



October 20, 2022

Status Report – Prescription Drug Monitoring Program

Members of the Legislative Audit Committee:

Attached is the status report from the Department of Regulatory Agencies (Department) on its implementation of recommendations contained in the Office of the State Auditor's June 2021 *Prescription Drug Monitoring Program (PDMP) Performance Audit*.

OSA Review of Documentation

As part of the status report process, we requested and received supporting documentation for each recommendation that the Department reported as having been implemented or partially implemented. For example, we reviewed:

- The 2021-2022 Report from the Colorado Consortium for Prescription Drug Abuse Prevention Task Force (Task Force).
- The PDMP registration enforcement policies developed by Colorado healthcare boards and revised pharmacy rules and policies related to PDMP.
- The Department's PDMP database vendor reports, such as on prescribing practices, patients who are exempt from reporting, reverification of PDMP database users, as well as pharmacy zero reports and 14-Day warning letters.
- The Department's amended contract with the current PDMP database vendor, and the Request for Proposal for the vendor contract that will be effective November 1, 2022.

Based on our review, the supporting documentation substantiates the Department's reported implementation statuses. As noted in the status report, the Department has not fully implemented recommendations 3C and 3D, and does not plan to take further action to implement them, as it

agreed to during the audit. The Department reports that it lacks the statutory authority to share PDMP data with the healthcare boards, and that the Task Force does not recommend that the Department share PDMP information with the boards for the purpose of enforcement.



COLORADO

**Department of
Regulatory Agencies**

Division of Professions and Occupations

October 13, 2022

Kerri L. Hunter, CPA
State Auditor
Colorado Office of the State Auditor
1525 Sherman St., 7th Floor
Denver, CO 80203

Dear Auditor Hunter:

In response to your request, the Department of Regulatory Agencies has prepared the attached status report on the implementation status of audit recommendations contained in the Colorado Prescription Drug Monitoring Program performance audit report. The report provides a brief explanation of the actions taken by the Department of Regulatory Agencies to implement each recommendation.

The Department appreciates the opportunity to provide an update on the progress of our implementation of the committee's audit recommendations. We value the continued collaboration and communication with the Auditor's office and this committee. The process and the experience has improved the program and directly benefits the public. We are happy to report on the many positive steps in implementing the recommendations from the Audit Report, many of which were completed well ahead of the anticipated implementation date. The PDMP is a critical link in Colorado's fight against opioid addiction, misuse, overdose, and diversion and the Department is committed to ensuring it functions as efficiently and effectively as possible.

If you have any questions about this status report and the Department's efforts to implement the audit recommendations, please contact Ronne Hines, Division Director, Division of Professions and Occupations, at 303-894-7770 or ronne.hines@state.co.us.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Patty Salazar'.

Patty Salazar, Executive Director
Department of Regulatory Agencies

Audit Recommendation Status Report

Audit Name:	Colorado Prescription Drug Monitoring Program Performance Audit
Audit Number:	1933P
Agency:	Department of Regulatory Agencies
Date of Status Report:	October 13, 2022

Section I: Summary

Rec. Number	Response from Audit Report	Original Implementation Date	Current Implementation Status	Current Implementation Date
1A	Agree	January 2023	Implemented	September 2022
1B	Agree	January 2023	Implemented	July 2022
1C	Agree	January 2023	Implemented	July 2022
2A	Agree	July 2023	Partially Implemented	July 2023
2B	Agree	July 2023	Partially Implemented	July 2023
3A	Agree	July 2023	Implemented	October 2022
3B	Agree	July 2023	Implemented	August 2021
3C	Agree	January 2023	Partially Implemented ¹	July 2022
3D	Agree	September 2023	Not Implemented ²	N/A
4A	Agree	May 2022	Implemented	November 2021
4B	Agree	September 2022	Implemented	November 2021
4C	Agree	September 2022	Implemented	July 2021
5A	Agree	June 2022	Implemented	October 2021
5B	Agree	June 2022	Implemented	September 2021
5C	Agree	June 2022	Implemented	September 2021

¹ No further implementation to be done for this recommendation-see narrative.

² No implementation to be done for this recommendation-see narrative.

