Office of the Auditor General
Performance Audit Report

Michigan Automated Prescription System

Bureau of Professional Licensing
Department of Licensing and Regulatory Affairs

April 2021

State of Michigan Auditor General
Doug A. Ringler, CPA, CIA

641-0220-20

The auditor general shall conduct post audits of financial transactions and accounts of the state and of all branches, departments, offices, boards, commissions, agencies, authorities and institutions of the state established by this constitution or by law, and performance post audits thereof.

The auditor general may make investigations pertinent to the conduct of audits.

Article IV, Section 53 of the Michigan Constitution

OAG
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Report Summary

Performance Audit
Michigan Automated Prescription System (MAPS)
Bureau of Professional Licensing (BPL)
Department of Licensing and Regulatory Affairs (LARA)

Report Number:
641-0220-20

Released:
April 2021

BPL administers MAPS, a Web-based system that maintains a history of controlled substance prescriptions dispensed in Michigan. MAPS was established, in part, to enable regulatory and law enforcement agencies to help prevent abuse and diversion of controlled substances. Sections 333.7333a and 333.7303a of the *Michigan Compiled Laws* require pharmacists, dispensing prescribers, and veterinarians to report dispensed controlled substances in MAPS and require prescribers to utilize MAPS to review patients' prescription history reports before prescribing more than a three-day supply of controlled substances. During fiscal year 2019, LARA expended $2.6 million for MAPS and related administrative costs. As of November 15, 2019, BPL had six full-time MAPS section employees.

Audit Objective	Conclusion
Objective #1: To assess the sufficiency of BPL's efforts to ensure compliance with the laws and rules governing MAPS.	Sufficient, with exceptions

Findings Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
We estimated that non-veterinarian prescribers wrote 4.3 million prescriptions in 2019 and had not reviewed the patient's history report (Finding #1).	X		Agrees

Observations Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
A zero-reporting requirement would improve the efficiency of BPL's monitoring efforts and help ensure MAPS data is complete and accurate, which is essential for identifying potential abuse, diversion, and overprescribing of controlled substances (Observation #1).	Not applicable for observations.		

Audit Objective	Conclusion
Objective #2: To assess the sufficiency of BPL's efforts to use MAPS data to assist in the prevention of abuse, diversion, and overprescribing of controlled substances.	Sufficient

Findings Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
None reported.	Not applicable.		

Observations Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
See Observation #1.	Not applicable for observations.		

Audit Objective	Conclusion
Objective #3: To assess the effectiveness of select LARA security and access controls over MAPS.	Moderately effective

Findings Related to This Audit Objective	Material Condition	Reportable Condition	Agency Preliminary Response
An estimated 680 licensed medical professionals likely had inappropriate access to MAPS and 64 former State employees had access 13 days to 782 days after terminating their State employment (Finding #2).	X		Agrees
Ten (50%) third party service organization (TPSO) controls reviewed did not have sufficient evidence to support operating effectiveness on an ongoing basis (Finding #3).		X	Agrees
LARA provided six MAPS section employees with the unmonitored ability to create, edit, delete, or disclose confidential prescription data (Finding #4).		X	Agrees

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Doug A. Ringler, CPA, CIA
Auditor General

Laura J. Hirst, CPA
Deputy Auditor General

OAG
Office of the Auditor General

Doug A. Ringler, CPA, CIA
Auditor General

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April 1, 2021

Ms. Orlene Hawks, Director
Department of Licensing and Regulatory Affairs
Ottawa Building
Lansing, Michigan

Dear Ms. Hawks:

This is our performance audit report on the Michigan Automated Prescription System, Bureau of Professional Licensing, Department of Licensing and Regulatory Affairs.

We organize our findings and observations by audit objective. Your agency provided preliminary responses to the recommendations at the end of our fieldwork. The *Michigan Compiled Laws* and administrative procedures require an audited agency to develop a plan to comply with the recommendations and to submit it to the State Budget Office upon completion of an audit. Within 30 days of receipt, the Office of Internal Audit Services, State Budget Office, is required to review the plan and either accept the plan as final or contact the agency to take additional steps to finalize the plan.

We appreciate the courtesy and cooperation extended to us during this audit.

Sincerely,

Doug Ringler

Doug Ringler
Auditor General

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MICHIGAN AUTOMATED PRESCRIPTION SYSTEM

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AUDIT OBJECTIVES, CONCLUSIONS, FINDINGS, AND OBSERVATIONS

COMPLIANCE WITH LAWS AND RULES

BACKGROUND

The Department of Licensing and Regulatory Affairs (LARA) implemented the Michigan Automated Prescription System* (MAPS) as Michigan's electronic system for monitoring controlled substances* dispensed in the State by pharmacists, dispensing prescribers, and veterinarians.

The compliance requirements include:

- Reporting

  Beginning January 3, 2002, Section 333.7333a of the *Michigan Compiled Laws* generally requires pharmacists, dispensing prescribers, and veterinarians to report dispensed controlled substances in MAPS. The legislation does not require dispensers to notify MAPS when no controlled substances are dispensed (Observation #1).

- Registration

  Beginning June 1, 2018, Section 333.7303a(5) of the *Michigan Compiled Laws* requires prescribers to register with MAPS before prescribing or dispensing a controlled substance to a patient.

- Patient's History Report Review

  Beginning June 1, 2018, Section 333.7303a(4) of the *Michigan Compiled Laws* requires prescribers to review the patient's history report in MAPS before prescribing or dispensing controlled substances in a quantity that exceeds a three-day supply. Patient history reports need to be checked for only the initial prescription, not refills.

Controlled substances as identified under the federal Controlled Substances Act are classified in 1 of the 5 following schedules based on whether they have an accepted medical use in treatment in the United States, their relative abuse potential, and their likelihood of causing psychological or physical dependence:

- Schedule I - Have no accepted medical use in the United States, have a lack of accepted safety for use under medical supervision, and have a high potential for abuse. Examples include ecstasy, heroin, and LSD.

- Schedule II - Have a high potential for abuse which may lead to severe psychological or physical dependence. Examples include Adderall, Dilaudid, fentanyl, hydrocodone, oxycodone, Ritalin, and Vicodin.

** See glossary at end of report for definition.*

- Schedule III - Have a high potential for abuse that is less than substances in Schedules I or II, and abuse may lead to moderate or low physical dependence or high psychological dependence. Examples include anabolic steroids, ketamine, and Tylenol with codeine.

- Schedule IV - Have a low potential for abuse relative to substances in Schedule III. Examples include Ambien, Darvocet-N, diazepam, tramadol, Valium, and Xanax.

- Schedule V - Have a low potential for abuse relative to substances in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Examples include Lyrica, Phenergan with codeine, and Robitussin AC.

AUDIT OBJECTIVE

To assess the sufficiency of the Bureau of Professional Licensing's (BPL's) efforts to ensure compliance with the laws and rules governing MAPS.

CONCLUSION

Sufficient, with exceptions.

FACTORS IMPACTING CONCLUSION

- BPL conducted a quarterly prescription audit process to verify the accuracy of MAPS key data fields, such as prescriber information and prescription drug name, date, quantity, and days supply.

- BPL conducted a quarterly review to identify and follow up prescriptions written by unregistered providers. Based on our analysis, we estimated that 98.9% of prescribers were registered in MAPS, covering 99.9% of the 39.5 million controlled substance prescriptions written from October 1, 2017 through November 13, 2019.

