PERFORMANCE AUDIT

Office of the Washington State Auditor
Pat McCarthy

Prescription Monitoring Program: Evaluating system processes and program oversight

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Executive Summary

State Auditor's Conclusion (page 36)

More than 9,000 Washington residents have died from opioid prescription drug overdoses over the last two decades, according to Department of Health data. Many more have had their lives affected by opioid-use disorders. In 2020, more than a quarter of opioid-related deaths in Washington involved commonly prescribed opioids, according to the Addictions, Drug and Alcohol Institute at the University of Washington. The Department of Health's Prescription Monitoring Program began operating more than 10 years ago to improve patient care, reduce the abuse of controlled substances and help medical professionals reduce overprescribing. Through this independent, in-depth performance audit, our Office has identified detailed steps that will help the relatively small program – it currently has a staff of seven – improve the effectiveness of this system.

Checks to ensure compliance with the program should be improved, such as confirming available prescription information is complete and checking the appropriateness of waivers granted to non-participating pharmacies. Importantly, select independent oversight agencies should be allowed to access prescription data. One goal of this audit was to identify problematic prescribing and dispensing patterns, but we could not perform that analysis due to legal restrictions on program data. State and legislative auditors in other states, such as Colorado, Louisiana and Oregon, have used their access to this type of data to identify instances of doctor and pharmacy shopping by patients, severe cases of overprescribing by health care providers, and prescriptions involving dangerous drug combinations. That level of accountability is needed in Washington, to help prevent drug misuse, overdose and tragedy.

Background (page 6)

When prescription medications are misused or overprescribed, they can contribute to dangerous drug interactions, substance use disorder, overdoses and deaths. Prescription monitoring program (PMP) databases offer medical professionals a tool to help them reduce overprescribing of opioids and other controlled substances. By accessing their state's PMP system, medical professionals can review medications their patients received in the past before prescribing or dispensing new or additional medicines.

Washington's PMP began operating in 2011 and is administered by the Department of Health (DOH). State law requires pharmacies to submit to the PMP system all

Schedule II-V controlled-substance prescriptions that have been given to a patient. In addition, most medical professionals must check the PMP before prescribing controlled substances. The Washington State Hospital Association and the Washington State Medical Association jointly oversee the Better Prescribing, Better Treatment Collaborative, which uses PMP system data from DOH to create opioid prescribing reports. The Collaborative distributes these reports to educate medical professionals about their prescribing practices and how they compare to their peers.

DOH needs a more comprehensive process to ensure PMP data is sufficiently complete and timely to meet the needs of prescribers who are making decisions about patient care (page 15)

To ensure medical professionals have complete information when prescribing, it is important to monitor whether pharmacies have promptly submitted prescription records. DOH does not monitor PMP data to see if pharmacies submit prescription records within one day of distributing a prescription. Until recently, DOH did not contact pharmacies that failed to correct records with errors that the PMP system automatically blocked from uploading. And because DOH does not ensure that pharmacies correct records with errors, prescribers may not have access to complete PMP data. In addition, DOH lacks a process to determine whether pharmacies have submitted all required prescriptions to the PMP system. Overall, DOH has not prioritized monitoring pharmacy compliance with PMP reporting rules.

Improving and expanding opioid prescribing reports to more medical professionals could help provide better patient care (page 25)

Opioid prescribing reports help some of Washington's medical professionals understand their own prescribing activity and how it compares to their peers. Since 2019, the Collaborative has used PMP data to send opioid prescribing reports to medical professionals. Further enhancements to the reports could increase their usefulness to prescribers. Expanding the prescribing reports to other health care professions would require engagement with their associations and additional resources. As the lead state health agency, DOH can bring together stakeholders to help the Better Prescribing, Better Treatment Collaborative improve the reports and expand their reach.

State law does not allow DOH to share PMP identifiable data for the purpose of independent oversight of the program (page 31)

State law restricts access to PMP data to protect patients, prescribers and pharmacies. The restrictions curtail independent oversight that might identify opportunities for improvement. Auditors in other states used PMP data to identify prescribing and dispensing patterns of concern, which we could not replicate due to the data restrictions. In addition, our ability to examine certain system processes was limited. These restrictions in state law inhibited our ability to complete this planned audit work. Furthermore, neither DOH nor the regulatory licensing boards and commissions analyze PMP data in search of those concerning patterns.

Recommendations (page 37)

We recommended the Department of Health perform additional compliance activities and update its administrative rules in the WAC to help ensure pharmacies submit all required prescriptions records in a timely manner. We also recommended DOH participate in a workgroup with the Better Prescribing, Better Treatment Collaborative to help improve and expand opioid prescribing reports to more medical professionals. We also made recommendations to the Pharmacy Commission that it make some additions to pharmacy inspection processes that will help ensure completeness of PMP data. Finally, we made a recommendation to the Legislature to amend state law so that independent auditors, such as 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.

Next steps

Our performance audits of state programs and services are reviewed by the Joint Legislative Audit and Review Committee (JLARC) and/or by other legislative committees whose members wish to consider findings and recommendations on specific topics. Representatives of the Office of the State Auditor will review this audit with JLARC's Initiative 900 Subcommittee in Olympia. The public will have the opportunity to comment at this hearing. Please check the JLARC website for the exact date, time, and location (www.leg.wa.gov/JLARC). The Office conducts periodic follow-up evaluations to assess the status of recommendations and may conduct follow-up audits at its discretion. See **Appendix A**, which addresses the I-900 areas covered in the audit. **Appendix B** contains information about our methodology. See the **Bibliography** for a list of references and resources used to develop our understanding of prescription monitoring programs.

Background

The evolving nature of the opioid epidemic continues to be a concern in Washington

The opioid epidemic across the nation has had far-reaching health and social consequences. It affects not only the people who use the drugs, but the lives of those around them. As a class of drugs, opioids include some prescription medicines commonly referred to as painkillers as well as street drugs such as heroin. When prescription drugs are misused or overprescribed, they can contribute to dangerous drug interactions, substance use disorder, overdoses and deaths. And Washington has not been spared the consequences of opioid misuse.

Over the past two decades, Washington experienced this epidemic in three distinct waves. The state's Opioid and Overdose Response Plan for 2021-2022 reported that the rate of overdose deaths involving prescription opioids significantly increased during the first wave, which started in 1999-2000. Then, an increase in deaths related to heroin and synthetic opioids occurred during the second and third waves, which began in 2010 and 2016, respectively. More than 9,000 Washington residents have died from opioid prescription drug overdoses over the last two decades, according to Department of Health (DOH) data.

Prescription medicines are no longer considered the top contributor to opioid-related deaths in Washington. For example, by 2021, the rate of patients prescribed opioids in our state had dropped by 45 percent since its height in 2015, when nearly one in 10 people were prescribed an opioid. Nonetheless, more than a quarter of opioid-related deaths in 2020 involved commonly prescribed opioids, according to the Addictions, Drug and Alcohol Institute at the University of Washington.

As the Centers for Disease Control and Prevention points out, improving the way opioids are prescribed can still help to reduce the number of people who misuse, abuse or overdose from them. Prescription monitoring programs can be used to help ensure patients retain access to safe, effective pain management while reducing opioid over-prescribing.

State-operated prescription monitoring programs offer medical professionals an important tool to help reduce overprescribing of opioids and other controlled substances

Prescription drug monitoring programs use electronic databases that collect information on those prescription drugs pharmacies must report when they dispense them to patients. State laws vary on which specific prescriptions must be reported to the database, but they typically include drugs assigned to schedules II through IV from the federal Controlled Substances Act. The Act assigns drugs to one of five schedules based on its medical use, potential for abuse and risk of dependence. **Exhibit 1** lists some examples in each of the five schedules. Washington's Prescription Monitoring Program (PMP) also includes drugs in Schedule V.

Exhibit 1 – U.S. Schedules I-V for controlled substances, with examples of drugs in each category

Schedule	Description	Examples
Schedule I	No accepted medical use, high potential for abuse	Heroin, LSD, ecstasy
Schedule II	Accepted medical use, high potential for abuse, potentially leading to severe psychological or physical dependence	Codeine, Demerol, Hydrocodone, morphine, OxyContin, Percocet; psychostimulants such as Adderall and Ritalin
Schedule III	Accepted medical use, less potential for abuse than Schedule I or II drugs, with a moderate to low potential for physical and psychological dependence	Anabolic steroids, ketamine, testosterone, Tylenol with codeine
Schedule IV	Accepted medical use, lower potential for abuse than Schedule III drugs and low risk of dependence	Benzodiazepines such as Xanax, Valium and Ativan
Schedule V	Accepted medical use, lower potential for abuse than Schedule IV drugs	Medicines containing small amounts of certain narcotics, including some cough syrups and pain relievers

Source: Auditor created from sources including U.S. Drug Enforcement Administration (https://www.dea.gov/drug-information/drug-scheduling) and United States Government Accountability Office Report, GAO-21-22, October 2020.

PMP databases contain information about the medical professionals who wrote the prescriptions, the drugs prescribed, the number of times refilled, the pharmacy that dispensed them, and the patient concerned. Due to the sensitive nature of the information contained in these databases, state laws restrict who may view this data in order to protect prescriber, pharmacy and patient privacy.

Health care professionals can use this data to help inform their decisions about patient care

PMP databases allow medical professionals, including pharmacists, to review medicines patients previously received before prescribing or dispensing prescriptions for opioids and other controlled substances. The information is particularly important for professionals such as doctors and nurses because patient records usually reflect only the prescriptions written within their office, hospital or medical group. These internal patient records generally do not include prescriptions written by those outside the group, and a patient may not remember to tell the new doctor about all the medicines they take. The PMP system ideally captures all controlled prescription drugs written and dispensed for a particular patient, and can thus guide the prescriber's decisions about what medicines are safe to prescribe. This helps ensure the prescriber does not duplicate controlled substance prescriptions written by someone else or write a new prescription that might cause a dangerous drug interaction if it is combined with opioids.

Federal agencies have supported the development of PMPs across the United States

Since 2003, the U.S. Department of Justice has supported states as they established and improved their PMPs through the Harold Rogers Prescription Drug Monitoring Program Grant Program, administered by the Bureau of Justice Assistance. Since then, federal grants have also been made available through the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the Centers for Medicare and Medicaid Services. As of September 2021, the Prescription Drug Monitoring Program Training and Technical Assistance Center reported that there are 54 operational prescription monitoring programs across America and three U.S. territories. This includes 49 states; St. Louis County, Missouri; the District of Columbia; and Guam, the Northern Mariana Islands and Puerto Rico. (See the Bibliography for a link to the report: *PDMP Policies and Capabilities: Results From 2021 State Assessment*.)

Washington's Prescription Monitoring Program, under DOH, gives health care professionals access to essential statewide data

The state Legislature established Washington's Prescription Monitoring Program (PMP) in 2007 under RCW 70.225.020, to improve patient care, reduce the abuse of controlled substances and help medical professionals reduce overprescribing. The PMP's electronic database was to store prescription records for Schedule II-V controlled substances and make that information available to medical professionals

as a patient care tool. It designated the Department of Health (DOH) as the lead state agency to administer and oversee the program. The agency put the PMP data system for the program into full operation in 2011.

Funding for the PMP had been assembled from multiple federal grants; this created uncertainty about the level of services the program could continue to offer over time. Then, during the 2021 legislative session, the program was allocated dedicated funding to ensure it had a sustainable source of funding moving forward.

DOH makes PMP de-identified data available on its website for public health purposes. The agency withholds some information so the data cannot be used to identify individual patients, prescribers or pharmacies. The dataset is also confined to the prescription level. It can be used to identify the total number of prescriptions in the state, the number by type of drug prescribed, and the total quantity prescribed. However, it is not suitable for audit analyses seeking to identify prescribing or dispensing patterns that may suggest areas of concern.

DOH assigns a director and a staff of seven to support the program. This includes a program manager, a compliance officer and two other staff who are dedicated to customer service, day to day operations, compliance and policy work. There are also three epidemiologists that focus on analyzing public health data for DOH's website. One of the seven staff positions was vacant during the audit period.

