# OFFICIAL STATE CABINET AGENCY RESPONSE TO THE PERFORMANCE AUDIT ON THE WASHINGTON STATE PRESCRIPTION MONITORING PROGRAM – SEPTEMBER 29, 2022

The Washington State Department of Health (DOH), the Pharmacy Quality Assurance Commission (PQAC), the prescribing boards and commissions, and the Office of Financial Management provide this management response to the State Auditor's Office (SAO) performance audit report received on September 8, 2022.

## SAO PERFORMANCE AUDIT OBJECTIVES

The SAO's audit addressed two objectives:

- Is the program data sufficiently complete, accurate and timely to meet the needs of prescribers and other users when making decisions about patient care?
- Could the state's Prescription Monitoring Program (PMP) system be used to monitor opioid prescribing and dispensing patterns and help reduce opioid abuse and misuse?

## SAO Recommendation to the Legislature in brief:

1. We recommend the Legislature amend state law so that independent state auditors, including the Office of the Washington State Auditor and the Joint Legislative Audit and Review Committee (JLARC), can have the authority to access identifiable PMP data.

**STATE RESPONSE:** We disagree with the recommendation to amend state law so that independent state auditors can access identifiable PMP data.

Using PMP data for enforcement, as the SAO suggested, is not in line with the Legislature's intent to establish a PMP as a database for prescribers and dispensers. The intent is stated in RCW 70.225.020(1):

> ***"…with the intent of eventually establishing an electronic database available in real time to dispensers and prescribers of controlled substances."*** (Chapter 259, Laws of 2007)

We believe the intent of the legislation is clear: the Legislature created the PMP to be an electronic database available to prescribers and dispensers to ensure they are aware of a patient's Schedule II-V prescription history so they can make informed prescriptive decisions.

In 1999, The Institute of Medicine produced the report, *"To Err is Human: Building a Safer Health System."* The report's focus on medication errors led to the PMP. The PMP was designed for prescribers to voluntarily use because they feared reporting to regulatory bodies. That fear is recognized in the 1999 report and consideration of it continued as we initiated and evaluated the PMP.

The performance audit report states that a goal of the audit was to identify problematic prescribing and that the SAO could not achieve that because of the restriction on access to PMP data. PMP data alone cannot accurately identify if a provider's prescribing practice is inappropriate. Subject matter experts (SME) from prescribing professions, PMP epidemiologists, and board and commission members have said to definitively determine if inappropriate prescribing or doctor shopping has occurred, both PMP data and a patient's medical record must be analyzed. Without access to a patient's medical record, PMP data cannot be used to achieve the SAO's stated goal.

The law states that boards and commissions cannot access a patient's medical record without an open investigation into an individual prescriber (RCW 18.71.015 and RCW 18.130.050(11) and (18)). This

limitation on access has been upheld in two court cases (*Seymour v. DOH* and *Yoshinaka v. DQAC*). If Washington begins opening disciplinary cases against providers who prescribed over an arbitrary threshold, many chronic pain and hospice providers and their patients may be disproportionately harmed by these investigations. Additionally, if DOH opens investigations against providers who prescribe over an arbitrary threshold, other important disciplinary cases may take longer as board and commission caseloads increase. Finally, the 2021 American Medical Association (AMA) Overdose Epidemic Report urged the Centers for Disease Control to consider the harm arbitrary thresholds cause pain patients.

Additionally, the performance audit report points to audits in Colorado, Oregon, and Louisiana where auditors could access PMP data to identify potential doctor shopping as an example of why auditors should have access to PMP data. Yet, the SAO's report does not identify the outcomes of those audits and whether there was proof that doctor shopping or better results for patients resulted. As we stated above, PMP data alone cannot identify potential doctor shopping. Using PMP data to identify potential doctor shopping criminalizes patients and harms individuals with substance use disorder without further protecting Washington residents.