- BPL identified and followed up prescription record submission errors to ensure that errors were corrected. Our analysis noted that the number of outstanding error records as of December 17, 2019 was not significant, totaling less than .02% of all prescription records submitted during calendar year 2019.

- Material condition* related to the need for improved monitoring of prescriber compliance with mandatory utilization requirements (Finding #1).

** See glossary at end of report for definition.*

FINDING #1

Improved monitoring of prescriber compliance needed.

LARA should analyze all prescribers' utilization of the MAPS patient history reports to help ensure that prescribers are accessing the information available to them to make informed decisions and help prevent abuse of controlled substances.

Beginning June 1, 2018, Section 333.7303a(4) of the *Michigan Compiled Laws* generally required licensed prescribers to review a MAPS report of the patient's prescribed controlled substances before prescribing or dispensing a controlled substance that exceeds a three-day supply. Also, LARA's MAPS - Mandatory Registration and Use procedure requires MAPS section employees to use the MAPS compliance module to identify and follow up noncompliant prescribers.

LARA determines a prescriber's compliance with this requirement when triggered by complaints, tips, or other high-level analyses indicating potential prescribing improprieties. However, LARA had not analyzed compliance for all prescribers.

We estimated that prescribers did not obtain the required patient history report within 7 days prior to writing:

33.0% of controlled substance prescriptions written without prescriber review of patient history reports.

- 4.3 million (33.0%) of 13.0 million controlled substance prescriptions written by non-veterinarian prescribers from January 1, 2019 through December 31, 2019.
- 84,580 (32.0%) of 264,312 controlled substance prescriptions written by veterinarian prescribers from June 1, 2018 through December 31, 2019.

LARA indicated that it was still working with its vendor to refine the MAPS functionality to properly identify noncompliant prescribers.

We consider this finding to be a material condition because of the significance of the prescriber noncompliance rates, the fact that LARA had not established a systematic process to identify and resolve prescriber noncompliance, and the importance of the statutory requirement to help prevent potential abuse of controlled substances.

RECOMMENDATION

We recommend that LARA analyze the utilization of MAPS patient history reports for all prescribers and initiate follow-up or disciplinary action as appropriate.

AGENCY PRELIMINARY RESPONSE

LARA provided us with the following response:

Agrees.

LARA acknowledges the need for continuous improvement to further develop its efforts to initiate reviews of prescribers who fail to comply with the MAPS use requirement.

After the passage of PA 249 of 2017 (MCL 333.7303a(4)) on December 27, 2017, and with recognition that the new requirement could potentially impact the health care of many Michigan citizens, LARA pursued a strategy to educate, warn, then enforce in order to promote prescriber compliance with the new MAPS use requirement (effective June 1, 2018).

In 2018, to educate prescribers about the new MAPS use requirement and to educate them on MAPS generally, LARA staff presented at 56 distinct conferences and webinars throughout the State of Michigan. These presentations were conducted both leading up to, and after, the MAPS use requirement went into effect.

In 2019, LARA began to address specific prescribers' non-compliance with the mandatory MAPS registration requirement under MCL 333.7303a(5) (also effective June 1, 2018). That year, under authority granted in MCL 333.16226b, LARA issued 2,315 non-disciplinary warning letters to prescribers who appeared to be issuing controlled substance prescriptions but were not registered to MAPS.

In 2020, LARA issued 831 non-disciplinary warning letters (again, under authority granted in MCL 333.16226b) to prescribers who appeared to issue controlled substance prescriptions without complying with the MAPS use requirement.

Moreover, since the effective date of the MAPS use requirement, and in the context of larger prescribing issues, LARA has issued administrative complaints against licensees that specifically cite failures to comply with the MAPS use requirement (a violation of MCL 333.16221(w)). And in 2021, LARA will be issuing administrative complaints against prescribers who have failed to heed warnings, and which charge solely that the prescriber has failed to comply with the MAPS use requirement.

In addition to the efforts to educate, warn, and enforce, LARA has facilitated integrations between MAPS and electronic medical records systems (EMRs) throughout the State in order to make it easier for prescribers to accomplish a "one click" check of a patient's MAPS history directly from the EMR (rather than logging into a separate system). Between August 2017 and December 2019, MAPS has facilitated integrations for 321 health care facilities, covering a total of 49,865 prescribers.

LARA would also like to note that the effect of the MAPS use requirement and LARA's efforts to promote compliance therewith has more than tripled *the average prescriber requests per month in the time since the MAPS use requirement became effective:*

Time frame	***Average monthly MAPS checks***
6 months prior to effective date of the MAPS use requirement	*407,445*
6 months after the effective date of the MAPS use requirement	*1,052,666*
Last 6 months of 2020	*1,512,888*

Additionally, currently 99.8% of all controlled substance prescriptions filled in the State of Michigan were written by prescribers who are registered to MAPS.

LARA believes this evidence, especially when considered alongside the dramatic downward trends in the prescribing of the most commonly abused and diverted controlled substances, shows that the approach to educate, warn, then enforce, all while facilitating easy access, has been an effective strategy to promote compliance with the MAPS use requirement and to prevent potential abuse of controlled substances.

With these efforts, LARA does recognize as it relates to the finding by the OAG, that the Department should and can develop a more systematic and operationalized process to ensure licensed prescribers met the statutory requirement of being registered and checking MAPS prior to issuing a prescription for a controlled substance, Schedules II through V, exceeding a three-day supply. LARA is continuing to work on addressing this finding and agrees with the OAG for the need to pro-actively identify non-compliance of licensees who are not meeting this statutory requirement.

OBSERVATION #1

A zero-reporting requirement would improve BPL's ability to efficiently monitor dispenser reporting.

Prescription drug monitoring programs* (PDMPs), such as MAPS, can facilitate appropriate prescribing habits and help address the prescription drug epidemic. MAPS is designed to track controlled substances dispensed in the State of Michigan. Therefore, complete and accurate prescription drug information is critical to enable a PDMP to identify potential abuse, diversion, and overprescribing of controlled substances at the prescriber and dispenser levels. As of September 13, 2019, MAPS data included 4,636 unique dispensers who had reported dispensing at least one controlled substance from October 1, 2017 through September 13, 2019. However, we noted concerns in the following areas:

a. No Zero-Reporting Requirement

MAPS legislation, rules, and submission guidance do not require dispensers to report in MAPS when no controlled substances are dispensed for the reporting period (zero-report):

(1) Section 333.7333a of the *Michigan Compiled Laws* generally requires pharmacists, dispensing prescribers, and veterinarians to electronically report to MAPS when they dispense controlled substances.

(2) Board of Pharmacy Administrative Rule 338.3162d(2) requires dispensers to report to MAPS by the end of the next business day all controlled substances dispensed since the previous report.

(3) LARA's Data Submission Guide Section 4.4 encourages and provides a simple process to allow dispensers to zero-report.