In the 2019-2021 biennium, the program reported an operational budget of $2.8 million. About $1 million of this funding was paid to Bamboo Health, the third-party vendor that owns and operates the PMP data system, over a three-year period (July 1, 2019 – June 30, 2022). In addition, many other businesses, organizations and agencies play essential roles in multiple PMP processes. They include hospitals, pharmacies and the vendors that develop the pharmacy systems used to track the prescription drugs they give to patients.

Pharmacies must report all sales of Schedule II-V controlled substances in the PMP system promptly

Pharmacies are an integral part of ensuring that prescribers using the PMP database see the most current information available. Pharmacists must be registered to upload data into the PMP system. State law requires that each pharmacy report all Schedule II through V controlled substances in the PMP system as soon as information – listed in **Exhibit 2** – about the prescription is readily available, but no later than one business day from the day of distributing the drug to the patient.

Exhibit 2 – RCW 70.225.020 specifies the data pharmacies must upload to the PMP system "as soon as readily available"

(a) Patient identifier

(b) Drug dispensed

(c) Date of dispensing

(d) Quantity dispensed

(e) Prescriber

(f) Dispenser name

Additional information is required by DOH (WAC 246-470-030)

Source: Revised Code of Washington.

Pharmacies log dispensed drugs in the business's own computer system. Many pharmacies program their systems to automatically upload controlled prescription drug records to the PMP system, but a manual data-entry process is available for those pharmacies that need or prefer it. The PMP system then runs automated checks to ensure all required data is present and valid before accepting or rejecting the prescription record. The PMP system automatically transfers complete records into the database that prescribers use, and sends pharmacies notifications about the status of uploaded records and whether errors prevented any records from transferring to the database.

Organizations regulating health care professionals require prescribers to check the PMP database before prescribing certain medicines

The role of health care professional boards and commissions is to protect public health and to act as the licensing, rulemaking and disciplinary bodies for professionals licensed to practice in the state. They also serve as an educational resource for their members. Investigators from medical boards and commissions may use data from the PMP system when conducting an investigation, which may include examining the medical professional's prescribing practices.

In 2017, the Legislature took another step in the state's efforts to reduce the number of people who become addicted to opioids, involving all boards and commissions overseeing health care professions with prescribing authority (listed in the sidebar). The laws required them to adopt rules establishing requirements around the prescribing of opioids, and to have the rules in place by January 1, 2019. These rules are intended to ensure prescribers check the PMP to get the patient's prescription history before making decisions about patient care.

These rules vary between the different boards and commissions since each is a separate governing body that has oversight authority over particular professions. The Nursing Care Quality Assurance Commission, for example, requires nurse practitioners to check the PMP system at several checkpoints during treatment. These checkpoints include: the first time the nurse practitioner prescribes an opioid for a patient; at the first refill; during transitional periods; pre-operatively; and whenever the patient reports chronic pain. The Medical Commission requires physicians in practices where electronic health records have been integrated with the PMP system to check it when they write any prescription for opioids; those who lack this access must check it upon the first refill.

In addition, all health care professionals wishing to prescribe opioids in Washington are required by rule to register to access the PMP system or demonstrate proof they can access it some other way, such as through their hospital or group practice account.

Washington boards and commissions overseeing health care professions with prescribing authority

Dental Quality Assurance Commission

Medical Commission

Nursing Care Quality Assurance Commission

Board of Osteopathic Medicine and Surgery

Podiatric Medical Board

PMP-driven prescriber reports help medical professionals evaluate their own prescribing practices and how it compares to their peers

Helping health care professionals understand their own opioid prescribing practices is a key tool in promoting safer practices. Data drawn from prescription monitoring programs and distributed in confidential reports can help medical professionals reevaluate their prescribing practices when they see how they compare to their peers in similar fields of health care. Such detailed reports can also alert a prescriber to possibly fraudulent prescriptions issued in their name, by showing that a pharmacy filled a prescription they know they did not write. Such cases might be a simple mistake remedied by a call to the pharmacy, but it may prompt a report to law enforcement.

Many states use prescribing reports to help inform prescribers' behavior

Thirty-six states, including Washington, and the District of Columbia have developed reports to help medical professionals who prescribe opioids understand their prescribing behavior. In Washington, opioid prescribing reports are developed and distributed by a peer quality-improvement program known as the Better Prescribing, Better Treatment Collaborative (referred to as the Collaborative). The Collaborative is composed of representatives from the Washington State Medical Association and Washington State Hospital Association, DOH and the Health Care Authority.

The Collaborative currently sends opioid prescribing reports to health care professionals who meet two criteria:

- Have written at least one prescription for an opioid medication that must be reported to the PMP system in the last quarter
- Work in a hospital or medical group that has signed up to receive the reports

The Hospital Association's subscribers are primarily chief medical officers for hospitals. The Medical Association sends out reports to individual prescribers and medical groups. These reports show considerable detail. For example, one metric shows how often someone has prescribed more than seven days of an opioid medication to an adult patient with acute pain who had not taken any opioids in the prior 105 days. (The seven-day limit on prescriptions is based on a prescribing guideline set by the Health Care Authority's opioid clinical policy.) The report displays how the prescriber's results on this metric compares to others in that

See the Bibliography for links to the websites of the Washington State Medical Association and Washington State Hospital Association, which contain information about the opioid prescribing reports and other work they do on opioid stewardship.

specialty – both at the state level and within their hospital or medical group. After reviewing the report, prescribers can contact the Medical Association to speak with a clinical expert who answers questions about the report, and can suggest alternative prescribing approaches if a prescriber needs advice

After initial challenges in content and distribution, the Collaborative's reports on opioid prescribing are now the primary source of provider peer comparisons

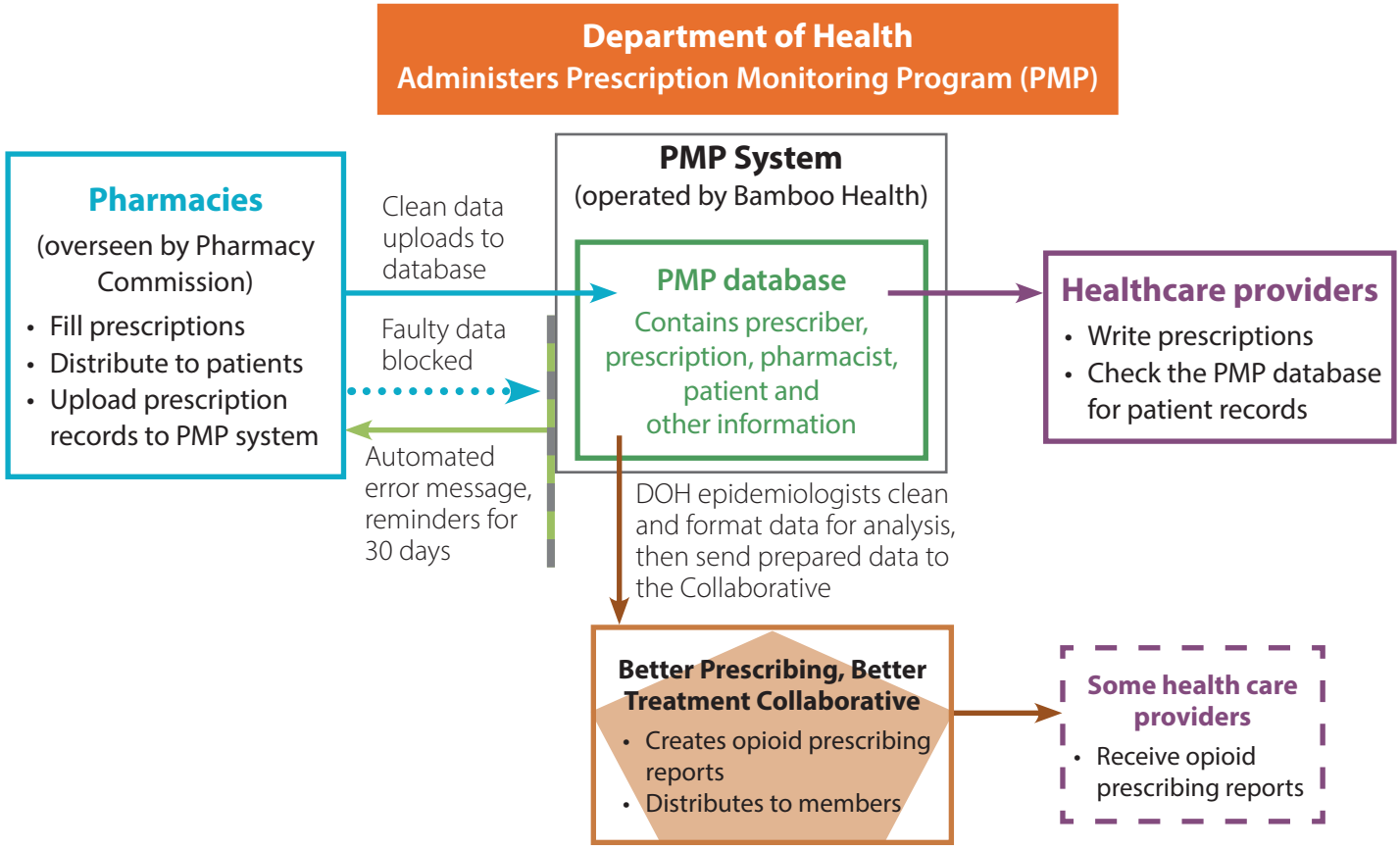
The hospital and medical associations began sending opioid prescribing reports in 2017. At that time, the reports covered Medicaid prescribing only and used Medicaid data supplied by the Health Care Authority rather than PMP data supplied by DOH. In 2019, DOH also began sending opioid prescribing reports using PMP data. Those receiving them were confused by the two overlapping reports. Some prescribers who received reports from DOH did not think the comparisons made were very helpful, or feared regulatory action might be taken because the reports came from a regulatory agency. Within the same year, DOH decided to stop its own efforts around the reporting aspect of prescriber opioid education, as the Collaborative continued to issue its reports.

Since then, DOH's only contribution to the opioid prescribing reports has been to supply prepared PMP data to the Collaborative. For that reason, when we refer to the Collaborative throughout this report, we are speaking about its most active participants: the hospital and medical associations.

Whether prescribing, dispensing or reporting about controlled prescription drugs, all participants in the PMP need system data to be complete, timely and accurate

If prescribers are to make the best decisions when prescribing opioids or other controlled prescription drugs, the data they use in the PMP system must be complete, timely and accurate. The diagram in **Exhibit 3** (on the following page) illustrates some key users of the PMP system and how they interact with the data and each other.

Exhibit 3 – Some key users of the PMP system and its data



Source: Auditor created.

This audit examined how to improve data quality for prescribers and reduce the risk of overprescribing of prescription opioids

We conducted this audit due to the importance of health care professionals having access to prescription data to help inform their decisions about patient care. The audit answered the following questions:

- Is 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 PMP system be used to monitor opioid prescribing and dispensing patterns and help reduce opioid abuse and misuse?

The first section of the report (pages 15-24) discusses opportunities for DOH to strengthen its monitoring process to ensure PMP data is sufficiently complete and

timely to meet the needs of prescribers who are making decisions about patient care. The second section (pages 25-30) focuses on how to improve and expand opioid prescribing reports to more medical professionals to help them provide better patient care. The final section (pages 31-35) discusses the limitations to the types of analyses and reviews we could perform in this audit due to legal restrictions around access to certain PMP data.

RCW 70.225.040 limits the situations in which individuals or organizations are allowed to access PMP data. RCW 70.225.040(3) specifies who the department may provide PMP data to. The State Auditor's Office is not included in any of these confidentiality exemptions, which severely limited the types of analyses we could perform in this audit.