According to harm reduction SMEs, there are negative impacts related to the criminalization of drug use that further exacerbate the overdose epidemic. A neuropsychopharmacy article from the National Library of Medicine recognizes that addiction should be treated, not penalized. It also notes that inequitable enforcement targets communities of color, that punishment is ineffective at eliminating substance use disorder, and that there is inequitable access to substance use treatment. An article from World Psychiatry, also from the National Library of Medicine, recommends a public health — rather than criminal justice — approach to drug use disorders. Finally, an article from the National Institute on Drug Abuse outlines how punishing drug use heightens stigma and leads to negative outcomes for many Americans.

**PMP data is highly sensitive, perhaps the most sensitive data possessed by the state. It is important to ensure that when access to PMP data expands, that access increases protections for Washington residents and is in line with the law's original intent.** Patients have an expectation to privacy when meeting with their healthcare provider.

We do not believe that this recommendation meets Washington State Agency Privacy Principles guidance or is in line with the original intent of the law. Of note, during the opioid prescribing rulemaking to implement ESHB 1427 (Chapter 297, Laws of 2017), pain advocates raised strong concerns that an unintended consequence of opioid regulation is that fewer prescribers are willing to prescribe controlled substances. This can leave many patients without access to legitimately needed pain medications. The rules for this law went into effect on January 1, 2019. Since that time, the Washington Medical Commission (WMC) received 44 complaints of under prescribing, and 35 of these occurred immediately after the rules became effective. We saw similar impacts on patient access when the chronic non-cancer pain prescribing rules went into effect in 2013 and an entire community health system discharged their chronic pain patients and refused to prescribe opioids. Regulatory action in the prescribing arena has demonstrable impacts on practitioner action and patient access in Washington.

Additionally, the SAO report uses the audits in the three other states as examples of why the Legislature should amend Washington's statute to allow SAO access to PMP data. However, those states have significant differences in structure and experience.

When we reference the Oregon state audit, we see that law enforcement agencies (LEA)s can only obtain PMP data when there is an active investigation and a valid court order. And, the Colorado state audit shows that regulatory boards and LEAs can only access PMP data with a court order or subpoena. This is not the case in Washington. Our laws state that LEAs, the Drug Enforcement Administration (DEA), and health professional licensing, certification, and regulatory agencies can look up PMP data as part of an investigation without requiring a court order or subpoena.

DOH could not find any outcomes of the audit findings in these other states, on whether the state licensing bodies found that prescribers identified in the audits as overprescribing were ultimately determined to be overprescribing, or if the patients identified as doctor shopping were *actually* doctor shopping. Without compelling outcomes that point to an improvement in patient safety, we do not believe that expanding access to PMP data is in the best interest of Washington residents.

The report notes that auditors could not assess if PMP data alone would be sufficient to identify inappropriate prescribing or doctor shopping. DOH believes that if the PMP data is sufficient, then the other state audits would have included data to demonstrate that.

SAO states a goal of gaining access to PMP data is to identify dangerous prescribing combinations. While experts traditionally say opioids, benzodiazepines, and sleep aids are considered dangerous and higher risk when prescribed together, the Washington prescribing rules do not prohibit co-prescribing these substances. While they require documentation of the medical decision-making, there are numerous clinical reasons why such combinations would be necessary. Almost none of the data contained in the PMP would explain the reasoning for co-prescribing such combinations.