Requiring dispensers to report even if they did not dispense controlled substances would confirm a complete population of dispensed controlled substances in MAPS or highlight forgotten or intentionally neglected reporting.

b. Monitoring

The MAPS dispensary reporting exception report identifies dispensers who do not submit a dispensary report to MAPS for at least two days. For example, the exception report dated September 13, 2019 identified 2,427 dispensers who had not reported for at least two days, including 1,246 who had never reported. Although we acknowledge that the report likely includes a significant number of dispensers who were inactive or, in fact, had not dispensed any controlled substances, establishment of a zero-reporting requirement would all but eliminate the

** See glossary at end of report for definition.*

latter from the report, making it a more manageable, useful monitoring tool.

c. Other States' Requirements
Our limited research of prescription drug monitoring reporting requirements identified 18 other states that require zero-reporting by dispensers, including 4 of the other 5 states in the U.S. Department of Health and Human Services (HHS) Region 5*, as follows:

HHS Region 5 States	Required Zero-Reporting
Illinois	No
Indiana	Yes
Michigan	No
Minnesota	Yes
Ohio	Yes
Wisconsin	Yes

** See glossary at end of report for definition.*

PREVENTION OF ABUSE, DIVERSION, AND OVERPRESCRIBING OF CONTROLLED SUBSTANCES

BACKGROUND

Opioids* (painkillers) and benzodiazepines* (tranquilizers) are the leading cause of Michigan's prescription drug epidemic. Michigan's total number of overdose deaths involving an opioid increased more than 17-fold from 115 deaths in 1999 to 2,036 deaths in 2018 (see Exhibit #1). According to the National Institute on Drug Abuse, roughly 21% to 29% of patients who are prescribed opioids for chronic pain misuse them and 8% to 12% develop an opioid use disorder. Opioids can be classified as Schedules II through V controlled substances and include drugs such as Demerol, Dilaudid, fentanyl, hydrocodone, methadone, morphine, oxycodone, oxycontin, oxymorphone, percocet, tramadol, ultram, and vicodin. Benzodiazepines are classified as Schedule IV controlled substances and include drugs such as alprazolam, ativan, diazepam, lorazepam, Valium, and Xanax.

PDMPs can be used to understand the behavior of the prescription drug epidemic, identify inappropriate prescribing trends, proactively provide information to users to protect high-risk patients, and evaluate interventions. MAPS contains detailed prescription data for controlled substances dispensed in Michigan. Analysis of that data for trends or improprieties enables regulatory and law enforcement agencies to help prevent abuse, diversion, and overprescribing of controlled substances.

From October 1, 2017 through December 31, 2019, dispensers reported 41.3 million prescription records to MAPS and users requested or initiated 29.8 million patient history reports.

See Exhibits #2 and #3 for controlled substance prescription trends in Michigan with callouts for important dates related to drug classification, law changes, and MAPS implementation.

AUDIT OBJECTIVE

To assess the sufficiency of BPL's efforts to use MAPS data to assist in the prevention of abuse, diversion, and overprescribing of controlled substances.

CONCLUSION

Sufficient.

FACTORS IMPACTING CONCLUSION

- The number of opioid prescriptions dispensed in Michigan from calendar year 2017 to calendar year 2018 decreased by 16.4%, ranking 1st of the 5 HHS Region 5 states that published such data.

** See glossary at end of report for definition.*

- BPL staff developed risk factors to evaluate MAPS prescription data at the individual prescriber and dispenser level to identify trends or potential improprieties that may warrant follow-up.

- BPL's analysis of MAPS data resulted in 195 memorandums requesting an investigation of prescribers or dispensers. Twelve (60%) of the 20 memorandums that we reviewed resulted in investigations, and as of February 28, 2020, 7 (58%) of the 12 investigations resulted in administrative actions against the prescribers and/or dispensers.

- MAPS administrator and BPL regulation agent users obtained 15,218 patient history reports from October 1, 2017 through December 31, 2019 to review for investigative purposes and assist with troubleshooting, an average of more than 18 requests per day, indicating substantial use of MAPS data to further BPL's mission*.

- A contracted study performed in 2018 to help evaluate the impact of MAPS showed declines in the number of patients filling more than a 30-day supply of opioids, the average number of controlled substance prescriptions filled per day, and the average number of opioid prescriptions filled per day making them less available for abuse or diversion.

- Our analysis of MAPS data for Schedule II through Schedule IV controlled substances did not identify significant noncompliance with Board of Pharmacy Administrative Rules related to the filling and refilling of prescriptions.

- BPL provided relevant information to registered opioid prescribers, as recommended by the PDMP Training and Technical Assistance Center, on a quarterly basis. These reports provide summarized information to allow prescribers an opportunity for self-examination and a more efficient method for reviewing associated risk with their prescribing practices.

- BPL received the Formula 1 Award for Best Process Improvement Engineered with the Use of Metrics from the Michigan Office of Performance and Transformation in 2017 for BPL's efforts to improve the prescription drug and opioid abuse tracking process. BPL also received an Honorary Mention for the Best Business Transformation Project from the Process Excellence Network* (PEX) in 2019 for its efforts to improve processes for combating prescription drug and opioid abuse.

** See glossary at end of report for definition.*

SELECT SECURITY AND ACCESS CONTROLS

BACKGROUND

Security* controls are the management, operational, and technical controls designed to protect the availability*, confidentiality*, and integrity* of a system and its information.

Access controls* limit or detect inappropriate access to computer resources, thereby protecting the resources from unauthorized modification, loss, and disclosure. For access controls to be effective, they should be properly authorized, implemented, and maintained.

As of November 13, 2019, 78,821 users had access to MAPS, including 56,718 users with a licensed medical professional (prescriber or dispenser) role, 19,442 users with a delegate role, and 2,661 users with law enforcement, government agency staff, or benefit plan manager roles. The purpose for and how MAPS user access is granted is as follows:

- Licensed medical professionals access MAPS to obtain information relevant to providing medical or pharmaceutical treatment to their patients. These users are required to provide their Michigan professional license number, controlled substance identification number (ID), and/or Drug Enforcement Agency (DEA) number, as appropriate. MAPS automatically approves user access upon electronic verification of the required active license(s) with the appropriate source databases. MAPS section employees can also approve access upon manual review.

- Delegate users access MAPS in lieu of licensed medical professionals. Users with active licensed medical professional (prescriber or dispenser) roles may authorize delegate users whose MAPS access is tied to the licensed medical professional's user credentials.

- Law enforcement, government agency staff, or benefit plan manager users access MAPS to obtain information for drug-related criminal investigations or related evidentiary purposes. Also, U.S. Department of Veterans Affairs prescriber and dispenser users access MAPS to obtain information relevant to providing medical or pharmaceutical treatment to their patients. These users must submit an access request form to MAPS section employees for approval.

AUDIT OBJECTIVE

To assess the effectiveness* of select LARA security and access controls over MAPS.

** See glossary at end of report for definition.*

CONCLUSION

Moderately effective.

FACTORS IMPACTING CONCLUSION

- All six administrator users had completed confidentiality forms.
- LARA's controls ensured that the initial approval of MAPS users was properly documented.
- LARA's controls effectively ensured that MAPS application security settings substantially complied with State of Michigan Technical Standards.
- All 35 user roles had appropriate privileges and access rights.
- LARA's controls ensured that MAPS report requests were properly approved and securely transmitted.
- Material condition related to the need for improved MAPS user access recertification controls (Finding #2).
- Reportable conditions* related to the need to improve processes for evaluating the effectiveness of LARA's third party service organization's (TPSO's) controls and monitoring MAPS administrator user activity (Findings #3 and #4).