Audit Results

The Department of Health (DOH) needs a more comprehensive process to ensure PMP data is sufficiently complete and timely to meet the needs of prescribers who are making decisions about patient care

Results in brief

To ensure medical professionals have complete information when prescribing, it is important to monitor whether pharmacies have promptly submitted prescription records. DOH does not monitor prescription monitoring program (PMP) data to see if pharmacies submit prescription records within one day of distributing a prescription. Until recently, DOH did not contact pharmacies that failed to correct records with errors that the PMP system automatically blocked from uploading. And because DOH does not ensure that pharmacies correct records with errors, prescribers may not have access to complete PMP data. In addition, DOH lacks a process to determine whether pharmacies have submitted all required prescriptions to the PMP system. Overall, DOH has not prioritized monitoring pharmacy compliance with PMP reporting rules.

To ensure providers have complete information when prescribing, it is important to monitor whether pharmacies have promptly submitted prescription records

Three essential requirements for a successful prescription monitoring program call for the data it contains – about the drug, patient, prescriber and pharmacist – to be complete, accurate and available to prescribers in a timely manner. These three elements are tightly interwoven, each contributing information that is useful to prescribers. For example, a pharmacy's data upload that lacks several required prescriptions could mislead a prescriber into ordering medicine for a patient who is already taking that drug. Similarly, an incomplete record, regarded by the PMP system as an error and not transferred to the database, may not be corrected and resubmitted promptly by the pharmacy, which denies the prescriber

a complete view of the patient's medicines. The Prescription Drug Monitoring Program Training and Technical Assistance Center, at the nonprofit Institute for Intergovernmental Research, offers PMP administrators guidance on best practices they should use to help ensure their PMP data meets those requirements.

The audit identified three main issues with DOH's current process for monitoring whether pharmacies are complying with PMP reporting rules and reasons why those issues are occurring. Specifically, we found:

- DOH does not monitor whether pharmacies promptly submit prescription records
- DOH does not ensure that pharmacies correct submission errors
- DOH lacks a process to determine if pharmacies have submitted all required prescriptions to the PMP system

DOH does not monitor PMP data to see if pharmacies submit prescription records within one day of distributing a prescription

As the administrator of the PMP, DOH is responsible for monitoring whether pharmacies submit prescription information to the PMP system. RCW 70.225.020(3)(b) states: "…each dispenser must submit the information as soon as readily available, but no later than one business day from the date of distributing..." The Prescription Drug Monitoring Program Training and Technical Assistance Center suggests PMP administrators crosscheck the date prescriptions were filled against the date they were uploaded to the PMP system to see which pharmacies submitted information outside of the statutory timeframe.

DOH does not currently assess whether pharmacies have uploaded their data to the PMP within one day of distributing. Instead, starting in January 2022, DOH initiated a process to check for pharmacies that have not submitted any prescription records to the PMP on a given day. The agency performs this review a couple of times a month. DOH then contacts some of the pharmacies that have not submitted data for the highest number of consecutive days, alerting them to the gap in reporting dates and helping them resolve the issue.

Although this strategy can prompt some delinquent pharmacies into regular reporting, it does not allow DOH to see if the prescriptions themselves are late. Nor does it allow DOH to identify trends, such as pharmacies that miss multiple, non-consecutive days of reporting. As a result of using this analytical method, DOH cannot identify which pharmacies most often take more than one business day to upload data on the prescriptions they have sold.

DOH has yet to address conflicting interpretations of submission requirements and consequent data inconsistencies

DOH has been hesitant to conduct an analysis on the timeliness of prescription record submissions to the PMP because DOH officials said pharmacies were inconsistent in how they fill in the date fields needed for the analysis. The pharmacies inconsistent use of these fields is likely due to conflicting interpretations about how to comply with data submission requirements. There are two issues that lead to conflicting interpretations.

- **First, agency rules do not align with state law.** Statute currently requires pharmacies to submit records within one business day of "distributing" a prescription. DOH administrative rules do not clearly reflect this: instead, WAC 246-470-030(3) requires records to be submitted within one day of "dispensing." DOH officials said pharmacists might interpret "dispensing" as either when filled behind the counter or when sold to the patient, and this may impact how they complete the "date filled" for the prescription record. Regardless of their interpretation of the term "dispense," the WAC and RCW should align.
- **Second, prescription records do not require pharmacies to fill in both the "date filled" and the "date sold" field.** Currently, the PMP database software only requires pharmacies to enter the "date filled" when they upload a record. Ideally, a pharmacy should also fill in the "date sold" field to record the date the drug was actually given to the patient. Our analysis of PMP data found 28 percent of records did not include data in the "date sold" field. This leaves DOH uncertain about if and when the prescription was actually given to the customer.

Amending its rules to align with state law, and clarifying the conditions in which pharmacies should enter "date sold" data, would make it easier for DOH to interpret the fields when conducting a timeliness analysis. Additionally, DOH could work with its vendor to make the "date sold" field in the PMP system situationally required, so that a pharmacy would be required to complete it once the drug was distributed to the patient.

A quarter of prescription records were not submitted within one day of distributing as required

To assess the timeliness of records submitted to the PMP, we conducted an analysis to determine whether pharmacies uploaded prescription records to the PMP system in the required timeframe. After analyzing PMP system data for March 13, 2022, to April 13, 2022, we found about 25 percent of prescription records had been uploaded late. About 4 percent of the records were late by three or more days, which represents about 27,000 records that were not available to prescribers during

that time. We could not determine whether any specific pharmacies had persistent issues with timely reporting due to PMP data restrictions, as discussed on page 34. For additional detail about our methodology, see Appendix B.

DOH also does not systematically identify significant variations in the number of records pharmacies submit to the PMP system over time. For example, a pharmacy that goes from uploading a large number of records every day to reporting a small number could indicate the pharmacy is not submitting all its prescriptions – either for one day or over a longer period. Such an issue would not necessarily be treated as a compliance problem, because a change in a pharmacy's operations might produce changes in its submission volume. Nonetheless, the change might indicate broader problems that can be corrected. DOH can follow up and help the pharmacy if technical assistance is needed or identify the cause of fewer submissions if it is aware of the changed submissions pattern. The practice of identifying submission variations over time is recommended by the Prescription Drug Monitoring Program Training and Technical Assistance Center. Furthermore, ensuring that information about medications is available to prescribers as soon as possible after the pharmacy has filled the prescription is critical to helping health care professionals make the best decisions about patient care.

Because DOH does not ensure that pharmacies correct records with errors, prescribers may not have access to complete PMP data

After pharmacies upload prescription data to the PMP system – but before that data is transferred to the actual PMP database – the system performs automated checks to identify missing, invalid or incorrectly formatted data. The PMP system automatically blocks problematic records from uploading to the database and notifies the pharmacy that uploaded the information of the errors. Pharmacies then receive an email notification every day, for up to 30 days, until they correct those errors.

We tested these automated system checks and notifications, as well as other system controls described in Appendix B, and found that they worked as intended. These processes alone cannot guard the system from all inaccurate data, but they do help to improve the quality of data prescribers see when they turn to the PMP system for their patients' prescription histories.

Until recently, DOH did not contact pharmacies that failed to correct records with errors, and still lacks a documented process to periodically review errors

In the past, DOH did not monitor PMP data to ensure pharmacies were correcting records rejected by the system due to errors. However, in April 2022, DOH reported staff had begun to identify and contact the pharmacies with the greatest number of uncorrected errors; this is recommended as a leading practice by the Prescription Drug Monitoring Program Training and Technical Assistance Center. The Center also suggests PMP administrators identify the most commonly made types of errors in order to help pharmacies make those errors less often, which DOH does not do. Nor did DOH have established policies and written procedures during our audit period to help ensure this monitoring work continues even if it hires new staff to conduct reviews. However, an official from DOH reported that they have started to develop a protocol for this review.

We analyzed PMP data on prescription records that did not upload to the PMP database due to outstanding errors. We identified approximately 12,000 uncorrected records out of an estimated 12 million uploaded to the PMP system in the past year. This is about 0.1 percent of records submitted in a year.

Our analysis found around half of pharmacies with an uncorrected error had fewer than five prescription records that were not added to the PMP database for this reason. Additionally, roughly half of records with uncorrected errors came from just eight pharmacies. As an example, one pharmacy had about 2,800 records with uncorrected errors in December 2021 but only six in the entire rest of the year. An established process to monitor errors periodically would have detected this anomaly, and possibly given PMP administrators information they could use to help other pharmacies make similar errors less often.

DOH officials said monitoring PMP data for uncorrected errors is a relatively low-priority activity because only a very small percentage of records uploaded to the PMP system are rejected for errors. However, given that most errors came from a small number of pharmacies, reaching out to just the handful of pharmacies with the most errors would lead to the correction of thousands of errors, with that many more records available to prescribers within the PMP system.

Because pharmacies are not required to correct errors in a timely manner, some errors are never corrected

Pharmacies are responsible for correcting errors; however, neither the statute (RCW 70.225.020) nor the administrative rules (WAC 246-470-030) governing the PMP submission have clearly established a requirement to do so in a certain amount of time. Furthermore, for egregious cases, the state lacks a way to hold a pharmacy accountable for repeatedly failing to correct errors.

The Prescription Drug Monitoring Program Training and Technical Assistance Center advises PMP administrators to notify the appropriate state authority if a pharmacy fails to correct errors within the specified timeframe.

The automatic notifications the PMP system sends to pharmacies regarding data submissions with errors cease after 30 days. From that point, pharmacies receive no further reminders to correct the data from either the automated system or from DOH. Unless the pharmacy discovers the problem through its own internal reconciliation processes later in the year and corrects it, the error is likely to remain uncorrected and absent from the PMP database.

DOH lacks a process to determine whether pharmacies have submitted all required prescriptions to the PMP system

DOH cannot determine whether pharmacies have uploaded all required prescriptions without the help of the Pharmacy Commission

In order to identify prescription records that are missing from the PMP database, DOH or the Pharmacy Commission would need to compare a pharmacy's own files against the records it has uploaded to the PMP system. DOH cannot do this on its own because it cannot access pharmacies' files, and so cannot verify what drugs a pharmacy has actually dispensed. Although the Pharmacy Commission can access pharmacy files during its routine inspections of pharmacies, the Commission does not perform any checks concerning what data pharmacies have or have not uploaded to the PMP system.

Pharmacies can compare the total number of controlled prescription drugs they have sold against the number they have uploaded to the PMP system, but DOH does not require them to reconcile these numbers. The Federal Information System Controls and Audit Manual recognizes the need to reconcile data between the source and target application to ensure that the data transfer is complete and accurate, and recommends such reconciliations as a best practice.

A Pharmacy Commission official said it is unlikely pharmacies would dispense drugs without that information being submitted to the PMP, noting that most pharmacy systems are automated. This means the software is programmed to automatically upload files with prescription data without hands-on involvement from pharmacists, which reduces the likelihood of human error or data manipulation.

Because neither DOH nor the Commission has established requirements for pharmacies to perform an independent review and reconciliation, the state lacks an assurance pharmacies submit all the records they should. Furthermore, failed uploads due to technical problems – such as server connectivity issues, computer crashes, power outages or problems with vendor software – can go undetected. This means prescribers may lack prescription records they need to inform their decisions about patient care.

DOH grants waivers to pharmacies that do not dispense controlled substances, but no one performs checks to ensure the waivers are warranted

Pharmacies can request an annual waiver from reporting prescription information to the PMP if they do not dispense any scheduled drugs Washington requires they report. As part of the request, the pharmacy must attest that it qualifies for the waiver and that, if it starts dispensing controlled prescription drugs, it will cancel the waiver. Agency officials said that roughly two-thirds of in-state pharmacies with waivers are hospitals with internal policies that allow them to dispense no more than one day's supply of medicines to an outpatient. As of June 2022, 18 percent of the more than 2,300 pharmacies licensed to practice in Washington held reporting waivers issued by DOH.

We interviewed PMP administrators in these states

- Colorado
- Connecticut
- Iowa
- Kentucky
- Maryland
- Massachusetts
- Minnesota
- New Jersey
- Oregon
- Wisconsin

See Appendix B for more information.