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**Recommendations to the Department of Health:**

**SAO Recommendations 1-5:** To ensure pharmacies are submitting prescription records timely and have clear guidance, we recommend DOH:

1. Continue to work with the Prescription Monitoring Program (PMP) system vendor to develop other methods to monitor pharmacy submissions over time to identify pharmacies with recurring problems.
2. Conduct periodic analyses of PMP data to identify pharmacies that have:
    a. Not regularly submitted prescriptions to the PMP within one business day of distributing
    b. Significant reductions in the number of prescription records uploaded to the PMP compared to their normal activity
3. Once DOH has completed the analyses in recommendations 1 and 2,
    a. Follow up with these pharmacies and provide guidance to help educate them on submission requirements.
    b. Develop a process to determine what steps DOH will need to take to educate pharmacies, how the agency will determine if it is ineffective, and when a complaint should be forwarded to the Pharmacy Commission.
4. Update administrative rules [WAC 256-470-030(3)] to align with state law [RCW 70.225.020(3)(b)] to require pharmacies upload data within one business day of *distributing* prescriptions.
5. Update both rules [WAC 256-470] and the dispenser guide to require pharmacies to include data in the "date sold" field if the prescription has already been sold prior to the time of upload.

**STATE RESPONSE:** DOH agrees to continue collaborating with the PMP vendor around enhancing compliance and identifying pharmacies with recurring problems. DOH also agrees that receiving data in a timely manner is important for two reasons. One, to ensure prescribers have access to a patient's Schedule II-V prescriptions. And two, to conduct periodic analysis of PMP data to identify pharmacies that have not regularly submitted prescriptions within two business days of distributing.

However, between the varying definitions of 'date filled,' not knowing the business schedule of the pharmacies, and the limited tools available to the PMP staff, there are many complexities around tracking one business day uploading.

The PMP system does not currently have the functionality to track what days pharmacies are open. With over 2,300 pharmacies reporting to the Washington PMP, tracking and maintaining pharmacy hours would take a significant amount of staff time. Since there isn't the functionality to track this in the PMP system itself, this would be a manual and inefficient process for staff. It is unclear how much additional staff would be necessary to take on this work. Currently 90% of submissions are received within two business days and only 4% are received past three days. The PMP will prioritize following up with pharmacies that take more than two business days to report dispensing drugs.

DOH agrees to explore this potential functionality with the PMP vendor to determine its feasibility, implementation timeline, and cost to DOH. We agree that pharmacy education is important and pharmacies that refuse to come into compliance should be referred to the Pharmacy Quality Assurance Commission. These compliance processes are in place and are part of the standard compliance work of PMP staff.

DOH will continue to provide guidance to delinquent pharmacies to help educate them on submission requirements. The PMP will also continue to work with the PMP vendor to develop and refine features that will further develop compliance processes within the PMP.

DOH will continue to develop, document, and refine compliance processes. We will explore the best approach to clarifying that pharmacies must upload prescriptions to the PMP within one business day of distributing a prescription. And, to explore the best approach to ensure dispensers report the date they distributed a prescription to a patient.

**Action Steps and Time Frame:**

- Continue to work with the PMP system vendor to explore new methods to monitor pharmacy submissions and develop and refine the compliance module available in the PMP system. *By July 31, 2023.*
- Conduct periodic analysis of PMP data to identify pharmacies not regularly submitting prescriptions to the PMP within two business days. *By July 31, 2023.*
- Work with the PMP vendor to explore the feasibility of new functionality that could track variations in dispenser uploads. *By July 31, 2023.*
- Continue to develop, document, and refine PMP compliance processes and pharmacy education to improve pharmacy submission rates and data accuracy in the PMP. *By July 31, 2023.*
- Review, revise, and document the process for educating uploaders and Pharmacy Commission complaints. *By Jan. 31, 2023.*
- Explore the best approach to clarify to pharmacies that they must upload prescriptions within one business day of dispensing. *By Sept. 30, 2023.*
- Explore the best approach to ensure dispensers report the date a prescription was distributed to a patient. *By Sept. 30, 2024.*

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**SAO Recommendations 6-7:** To ensure errors that prevent pharmacy data from appearing in the PMP database are addressed in a timely manner, we recommend DOH:

6. Establish a process to monitor errors to:
    a. Ensure pharmacies that have a significant number of errors correct them in a timely manner.
    b. Identify common types of errors and determine whether it would be appropriate to provide training or additional guidance to pharmacies.
    c. Notify the Pharmacy Commission if a pharmacy displays a history of excessive errors or fails to correct errors within the required timeline.