** See glossary at end of report for definition.*

FINDING #2

Access recertification controls need improvement.

LARA needs to improve its MAPS user access recertification controls to help prevent and detect inappropriate access and protect confidential information from unauthorized use, disclosure, modification, or destruction.

State of Michigan Technical Standard 1340.00.020.01 requires State agencies to review and verify that accounts are still required and compliant with the account settings and access permissions semiannually for privileged accounts and annually for all other accounts.

In October 2019, LARA implemented a monthly process to begin recertifying active MAPS users with licensed medical professional roles and by November 12, 2019, it had inactivated 551 accounts of users whose professional licenses were no longer active. However, we noted that LARA had not verified the status of licensed medical professional users' controlled substance ID or DEA numbers and had not performed recertification procedures for any of the 19,442 delegate users or 2,661 users who had non-medical professional roles.

We reviewed LARA's access controls and compared the November 13, 2019 listing of 78,821 active MAPS users with the Michigan Professional Licensing User System (MiPLUS) and the State's Human Resources Management Network (HRMN). We identified 5,165 unique users whose credentials, originally used to authorize their MAPS access, no longer matched the State licensing or employment information. Further analysis of the 5,165 users identified:

MAPS access of an estimated 744 active users was likely inappropriate.

a. An estimated 680 active MAPS licensed medical professional users whose access was likely inappropriate. These users' professional license numbers or controlled substance IDs, as indicated in MiPLUS, were either inactive or invalid, rendering the users ineligible based on the information on file.

b. 64 active MAPS State employee users whose access was inappropriate. These users had terminated State employment from 13 to 782 days, or an average of 301 days, prior to November 13, 2019 and, therefore, were no longer an eligible MAPS user. Although none of these users had logged into MAPS after their departure date, the risk of unauthorized access remains until the user accounts are inactivated.

LARA indicated that, for licensed users, it had not implemented recertification controls prior to October 2019 because when it launched the new vendor hosted and managed MAPS application in April 2017, LARA was migrating its licensing application to MiPLUS. Also, LARA planned to establish the process after MiPLUS was fully implemented to enable periodic automatic recertification. Lastly, LARA indicated that, for non-licensed users, it had stopped its annual recertification during the transition

to the new MAPS application to focus resources on other operational priorities.

We consider this to be a material condition because of the significant number of active users that we identified whose access was, or may have been, inappropriate; the confidential nature of the prescription data contained in MAPS; and the interstate functionality that allows MAPS users to access confidential patient data of 31 other participating states, Washington D.C., and the U.S. Military Health System.

RECOMMENDATION

We recommend that LARA improve its MAPS user access recertification controls.

AGENCY PRELIMINARY RESPONSE

LARA provided us with the following response:

LARA agrees and has taken active measures to improve in this area.

LARA now has measures in place that have effectively ensured that MAPS users have proper credentials for access to the system, including a monthly manual match of active MAPS users to MiPLUS. In addition, LARA has implemented a yearly reverification process for all non-health professional users and delegates, and is working with the MAPS vendor, Appriss Health, to implement an automated reverification process of MAPS users, which will be operational in the coming weeks. LARA also notes the following regarding Audit Finding #2:

- *There is a meaningful difference between the potential for inappropriate access and the actual misuse of data. There has been no indication of inappropriate access and/or use of MAPS data occurring outside of medical treatment.*

- *The relatively few users identified during the course of the audit as potentially having unsupported access to MAPS have had their access terminated. These users represented a small percentage (6.5%) of the approximately 78,000 active MAPS users and predominately consisted of medical residents no longer practicing in the State of Michigan; there is no evidence that any of these users used MAPS data inappropriately.*

- *Regarding the 64 state employees that the finding notes that should not have had access to MAPS, there were no instances of those users logging into MAPS after their departure from State employment. Additionally, LARA has had a control in place, whereby every request made by a non-medical professional, is first reviewed by a MAPS analyst before approval of the request; however, the control did not include confirming the requestor's employment status.*

While there is a control on the backend, there needs to be a control on the front end to prevent inappropriate access all together. To the OAG's finding, LARA realizes it can do a better job of having authorized users recertify and to take steps to remove individuals from having any ability to access MAPS who have left State employment or identified as no longer meeting the requirement to have access. LARA recognizes the significance of this finding by the OAG and therefore will continue to make this a priority to improve MAPS user access recertification controls to mitigate the risk it poses to prevent anyone not properly authorized and recertified from having potential access to such sensitive patient records and information. LARA will strive to maintain proactive measures to avoid inappropriate access as another way to also prevent the potential for misuse of the data by non-authorized users.

FINDING #3

Evaluation of TPSO controls needs improvement.

LARA should improve its process to evaluate the operating effectiveness of its TPSO's controls to help protect the security of MAPS data and achieve LARA's operating, reporting, and compliance objectives.

The State of Michigan Financial Management Guide (FMG) (Part VII, Chapter 1, Section 1000) requires oversight of a TPSO's controls when those services have a material effect on the department's operations and reporting. The FMG indicates that oversight includes gaining an understanding of the TPSO's controls, obtaining assurance that the controls are functioning as intended, and evaluating the effectiveness of the controls on an ongoing basis.

LARA contracted with a TPSO to provide MAPS and relied on the State's System Security Plan (SSP) process to evaluate the TPSO's controls. LARA used the SSP process to identify 192 relevant National Institute of Standards and Technology* (NIST) controls and indicated that it reviewed evidence from the TPSO to determine whether the controls were properly designed, implemented, and operating effectively. However, for 10 (50%) of the 20 controls that we reviewed, LARA relied on the following evidence that we considered insufficient:

- System and Organization Controls* (SOC) 2, type 2 report - The scope did not include the MAPS application and the portion of the report that the TPSO provided to LARA did not contain the details or results of tests performed.

- Health Insurance Portability and Accountability Act (HIPAA) compliance report - Evaluated the operating effectiveness of various NIST controls, however, only from September 27, 2017 through December 5, 2017. It did not evaluate their operating effectiveness on an ongoing basis.

- Federal Risk and Authorization Management Program* (FedRAMP) certification - Certified the TPSO's subcontractor that provided hosting and related services, however, did not provide assurance of the operating effectiveness of certain controls that were the responsibility of the TPSO.

- TPSO policies and procedures - Did not provide assurance that the controls had been implemented as designed or were operating effectively.

LARA utilized the State's standard contract language for applications which did not require that the TPSO obtain an annual third-party assurance report, such as a SOC report, to address the operating effectiveness of the TPSO's controls over the application. Also, LARA informed us that it did not obtain an annual third-party assurance report specific to MAPS because of

** See glossary at end of report for definition.*

uncertainties surrounding the roles and responsibilities for obtaining such a report. In addition, LARA believed that its control evaluation was sufficient because it received the Authority to Operate from the Department of Technology, Management, and Budget's Michigan Cyber Security and Infrastructure Protection upon completion of its MAPS's SSP.

RECOMMENDATION

We recommend that LARA ensure that it properly evaluate the operating effectiveness of its TPSO's controls.

AGENCY PRELIMINARY RESPONSE

LARA provided us with the following response:

LARA agrees and has taken active measures to improve this process.

LARA acknowledges the requirement to consider Appriss as a TPSO and has now done so. LARA received and reviewed Appriss' most recent SOC 2 report for 2020, which LARA used to evaluate Appriss' systems relevant to security, availability, processing integrity, and confidentiality.