DOH does not validate a pharmacy's reason for requesting a waiver before excusing it from reporting prescription information to the PMP system. When a pharmacy applies for or renews its annual waiver, DOH approves the request without seeking any additional information to verify that the pharmacy does not dispense controlled prescription drugs. We spoke with PMP administrators in 10 other states (listed in the sidebar), and eight said they issue waivers. Of the eight, three conduct checks to see if the pharmacy requesting a waiver has reported any controlled substances to their PMP systems. If it has, administrators said they either rescind the waiver or contact the pharmacy to determine if it should actually have an exemption from reporting.

Once DOH grants a waiver, the system will identify the pharmacy as exempt from reporting to the PMP until the annual waiver expires. Once marked as exempt in the PMP system, a pharmacy with a waiver could dispense prescriptions for controlled prescription drugs without reporting them, which could lead to records missing from the PMP. Even if DOH checked the PMP system for prescriptions a pharmacy sold in the past before approving a waiver request, the agency could not detect the more concerning cases: those pharmacies with waivers that should legally report prescriptions to the PMP but do not.

The Pharmacy Commission is not involved with the PMP waiver process. The Commission has not performed checks to see if any pharmacies dispensing controlled drugs had received a waiver from DOH. The Commission said that if DOH supplied a list of pharmacies with waivers, then its pharmacy inspectors

could perform such checks during their regular inspections and inform DOH of their findings, so DOH could determine if it needs to cancel waivers for pharmacies that should not have them.

The Prescription Drug Monitoring Program Training and Technical Assistance Center notes that validating a pharmacy's reasons to obtain a waiver from reporting is a leading practice. Furthermore, it states the pharmacy's reasons should be independently confirmed by the agencies with authority to perform inspections at the pharmacy's location or by PMP staff. This should occur before the waiver is issued and at least once during each waiver period.

DOH has not prioritized monitoring pharmacy compliance with PMP reporting rules

DOH has not prioritized the compliance activities that would help ensure pharmacies submit all required prescription records. Agency officials pointed to three areas that they said limited their ability to assign this work a higher priority.

- Limitations in current levels of staffing
- Limitations in PMP system analysis tools
- The agency's lack of authority to enforce compliance with reporting rules

Staffing limitations. DOH said that a primary reason the agency does not conduct more PMP compliance activities is the additional staff time it would require to do the work. The PMP team at DOH currently has seven employees, which includes a supervisor and three epidemiologists who analyze public health data for DOH's website. The team's compliance officer is responsible for activities related to ensuring pharmacies submit controlled substances information to the PMP system, and has other duties in addition to compliance duties. DOH also said that addressing some items – such as dealing with the small proportion of PMP records with uncorrected errors – was not an effective use of staff time given other priorities competing for the compliance officer's time.

Other DOH employees cannot easily step in to perform these activities because DOH lacks written procedures for any of its compliance work pertaining to the PMP. Compliance efforts would effectively halt if the compliance officer were to go on extended leave or abruptly leave the position.

Limitations in analysis tools to monitor compliance. DOH said that the PMP system lacks the analysis tools to easily monitor compliance. Agency officials said they have been working with the vendor, Bamboo Health, to implement three changes to the PMP system. They anticipate the changes may help improve some of the compliance issues we identified on pages 16-22.

- *Automatically invalidating waivers.* This update to the PMP system would reconfigure the system so it invalidates a pharmacy's waiver from reporting if that pharmacy uploads prescription information to the PMP. This update was a long-standing request, and DOH expects this enhancement will be functional in 2023.
- *Improved error correction tool.* DOH has been using a software tool to identify pharmacies that have not corrected errors in the records they submitted to the PMP, but says the tool is not user friendly, especially for copying and exporting data. DOH is working with the vendor to improve the tool.
- *Improved tool to track submission timeliness.* The dashboard tool the compliance officer currently uses to see if pharmacies are uploading prescription information to the PMP system provides only limited information, such as how many pharmacies were delinquent two days in the past. DOH acknowledged this inadequate dashboard limits staff's ability to conduct certain types of analysis. DOH expects the vendor to release a new dashboard in summer 2022.

  Previously, DOH had access to a different tool – a Tableau-based feature supplied by Bamboo Health – that provided a more comprehensive picture of pharmacy compliance. This tool stopped working in the middle of 2020. DOH officials said they have been working with Bamboo Health to fix the tool, but issues remain, and so the agency must rely instead on the dashboard for tracking compliance. If the Tableau tool were to begin reliably working again, DOH said it might make it easier for them to complete the compliance work, making staff capacity less of an issue.

  Using the old tool, DOH could see data for each licensed pharmacy in the state for the previous 30 days, including:

  - Number of days a file was uploaded to the PMP system
  - Number of days without a file uploaded to the system
  - Number of records with errors
  - Error rate
  - Total records uploaded

Lack of authority to enforce compliance. DOH is responsible for ensuring that pharmacies submit prescription information as state law requires. While DOH can conduct certain monitoring activities, the department does not have the authority to enforce pharmacy compliance. If DOH finds a pharmacy has not complied with PMP rules, it can refer the case to the Pharmacy Commission. The Commission, as the pharmacy regulatory body, has the authority to enforce regulations through sanctions on pharmacies. However, a representative from the Commission said its only options are to deny, suspend or revoke a pharmacy's license: it lacks any options for less extreme enforcement actions such as a fine. DOH officials said they have not referred any cases to the Pharmacy Commission in recent years.

Given the limits of DOH's authority, the agency must work closely with the Pharmacy Commission to ensure pharmacies are following the law and submitting prescription information to the PMP as required. However, the Pharmacy Commission has expressed concerns about its own limited staffing and authority to help with the tasks we suggest on pages 20-22. It has said it would need additional resources to carry out this work.

Improving and expanding opioid prescribing reports to more medical professionals could help provide better patient care

Results in brief

Opioid prescribing reports help some of Washington's medical professionals understand their own prescribing activity and how it compares to their peers. Since 2019, the Washington State Hospital Association and Washington State Medical Association, which jointly oversee the Better Prescribing, Better Treatment Collaborative, have used PMP data to send opioid prescribing reports to medical professionals. Further enhancements to the reports could increase their usefulness to prescribers. Expanding the prescribing reports to other health care professions would require engagement with their associations and additional resources. As the lead state health agency, DOH can bring together stakeholders to help the Better Prescribing, Better Treatment Collaborative improve the reports and expand their reach.

Opioid prescribing reports help some of Washington's medical professionals understand their own prescribing activity and how it compares to their peers

Since 2019, the Washington State Hospital Association and Washington State Medical Association, which jointly oversee the Better Prescribing, Better Treatment Collaborative, have used PMP data to send opioid prescribing reports to medical professionals. Since then, the prescribing reports have been distributed through an opt-in program: prescribers are enrolled when their hospital or medical group's chief medical officer signs them up. The associations said they have enrolled every hospital in the state, but they have not yet enrolled some of the smaller, independent clinics and medical groups that are not affiliated with those hospitals. The program began allowing prescribers to enroll on an individual basis in January 2022, but none have done so yet. Once enrolled, prescribers receive a tailored report that shows how their prescribing compares against others in their same specialty – both at the state level and within their hospital or medical group.

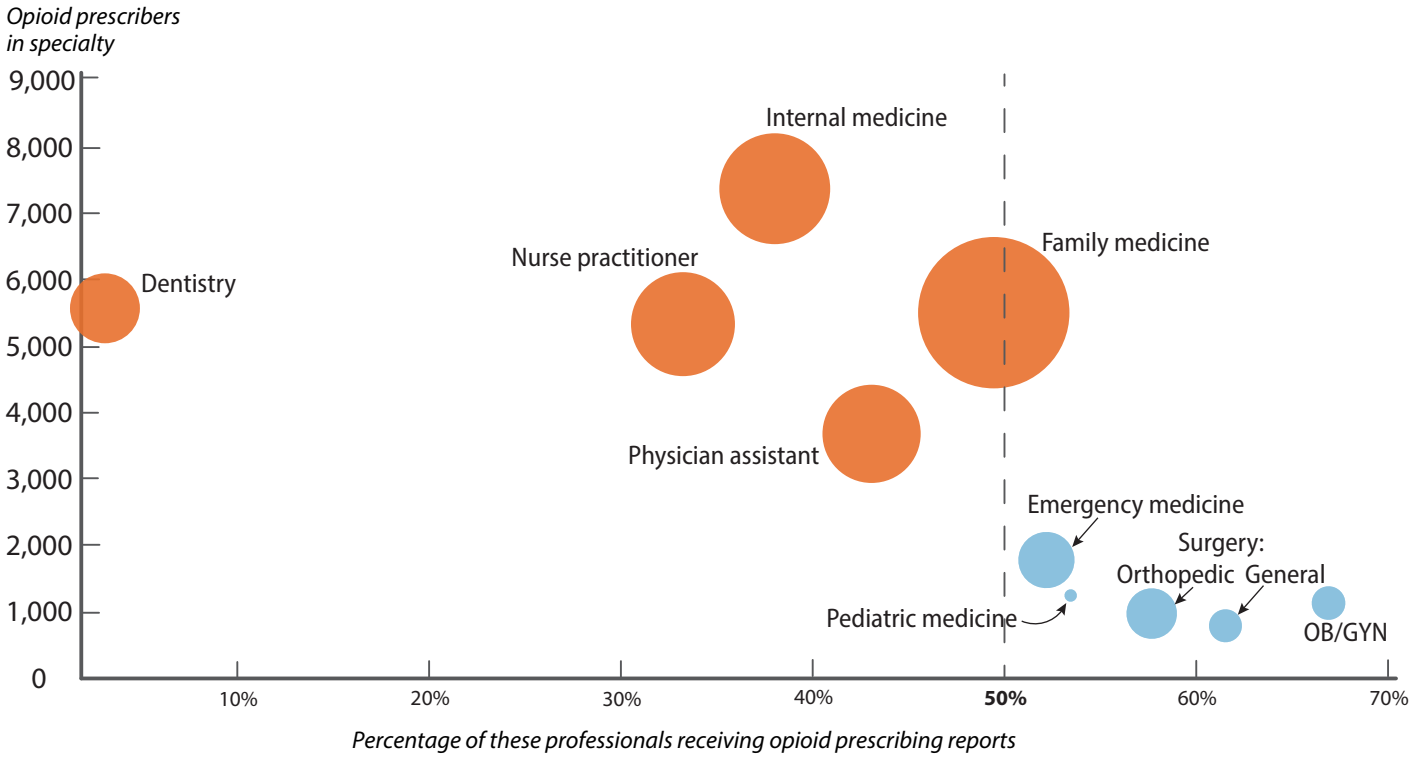
About 39 percent of all opioid prescribers receive these reports and participation varies by profession

The Hospital Association provided a table summarizing the number of opioid prescribers who receive these reports, covering a three-and-a-half-year period. We found that of the state's approximately 40,500 opioid prescribers, around 15,800 (39 percent) received these reports. This accounted for about 51 percent of opioid prescriptions written in the state.

Participation varies widely by profession. For example, 67 percent of the obstetrics/gynecology professionals who prescribe opioids receive the report, compared to only 1 percent of the opioid prescribers in dentistry. Nurse practitioners prescribe the third-highest number of opioids, yet just 32 percent of these prescribers receive a report. **Exhibit 4** illustrates the top 10 opioid-prescribing professions in the state by specialty and the percent of prescribing professionals who received the reports. (**Appendix C** lists the top 30 professions.)

Exhibit 4 – Fewer than half of the nurse practitioners, dentists and internal medicine doctors who prescribe opioids received opioid prescribing reports

Bubble size indicates the number of opioid prescriptions written between January 2018 and September 2021. Orange indicates more than 1 million prescriptions.



Note: Percentages calculated based on unaudited data provided by the Washington State Hospital Association.

Source: Washington State Hospital Association.