Section II: Narrative Detail

Recommendation 1A

The Department of Regulatory Agencies (Department) should work with the General Assembly to improve the effectiveness of Colorado's Prescription Drug Monitoring Program (PDMP) in meeting its legislative intent to address prescription drug misuse, abuse, and diversion by proposing that the General Assembly consider whether statute should be amended to require:

- A. Prescribers to check the PDMP database before prescribing each opioid and, at least, before prescribing each benzodiazepine.

Current Implementation Status	Implemented
Current Implementation Date	SB22-027 on 5/27/2022 & HB22-1115 on 9/5/2022
Status Update Narrative	<p>The Department worked with the General Assembly prior to the 2022 session to help draft bill language to improve the effectiveness of Colorado's PDMP. Specifically, the Department focused on language that changed the statute to require prescribers to check the PDMP database before prescribing any opioid and any benzodiazepine.</p> <p>SB22-027, which was signed into law and became effective upon signature, and HB22-1115, which was signed into law and became effective 90 days after adjournment, include this recommendation and no rulemaking is required to implement this statutory requirement. The Department communicated with prescribers and pharmacists about both of these bills, which included email blasts, live webinars, and a recorded training webinar.</p>

Recommendation 1B

The Department should work with the General Assembly to improve the effectiveness of Colorado's PDMP in meeting its legislative intent to address prescription drug misuse, abuse, and diversion by proposing that the General Assembly consider whether statute should be amended to require:

- B. The Department to develop criteria to identify patients who appear to be doctor shopping, and based on the criteria, refer those patients to law enforcement, as appropriate.

Current Implementation Status	Implemented
Current Implementation Date	7/1/2022
Status Update Narrative	<p>Pursuant to statute (12-280-404, C.R.S.), the Board of Pharmacy sets thresholds that identify such patients for prescribers and pharmacies. Based on this audit recommendation, the Department revisited existing criteria for sending unsolicited reports and presented them for review and discussion at the September 16, 2021 Board meeting. After review and discussion, the Board decided that the current thresholds were appropriate and effective, and therefore decided no change was necessary.</p> <p>The Department worked with the General Assembly on this recommendation and, as a result, SB22-027 required the Department to work with the PDMP Task Force to "evaluate and</p>

	<p>make recommendations to the Executive Director, after engaging in a stakeholder process, regarding balancing the program as a healthcare tool with the enforcement of Article 280” (the establishment of the PDMP is housed in Article 280). The Department worked with relevant healthcare Boards, the Colorado Consortium for Prescription Drug Abuse Prevention (Task Force), and through a stakeholder process to collect feedback for the report to evaluate the effectiveness of unsolicited reporting.</p> <p>The Task Force Report concluded that the General Assembly should proceed with caution when considering changes to current law regarding licensing board access and unsolicited reporting from the PDMP as it could not find evidence demonstrating PDMP data access by law enforcement and licensing Boards improves patient safety.</p>
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Recommendation 1C

The Department should work with the General Assembly to improve the effectiveness of Colorado’s PDMP in meeting its legislative intent to address prescription drug misuse, abuse, and diversion by proposing that the General Assembly consider whether statute should be amended to require:

- C. The Department to develop criteria to identify prescribers who fall significantly outside of prescribing norms and limits for their specialty, and based on the criteria, refer them to the appropriate regulatory board or law enforcement for investigation, as appropriate.

Current Implementation Status	Implemented
Current Implementation Date	7/1/2022
Status Update Narrative	<p>In alignment with this recommendation, SB22-027 required the Department to work with the PDMP Task Force to “evaluate and make recommendations to the Executive Director after engaging in a stakeholder process, regarding balancing the program as a healthcare tool with the enforcement of Article 280” (the establishment of the PDMP is housed in Article 280). The Department worked with relevant healthcare Boards, the Colorado Consortium for Prescription Drug Abuse Prevention (Task Force), and through a stakeholder process to collect feedback for the report to evaluate the effectiveness of providing information to law enforcement for investigation.</p> <p>The Task Force Report concluded that the General Assembly should proceed with caution when considering changes to current law enforcement access to PDMP data and does not recommend changes to Colorado law regarding law enforcement access to the PDMP. The evaluation could not find evidence that lowering barriers to law enforcement access was associated with beneficial outcomes to patients or decreased aberrant controlled substance prescribing.</p>