FINDING #4

LARA needs to monitor administrator user activity to help detect unauthorized modification, destruction, or disclosure of confidential MAPS data.

Monitoring of MAPS administrator user activity needed.

State of Michigan Technical Standard 1340.00.040.01 requires that information systems have the capability to audit the use of administrator privileges and that the audit records be reviewed at a frequency determined by LARA for events such as potentially suspicious activity, suspected violations, and inappropriate or unusual actions.

All six of the MAPS section employees have administrator user access to MAPS which grants elevated privileges including the ability to manage user access; approve prescription history requests; and create, edit, or delete prescription records. However, LARA had not monitored the MAPS section employees' user activity.

RECOMMENDATION

We recommend that LARA monitor MAPS administrator user activity.

AGENCY PRELIMINARY RESPONSE

LARA provided us with the following response:

Agrees.

LARA acknowledges the need to improve the monitoring of administrator users and has put in place an effective procedure to semi-annually audit MAPS administrator user activity by verifying that all MAPS activity performed by a MAPS administrator is done so for justifiable reasons consistent with the MAPS statute.

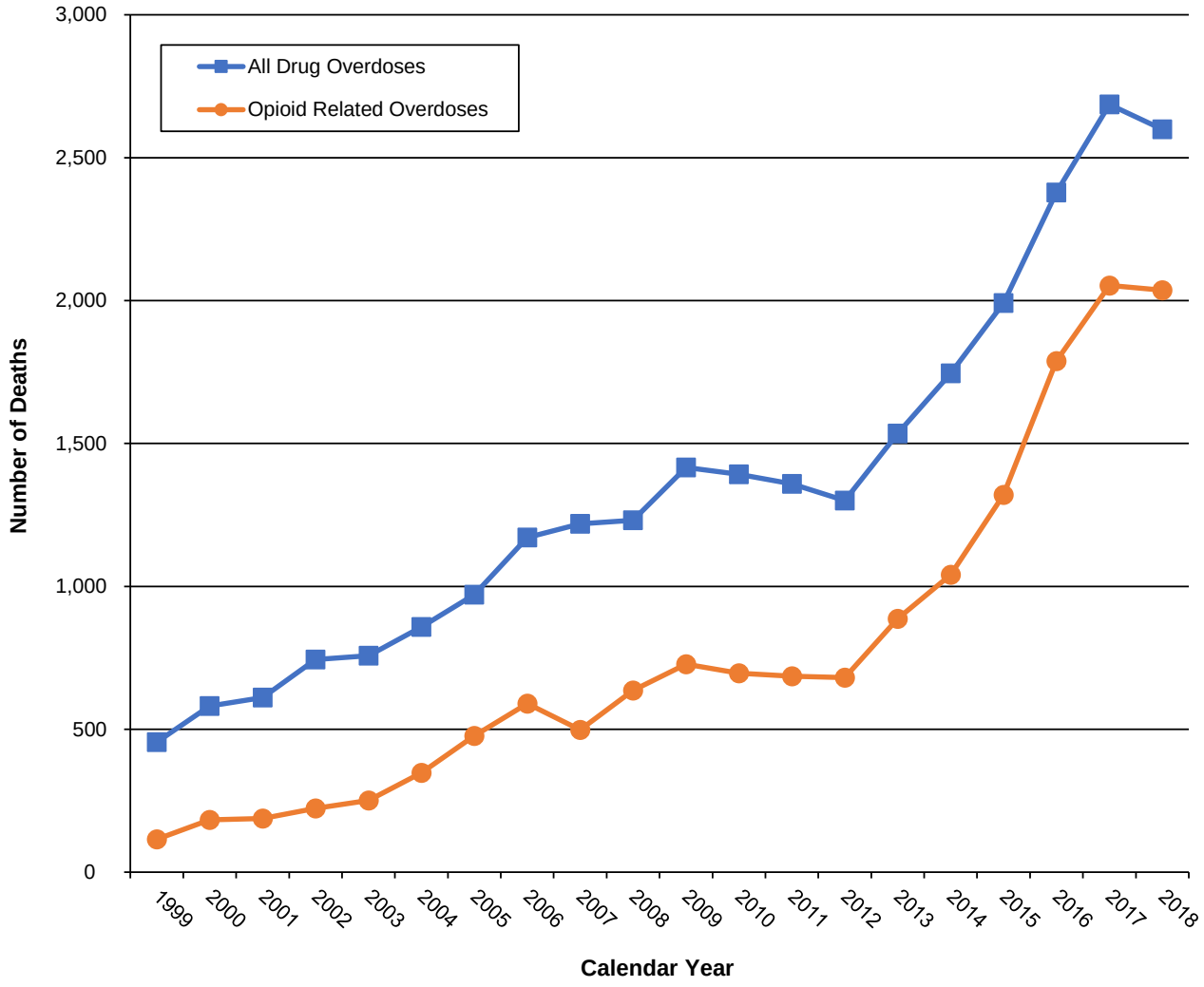
The new audit procedure, combined with the capability to access system audit records beyond one year after the date of creation, brings MAPS into compliance with State of Michigan Technical Standard 1340.00.040.01. These measures were put in place once the OAG auditors identified this as an issue during the audit process and LARA quickly put together a plan to put controls in place given the potential risk and importance of protecting the data.

SUPPLEMENTAL INFORMATION

UNAUDITED
Exhibit #1

MICHIGAN AUTOMATED PRESCRIPTION SYSTEM
Department of Licensing and Regulatory Affairs