Professionals unaffiliated with a hospital or medical group do not receive these reports

The primary reason prescribers do not receive opioid prescribing reports is that they are unaffiliated with a hospital or medical group that signed up to receive the reports. Individual prescribers can now sign up to receive reports, but may not be aware that they can do so. Additionally, some very high prescribers do not receive reports because the Collaborative does not send reports to those who only treat chronic pain.

Further enhancements to the reports could increase their usefulness to prescribers

We identified opportunities for the Collaborative to make their reports more useful to more prescribers. We interviewed representatives from the hospital, medical and other associations for their perspectives on the opioid prescribing reports. (See sidebar for a list of other associations we interviewed.)

Their suggestions to improve the reports coalesced around four areas:

- Improve peer comparisons to make them more meaningful for different professions
- Expand the reports to include data from, and comparisons for, providers treating patients with chronic pain
- Include data on prescribers' co-prescribing practices
- Provide more guidance to medical professionals on best practices related to opioid prescribing

Below, we summarize briefly the results of the conversations in each area.

List of other associations we interviewed

- Advanced Registered Nurse Practitioners United of Washington
- Dental Association
- Podiatric Medical Association
- Optometric Physicians of Washington

Improve peer comparisons to make them more meaningful for different professions

In our interviews with associations that are not involved with the Collaborative, yet represent health care professionals who prescribe opioids, two out of four said that meaningful peer comparisons are critically important. Some expressed concerns that existing peer comparisons in the reports are too broad to be useful to them. For example, most medical doctors receive reports that compare them to peers in their specialty, such as oncology or pediatrics, but advanced registered nurse practitioners are treated as one peer group regardless of the specialty they work in. Representatives of the Collaborative said that they are open to creating smaller specialty peer-comparison groups, but would need more information from the other associations about their members to do so. The Collaborative would need to engage with the newly enrolled associations to ensure the comparison data was meaningful.

Expand the reach of reports to providers treating patients with chronic pain

The Collaborative would like to enhance opioid prescribing reports to provide information that supports professionals caring for patients with chronic pain. The current reports only address prescribers treating acute pain, usually treated with short courses of medicine. Chronic pain patients often take higher dosages of opioids over a longer period of time, which makes prescribing for them more complex. To address this complexity, the Collaborative would want to develop peer comparisons that are clinically relevant. Otherwise, medical professionals who prescribe for chronic pain could easily appear as outliers compared to other groups that only treat acute pain. The Collaborative has estimated reports with information on chronic prescribing could reach roughly 1,000 opioid prescribers in the state.

Include data on prescribers' co-prescribing practices

Patients taking a combination of opioids and psychostimulants or benzodiazepines have much higher rates of lethal drug overdoses than prescription opioids alone. (See the Bibliography for an analysis by DOH on this topic: "Prescription-related Risk Factors for Prescription Opioid Overdose Deaths in Washington State.") Representatives of the Collaborative said they would like to enhance the reports to call these dangerous combinations of drugs to prescribers' attention. For example, a prescriber may inadvertently prescribe opioids to a patient already taking a benzodiazepine because the information was not in the patient's health records and he or she did not check the database before writing the new prescription. Additionally, if a prescriber did not realize the combination was dangerous in the first place, then receiving a report highlighting it could prompt them to ask questions and reevaluate their prescribing practices.

Provide more guidance to medical professionals on best practices related to opioid prescribing

Another way to make opioid prescribing reports more useful to medical professionals is to ensure those who want to adjust their prescribing practices have sufficient information to do so. The Medical Association said it intended to start a coaching program for groups that are interested, but was unable to pursue doing so during the COVID-19 pandemic. The Medical Association has also expressed an interest in identifying those who prescribe the greatest number of opioids and proactively contacting them to provide guidance on best practices related to opioid prescribing. Given Washington does not monitor PMP data for overprescribing (as described in the next section of this report), this effort on the part of the Collaborative could be an important mechanism to improve patient safety by identifying and working with health care professionals whose prescribing activity raised concerns.

Expanding the prescribing reports to other health care professions would require engagement with their associations and additional resources

The hospital and medical associations said they would need additional support and funding in order to expand the distribution of opioid prescribing reports to more prescribers and increase the utility of the reports. Expanding the program in both these ways would require resources that the Collaborative currently lacks. These resources include inter-organizational cooperation, certain specialized knowledge and staff.

The Collaborative has limited interactions with prescribers who are not involved with the hospital and medical associations. Broad though their membership may be, these two associations do not include every health care professional who prescribes opioid medicines. The Collaborative would need to work with organizations like Advanced Registered Nurse Practitioners United and the Washington State Dental Association to promote the opioid prescribing reports to their members. All four associations we spoke with said they would be willing to encourage their members to sign up for the reports, either currently or if the reports were made more useful for their members in the ways described above. Individual prescribers can now sign up to receive the reports, but may not be aware that they can do so; contacting them through their professional associations could raise awareness and prompt them to enroll.

The Collaborative would need input from other medical professional associations to make meaningful peer comparisons in the reports. In addition to reaching their members, other associations would need to supply expertise on how their members prescribe and the types of specializations within their profession. Without this help, the Collaborative would struggle to offer meaningful peer comparisons. Such cooperation would likely require the associations to identify staff or volunteers to work with the Collaborative as it develops new reports. For example, a doctor with the Medical Association volunteers his time to develop meaningful comparisons using specialty information and to respond to prescriber questions about the reports. Adding new professions to the reports would require a person with similar expertise for each field to serve in this role.

The Collaborative has limited capacity to expand and improve the reports. Representatives from the Collaborative said they have limited resources available to expand the reports to more prescribers and to make other improvements that would increase their utility and adoption. The Collaborative is entirely funded and staffed by the hospital and medical associations with no support from the state to produce the reports. Across these two associations, several employees work on the opioid prescribing reports in addition to their other duties. Their work adds up to about .75 FTE at the Medical Association and 1.5 FTE at the Hospital Association, not including volunteer time.

Association representatives said that to begin expanding the reach of the reports to other professions, such as dentistry professionals, the hospital and medical associations would need half a full-time equivalent position at each organization. These staff would be needed to enroll new prescribers, maintain contact and prescriber specialty information, prepare the reports, and answer prescriber questions. Additional staffing may be needed to enhance their reports about chronic and co-prescribing. Representatives from both the hospital and medical associations added that a sustaining budget allocation would be needed to expand the program to cover the additional work.

DOH can bring together stakeholders to help the Collaborative improve the reports and expand their reach

DOH is in a unique position to help the Collaborative expand the reach and scope of opioid prescribing reports. Officially, DOH is already a member of the Better Prescribing, Better Treatment Collaborative, but their role is limited to providing PMP data to the Washington State Hospital Association. As the lead state health agency, DOH could bring together multiple parties in a workgroup to assist the Collaborative. PMP staff also have a deep understanding of the PMP and know about state and federal resources that might help the hospital and medical associations administer the Collaborative. DOH can also provide necessary assistance in reviewing the data-sharing agreement for the coordinated quality improvement program. In doing so, the workgroup partners may determine that a statutory change would be needed to broaden the reach of the reports to other health care providers.

In turn, representatives from the Collaborative expressed interest in partnering further with DOH, with the goal of bringing partner organizations together to promote, expand and improve the prescriber reports. Partner organizations would of course include those other health care professions outside the reach of the current Collaborative, allowing their input on prescriber-report content and distribution.

DOH can take the lead in assembling a consistent working group with current and new stakeholders; the workgroup provides the venue for systematically developing ways to promote the program, obtain stable funding, facilitate connections and share data. A workgroup can move the Collaborative forward in a way that the hospital and medical associations on their own cannot. Without the involvement of DOH and these important stakeholders, the Collaborative would likely find it difficult to establish a clear strategic direction that helps ensure the opioid prescribing reports grow and develop in a manner that most effectively serves prescribers and ultimately patients in Washington.

State law does not allow DOH to share PMP identifiable data for the purpose of independent oversight of the program

Results in brief

State law restricts access to PMP data to protect patients, prescribers and pharmacies. The restrictions curtail the independent program oversight that could identify opportunities for improvement. Auditors in other states used PMP data to identify prescribing and dispensing patterns of concern, which we could not replicate due to the data restrictions. In addition, our ability to examine certain system processes was limited. These restrictions in state law inhibited our ability to complete this planned audit work. Furthermore, neither DOH nor the regulatory licensing boards and commissions analyze PMP data in search of those concerning patterns.

State law restricts access to PMP data to protect patients, prescribers and pharmacies

State law limits access to data in the PMP to protect medically sensitive data which might disclose details about a person's health and the physicians treating them from anyone without a legitimate reason to know. In addition to identifying prescribing health care professionals and pharmacies, PMP data directly identifies the patient and shows exactly what drugs a patient receives and in what quantities. In turn, that can reveal information about a person's medical conditions and private life. Since this data is very sensitive, it is logical that prescription monitoring statutes would put strong guardrails around who may have access to it and why. The statute further protects data in the PMP that can indirectly identify a patient without having the patient's name, which might include their health care team or pharmacy location. Ultimately, these restrictions are in place to protect patients.

The restrictions curtail the independent program oversight that could identify opportunities for improvement

Performance audits use all types of data, some of which is confidential or proprietary, to address the efficiency and effectiveness of government programs with the aim of improving them. These audits typically result in a report that makes

recommendations to the audited agency. Auditors are routinely given access to confidential information so they can conduct audit analyses. Data analyzed during an audit is presented in aggregate to support our findings and recommendations, but is not released to the public.

Current state law (RCW 70.225.040) concerning access to PMP data specifies who DOH can permit to access different types of data in the PMP and for what purposes. The law was written to exclude any agency or organization unless named in the section. It does not name auditors, program oversight, or any other kind of external review of the program, including the State Auditor's Office or the Legislature's Joint Legislative Audit and Review Committee (JLARC). It thus restricts auditors from obtaining information needed for audits like this one.

One provision of the PMP statute does allow access to some data that can be used to conduct audits. RCW 70.225.040(5)(a) allows DOH to release de-identified data for research or educational purposes. "De-identified" means it cannot include any information that could be used to directly or indirectly identify a prescriber, dispenser or patient. We were able to obtain some prescription monitoring data to assess certain aspects of program performance because that data did not include any patient, prescriber or dispenser identifiers. However, we were unable to conduct the other work we had planned because it involved PMP data that would directly or indirectly identify these people and businesses.

Such restrictions on data access consequently limit the type of external oversight that can be conducted with PMP data, including opportunities to identify improvements in the PMP or its system. Because the law is so specific and inhibited our ability to conduct intended reviews (described below), it may likewise affect JLARC's ability to do similar work. This is because JLARC, like our Office, is not listed in the statute as an entity authorized to receive data. It is important to note that the statutory language granting access to records is different for JLARC and our Office, so it is not entirely clear whether JLARC would be prevented from accessing the same information.

These restrictions inhibited our ability to complete planned audit work

Due to legal restrictions preventing us from viewing identifiable data in the PMP database, we could not entirely answer our second audit question: *Could the state's PMP system be used to monitor opioid prescribing and dispensing patterns and help reduce opioid abuse and misuse?* To answer this question, we would have sought patterns in Washington's data that suggested potentially dangerous or illegal prescribing or dispensing was occurring. That is, if there were a nexus of extreme outliers based on people who received prescriptions from many health care providers, the providers who wrote those prescriptions, and the pharmacists who

filled them. We would have provided a summary of the results of this analysis to DOH and the Legislature so they could determine if monitoring PMP data in this way would be an effective approach to improving patient and public safety.

The analysis we planned would not have required patient names, addresses or other personal information that would have directly disclosed a patient's identity. Nor would it have required the names or identification numbers of providers, such as their drug enforcement agency number. Unique identifiers can be substituted for such data to anonymize people's identities. However, our analysis would have required other protected information that was not available to us, such as health care provider and pharmacy addresses.

Additionally, to help inform our analysis and interpretation of the data, we had planned to contract with a clinician familiar with opioid prescribing for acute and chronic pain. Any analysis we performed would have had limitations, as making a full determination as to whether prescribing is inappropriate would likely require a full review of the medical record by a regulatory board or commission.