Recommendation 2A

The Department should ensure that Colorado prescribers and pharmacists register as users of the PDMP database, as statutorily required, so that they can use it to help prevent opioid misuse and abuse, by:

- A. Implementing controls, such as automated controls in the new licensure system and manual processes until the new system is implemented, to identify licensed prescribers and pharmacists who are unregistered as PDMP database users, notify them of their noncompliance, and require them to register, such as before they can renew their professional licenses.

Current Implementation Status	Partially Implemented
Current Implementation Date	July 2023
Status Update Narrative	<p>The Department has contracted with its vendor to develop the new licensing platform, which will include automated controls to identify and require licensed and DEA-registered prescribers and licensed pharmacists to register with the PDMP. The vendor anticipates the new system will go into production in 2023. Corresponding technological requirements were also included in the PDMP RFP and are also included in the current PDMP contract.</p> <p>Until such a time where technology can be leveraged to require registration through the licensing system, the Department used manual processes to increase registration such as active attestations of PDMP registration during license renewal, added a field for practitioners to add their DEA number, provided PDMP training sessions, and communications regarding providers' legal requirement to register and maintain a PDMP account.</p>

Recommendation 2B

The Department should ensure that Colorado prescribers and pharmacists register as users of the PDMP database, as statutorily required, so that they can use it to help prevent opioid misuse and abuse, by:

- B. Working with the healthcare profession boards to develop and implement mechanisms to enforce prescribers and pharmacists to register, such as a fine for those who do not comply with the registration requirement, within a certain amount of time of obtaining or renewing a professional license.

Current Implementation Status	Partially Implemented
Current Implementation Date	July 2023
Status Update Narrative	<p>The Department worked with all of the healthcare profession Boards to develop and implement consistent PDMP registration enforcement policies. As a result, all six healthcare provider Boards and the Board of Pharmacy delegated authority to the Department to open Board-initiated actions for possible PDMP registration violations and issue determination as provided in policy. During the review of complaints that the Department receives against health care providers, a process has been implemented that manually verifies if the respondent in the complaint is in compliance with</p>

	<p>their registration requirement, and if not, an enforcement process follows.</p> <p>In addition to the manual enforcement process, the Department is working with both the new licensing system vendor as well as the newly contracted PDMP vendor, to align registration interoperability requirements, where possible, to enhance pathways towards registration enforcement. For example, prescribers and pharmacists who aren't already registered will be required to do so by the registration system while going through the registration process. The Department will work with the Boards to ensure enforcement for those who do not comply with the requirement within a set amount of time.</p>
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Recommendation 3A

The Department should ensure that prescribers comply with statute to query the PDMP database and adhere to statutory limits on opioid prescriptions by:

- A. Working with its PDMP database contractor to implement the functionality to, at a minimum:
 - i. Track and monitor whether prescribers query the database before prescribing a second opioid prescription.
 - ii. Identify patients who are exempt from queries and state prescribing limits.
 - iii. Identify prescribers that exceed statutory prescribing limits.
 - iv. Implement controls to ensure data accuracy in fields needed to determine statutory compliance, such as days' supply and refill fields.

Current Implementation Status	Implemented
Current Implementation Date	Effective 10/1/2022
Status Update Narrative	<p>The Department worked with its current PDMP database vendor to implement a requirement that the vendor provide monthly reports addressing 3Ai, 3Aii, and 3Aiii. In regards to 3Aiv, the Department worked with the vendor to implement controls for data accuracy.</p> <p>The PDMP vendor has also implemented controls to require that prescriptions submitted to the PDMP have a Days Supply value between 1 and 366, and the Quantity Dispensed value to be between 0.001 and 5400. This ensures that prescriptions with Days Supply and Quantity values of 0 or above realistic maximum thresholds are blocked from being uploaded and instead generate fatal errors which require correction by the pharmacy.</p> <p>In addition, in 2021, the Department released an RFP to procure a PDMP database vendor effective 7/1/22. That RFP included these requirements and the resulting contract does as well. The contract has been finalized and is going through the signature process currently. The effective date of the contract will be 11/1/2022.</p>

Recommendation 3B

The Department should ensure that prescribers comply with statute to query the PDMP database and adhere to statutory limits on opioid prescriptions by:

- B. Implementing a method(s) to make querying the PDMP database more efficient. This may include, but should not be limited to, implementing a method to help integrate DEA licensed prescribers' electronic health records in the State with the PDMP database.