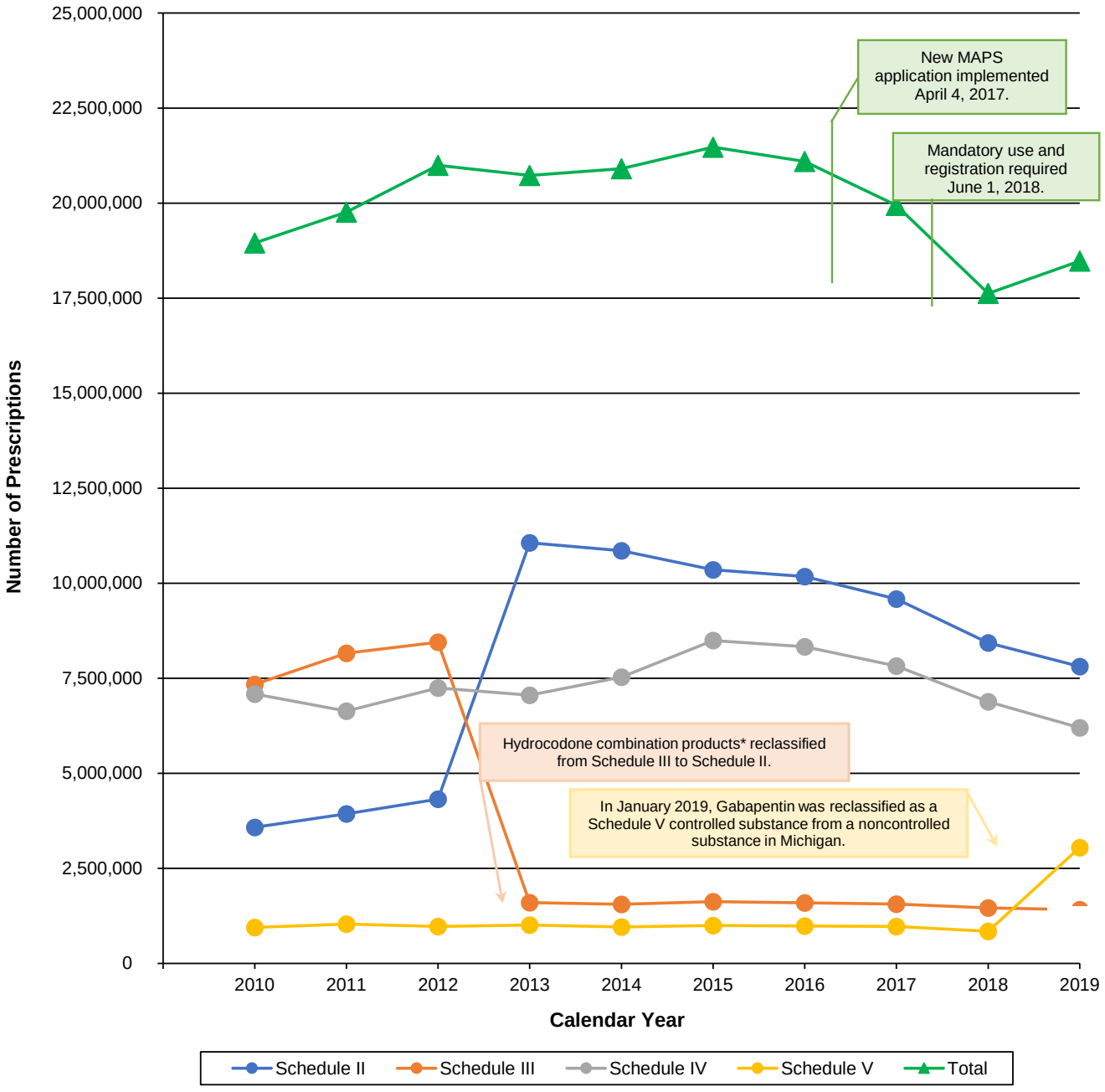
Number of Michigan Deaths From Drug Overdoses by Year
Calendar Years 1999 Through 2018



Source: The OAG prepared this exhibit using data provided by the Michigan Department of Health and Human Services.

MICHIGAN AUTOMATED PRESCRIPTION SYSTEM
Department of Licensing and Regulatory Affairs

Controlled Substance Prescriptions by Year
Calendar Years 2010 Through 2019



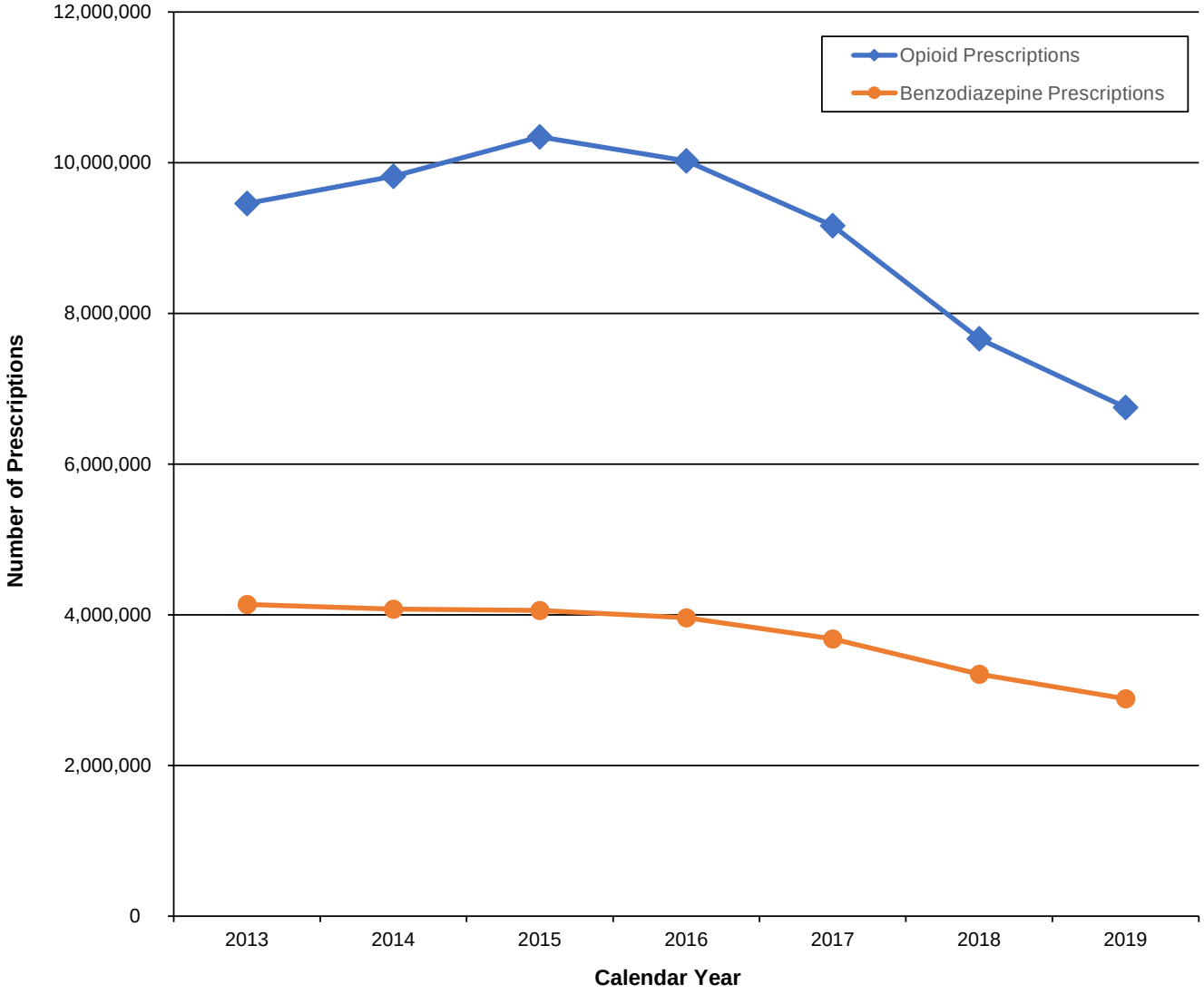
BPL's Drug Utilization Reports indicated that opioid prescriptions and all controlled substance prescriptions dispensed in Michigan decreased by 25.9% and 17.9%, respectively, from calendar years 2015 through 2018.

Source: The OAG prepared this exhibit using BPL's Drug Utilization Reports from calendar years 2010 through 2019.

* *See glossary at end of report for definition.*

MICHIGAN AUTOMATED PRESCRIPTION SYSTEM
Department of Licensing and Regulatory Affairs

Opioid and Benzodiazepine Prescriptions by Year
Calendar Years 2013 Through 2019



The opioids and benzodiazepines presented in this exhibit are classified as Schedule II through V and Schedule IV controlled substances, respectively, based on the drug.

Source: The OAG prepared this exhibit using BPL's Drug Utilization Reports from calendar years 2013 through 2019.