Auditors in other states used PMP data to identify prescribing and dispensing patterns of concern, which we cannot replicate

Other states do not restrict audit access to prescription monitoring data as Washington does. For example, certain audits conducted in three states – Colorado, Louisiana and Oregon – could not be performed in Washington. These state and legislative audits used prescription monitoring data that identified issues such as:

1. Potential instances of doctor shopping
2. Unusually high quantities of opioids prescribed
3. Dangerous combinations of drugs prescribed

Brief descriptions of how audits helped identify these areas of concern using PMP system data follow.

1. **Doctor and pharmacy shopping.** People seeking to acquire more of a controlled prescription drug than a health care provider would authorize often resort to one of two common tactics. In doctor shopping, patients seek prescriptions from multiple health care providers simultaneously; in pharmacy shopping, patients bounce from pharmacy to pharmacy in hopes of getting multiple prescriptions filled without anyone detecting illicit activity. Prescription monitoring programs help prevent both tactics by giving prescribers a tool that reveals if patients have been obtaining controlled prescription drugs from other prescribers.

   All three state audits conducted independent analyses and identified potential doctor and pharmacy shopping. These audits found patients who had received many prescriptions from many different doctors. (See **Appendix D** for some additional detail on these audit results.)

2. **High quantities of opioids prescribed.** Opioids are dangerous in high quantities, but some chronic pain patients build up a tolerance to opioids that requires they take higher doses than would be prescribed for a typical acute-pain patient. Health care providers who specialize in hospice or palliative care, pain management, oncology or surgery may be justified in prescribing high quantities due to the nature of their patients' condition.

   In Colorado, auditors identified 85 providers who prescribed at least 26 times the number of opioids as the average for all other prescribers but did not practice any of the specialties listed above. Performing an analysis comparable to Colorado's would require access to patient identifiers and prescriber identifiers, which Washington statute prohibits.

3. **Dangerous drug combinations.** There are many medications that should not be mixed with each other, but opioids have some particularly dangerous combinations. Psychostimulants and benzodiazepines may be particularly dangerous when combined with opioids. DOH's own research (see the bibliography for the DOH analysis, "Prescription-related Risk Factors for Prescription Opioid Overdose Deaths in Washington State") suggests that taking either of these categories of drugs with opioids increases the risk of overdose-related death by three to four times. PMP databases allow prescribers to check whether a patient has received these medicines from another prescriber to avoid inadvertently prescribing these drug combinations.

   Audits in Colorado and Oregon conducted independent analyses of PMP data and identified thousands of instances in which health care providers prescribed certain dangerous drug combinations. (See Appendix D for some additional detail on these audit results.)

Data restrictions also limited our ability to examine certain system processes

The same data restrictions also curtailed our analysis of the timeliness of pharmacy submissions, part of our first objective. The data we were allowed to view lacked information identifying the pharmacy, and so we could not determine whether some pharmacies were persistently late in uploading their prescription records. Access to pharmacy identifiers would have enabled us to identify the days that pharmacies were engaging in business activities. This would have allowed a more comprehensive evaluation.

In addition, we could not review the pharmacy table that identifies all dispensers who are required to upload data to the PMP system. DOH officials said they review this table and fill in missing fields, but we could not confirm they do so. This review and correction process is a foundational aspect of the PMP system because the names and contact details in this table feed the system's automated messages including delinquency notices or warnings when prescription records fail to upload.

Neither DOH nor the regulatory licensing boards and commissions analyze PMP data for unusual prescribing and dispensing patterns

Although DOH conducts epidemiological analysis using PMP data, neither DOH nor the state's regulatory licensing boards and commissions analyze PMP data in such a way as to identify patients, prescribers and pharmacists who are acting against the interests of patients and the public.

The PMP program staff at DOH believe that the PMP system should be used only as a repository for data, and that using it as an enforcement tool against prescribers is inappropriate. They fear doing so would lessen prescriber trust in the PMP and be ineffective, as such analyses might flag legitimate prescribing activity. Determining whether a prescriber's decision was appropriate or not would likely require a full review of the medical record by a regulatory board or commission. Moreover, in our conversations with boards and commissions, we were told that they would have to open a formal investigation in order to assess someone's prescribing practices. These officials also said that the PMP data might not have sufficient detail to justify opening a formal investigation because other factors regarding the patient's medical condition are not in the PMP database but only in the patient's record. Additionally, one commission said that they did not have the staff and resources needed to conduct such an analysis and do not believe they have the legal authority to do so. We could not assess whether the detail in the PMP would be sufficient because we were not able to access the data that might confirm or refute these concerns.

State Auditor's Conclusions

More than 9,000 Washington residents have died from opioid prescription drug overdoses over the last two decades, according to Department of Health data. Many more have had their lives affected by opioid-use disorders. In 2020, more than a quarter of opioid-related deaths in Washington involved commonly prescribed opioids, according to the Addictions, Drug and Alcohol Institute at the University of Washington. The Department of Health's Prescription Monitoring Program began operating more than 10 years ago to improve patient care, reduce the abuse of controlled substances and help medical professionals reduce overprescribing. Through this independent, in-depth performance audit, our Office has identified detailed steps that will help the relatively small program – it currently has a staff of seven – improve the effectiveness of this system.

Checks to ensure compliance with the program should be improved, such as confirming available prescription information is complete and checking the appropriateness of waivers granted to non-participating pharmacies. Importantly, select independent oversight agencies should be allowed to access prescription data. One goal of this audit was to identify problematic prescribing and dispensing patterns, but we could not perform that analysis due to legal restrictions on program data. State and legislative auditors in other states, such as Colorado, Louisiana and Oregon, have used their access to this type of data to identify instances of doctor and pharmacy shopping by patients, severe cases of overprescribing by health care providers, and prescriptions involving dangerous drug combinations. That level of accountability is needed in Washington, to help prevent drug misuse, overdose and tragedy.

Recommendations

For the Legislature

To allow greater oversight of the PMP by independent state auditors, as described on pages 31-35, 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, can have the authority to access identifiable PMP data.

For the Department of Health (DOH)

To ensure pharmacies are submitting prescriptions records timely and have clear guidance, as described on pages 16-18, 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 in order 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.

To ensure errors that prevent pharmacy data from appearing in the PMP database are addressed in a timely manner, as described on pages 18-20, 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.

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 understand and follow them

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

As an alternative to revising the waiver process, DOH can instead stop offering waivers and require pharmacies to submit zero-data reports attesting that they have no prescriptions to submit to the PMP for that day.

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.

Once DOH implements recommendations 12 and 13, the Pharmacy Commission will be able to complete the next step. This is documented in the recommendations for the Pharmacy Commission on page 40.

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 and Washington State Medical Association 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.

For the Pharmacy Commission:

To ensure pharmacies that request waivers do not dispense controlled substances, as described on pages 21-22, we recommend the Pharmacy Commission:

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.

To ensure pharmacies submit all required prescription records to the PMP, as described on pages 20-21, we recommend the Pharmacy Commission:

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

To ensure the Commission can perform the additional work described in recommendations 15 and 16:

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

Agency Responses

STATE OF WASHINGTON

September 29, 2022

The Honorable Pat McCarthy
Washington State Auditor
P.O. Box 40021
Olympia, WA 98504-0021

Dear Auditor McCarthy:

Thank you for the opportunity to review and respond to the State Auditor's Office performance audit on the Prescription Monitoring Program (PMP). The Department of Health, prescribing boards and commissions, and the Office of Financial Management worked together to provide this response.

While we appreciate the work of the performance audit team, we sharply disagree with your recommendation to change state law to gain access to Washingtonians' personally identifiable health information from the PMP. As we shared with your team while they scoped the audit, the Legislature deliberately prescribed *in law* who can access this personally identifiable health information and under what conditions. We believe the legislative intent, the statute, and supporting case law are clear.

The PMP was designed as a tool for prescribers and dispensers to access patient Schedule II-V prescription history to make informed prescribing decisions.

The SAO's audit objective, *Could the state's PMP system be used to monitor opioid prescribing and dispensing patterns and help reduce opioid abuse and misuse,* attempts to evaluate the PMP against a purpose for which it was not intended.

According to the Washington State Agency Privacy Principles guidance, public agencies have an obligation to handle personal information about Washington residents responsibly and in a fair and transparent way. We do not believe that this recommendation meets the principal intent of this guidance. As we shared with your team, access to the PMP alone would not provide the information SAO needs to make the determinations implied in the audit objective. Investigators with training and experience in investigating health care provider discipline cases need access to medical records to gather pertinent information. This information must then be shared with board and commission members with medical expertise who can make informed decisions on the appropriateness of a provider's prescribing practice. Without access to medical records and these subject matter experts, amending state law to allow expanded access to the sensitive, personally identifiable information contained in the PMP would undermine the existing protections of this highly sensitive personal data while failing to achieve the SAO's stated audit objective.

Importantly, the governor, Legislature, state agencies, boards, commissions and many other stakeholders have worked to find a balance between regulating and safely dispensing opioids. Pursuing a change in law may have far reaching unintended consequences. These include upsetting this delicate balance, breaking trust among these stakeholders who have worked diligently toward finding solutions that improve patient outcomes while protecting personal information, and ensuring the safe dispensing of opioids, when appropriate.

Page 2

We acknowledge that the PMP has opportunities to improve reporting compliance. However, we strongly disagree that expanding access to PMP data is an appropriate or effective recommendation. Please thank your team for their work on this audit.

Sincerely,

Umair Shah, MD, MPH
Secretary of Health

David Schumacher
Director
Office of Financial Management

Teri Ferreira, R.PH, Chairperson
Washington State Pharmacy Quality Assurance Commission

Kim Morgan, LVT, Chairperson
Veterinary Board of Governors

Dr. Lyle McClellan, Chairperson
Washington State Dental Commission

Dr. Chat D. Aschten, N.D. FABNO, Chairperson
Board of Naturopathy

DJ Wardle, DPM, Chairperson
Board of Podiatric Medicine

Dr. Alexander W. Sobel, DO, FAACS
Washington State Osteopathic Medical Board

Paula R. Meyers, MSN, RN, FRE
Executive Director
Nursing Care Quality Assurance Commission

Micah T. Matthews
Deputy Executive and Legislative Director
Washington Medical Commission

Glen Owen, OD, Chairperson
Board of Optometry

cc: Jamila Thomas, Chief of Staff, Office of the Governor
Kelly Wicker, Deputy Chief of Staff, Office of the Governor
Nick Streuli, Executive Director of Policy and Outreach, Office of the Governor
Emily Beck, Deputy Director, Office of Financial Management
Mandeep Kaundal, Director, Results Washington, Office of the Governor
Tammy Firkins, Performance Audit Liaison, Results Washington, Office of the Governor
Scott Frank, Director of Performance Audit, Office of the Washington State Auditor

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.

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.*

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.*

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.*

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.*

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.*

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.

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.*

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.

Washington State Hospital Association

September 29, 2022

The Honorable Pat McCarthy
Washington State Auditor
P.O. Box 40021
Olympia, WA 98504-0021

RE: Prescription Monitoring Program Performance Audit Report

Dear Auditor McCarthy,

On behalf of the Washington State Hospital Association (WSHA), thank you for the opportunity to provide feedback on the Prescription Monitoring Program (PMP) Performance Audit report. WSHA represents over 100 hospitals and health systems in our state, and our hospital members range from large statewide health care delivery systems to small rural hospitals that are the only health care safety net serving rural, remote communities. WSHA has been a leader in reducing harm related to opioid misuse by living by its' mission. We are a trusted collaborative partner and innovator that advances important elements in acute prescribing, prevention and treatment programs across the state.

The PMP is a vital tool for health care providers to prevent medication misuse. We appreciate the Office of the Washington State Auditor's (SAO) work to identify potential improvements to the PMP program. We are grateful for your engagement with WSHA staff during the audit process. We offer the following feedback on the report:

- WSHA opposes the recommendation for SAO to access "identifiable" PMP information;
- WSHA supports the recommendations to enhance the opioid prescribing reports issued by the Better Prescribing, Better Treatment Collaborative (BPBT);
- WSHA disagrees with the recommendation for a Department of Health (DOH)-led workgroup; and
- SAO's report lacks important information about the opioid stewardship work conducted by BPBT and WSHA.