Current Implementation Status	Implemented
Current Implementation Date	8/31/2021
Status Update Narrative	<p>All registered users are able to access the PDMP database in any internet browser, and those that work with electronic health records can be directly integrated into the PDMP. In addition, based on this recommendation, the Department has been working with another organization that offers an integration pathway, RxCheck, that comes at no integration cost to the user (licensed prescriber) or their organization. RxCheck was implemented, pursuant to HB 21-1276, and has been available since 8/31/2021, which has further helped integrate DEA licensed prescribers' electronic health records with the PDMP database.</p> <p>In addition, pursuant to HB 22-1115, the Department will be implementing integration funding opportunities for providers throughout Colorado. The Gateway integration option currently requires organizations to pay access fees and the large majority of PDMP integrations are through PMP Gateway. Regardless of the integration pathway, health IT vendors often charge PDMP integration implementation fees. Pursuant to HB 22-1115 (Section 12-280-403(10), C.R.S.), the Department will implement a process to offset some or all of these implementation costs. Organizations, in collaboration with their IT vendor, have a choice in which integration pathway is the best option for them.</p>

Recommendation 3C

The Department should ensure that prescribers comply with statute to query the PDMP database and adhere to statutory limits on opioid prescriptions by:

- C. Working with the General Assembly to clarify, as needed, the Department's authority to share PDMP data with healthcare profession boards.

Current Implementation Status	Partially Implemented with no further implementation planned.
Current Implementation Date	7/1/2022
Status Update Narrative	<p>As directed in this recommendation, the Department worked with the General Assembly to clarify the Department's authority to share PDMP data with healthcare profession Boards. This work was captured in SB22-027, which did not clarify the Department's authority to share PDMP data with healthcare profession boards, and instead required the Department to work with the PDMP Task Force to evaluate and make recommendations to the Executive Director regarding balancing the program as a healthcare tool with enforcement by sharing PDMP data with the healthcare licensing Boards.</p>

	<p>Toward this end, the Department worked with relevant healthcare Boards, the Colorado Consortium for Prescription Drug Abuse Prevention (Task Force), and stakeholders to collect feedback and evaluate the effectiveness of providing unsolicited PDMP reports to licensing Boards and provided this information to the PDMP Task Force.</p> <p>The Task Force Report recommended the General Assembly proceed with caution when considering changes to the Department's authority to share PDMP data with healthcare profession Boards, concluding it does not recommend such reporting to Boards for the purposes of enforcement. The evaluation could not find evidence that sharing data with healthcare Boards was associated with beneficial outcomes to patients or decreased aberrant controlled substance prescribing.</p>
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Recommendation 3D

The Department should ensure that prescribers comply with statute to query the PDMP database and adhere to statutory limits on opioid prescriptions by:

- D. Working with the relevant healthcare profession boards to implement processes to notify the boards of prescribers who do not comply with the statutory requirement for querying the PDMP database or with limits on opioid prescriptions, and developing enforcement mechanisms for prescribers with ongoing noncompliance.

Current Implementation Status	Not Implemented with no implementation planned
Current Implementation Date	N/A
Status Update Narrative	<p>The Department agreed to implement enforcement mechanisms to the extent they are statutorily and technologically possible, and worked with relevant healthcare profession Boards, the Consortium, and the Task Force to collect stakeholder feedback to evaluate this request. The conclusion was that current Colorado law does not allow for PDMP data to be used for unsolicited reporting to licensing boards, which prevents implementing proactive enforcement mechanisms. Regarding whether the law should be changed to allow this, the PDMP Annual Report reflected the conclusion of the stakeholder process that the General Assembly should proceed with caution when considering unsolicited reporting to licensing Boards and recommend the law not be changed to allow for reporting to Boards for the purposes of enforcement. This also aligned with the legislative evaluation requirement in SB22-027 regarding balancing the PDMP as a healthcare tool versus enforcement.</p> <p>The 2021 Task Force Report also evaluated the collection of patient diagnostic information necessary to identify potential prescriber non-compliance with statute. The report concluded that collecting such diagnostic information is not allowed by Colorado statute, which limits the data elements that can be collected to those necessary to determine compliance and enforcement.</p>