7. Establish a timeframe in agency rules to ensure pharmacies correct prescription records in a timely manner. Automatic notifications sent to pharmacies should include the requirements for correcting errors and the consequences for noncompliance.

**STATE RESPONSE:** DOH agrees that PMP error corrections are important for the safety of Washington residents. We will explore developing the functionality to track pharmacies with a significant number of uncorrected errors so that we can increase compliance from pharmacies with the PMP vendor.

DOH agrees to identify the most common error types and provide pharmacy education. As a result of this audit, PMP staff analyzed the most common errors they saw. We determined that the three most common errors involved data fields that are not required in RCW or WAC, are not seen by providers, and are not used by epidemiologists. Based on this analysis, we decided to make those data fields optional, which will significantly diminish the number of existing errors in the system. To date, all outstanding prescriptions with these error types, roughly 7,300, have been pushed into the PMP system by the vendor. DOH appreciates the SAO staff for bringing this to light and will continue to analyze common errors to determine the best course of action to decrease the system error rate.

DOH also agrees to notify the Pharmacy Quality Assurance Commission of pharmacies with excessive uncorrected errors. And, DOH will explore the best approach to set and clarify the timeframe for pharmacies to correct submission errors.

**Action Steps and Time Frame:**

- Establish a new process for tracking errors based around the new compliance tracker from the PMP vendor due in fall of 2022. By *March 31, 2023.*
- Analyze error submissions to determine other common errors and how to best correct them. *By March 2023.*
- Provide training and guidance to pharmacies on common errors and how to avoid and correct them. *By July 31, 2023.*
- Notify PQAC of pharmacies that have excessive errors and fail to correct them. *By March 2023.*
- Begin working with the PQAC to explore guidelines around "excessive errors" for pharmacies and a reporting process. *By July 31, 2023.*
- Explore the best approach to set and clarify a timeframe for error corrections. *By March 31, 2024.*

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**SAO Recommendations 8-9:** To ensure the agency can perform this additional monitoring to periodically check the completeness of the PMP data, described in recommendations 1-6, we recommend DOH:

8. Assess the resources needed to perform this monitoring and determine whether additional funding is needed and should be requested.
9. Clearly document policies and procedures for monitoring pharmacies for compliance, and ensure DOH staff understands and follows them.

**STATE RESPONSE:** DOH agrees to assess the resources it needs to undertake new compliance monitoring work. We also agree to continue to document and train staff on policies and procedures for monitoring pharmacies for compliance.

**Action Steps and Time Frame:**

- Assess new compliance module functionality and determine necessary staff resources based on new features available in the module. *By July 1, 2023.*

- Review, revise, and train staff on existing procedures. Establish new procedures as new functionality and features are available. *By March 31, 2023.*

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**SAO Recommendations 10-11:** To ensure pharmacies that request waivers do not dispense controlled substances, as described on Pages 21-22, we recommend DOH take the following steps to improve the waiver process:

10. Before approving any waiver, check the PMP system to see if the requesting pharmacy has reported distributing any controlled substances in the past
11. Give the Pharmacy Commission a list of the approved waivers

**STATE RESPONSE:** DOH disagrees with the recommendation that staff should look at a pharmacy's uploading history before it approves a waiver. In the past we have performed spot checks for this and have found no violations. Pharmacies often change business practices; thus, past upload history is not a good indicator of current dispensations. The PMP has worked with the vendor to develop features that would enhance the waiver process. We expect a tool by the end of June 2023, that would look for uploads from pharmacies that hold a waiver and withdraw the waiver if any dispensations are uploaded. We will provide the Pharmacy Quality Assurance Commission with a list of pharmacies with these waivers.