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WSHA Opposes the Recommendation for SAO to Access "Identifiable" PMP Information
WSHA is very concerned about the recommendation on pages 5, 31-35, and 37 to change statute to allow SAO access to "identifiable" PMP information and urges the legislature to reject the recommendation.

PMP information is sensitive and should not be accessible to individuals or entities lacking the necessary clinical background, training and education. The PMP data available to WSHA and WSMA is evaluated through a safety and quality perspective and Coordinated Quality Improvement Program with the intent of providing information to prescribers to inform their clinical decision-making. The professionals compiling and reviewing the prescribing reports possess the necessary expertise to contextualize prescription data and distinguish between care scenarios. They are also aware of the broader trends in addressing prescription drug misuse and overdose prevention.

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DOH and WSHA agree PMP information should continue to be used for quality improvement, not enforcement. SAO implies in its' report and stated during the exit conference with WSHA and WSMA on September 14, 2022 that PMP data could be provided to licensing boards and commissions for enforcement actions. This would be a major departure from the current quality improvement focus of BPBT and the prescribing reports. WSHA is not alone in our opposition to this. The report states on page 35, "The PMP program staff at DOH believe that the PMP system should be used only as a repository for data and that using it as an enforcement tool against prescribers is inappropriate." The report also states on page 35, doing so "would lessen prescriber trust in the PMP and be ineffective, as such analysis might flag legitimate prescribing activity." Using PMP data for enforcement actions could deter prescribers from prescribing opioids and other controlled substances to patients in order to avoid an investigation by their licensing board. This would chill patients' access to medications and may exacerbate health care inequities in communities with few prescribers willing to prescribe opioids or other controlled substances. Additionally, DOH acknowledged that such an arrangement could potentially burden them with unwarranted investigations into individual prescribers' "legitimate prescribing activity."

The recommendation raises strong concerns about data privacy. Granting SAO access to "identifiable" PMP information potentially adds sensitive health and clinical information to the public record. SAO does not address this issue in the report, which is deeply concerning. Adding such information to the public record would raise significant concerns for patients, prescribers, pharmacists and other stakeholders who expect the data to be confidential.

SAO does not have clinical expertise nor is clinical evaluation within its' mission. SAO's mission is to "[provide] citizens with independent and transparent examinations of how state and local governments use public funds, and develops strategies to make government more efficient and effective." Given this explicit mission, we don't believe accessing sensitive information fits within that scope. Furthermore, the report does not address the long-term plan or vision of what SAO would do with this data. SAO stated during our September 14, 2022 exit conference that a future audit could be conducted using PMP information. But that possibility alone is insufficient justification to make such a significant law change. It could also duplicate the work conducted within the BPBT Collaborative that WSHA and WSMA support with analyzing PMP data for prescribers working within this peer-driven clinical improvement program.

SAO's recommendation contradicts the legislature's intent. The PMP law contains a quality improvement process driven by relevant professional associations to change prescriber behavior based on best practices and current science set within a non-punitive, just culture practice. An evidence-based approach is used to sustain significant improvement. Inserting SAO into this is a clear contradiction of the legislature's intent and would place at risk current and future progress and provider engagement***.***

It is unclear what SAO intends to replicate from other states if the legislature grants SAO PMP access. On pages 3 and 33-34 SAO justifies this recommendation based on laws in Colorado and Oregon, with minimal details. The report says that the auditors "have used their access to this type of data to identify instances of doctor and pharmacy shopping by patients, severe cases of overprescribing by doctors, and prescriptions involving dangerous drug combinations." However, the report does not provide any details other than the brief descriptions on page 33-34 and the table on pages 53-54. SAO also states on page 53, "Please note that we did not examine the subsequent outcomes of these audits and whether the recommendations were implemented." This lack of examination raises many questions that should be

answered before changing state law, such as:

- Why are state auditing agencies performing this function?
- How do auditing agencies in those states conduct their audits?
- What have been the outcomes from state audits?
- How did the auditing agencies acquire the necessary expertise to conduct their audits?
- Do the agencies apply a quality improvement or enforcement lens to their audits?

SAO's recommendation is redundant when viewed in the context of the full report. Pages 25-30 and 39-40 contain SAO's recommendations to improve the prescribing reports issued by BPBT. The report also recommends steps on pages 15-24 and 37-40 for DOH to take to ensure accurate information is provided by pharmacies into the PMP. SAO should allow BPBT, DOH and the stakeholders identified in the report to act on the recommendations before proposing such a drastic change to upend the carefully crafted PMP law that has shown demonstrated improvement in prescribing outcomes.

WSHA Supports the Recommendations to Enhance the Opioid Prescribing Reports Issued by BPBT
WSHA supports the recommendations listed on pages 27-29 and 39-40 to enhance BPBT's work. In particular, WSHA agrees with the recommendations to:

- Enhance prescribing reports by including potentially dangerous drug combinations;
- Identify new strategies to enroll new prescribers in the prescribing report program; and
- Examine the feasibility of shifting the prescribing report program to an opt-out program.

These are practical measures to increase BPBT's reach to build on its' prior successes. However, the success of these recommendations will depend on available resources to fund the expansion of BPBT's work. Because of this, we appreciate SAO recommending DOH "[e]valuate the funding needed to expand the Collaborative and potential funding sources, such as federal grants and state funding" and encourage the legislature to allocate resources to support BPBT.

WSHA Disagrees with the Recommendations for a DOH-Led Workgroup
WSHA disagrees with the recommendation on pages 30 and 39 for a DOH-led workgroup "to discuss the needs of the [BPBT]." This recommendation could hinder BPBT's successes with peer-driven, non-punitive clinical improvement work and place in jeopardy protection from disclosure and discovery under CQIP that are key to providers having open and safe improvement-oriented discussions. SAO's recommended "advisory role" implies that DOH would direct and lead the workgroup. This would depart from the current arrangement where WSHA and WSMA staff lead opioid stewardship work based on trends and emerging best practices. This could chill open discussions within BPBT about prescribing practices or even result in the loss of confidentiality among workgroup participants. Additionally, mandating the agency responsible for licensing and enforcement to lead the workgroup may create a perception among prescribers that punitive or other heavy-handed changes could be forthcoming from DOH. We do not consider this recommendation to be value added or to meet the intent of the program. DOH cannot ensure that its' expanded role in BPBT and opioid stewardship would not hinder BPBT's ongoing progress in creating peer-driven advancements in opioid stewardship.

SAO's Report Lacks Important Information about the Work Conducted by BPBT and WSHA
The report's narrative regarding BPBT and WSHA provides limited information about the totality of the work undertaken by BPBT and WSHA. Unfortunately, this description does not convey the scope and

breadth of the work, nor does it convey the successes achieved to-date. Because of this, we recommend SAO add additional context about BPBT and WSHA to provide readers a clear understanding of the opioid stewardship work being conducted in Washington State.

BPBT is a collaboration between WSHA, the Washington State Medical Association (WSMA), Washington DOH, and the Washington Health Care Authority. Commencing in 2019, HB 1427 extended PMP access to WSHA and WSMA for data analysis and peer-driven, non-punitive clinical improvement in reducing above guidelines with acute opioid prescribing.

BPBT has empowered providers to be good stewards of acute opioid prescribing patterns by informing prescribing providers in our hospitals with quarterly reports. These reports enable members to engage and leverage the prescribing patterns of clinical peers for learning and reducing above guideline prescribing. BPBT also promotes sharing of evidence-based best practices in reducing harm related to above guideline prescribing. Although BPBT is relatively "young" since inception, the program has empowered Washington State providers to be good stewards of acute opioid prescribing patterns with notable improvement in pediatric, adult and adults 65 years and older.

BPBT's key success is that above guidelines acute opioid prescribing has reduced over the last 4 years. Pediatric above guideline acute opioid prescribing has reduced from 34% (2018) to 18% (2021), adults from 14% (2018) to 6% (2021) and adults 65 years/>, 19% (2018) to 9% (2021).

WSHA continues to serve as a trusted leader, collaborator, and convener of efforts to reduce opioid misuse. WSHA has been instrumental in not only providing informative quarterly reports that identify prescribing patterns, but also in evaluating opportunities that include education, awareness, and best practices for safe acute opioid prescribing. Some of WSHA's successes include:

- Preparing quarterly reports for hospital chief medical officers that support and inform on statewide and individual hospital prescribing practices in pediatrics and adults. Chief medical officers are also able to stratify data across provider specialties and trend patterns over time;
- Engaging hospital chief medical and quality officers with above guideline prescribing quality improvement strategies. This engagement has included quarterly educational webinars on how to utilize PMP data via the secured/opt-in, facilitated quality improvement discussions, support for safe storage and Safe Medication return programs, and the sharing of information for prescription take back day and opioid overdose awareness day;
- Surveying hospital chief medical officers on the best strategies to support data collection and dissemination of data to promote meaningful action;
- Engaging with key state stakeholders to review and promote synergy within the state's opioid response plan that includes acute prescribing, prevention and treatment. This strategy to connect and convene has provided all Washington State hospitals support within the Starts with One campaign, the state's safe medication return program, Safe Storage, MED-Project and other activities. Hospitals are most receptive to customizable campaign materials for their campuses. Notably, several hospital clinical leaders in both rural and larger health systems have engaged in the Starts with One campaign's development of a provider toolkit. This toolkit, underpinned in an equitable approach, supports our prescribing providers with communication resources to engage patients and care givers with information on alternatives to opioid treatment and safe practices when opioid prescribing is needed in acute pain scenarios; and

- WSHA has been supportive and engaged in CoMagine Health's opioid stewardship aims within the US Centers for Disease Control and Prevention's Opioid Data to Action Peer-to-Peer initiative. WSHA served as a panelist for a multi-state stakeholder learning event. WSHA spoke about BPBT, improvement trajectory with supporting prescribing patterns, and how sharing feedback in a quality improvement, non-punitive manner has facilitated improvement.

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Thank you again for the opportunity to comment on the PMP Performance Audit report. Should you have additional questions on WSHA's recommendations, please contact David Streeter via email at DavidS@wsha.org.

Sincerely,

Darcy Jaffe
Senior Vice President, Safety and Quality
Washington State Hospital Association

Chelene Whiteaker
Senior Vice President, Government Affairs
Washington State Hospital Association

Washington State Medical Association
Physician Driven, Patient Focused

September 29, 2022

The Honorable Pat McCarthy
Washington State Auditor

Delivered electronically

Dear Auditor McCarthy,

On behalf of the Washington State Medical Association (WSMA) representing over 12,000 physician and physician assistants, thank you for the opportunity to provide feedback on the Office of the Washington State Auditor's (SAO) performance audit, *Prescription Monitoring Program: Evaluating system processes and program oversight.*

While the WSMA supports the intent of this audit – to improve the effectiveness of Washington state's Prescription Monitoring Program (PMP) – and believe several recommendations would be beneficial, **we are deeply troubled by the recommendation that the Legislature amend state law to permit the SAO access to sensitive identifiable PMP data.** We are concerned a blunt approach that seeks to identify prescribing "outliers" absent any patient-specific clinical context and referring those "outliers" to regulatory authorities will accelerate the well-documented problem of patients struggling to access appropriate pain medications. These concerns were expressed to SAO throughout the audit process but are not reflected in the final report. As such they are discussed at length in this letter.

Our state has been a national leader in responding to the opioid epidemic. With the help of many stakeholders, physician experts and public policy makers, we have established and implemented policies and programs that have led to a significant decrease in prescription opioid dispensing. At the same time these efforts have allowed for appropriate, evidence-based access to opioid medication. The approach recommended in the draft report to permit SAO access to identifiable PMP data is counter to that spirit.