Recommendation 4A

The Department should work with the State Board of Pharmacy to ensure pharmacies comply with rules to submit all dispensed controlled substance prescriptions to the PDMP database timely, by:

- A. Requiring zero reports from all pharmacies when they do not dispense controlled substances during that business day, using the reports to identify pharmacies that are noncompliant with rules for submitting data, and following-up to ensure the pharmacies submit prescription data timely.

Current Implementation Status	Implemented
Current Implementation Date	11/30/2021
Status Update Narrative	<p>The Board of Pharmacy approved updates to Rule 23.00.30 at its September 30, 2021 Rulemaking hearing, which took effect on November 30, 2021. Rule 23.00.30(b) requires pharmacies to submit Zero Reports for dates in which the pharmacy was open for business but had no prescriptions to report to the Colorado PDMP. Rule 23.00.30(c) and (d) require pharmacies to submit an Exemption/Waiver form to attest that the pharmacy does not dispense controlled substances to Colorado patients and to be exempted from PDMP data submission compliance monitoring.</p> <p>Based on these rules, Department staff contacted pharmacies that were delinquent in submitting prescription data or Zero Reports. These changes have enhanced the Department's ability to identify noncompliance and support enforcement to ensure pharmacies submit prescription data timely. Lastly, the technical requirement of zero reporting was included in the PDMP RFP. The Board also approved updates to Policy 30-8 at its March 17, 2022 Board meeting, which provides staff additional flexibility to contact pharmacies regarding isolated delinquencies before resorting to 14-Day warning letters.</p>

Recommendation 4B

The Department should work with the State Board of Pharmacy to ensure that pharmacies comply with rules to submit all dispensed controlled substance prescriptions to the PDMP database timely, by:

- B. Establishing a process to ensure pharmacies correct data containing errors timely, and resubmit that data in line with rule.

Current Implementation Status	Implemented
Current Implementation Date	11/30/2021
Status Update Narrative	<p>The Department took several actions to improve this process. Pharmacies receive an automated report when data they submit contains errors. Beyond receiving this automated report, Rule 23.00.50 was amended to reduce the timeline for pharmacies to fix errors from 30 days to 10 business days. The Rule also established a process whereby Department staff may work with pharmacies to ensure errors are corrected and resubmitted to the Colorado PDMP and if they do not, may be referred to the Board for discipline.</p>

Recommendation 4C

The Department should work with the State Board of Pharmacy to ensure that pharmacies comply with rules to submit all dispensed controlled substance prescriptions to the PDMP database timely, by:

- C. Developing and implementing enforcement mechanisms, such as penalties, for pharmacies that are consistently noncompliant with rules for submitting data.

Current Implementation Status	Implemented
Current Implementation Date	7/15/2021
Status Update Narrative	<p>The Department worked with the Board of Pharmacy to ensure effective enforcement mechanisms are in place and continues to do so. The Department presented Board of Pharmacy Policy 30-7 (New Pharmacies that Fail to Register and Submit Data) and 30-8 (Pharmacies that Fail to Submit Required Data) for revision consideration at its July 15, 2021 Board meeting. After a discussion, which took into consideration the OSA PDMP Audit Report, the Board decided that there were no updates necessary to both of the policies to enable implementation of this recommendation.</p> <p>Subsequent to Rule 23.00.30(b), (c) and (d) regarding PDMP compliance enforcement going into effect, the Board reviewed Policy 30-8 again at its March 17, 2022 Board meeting and adopted changes, which provides staff additional flexibility to contact pharmacies regarding isolated delinquencies before resorting to 14-Day warning letters. The Board delegated authority to Program staff through this updated policy to allow for more frequency and direct contact with pharmacies to troubleshoot and resolve data delinquencies. The policy outlines an updated enforcement process for situations where such troubleshooting is not able to provide a resolution.</p>