**Action Steps and Time Frame:**

- Work with the vendor to schedule the development and release of the waiver withdrawal tool. *By July 1, 2023.*
- Conduct a work session with the PQAC inspectors and the PMP team to develop a system whereby the inspectors can relay the information obtained during their inspections. *By March 31, 2023.*
- Begin providing the Pharmacy Commission with a list of pharmacies that have a waiver from reporting to the PMP because they do not dispense Schedule II-V drugs. *By March 31, 2023.*

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**SAO Recommendations 12-13:** To ensure pharmacies submit all required prescription records to the PMP, as described on Pages 20-21, we recommend DOH:

12. Consult with the agency's assistant attorney general to determine whether DOH has the authority to require pharmacies to perform a reconciliation between the records submitted to the PMP system and their own records.
    - If DOH has that authority, amend WAC 246-470 to require this reconciliation.
    - If DOH does not have the authority, then work with the Legislature to update state law to obtain this authority.
13. Ensure all licensed Washington pharmacies receive the system reports needed to ensure that the pharmacy system reconciles to the PMP system.

**STATE RESPONSE:** DOH agrees to consult with its assistant attorney general to determine if DOH has authority to require pharmacies to perform a reconciliation between the records submitted to the PMP and its records. However, it is unclear if this recommendation is feasible for pharmacies when we consider staff resources and workload. It is also unclear how feasible it would be for DOH and PQAC staff to monitor these reconciliations. Most pharmacies have contracted uploaders who upload daily all records to the corresponding state PMP. DOH is unclear about how this technology functions as each pharmacy chain manages its own processes, contracted uploaders, and software. A statutory change may be necessary for PQAC or DOH to have enforcement authority over non-resident pharmacies for non-compliance with PMP regulatory obligations.

DOH will work with PQAC to explore the feasibility of this recommendation both in terms of pharmacy and PQAC resources. We will also work with the Legislature and PQAC to provide relevant information on the feasibility of requiring these reconciliations.

DOH disagrees with this recommendation to provide reports to pharmacies for reconciliation. It is unclear if it is feasible because each independent or pharmacy chain manages its own processes, contracted uploaders, and software. These entities have independent systems, processes, and procedures, which DOH and PQAC do not have insight into. It is unclear where these system reports would come from or if the software pharmacies use can generate these kinds of reports. Pharmacy processes are independent of DOH and PQAC. There are too many unknowns to determine the viability of this recommendation.

**Action Steps and Time Frame:**

- Consult with an assistant attorney general to determine who has the authority to require pharmacies to perform the recommended reconciliation. *By March 1, 2023.*
- Begin to explore the feasibility of requiring PMP reconciliations with PQAC. *By July 1, 2023.*

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**SAO Recommendation 14:** To help improve and expand opioid prescribing reports to more medical professionals, as described on Pages 25-30, we recommend DOH:

14. Establish a workgroup to discuss the needs of the Better Prescribing, Better Treatment Collaborative. DOH should serve in an advisory role to this workgroup and explore how it could help it achieve its goals. This workgroup should:
    - Involve the Washington State Hospital Association (WSHA) and Washington State Medical Association (WSMA) as owners of the Collaborative.
    - Engage organizations representing Advanced Registered Nurse Practitioners and dentists so the program can be expanded to these professions. It should include other organizations if the workgroup determines it is valuable to do so.
    - Determine roles and responsibilities of workgroup members.
    - Evaluate the funding needed to expand the Collaborative and potential funding sources, such as federal grants and state funding.
    - Develop and set a strategic plan for expanding and further improving the Collaborative. The plan should address:
        - How to involve a professional with expertise from other associations to develop meaningful comparisons in the reports
        - Identifying strategies to enroll new prescribers, including prescribers not affiliated with hospitals or medical groups
        - Identifying process improvements, such as verifying prescribers' email addresses
        - How to provide meaningful reports to prescribers treating chronic pain patients
        - Enhancing reports by including potentially dangerous drug combinations
        - Developing educational activities on safe opioid prescribing
        - In the long term, determine whether there is value in making participation in receiving opioid prescribing reports an opt-out program and if so, what resources would be required