PROGRAM AND SYSTEM DESCRIPTION

BPL's mission is to protect, preserve, and improve the health, safety, and welfare of the citizens of Michigan through licensing and regulation of occupational and health professionals. BPL's Enforcement Division's mission is to identify violations of the public health and occupational codes, hold licensees accountable to their professional obligations under the law, and provide relevant information to the public.

BPL's Enforcement Division administers MAPS, provides guidance and support to MAPS users and other stakeholders, analyzes MAPS data, and identifies potential abuse, diversion, and overprescribing of controlled substances at the prescriber and dispenser level for follow-up or potential investigation.

MAPS is Michigan's PDMP, established in 2003 to track the dispensation of controlled substances. On April 4, 2017, LARA replaced the original MAPS application with a vendor hosted and managed application that is also used by 43 other states. The new application includes functionality that facilitates data sharing among Michigan, 31 other participating states, Washington D.C., and the U.S. Military Health System as of September 16, 2019. The new application also includes a module that attaches risk scores and potential red flags to the patient's prescription history report to aid prescribers in their patient care.

During fiscal year 2019, LARA expended $2.6 million for MAPS and related administrative costs. As of November 15, 2019, BPL had six full-time MAPS section employees.

AUDIT SCOPE, METHODOLOGY, AND OTHER INFORMATION

AUDIT SCOPE

To examine MAPS, BPL's use of MAPS data, and related records. 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.

As part of the audit, we considered the five components of internal control* (control environment, risk assessment, control activities, information and communication, and monitoring activities) relative to the audit objectives and determined that all components were significant.

PERIOD

Our audit procedures, which included a preliminary survey, audit fieldwork, report preparation, analysis of agency responses, and quality assurance, generally covered October 1, 2017 through December 31, 2019.

METHODOLOGY

We conducted a preliminary survey to gain an understanding of BPL's operations and MAPS. During our preliminary survey, we:

- Interviewed BPL management and staff to gain an understanding of their organizational structure, responsibilities, and activities.
- Reviewed applicable laws, policies, procedures, and guidelines.
- Analyzed MAPS expenditures incurred from October 1, 2017 through November 12, 2019.
- Conducted cursory review of available MAPS reports, including top practitioner, delinquent submitter, and prescriber scorecards. We also analyzed BPL's annual drug utilization reports for calendar years 2015 through 2018.
- Obtained an understanding of and assessed internal control applicable to BPL and MAPS.
- Researched Michigan's prescription drug issues, with an emphasis on opioids.

** See glossary at end of report for definition.*

- Reviewed the prescription record submission process for dispensers who cannot submit electronically.

OBJECTIVE #1

To assess the sufficiency of BPL's efforts to ensure compliance with the laws and rules governing MAPS.

To accomplish this objective, we:

- Reviewed 43 of the 551 prescription records audited by BPL from June 25, 2018 through June 30, 2019 to assess the effectiveness of BPL's prescription audit process for verifying the accuracy of MAPS prescription records submitted by pharmacies and correcting data errors when identified.

- Reviewed BPL's process for following up prescription record submission errors.

- Compared non-veterinarian prescriptions written in calendar year 2019 with patient history report requests to assess prescriber compliance by prescription. We conducted further analysis of:

    - 43 of the 8,828,224 prescriptions for which it appeared that the prescriber had run at least one history report for the patient.

    - 43 of the 4,124,481 prescriptions for which it appeared that the prescriber had never run a history report for the patient.

- Reviewed 25 of the 264,312 prescriptions written by veterinarians from June 1, 2018 through December 31, 2019 to assess prescriber compliance with the patient history report request requirement.

- Researched zero-reporting requirements in other states and analyzed the impact zero-reporting could have in Michigan.

- Reviewed BPL's process for identifying and following up unregistered prescribers. We also summarized MAPS prescription data by prescriber and compared the results with prescribers registered in MAPS. We reviewed MAPS registration and licensing data for 43 of the 24,173 prescribers who had written a prescription from October 1, 2017 through November 13, 2019 and did not appear to be registered in MAPS and used the results of this review to estimate compliance with mandatory registration.

- Analyzed prescription records for missing fields that were required and values that were anomalous or did

not meet validation requirements to ensure that MAPS data was reliable for purposes of our analysis.

Our samples were randomly selected to eliminate bias and enable us to project the results to the respective populations.

OBJECTIVE #2

To assess the sufficiency of BPL's efforts to use MAPS data to assist in the prevention of abuse, diversion, and overprescribing of controlled substances.

To accomplish this objective, we:

- Researched PDMP data for the 6 HHS Region 5 states (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin). We compared information of the 5 states for which PDMP data was available.

- Compared the information included in the quarterly reports sent to opioid prescribers with best practice guidance developed by the PDMP Training and Technical Assistance Center led by Brandeis University and supported by the Bureau of Justice Assistance for the U.S. Department of Justice.

- Reviewed quarterly prescription data summary reports and other supporting documentation for 43 of 330,442 opioid prescribers and quarter combinations from October 1, 2017 through December 31, 2019 to determine whether the reports were issued to opioid prescribers registered in MAPS.

- Gained an understanding of BPL developed risk factors used to evaluate prescribers and dispensers for potential improprieties. We reviewed 20 of the 195 memorandums forwarded to BPL's Pharmacy/Drug Monitoring Section as of January 22, 2020 in which MAPS section employees suggested an investigation of a dispenser or prescriber.

- Analyzed MAPS data for Schedule II through Schedule IV controlled substance prescriptions dispensed from October 1, 2017 through December 31, 2019 for indicators of noncompliance with Board of Pharmacy Administrative Rules related to refills and fill date timing.

- Reviewed publicly available reports related to MAPS, such as BPL's 2018 and 2019 drug utilization reports and the outcomes study contracted to help evaluate MAPS's impact. We also validated the accuracy of selected reported statistics.

- Analyzed MAPS data for prescriptions dispensed from October 1, 2017 through December 31, 2019 for

potential risk factors at the prescriber and dispenser level. Compared the results of this analysis to BPL's processes for identifying high-risk prescribers and dispensers.

- Summarized patient history reports run or requested in MAPS by user role and identified how many were initiated by MAPS section employees and BPL regulation agent users.

- Reviewed documentation of award recognition for BPL's processes related to MAPS.

Our samples were randomly selected to eliminate bias and enable us to project the results to the respective populations.

OBJECTIVE #3

To assess the effectiveness of select LARA security and access controls over MAPS.

To accomplish this objective, we:

- Gained an understanding of MAPS's user approval and recertification requirements.

- Reviewed the confidentiality agreements for the six MAPS section employees who had administrator access to MAPS as of November 13, 2019.

- Compared MAPS application security settings with those required by the State of Michigan Technical Standards.

- Reviewed the user privileges and role design for each of the 35 MAPS user roles.

- Compared the 78,821 MAPS users, active as of November 13, 2019, with MiPLUS and HRMN and reviewed LARA's user recertification process.

- Reviewed the registration forms for 43 of 2,562 MAPS users who had law enforcement, government agency, or benefit plan manager roles as of November 13, 2019 for proper approval.

- Assessed controls in place to monitor for unusual or suspicious activities for MAPS administrator users.

- Assessed LARA's process for evaluating the operating effectiveness of the controls managed by the TPSO responsible for MAPS, including:

    - Reviewing 20 of the 192 NIST controls covered by the MAPS SSP to determine whether the operating effectiveness of the controls was verified.

- Reviewing third-party assurance reports obtained by LARA.