Status Update Narrative

Recommendation 5A

The Department should improve its contract management practices to ensure that the contractor for the PDMP database complies with the Department's contract by:

- A. Improving contract monitoring to ensure timeliness of prescription uploads into the PDMP database, and compliance with uptime and downtime requirements. This could include, but should not be limited to, requiring the contractor to report on its upload times and uptime and downtime percentages; identifying contract noncompliance; following up with the contractor to require it to correct problems identified; and employing contract remedies for ongoing noncompliance, such as withholding payment until problems are addressed.

Current Implementation Status	Implemented
Current Implementation Date	10/5/2021

Status Update Narrative	<p>Per Contract Amendment 7, which was effective October 5, 2021, the Department's vendor, Bamboo Health (formerly Appriss Inc.), provides the Department a monthly Availability and Degradation Report for the previous month. The Report includes system uptime percentages during prime hours, non-prime hours (including scheduled maintenance) and, if applicable, information regarding unscheduled or unexpected system degradations including the date, description of the issue, impact, resolution, and root causes. Since inception of this Report, Bamboo Health has been compliant with its required system uptime percentages and no system degradations have been reported. This requirement is in the new PDMP vendor contract as well.</p> <p>Division also receives a monthly report listing the date and time each prescription is reported to the Colorado PDMP. The Division requested that Bamboo Health determine whether a report could be created regarding the timeliness of prescription uploads into the PDMP database. The Division was advised that prescriptions that are successfully submitted to the PMP Clearinghouse are uploaded to the PDMP database as soon as the prescriptions are processed. The Division has reviewed samples of data submissions and their availability in the PDMP database and has found no evidence of delays in uploading from PMP Clearinghouse to the PDMP database.</p>
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Recommendation 5B

The Department should improve its contract management practices to ensure that the contractor for the PDMP database complies with the Department's contract by:

- B. Working with Appriss to amend the current contract to clarify that the State, including the Department, has access to PDMP data without payment. If the current contractor is not amenable to amending the contract, the Department should ensure future contracts with a PDMP contractor confirm that the State has data access without payment.

Current Implementation Status	Implemented
Current Implementation Date	9/1/2021
Status Update Narrative	<p>The Department worked with the Department's vendor, Bamboo Health (formerly Appriss), to amend the contract to clarify that the State, including the Department, has access to PDMP data without payment. On September 1, 2021, the Department finalized the contract amendment that required the vendor to provide data, including data extracts to fulfill State audits, at no additional cost. The parties also agreed that if the level of effort required to meet any specific State's request regarding the data exceeds 10 hours, the vendor retains the right to pass a fee to the Department. The new contract effective 10/1/2022 with Bamboo Health includes the same requirement. The Contractor also retains the right to exclude any data that is considered to be proprietary. Such proprietary data may include where a vendor-specific patient matching algorithm is used.</p>

Recommendation 5C

The Department should improve its contract management practices to ensure that the contractor for the PDMP database complies with the Department's contract by:

- C. Revising the current Appriss contract to remove the provision related to account deactivation, which is no longer applicable; change the contract payment amount, as applicable; and clarify contractor responsibilities. The Department should also ensure future contracts with a PDMP contractor do not contain the account deactivation provision.

Current Implementation Status	Implemented
Current Implementation Date	9/29/2021
Status Update Narrative	The Department agrees that any contractual provision that is not needed should be removed. After internal discussions and discussions with the Department's vendor, Bamboo Health (formerly Appriss), it was determined that this provision should not be removed and instead processes should be changed to improve account compliance. The Department now receives a daily PDMP user account reverification report from Bamboo Health which identifies user accounts that fail daily reverification due to the user's Colorado professional license or DEA license either changing or going into a non-active status. Staff began using the daily reverification report on September 29, 2021 to either update user account information with updated license information or deactivate the PDMP account, as applicable, within 24 hours of receiving this report. Based on these changes, it was determined the contract provision should remain in the contract.