic Examination	Shant H. Garabedian, D.O.
Board of Pharmacy	R. Michael Dickenson, D.Ph.
Board of Podiatric Medical Examiners	Sheila Schuler, D.P.M.
Board of Veterinary Medical Examiners	Stephen Ladd, DVM

Board-Appointed Public Members

<i>Appointing Board</i>	<i>Member</i>
Board of Medical Examiners	Vacant
Board of Pharmacy	Lisa Tittle

The committee must meet at least annually and as often as deemed necessary either at the call of the chair or upon the request of at least three members. A quorum for official action is composed of seven members. The members of the committee are considered to be performing official duties as members of their original board or committee. They are entitled to the same per diem and travel reimbursements as for their original board or committee, and those amounts are paid by that original board or committee.

AUDIT SCOPE

Follow-up Review of October 2015 Findings

The General Assembly voted in 2016 for a two-year extension of the Board of Pharmacy. Due to the short turnaround and the fact that sunset performance audit would have to begin within a year, we determined our audit scope would be a review of the current status of the seven findings taken in the October 2015 sunset performance audit. We audited the department's activities for the period of January 1, 2016, through April 14, 2017. Management of the board is responsible for establishing and maintaining effective internal controls and for complying with applicable laws, regulations, and provisions of contracts and grant agreements.

Generally Accepted Government Auditing Standards

We conducted this performance audit 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.

PRIOR AUDIT FINDINGS AND CURRENT STATUS

BOARD OF PHARMACY

October 2015 Audit

Finding 1

While the Board of Pharmacy issues its licenses in a timely manner, with the exception of pharmacist licenses, the Health Related Boards' computer system could not track and monitor the licensing process to identify impediments

In the December 2009 sunset performance audit, we found that the Health Related Boards (HRBs) needed better methods and information to monitor licensing timeliness, and that the outdated computer system, Regulatory Board System (RBS), inhibited accurate monitoring and tracking of the timeliness of the licensing process. The Department of Health's follow-up report in August 2010 stated the HRBs were waiting to take corrective action until after selecting and implementing a replacement computer system. We reviewed the board's licensing process, benchmarks, and RBS reports for January 2, 2011, through December 31, 2014, and found the board was meeting its licensing benchmarks for all license types except pharmacists. The HRBs implemented the new Licensing and Regulatory System (LARS), the replacement for RBS, on April 20, 2015. According to staff, LARS does not have the capability to identify delays in the licensing process.

Recommendation

The Board of Pharmacy should work with the Commissioner of the Department of Health to improve the Health Related Boards' new computer system, LARS, to include the ability to track each step of the licensing process so that the Board of Pharmacy can control staff-caused delays in the licensing process.

In April 2015, the new licensing software Licensure and Regulatory System (LARS) went online. However, according to staff, at that point the system would not allow them to identify and track delays in the licensing process. In the May 2016 six-month follow-up to the audit, the executive director stated that the second phase of the LARS implementation would give them the ability to "monitor progress of an application through licensure."

After Board of Pharmacy audit fieldwork, LARS' second phase was implemented in May 2017 and provided management tools to monitor application processing timeliness. However, as a part of the Comptroller of the Treasury, Division of State Audit's simultaneous performance audit of the Board of Nursing, we identified some concerns with LARS' inability to capture the date the application was first received, in addition to the date the application was entered into the system. As a result, LARS is unable to assist management in monitoring all aspects of administrative processing of applications. This situation exists as of August 2017 for all health related boards, including the Board of Pharmacy.

October 2015 Finding 1 – Inability to Monitor the Licensing Process 2017 Status – Partially Resolved

Management's Comment

We concur. As of April of 2015, all health related applications are available for online submission. The online application process is tracked and monitored from beginning to end. For applications received in the mail, tracking and monitoring occurs in the same database, but begins when the application is manually keyed into the system by licensure staff. The Tennessee Department of Health is working to encourage all applicants to apply online.