- Reviewed 14 of the 136 hard-copy MAPS report requests received during October, November, and December 2019 for proper approval and secure transmission. We also reviewed 43 of the 44,373 approved law enforcement, government agency, and benefit plan manager electronic requests initiated from October 1, 2017 through December 31, 2019 for proper approval.

Our samples were randomly selected to eliminate bias and enable us to project the results to the respective populations.

CONCLUSIONS

We base our conclusions on our audit efforts and any resulting material conditions or reportable conditions.

When selecting activities or programs for audit, we direct our efforts based on risk and opportunities to improve State government operations. Consequently, we prepare our performance audit reports on an exception basis.

AGENCY RESPONSES

Our audit report contains 4 findings and 4 corresponding recommendations. LARA's preliminary response indicates that it agrees with all of the recommendations.

The agency preliminary response that follows each recommendation in our report was taken from the agency's written comments and oral discussion at the end of our fieldwork. Section 18.1462 of the *Michigan Compiled Laws* and the State of Michigan Financial Management Guide (Part VII, Chapter 4, Section 100) require an audited agency to develop a plan to comply with the recommendations and to submit it to the State Budget Office upon completion of an audit. Within 30 days of receipt, the Office of Internal Audit Services, State Budget Office, is required to review the plan and either accept the plan as final or contact the agency to take additional steps to finalize the plan.

SUPPLEMENTAL INFORMATION

Our audit report includes supplemental information presented as Exhibits #1 through #3. Our audit was not directed toward expressing a conclusion on this information.

GLOSSARY OF ABBREVIATIONS AND TERMS

access controls	Controls that protect data from unauthorized modification, loss, or disclosure by restricting access and detecting inappropriate access attempts.
availability	Timely and reliable access to data and information systems.
benzodiazepines	A type of prescription sedative commonly prescribed for anxiety or to help with insomnia. Benzodiazepines work to calm or sedate a person, by raising the level of the inhibitory neurotransmitter GABA in the brain. Common benzodiazepines include diazepam, alprazolam, and clonazepam.
BPL	Bureau of Professional Licensing.
confidentiality	Protection of data from unauthorized disclosure.
controlled substance	A drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of the federal Controlled Substances Act (Title 21, section 801, et seq., of the United States Code), which controls the manufacture, distribution, and dispensing of controlled substances. As used in this report, controlled substance refers to Schedule II through Schedule V controlled substances, unless indicated otherwise, as these are the only controlled substances that can be legally prescribed and meant to be tracked in MAPS.
DEA	Drug Enforcement Agency.
effectiveness	Success in achieving mission and goals.
Federal Risk and Authorization Management Program (FedRAMP)	A government-wide program that provides a standardized approach to security assessment, authorization, and continuous monitoring for cloud products and services.
FMG	State of Michigan Financial Management Guide.
HHS	U.S. Department of Health and Human Services.
HHS Region 5	Includes the states of Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin.

HRMN	Human Resources Management Network.
hydrocodone combination products	Drugs that contain both hydrocodone, a Schedule II controlled substance, and specified amounts of other substances, such as acetaminophen or aspirin.
ID	identification.
integrity	Accuracy, completeness, and timeliness of data in an information system.
internal control	The plan, policies, methods, and procedures adopted by management to meet its mission, goals, and objectives. Internal control includes the processes for planning, organizing, directing, and controlling program operations. It also includes the systems for measuring, reporting, and monitoring program performance. Internal control serves as a defense in safeguarding assets and in preventing and detecting errors; fraud; violations of laws, regulations, and provisions of contracts and grant agreements; or abuse.
LARA	Department of Licensing and Regulatory Affairs.
material condition	A matter that, in the auditor's judgment, is more severe than a reportable condition and could impair the ability of management to operate a program in an effective and efficient manner and/or could adversely affect the judgment of an interested person concerning the effectiveness and efficiency of the program. Our assessment of materiality is in relation to the respective audit objective.
Michigan Automated Prescription System (MAPS)	Web-based application that serves as Michigan's PDMP. MAPS is used to track controlled substances dispensed in Michigan. It is also used by prescribers and dispensers to assess patient risk to prevent drug abuse and diversion at the prescriber, pharmacy, and patient levels.
MiPLUS	Michigan Professional Licensing User System.
mission	The main purpose of a program or an entity or the reason that the program or entity was established.
National Institute of Standards and Technology (NIST)	An agency of the Technology Administration, U.S. Department of Commerce. NIST's Computer Security Division develops standards, security metrics, and minimum security requirements for federal programs.

observation	A commentary that highlights certain details or events that may be of interest to users of the report. An observation may not include all of the attributes (condition, effect, criteria, cause, and recommendation) that are presented in an audit finding.
opioids	A class of drug naturally found in the opium poppy plant. Opioids are often used as medicines because they contain chemicals that relax the body and can relieve pain. Prescription opioids are used mostly to treat moderate to severe pain.
performance audit	An audit that provides findings or conclusions based on an evaluation of sufficient, appropriate evidence against criteria. Performance audits provide objective analysis to assist management and those charged with governance and oversight in using the information to improve program performance and operations, reduce costs, facilitate decision-making by parties with responsibility to oversee or initiate corrective action, and contribute to public accountability.
prescription drug monitoring program (PDMP)	Electronic database that tracks controlled substance prescriptions dispensed. The MAPS is Michigan's PDMP.
Process Excellence Network (PEX)	A community of business transformation and process excellence professionals.
reportable condition	A matter that, in the auditor's judgment, is less severe than a material condition and falls within any of the following categories: a deficiency in internal control; noncompliance with provisions of laws, regulations, contracts, or grant agreements; opportunities to improve programs and operations; or fraud.
security	Safeguarding an entity's data from unauthorized access or modification to ensure its availability, confidentiality, and integrity.
SSP	System Security Plan.
System and Organization Controls (SOC) report	Designed to help organizations that provide services to user entities build trust and confidence in their delivery processes and controls through a report by an independent certified public accountant (CPA). Each type of SOC report is designed to meet specific user needs: • SOC 1 (Report on Controls at a Service Organization Relevant to User Entities' Internal Control Over Financial Reporting) - Intended for user entities and the CPAs auditing their financial statements in evaluating the effect of the service organization's controls on the user entities' financial statements.

- SOC 2 (Report on Controls at a Service Organization Relevant to Security, Availability, Processing Integrity, Confidentiality, or Privacy) - Intended for a broad range of users that need information and assurance about a service organization's controls relevant to any combination of the five predefined control principles.

  There are two types of SOC 1 and SOC 2 reports:

  - Type 1 - Reports on the fairness of management's description of a service organization's system and the suitability of the design of the controls to achieve the related control objectives included in the description, as of a specified date.

  - Type 2 - Includes the information in a type 1 report and also addresses the operating effectiveness of the controls to achieve the related control objectives included in the description, throughout a specified period.

- SOC 3 (Trust Services Report for a Service Organization) - Intended for those needing assurance about a service organization's controls that affect the security, availability, or processing integrity of the systems a service organization employs to process user entities' information, or the confidentiality or privacy of that information, but do not have the need for or the knowledge necessary to make effective use of a SOC 2 report.

- SOC for Cybersecurity. Intended to communicate relevant information about the effectiveness of an organization's cybersecurity risk management programs.

TPSO	third party service organization.

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