**STATE RESPONSE:** DOH disagrees with this recommendation. The Better Prescribing, Better Treatment (BPBT) Collaborative is an independent body, that is not under the authority of DOH. The Department does not have the resources or expertise to establish a workgroup to discuss the strategic vision for the BPBT Collaborative. As an independent collaborative, it is not bound to follow any suggestions that any convened workgroup by DOH would recommend. Prescriber feedback reports

produced by the BPBT Collaborative are entirely funded by the Washington State Medical Association (WSMA) and Washington State Hospital Association (WSHA) and DOH cannot guarantee funding support. Additionally, as the law is currently written, only WSMA and WSHA can receive the raw PMP data required to develop prescriber feedback reports.

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**Recommendation to the Pharmacy Commission:**

**SAO Recommendation 15:** To ensure pharmacies that request waivers do not dispense controlled substances:

15. Establish a process to review controlled substance dispensing and PMP waivers in its inspections and report back to DOH so that PMP program staff can determine the appropriateness of individual waivers once DOH has implemented the step above in recommendation number 11.

**STATE RESPONSE:** PQAC agrees with the recommendation to include in the inspection process whether a pharmacy has a PMP waiver and dispenses controlled substances and report this information back to the PMP program.

**Action Steps and Timeframe:**

- Conduct a work session with the PQAC inspectors to develop a system to ensure they note whether the pharmacies they inspect dispense controlled substances and whether the pharmacies have a waiver. *By Jan. 31, 2023.*
- Conduct a work session with the PQAC inspectors and the PMP team to develop a system whereby the inspectors can relay the information obtained during their inspections. *By March 1, 2023.*
- Ensure PQAC stakeholders are aware of this component of the inspection process. *By March 15, 2023.*
- Implement these processes. *By March 30, 2023.*

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**SAO Recommendation 16:** To ensure pharmacies submit all required prescription records to the PMP:

16. Incorporate a review of whether pharmacies have completed this reconciliation in their inspections once DOH has implemented the two steps in recommendations 12 and 13.

**STATE RESPONSE:** PQAC disagrees with the recommendation to review in its inspections whether pharmacies have completed this reconciliation once DOH has implemented the two steps in Recommendations 12 and 13.

Pharmacies do not have enough staff to manage current workloads of filling prescriptions, dispensing prescriptions, providing counseling, and administering vaccinations. The additional workload of ensuring all responsible pharmacy managers receive a file status report each day that the pharmacy submits information to the PMP, and that the pharmacy performs a daily reconciliation, is a near impossible task for pharmacies and responsible pharmacy managers to complete. If they had to do this, it would take away staff and time from other tasks and will negatively impact patient care. Adding another component to the inspection process will cause each inspection to take longer, and the commission already does not have enough staff to keep up with its inspections as the number of pharmacies and other pharmaceutical firms in our state has grown while our inspection staff has remained constant.

PQAC must be self-sustaining through its fees. See RCW 43.70.320. This recommendation and those associated with it are broader than the licensing activities of PQAC. (RCW 43.70.320(2))

**SAO Recommendation 17:** To ensure the Commission can perform the additional work described in recommendations 15 and 16:

17. Assess the resources necessary to perform this work and determine whether additional funding is needed and should be requested.

**STATE RESPONSE:** PQAC disagrees with the recommendation to assess the resources necessary to perform this work and determine whether additional funding is needed and should be requested.

As referenced in our response to Recommendation 16, PQAC must be self-sustaining through its fees. In addition, PQAC disagrees that pharmacies should have to complete a daily PMP reconciliation and that its inspectors should audit this during inspections. Therefore, there is no need to assess the resources necessary to perform this work.

It is important to note that PQAC cannot assess and evaluate the financial impact that Recommendation 16 would have on pharmacies and their staff as they are independent businesses.