October 2015 Audit

Finding 2

The Board of Pharmacy does not monitor disciplined licensees; has no formal, written policies and procedures for doing so; and has no formal relationship with its recommended peer assistance recovery network

In the December 2009 Health Related Boards' sunset performance audit, the Board of Pharmacy did not have formal, written procedures regarding its disciplinary monitoring practices and relied on peer assistance programs to monitor its licensees. The Department of Health commented that the board was in the process of adding a monitoring component to its existing disciplinary action database. At the time of the audit's follow-up report in August 2010, the Department of Health stated that the Board of Pharmacy had developed a manual disciplinary monitoring process that would be incorporated in the Regulatory Board System's replacement system. We found the board still has not developed formal, written procedures regarding its disciplinary monitoring practices. The board's administrative manager stated staff did not monitor disciplined licensees and was unaware of a disciplinary action database.

Recommendation

The Board of Pharmacy should develop a formal disciplinary monitoring system. As promised in the six-month follow-up to the previous audit, the Health Related Boards new computer system, LARS, should be updated to include monitoring assistance capabilities. In addition, the board should formalize its relations with the Tennessee Pharmacist Recovery Network and consider also using the Tennessee Peer Assistance Program to provide consultation, referral, and monitoring services to its licensees and itself.

The Board of Pharmacy reports implementing a new database in late 2015 that is being used to monitor disciplined licensees during the disciplinary period. However, the board has not developed accompanying formal policies and procedures. For example, there is no formal policy outlining the board's general approach and philosophy to disciplinary monitoring, such as which staff members are responsible for each aspect of the disciplinary monitoring process, and how disciplinary monitoring will be carried out. Such policies and procedures are needed to ensure continuity of board operations regardless of any personnel changes, as well as help ensure the board and department staff share a common understanding of the board's philosophy and approach.

Additionally, the board is in the process of formally contracting with a peer assistance recovery program for its licensees disciplined for alcohol and chemical misuse and dependency. As of August 2017, the contract was not yet finalized.

**October 2015 Finding 2 – Does Not Monitor Disciplined Licensees
2017 Status – Partially Resolved**

Management’s Comment

We concur, in part. While at the time of this audit a Request for Grant Proposals was being developed for a peer assistance grant, it had not been awarded. At this time, the grant process has been completed and a contract has been awarded to the Tennessee Research and Education Foundation and the Tennessee Pharmacist Recovery Network. The Board of Pharmacy actively monitors disciplined licensees through a program called Redcap in which actions are entered by staff and monitored by the Lead Investigator at least weekly or more often as required. A formal policy will be developed and placed in our policy and procedure manual to codify the requirement to actively monitor and correct this deficiency.

CONTROLLED SUBSTANCE DATABASE COMMITTEE AND DATABASE MONITORING PROGRAM

October 2015 Audit

Finding 3

Statutory and structural gaps may limit the effectiveness of the Controlled Substance Database monitoring program and the information it provides

Statutory exemptions as to who and when one must report to and check the database before writing or filling a prescription results in an incomplete picture of all medications dispensed. In the medical and pharmacy professions, the licensing boards are virtually policing themselves on compliance with requirements to report and/or check the database. Structural gaps in the monitoring program may also limit effectiveness and include a lack of an oversight or enforcement method regarding exemption requirements. Noncompliance is usually discovered by accident during inspections and other routine visits.

Recommendation

The General Assembly, the Controlled Substance Database Committee, the Board of Pharmacy, and the Board of Medical Examiners may wish to revise statutes and/or rules to eliminate exemptions and operational gaps or to establish procedures that allow for monitoring and oversight of approved documented exceptions and compliance with reporting and checking requirements. This will mitigate potential issues that may limit the database’s effectiveness.

In 2016, the Department of Health, the directors of the Board of Pharmacy and Controlled Substance Database monitoring program, and other stakeholders worked with the General Assembly to pass the “Tennessee Prescription Safety Act of 2016,” a complete revision of the previous controlled substance database and monitoring program statute.

We reviewed this statute, management’s comments in their six-month response, and spoke with the database director. We agree with management that the previous audit’s concerns have been addressed.

