

LEGISLATIVE AUDIT DIVISION

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MEMORANDUM

TO: Legislative Audit Committee Members
FROM: Hunter McClure, Associate Information Systems Auditor
CC: Department of Labor and Industry
Laurie Esau, Commissioner
Todd Younkin, Business Services Division, Administrator
Marcie Bough, Board of Pharmacy, Executive Officer
Nikki Griffis, Montana Prescription Drug Registry Program Manager
DATE: June 2021
RE: Information Systems Audit Follow-Up (21SP-01): *The Montana Prescription Drug Registry* (orig. 18DP-01)
ATTACHMENTS: Original Information Systems Audit Summary

Introduction

The *Montana Prescription Drug Registry* (18DP-01) report was issued to the Legislative Audit Committee in June 2019. The audit included nine recommendations to the Department of Labor and Industry (department). In April 2021 we conducted follow up work to assess implementation of the report recommendations. This memorandum summarizes the results of our follow-up work.

Overview

Our audit presented information about the *Montana Prescription Drug Registry* (MPDR) system located within the Department of Labor and Industry. MPDR oversight is the responsibility of the Board of Pharmacy (board) and is managed day to day by the department. Our audit focused on ensuring the department and the board work together to manage and secure the current and new MPDR system. The audit work included recommendations for developing a security plan and user management procedures for the current and new system, enhancing MPDR data integrity and reliability, prioritizing project and contract management over MPDR, and analyzing and soliciting shared resources for project, contract, and security management. Our audit contained nine recommendations to the department. They concurred with all recommendations. Our follow-up work found that five recommendations were implemented and four are in the process of being implemented.

Background

In 2011, the department was tasked by the legislature to electronically collect information on prescription drug orders with oversight responsibilities tasked to the board. The system needed to include reporting and disseminating prescription information for reviewing possible misuse and diversion and conducting research and investigations. This information is used by prescribers, pharmacists, public researchers, and law enforcement. Additionally, the legislation requires the board to establish an advisory group to provide information and advice regarding registry development and operation. The department implemented the MPDR in November 2012 to manage this responsibility.

Our original audit had four objectives. We wanted to determine:

- If the Board of Pharmacy is managing the vendor contract by ensuring contractual obligations are met,
- If the Board of Pharmacy is governing and defining security over personal health information,
- If the Board of Pharmacy is ensuring protection of personal health information through user management procedures, and
- If the Board of Pharmacy is ensuring integrity of registry data and if that data is being used to effectively prevent misuse and diversion.

Our audit work identified that since the Legislature assigned registry management to the board, further planning and direction have not been pursued to identify the resources needed to maintain MPDR and effectively use the data within the registry for patient safety. Due to shortcomings of the system the department implemented a new MPDR system in March 2021.

Audit Follow-up Results

Follow-up work to determine the status of recommendations included reviewing request for proposal documentation for the new MPDR system, system documentation, policy and procedure reviews, discussion with department staff, observations of system changes, and review of user access changes since the audit. The following sections summarize the progress toward implementation of the report recommendations.

RECOMMENDATION #1

We recommend the Department of Labor and Industry regularly coordinate with the Board of Pharmacy to establish, follow, and enforce project and contract management procedures to include:

- A. Definitions for communication expectations and responsibilities,**
- B. Management of project changes and enhancements, and**
- C. Adherence to state procurement standards.**

Implementation Status – Implemented

The purpose of this recommendation is to ensure that the department adheres to procurement standards and that MPDR expectations and changes are managed and communicated. At the time of the audit, we found that contract management and MPDR development weaknesses occurred throughout the initial 2012 system implementation and maintenance. For example, we found the board did not take an active role in addressing vendor issues.

As noted above, the department implemented a new MPDR system in March 2021. As part of the implementation process, they worked with the vendor to define communication expectations and responsibilities. A communication plan was put together in order to let relevant stakeholders know about the switch to the new MPDR system.