October 2015 Finding 3 – Gaps Limiting the Effectiveness of the Controlled Substance Database
2017 Status – Resolved

October 2015 Audit

Finding 4

Staff of the Controlled Substance Database monitoring program and the Department of Health do not proactively analyze the database to provide information to health regulatory boards and law enforcement

Statute requires the Controlled Substance Database Committee (committee) to examine the database to identify patterns of unusually high prescribing and dispensing and to refer pharmacists or prescribers found to have these patterns to Board of Pharmacy or Health Related Boards’ investigators. The committee is also required to make sure the database monitoring program assists in research, statistical analysis, criminal investigations, enforcement of state and federal laws involving controlled substances, and the education of healthcare practitioners. There are only two proactive analyses performed by monitoring program staff: 1) an annual “Top 50 Prescribers” list identifying those in Tennessee writing prescriptions for the highest amounts of opioids and benzodiazepines and 2) an annual report to the General Assembly revealing the aggregate prescribing and dispensing trends based on the database. Program staff indicated that they do not commonly use the database to initiate investigations of prescribers, to search for patients “doctor-shopping,” or search for specific practitioners with unusual prescribing or dispensing patterns, but they do refer practitioners to the Tennessee Bureau of Investigations or Board of Pharmacy investigators if they inadvertently find suspicious activity.

Recommendation

The staff of the Controlled Substance Database monitoring program and the Department of Health should initiate regular analyses of both prescribing and dispensing patterns. “The Top 50 Prescribers” list is a good tool to identify overprescribing, but there is no such comparable report for dispensing patterns. In order to utilize the database to its fullest potential, program staff should strive to perform additional proactive analyses of prescribing and dispensing patterns throughout the state. Program staff should also explore whether it is feasible to utilize the database to proactively identify practitioners with unusual prescribing and dispensing patterns and refer practitioners to their respective boards for follow-up.

We reviewed management's May 2016 six-month follow-up comments to the October 2015 audit and spoke with a deputy general counsel who works with the Controlled Substance Database monitoring program and uses the database. In addition to the "Top 50 Prescribers" list mentioned in the last audit, database staff now provides a list of the "Top 50 Pharmacies" ranked on highest morphine milligram equivalents to the Board of Pharmacy, who perform audits of those pharmacies. However, according to the deputy general counsel with the program, no other examples of reports were available primarily because few reports are printed due to privacy concerns. We also took into account the rewrite of the program's enabling statute which gives the Department of Health much more explicit authority to examine the database to identify unusual patterns of prescribing and dispensing and to refer such activities to the appropriate licensing board.

Management appears to be proactively using the database as much as they are able. The database itself does not have a reporting module, so queries have to be written ad hoc. Now the Department of Health is creating a data warehouse that will integrate with other information, such as vital records, and SAS has been acquired, allowing for analytics and data mining, making the data more useful than ever.

**October 2015 Finding 4 – No Proactive Use of the Controlled Substance Database
2017 Status – Resolved**

October 2015 Audit

Finding 5

Program staff and the Department of Health do not monitor the vendor that provides and maintains the Controlled Substance Database for compliance with contract requirements regarding data controls for ensuring validity and reliability, though it appears the vendor does have such controls in place

In 2011, the Department of Health entered into a contract with Optimum Technology, Inc., to provide the information technology service that would be the database for the Controlled Substance Database monitoring program. Though the contractor appears to provide the detailed security work required by contract, neither monitoring program staff nor Department of Health staff monitor the contractor's compliance with the contractual requirements.

Recommendation

The Department of Health's Director of the Office of Information Technology Services, the Director of the Controlled Substance Database monitoring program, and the Executive Director of the Board of Pharmacy should develop processes and procedures, with appropriate documentation, that ensure the vendor responsible for providing and maintaining the database complies with the terms of Attachment 3, Secure Application Development Guide of their contract, thereby providing reasonable assurance of the validity and reliability of the data in the Controlled Substance Database.

At the time of the previous audit, the end of the contract with the vendor (currently APPRISS, which bought Optimum) was approaching. The Department of Health subsequently wrote a one-year contract to give the department and vendor time to write a new contract including language to allow department staff to better validate and ensure reliable information. As of August 2017, this contract, including provisions regarding data validity and reliability, was in the process of being drafted.