In the department's follow-up response, they indicated the MPDR program is now managed by the department's project management, legal, and fiscal staff which coordinates with the vendor on a every other weekly basis. The department's Technical Services Division provides a project manager who coordinates project management with the vendor and tracks contract requirements and milestone activities, including project changes and enhancements. As part of our follow-up work, we were also able to verify that department staff coordinated with the State of Montana Procurement office to ensure state procurement standards are met. The department hired a new MPDR Program Manager in October 2020 to help oversee the new system implementation.

RECOMMENDATION #2

We recommend the Department of Labor and Industry and the Board of Pharmacy:

- A. Work with Department of Public Health and Human Services to immediately and permanently destroy or de-identify prescription drug data older than three years.**
- B. Develop a data destruction and retention plan to ensure destruction of shared prescription drug data.**

Implementation Status – *Implemented*

This recommendation's purpose is to ensure that personal health information (PHI) of Montana citizens is protected. It ensures that the department follows standards and destroys or de-identifies PHI collected for the registry older than 3 years. At the time of the audit, we found that MPDR was required to have an automated data destruction function developed but it had not been implemented.

We confirmed that the department worked with the Department of Public Health and Human Services (DPHHS) to destroy data older than 3 years. The department amended the current memorandum of understanding (MOU) with DPHHS to ensure timeliness of the destruction and de-identifying sensitive health data.

RECOMMENDATION #3

We recommend the Department of Labor and Industry work with the Board of Pharmacy to develop a governance structure and implement a security plan for the Montana Prescription Drug Registry that:

- A. Defines the security responsibilities,**
- B. Requires annual risk assessments,**
- C. Mitigates significant security risks as identified, and**
- D. Ensures compliance with HIPAA security rules.**

Implementation Status – *Being Implemented*

The purpose of this recommendation is to ensure that the MPDR system follows state policy and is secure. At the time of the audit, we found that security assurances provided by the vendor to the department and the State Information Technology Services Division (SITSD) were limited. For example, the Health Insurance Portability and Accountability Act (HIPAA) security safeguards were not assured through the security reports provided to SITSD.

The department has since revised their security assessment and authorization policy to require annual risk assessments that include security risk identification and risk mitigation. The department completed a system security review for the old system in May 2019. The security review identifies the governance structure by identifying the individuals responsible for the security of the system. It also identifies required rules for the system such as HIPAA. Additionally, a Plan of Action and Milestone (POAM) document was produced for the old system. A POAM outlines which security risks need to be addressed first and contains plans for remediation. With the recent implementation of the new MPDR system, the department plans on completing the security review for the new system in June 2021.

RECOMMENDATION #4

We recommend the Department of Labor and Industry coordinate with the Board of Pharmacy to:

- A. Establish a process to enforce review of Montana Prescription Drug Registry delegate users.**
- B. Develop and implement procedures to review administrative and vendor user activity.**

Implementation Status – *Implemented*

The purpose of this recommendation is to ensure that technical safeguards, required by HIPAA, are in place to secure PHI. Our audit work identified that registered users of the MPDR system were self-governing and that current access controls allowed for unauthorized access.

As part of the new MPDR system, the department required that the system must contain user role codes for registration of licensed health care providers, delegates, unlicensed users, law enforcement, and administrative users. The new system must also be able to create, manage, and supervise delegate user accounts. Since the implementation of the new system, the department has implemented processes to enforce review of MPDR delegate users with verification occurring every six months. Additionally, the MPDR program worked with the department's Technology Services Division to coordinate an independent review of administrative and vendor user activity.

RECOMMENDATION #5

We recommend the Department of Labor and Industry work with the Board of Pharmacy to implement formal procedures to ensure validation and quality assurance of Montana Prescription Drug Registry data.

Implementation Status – Implemented

This recommendation was intended to ensure data integrity in the MPDR system. During our audit, we found data control enforcement was not being conducted regularly and data validations and reviews were needed.

The new system requirements include functionality for data error handling and validation and required the vendor to describe how the system performs data integrity validation upon receipt of data. With the new system in place, the department has since implemented formal procedures to ensure data integrity.

RECOMMENDATION #6

We recommend the Department of Labor and Industry and the Board of Pharmacy follow administrative rule by requiring all data elements in pharmacy reporting be included in the Montana Prescription Drug Registry.

Implementation Status –Being Implemented

This recommendation was intended to ensure data collected in the MPDR system is usable for reporting purposes. During our audit, we found inconsistent and out-of-date reporting requirements for MPDR and that missing data fields diminished the usability and effectiveness of the system.

The new system requirements include functionality for reporting for all pharmacy data elements. This includes the ability to track pharmacy reporting compliance and have built in data analytics, statistical analyses, and reporting tools functionality. The new system's tools ensure that all data elements are included in the prescription data submitted to MPDR. Due to how recently the new system has been implemented, the department has not updated reporting requirement by rule yet. Draft proposed rule language will be presented to the Board of Pharmacy at their meeting in June 2021. The department will then proceed with the rulemaking process and plans to have the new requirements in place by the end of 2021.

RECOMMENDATION #7

We recommend the Department of Labor and Industry work with the Board of Pharmacy to protect patient safety and public health by developing and implementing data analysis tools and procedures to identify and address potential misuse and diversion of prescription drugs using Montana Prescription Drug Registry data.

Implementation Status – *Being Implemented*

This recommendation was intended to ensure that the department can identify patterns and trends within MPDR data to help pinpoint problems so that misuse and diversion is detected. Our audit work found that there were issues with duplicate unique IDs within the system and potential evidence of patient and prescriber misuse and diversion. For example, we found 215 duplicate patient IDs within the system.

The new system requirements include functionality for data analysis tools. These tools assist the department in identifying possible misuse and diversion of controlled substances. One of those tools can aggregate and analyze prescription information and alert the department to any potential misuse. With the new system in place, the department has since implemented these tools with detailed guides for registered users, such as doctors and pharmacists on how to use them. With feedback from the MPDR advisory group, the department was able to create specific clinical alerts with the new system that alerts prescribers when patients are potentially misusing prescription drugs. Feedback from the advisory group will be presented to the board in June 2021 to address any procedural changes. While they have developed these tools, they are waiting for feedback to implement them as procedures.

RECOMMENDATION #8

We recommend the Department of Labor and Industry and the Board of Pharmacy:

- A. Conduct a formal analysis to determine the resources needed to properly manage the Montana Prescription Drug Registry.**
- B. Complete this analysis before a request-for-proposal for a new prescription drug registry is issued.**

Implementation Status – *Implemented*

This recommendation was intended to address management and resource issues with the MPDR system. Our audit work found that coordination of resources was needed to support management of MPDR. At the time of the audit an administrative staff member was responsible for managing all aspects of MPDR.

In 2019, the department conducted an internal analysis to determine the resources needed to properly manage MPDR. This analysis identified the need to re-write the 1.0 FTE program manager position and shift appropriate workload to subject matter experts. Subject matter experts include board members and program support staff. Based on our follow up work they have incorporated this new analysis and have proper management over the new MPDR system.

RECOMMENDATION #9

We recommend the Board of Pharmacy work with the Prescription Drug Advisory Group to:

- A. Establish formal policies and procedures regarding business processes that include regular, ongoing meetings.**
- B. Expand advisory group membership to include other stakeholders important to prescription drug evaluations and discussions.**
- C. Revise and update administrative rule to better define potential misuse and diversion thresholds to improve patient safety.**

Implementation Status – *Being Implemented*

This recommendation was intended to address advisory deficiencies in the MPDR program. Our audit work found that even though an advisory group was created, it needed to provide more direction on the management of MPDR. This includes the need for more frequent meetings, inclusive membership, and transparency of the advisory group.

In February 2021, the advisory group was reconvened. The department has appointed multiple members to the advisory group who were also sourced for input into the requirement gathering for the new MPDR system. New formal policy and procedures for the advisory group have been drafted and will be presented at the June Board of Pharmacy meeting for approval. Part of the new advisory groups' agenda is to provide feedback on the new MPDR system's monitoring tools and help the Board of Pharmacy revise and update administrative rule to better define potential misuse and diversion.

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