**October 2015 Finding 5 – No Oversight of Vendor to Ensure Data Validity and Reliability
2017 Status – Partially Resolved**

Management’s Comment

We concur. At the time of the audit, the end of the contract with APPRISS (formerly Optimum Technology) was approaching. The Department of Health (TDH) is currently in the process of confirming the qualifications of potential vendors with a view toward negotiating a new contract. In the meantime, an extended short-term contract has been signed with the current vendor.

The CSMD has been working with tremendous intensity and teamwork with many stakeholders within TDH to ensure a new contract will include, along with many other improvements, provisions regarding data validity and reliability. The proposed contract language is nearing completion. While not a quick process, we anticipate a new contract will satisfy the expectations of TDH and our legislative stakeholders. For example, the validity of information in required fields will require the vendor to automate appropriate validation against an independent source at the time of submission to the vendor. The goal of the new contract is to have these improvements in place with a qualified vendor next year.

ADMINISTRATIVE ISSUES

October 2015 Audit

Finding 6

The Board of Pharmacy has no written policies or procedures for licensing, inspection, investigations, or the imposition of disciplinary actions and penalties that ensure staff and board members conduct business in a timely, consistent, and equitable manner

There are no operational policies and procedures detailing how the Board of Pharmacy will fulfill its statutory duties and how staff are to fulfill day-to-day duties.

Recommendation

The executive director, in conjunction with his chief inspector/investigator and board manager, should review the board's business operations and prepare policy and procedures manuals that include descriptions of how those operations are achieved by staff to the level of detail that a new employee can, with minimal assistance, understand how to accomplish a specific operation.

The board should consider, in consultation with the executive director and representatives from the Office of General Counsel, establishing disciplinary guidelines to assist the board in fulfilling its statutory responsibility. The guidelines—for example, a penalty matrix—would assist the board in being more consistent and equitable in its decision-making.

As of August 2017, board staff have created written inspection and investigation policies and procedures, a penalty matrix, and lists of computer entry steps for each license. However, the board and its staff have no written, formal policies and procedures outlining the board's business practices and operational processes. Formal policies and procedures are important to help ensure continuity of board operations regardless of any personnel changes.

October 2015 Finding 6 – Lack of Policies and Procedures for Board and Office Operations 2017 Status – Partially Resolved

Management's Comment

We concur. While board staff have created written inspection and investigation policies and procedures, a penalty matrix, and documented computer entry steps for each license type and these procedures have been in use since the audit period, we have not included them in a formal policy manual. We have, however, included these policies and timelines for investigation and computer entry in each employee's individual performance plan. We will ensure these procedures are included in a formal policies and procedures manual.

October 2015 Audit

Finding 7

Conflict-of-interest disclosure statements should be filed annually as required by the Health Related Boards' regulations and best practices

Health Related Boards' Policy 302.01 requires board members to sign the conflict-of-interest policy initially upon being appointed to the board and annually thereafter. We reviewed all available conflict-of-interest disclosure statements for board members who served during fiscal years 2010 through 2014. We found that 1) the Health Related Boards' staff stated some of the oldest forms were lost, and 2) the current board members had only filed one disclosure statement since the annual requirement went into effect three years ago in 2012.

Recommendation

As required by regulation of the Health Related Boards and as a best practice, conflict-of-interest disclosure statements addressing financial interests, prior employment, employment of family members, and other matters should be completed annually by all board members as a reminder to be aware of actual, potential, and appearances of conflicts of interest. The executive director should ensure that comprehensive conflict-of-interest disclosure statements are received from board members in a timely manner and that such members recuse themselves as warranted. The board should require disclosure statements to be updated if circumstances change before the annual statement is due.

We obtained and reviewed all conflict-of-interest files for Board of Pharmacy members serving in calendar 2016 and as of April 2017. Management's May 2016 response to the October 2015 audit stated that disclosure statements were acquired from all board members in January 2016, and that practice would continue every January thereafter. Our review found disclosure statements for all board members for 2016 and 2017.

October 2015 Finding 7 – Lack of Conflict-of-Interest Disclosure Statements
2017 Status – Resolved