Washington state has led the nation

The prescription contribution to the opioid epidemic was first identified in Washington state in the 2000s. Since then, lawmakers and policy makers in partnership with physicians and hospitals, have led the nation in innovative approaches that seek to reduce inappropriate opioid prescriptions *while ensuring access to appropriate care.*

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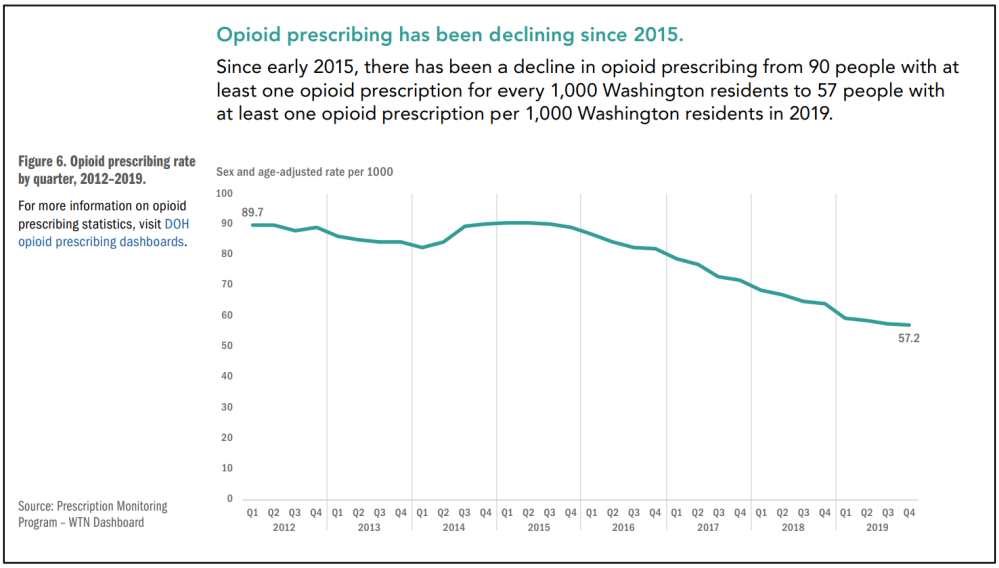
These initiatives include:

- Publication of first opioid prescribing guideline by the Agency Medical Directors Group (2007, 2015)
- Legislature repeals permissive intractable pain laws (2010)
- Legislature requires new standards for prescribers, including chronic pain rules as required by the HB 2876 (2010)
- Legislature creates Washington state Prescription Monitoring Program (PMP) (2011)
- Legislature sets forth seven best practices aimed at reducing unnecessary emergency department use in HB 2127. "ER is for Emergencies" is created, a program that has been replicated in states across the country and includes implementation of opioid prescribing guidelines for acute pain and the first integrations of PMP data into electronic health records (2012)
- The Health Care Authority (HCA) implements acute opioid prescribing policies as component of the Better Prescribing, Better Treatment (BPBT) Collaborative (2018)
- Legislature creates drug take-back program. For the first time residents have statewide access to disposing of unwanted or unneeded household prescriptions with the goal of decreasing diversion – the number one source of prescription drug abuse ("friend or relative") according to SAMHSA.
- Legislature requires promulgation of new standards for prescribers for all phases of pain (acute, subacute, chronic) (implemented 2019)
    - Requires physicians and other prescribers to check the PMP at clinically targeted intervals.
    - Includes pill limits for acute prescribing with exemption for clinical judgement.
    - Requires documentation of decision making around opioid prescribing in the medical record.
    - This legislation also gave WSMA access to PMP data for the purposes of conducting quality improvement under the BPBT Collaborative.
- HCA implements PMP check before prescribing a controlled substance to Medicaid patients (2021)
- Legislature passes PMP integration mandate and requirements for electronic prescribing of controlled substances (implemented 2022)

These efforts and others have led to a sustained reduction in the number of opioids prescribed:



Washington state should continue to lead through policy innovations that seek to reduce inappropriate prescribing while maintaining access to appropriate pain medications for patients that need them and avoid adopting non-patient centered approaches simply because other states have done so – as recommended in the audit.

Concerns with recommendation

According to the DOH, Washington's PMP was created by the Legislature to improve patient care and decrease prescription drug abuse by making controlled substance dispensing information available to physicians and other medical providers as a *patient care tool*, not a disciplinary or enforcement mechanism. As such the Legislature has historically restricted who can access the data to protect prescriber, pharmacy, and patient information. State law permits local, state, federally recognized tribes, or federal law enforcement to obtain PMP information for a bona fide investigation involving a designated person.

In its audit, the SAO recommends that the Legislature amend the law so that the SAO can access identifiable PMP data. SAO notes they would use the data to identify "1. Potential instances of doctor shopping 2. Unusually high quantities of opioids prescribed. 3. Dangerous drug combinations."

The report is silent on what criteria or metrics would be used in analyzing this data, as well as how state auditors (without clinical expertise) would determine medical appropriateness. For example, an oncologist would typically prescribe more opioids than an allergist – but simply looking at raw outlier data would not provide that critical context. While the SAO report makes a brief mention of contracting with a clinician "familiar with opioid prescribing for acute and chronic pain," such a clinician would not have access to patient medical records, and as such would have no way to contextualize the data and distinguish between care scenarios. The ability to meaningfully interpret prescribing patterns from PMP data would require significantly more resources than is contemplated in the report. This is acknowledged where it is noted that a full determination as to whether prescribing is inappropriate would likely require a full review of the medical record by a regulatory board or commission.

To be clear, the WSMA is deeply concerned that mining PMP data in this fashion and then referring it to disciplinary boards will contribute to further limiting access to appropriate pain treatment and could be detrimental to patient care.

Patient access to appropriate medications

While opioids are powerful drugs that can be associated with abuse, addiction, and diversion, they are also the most effective medications for relief from human pain and suffering when prescribed and utilized appropriately. Clinical experience has demonstrated that adequate and appropriate pain management leads to enhanced functioning and quality of life, while uncontrolled pain contributes to disability and despair. Unrelieved pain continues to be a serious health concern for the general population.

The state recognizes that the diagnosis and treatment of pain is integral to the practice of medicine and this concept was key when the boards and commissions drafted opioid prescribing rules in accordance with HB 1427. The intent and scope section of rules for allopathic physicians and physician assistants acknowledges the delicate balance that must be struck between preventing inappropriate treatments while ensuring patients that require them have access:

The Washington state medical quality assurance commission (commission) recognizes that principles of quality medical practice dictate that the people of the state of Washington have access to appropriate and effective pain relief. The appropriate application of up-to-date knowledge and treatment modalities can

serve to improve the quality of life for those patients who suffer from pain as well as reduce the morbidity, mortality, and costs associated with untreated or inappropriately treated pain. For the purposes of these rules, the inappropriate treatment of pain includes nontreatment, undertreatment, overtreatment, and the continued use of ineffective treatments.

Despite our best efforts, it is well documented that the regulatory environment in Washington state and across the country created by the response to the opioid epidemic has generated barriers to patients accessing appropriate pain medications.

We hear from patients and prescribers across the state that some practices are tapering patients off opioids, discharging them from their practices, or refusing to see new pain patients out of fear of facing serious sanctions. Those sanctions include malpractice liability, medical board discipline ranging from reprimand to revocation of their medical license, exclusion from federal and state programs, breach of contract actions from insurance carriers, hospital peer review, and criminal convictions.

These anecdotes are supported by reporting of this issue:

- Seattle Times: Amid pressure to prescribe fewer opioids, doctors struggle to ease patients' pain:
  - *He's largely stopped prescribing opioids — in part, he said, because his focus on procedures, like injections and implanted pumps, is taking up all his time; and in part because providers today have to wonder with every prescription whether they're leaving themselves open to a lawsuit or a visit from the Drug Enforcement Administration (DEA).*
- Human Rights Watch: Not Allowed to Be Compassionate" Chronic Pain, the Overdose Crisis, and Unintended Harms in the US:
  - *But in March 2018, Higginbotham's medical provider said he would be reducing her opioid medications by 75 percent to get her down to a dose he said was recommended in a guideline from the US Centers for Disease Control: 90 milligram equivalents of morphine. He told Human Rights Watch he believed Higginbotham had done well on the medication, but that his clinic was implementing a new policy over fears they could be held liable for high-dose opioid prescriptions:*
- National Cancer Institute: Opioid Use Drops among Cancer Patients at End of Life
  - *People with cancer nearing the end of their life are not getting needed opioids to control their pain, a new study indicates.*
  - *Beginning in the 2010s, many US states began enacting regulations to curb inappropriate opioid prescribing amid a growing epidemic of opioid overdose deaths. An unintended consequence of these regulations is that it became much harder for people with cancer to access pain medications, even at the end of life.*

From an economic standpoint, third parties often do not reimburse for the time and expertise to treat pain patients properly and effectively, creating a debilitating challenge for chronic pain patients. While addressing these systemic issues is outside the purview of this audit, we strongly urge you to consider how the recommendation to give the SAO access to clinical data might hasten the chilling effect on the treatment of pain patients in our state.

Fund a better approach: Better Prescribing, Better Treatment Collaborative (BPBT)

The BPBT collaborative is a peer-to-peer, clinician-driven, patient-centered, quality improvement program that promotes safe, appropriate prescribing to curb opioid misuse and overdose. The program is an innovative, public-private collaboration between Washington's Health Care Authority, the state Department of Health, the WSMA and the Washington State Hospital Association (WSHA).

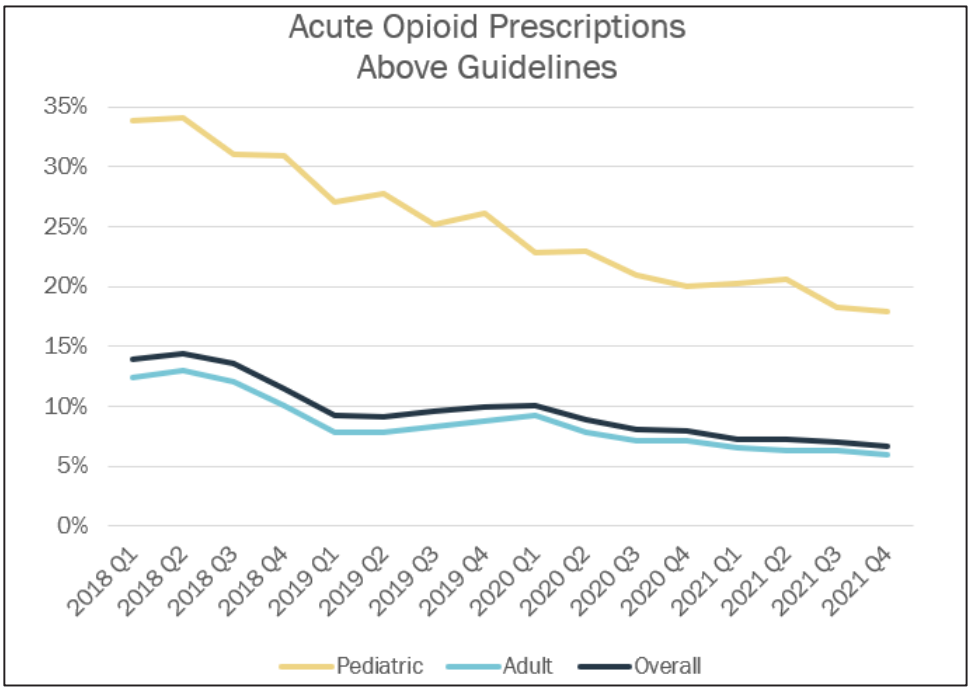
The Collaborative has significantly improved opioid prescribing behaviors and resulting patient care and outcomes by focusing upstream on acute prescribing and preventing inappropriate transitions to subacute and chronic prescribing.

The BPBT program promotes safe prescribing in three ways:

- **Washington State Opioid Prescribing Reports:** Each quarter, the WSMA sends prescribers in the state that are members of the Collaborative an opioid prescribing feedback report. Using data from the state PMP, the report shows how their opioid prescribing practices compare to others in their hospital, health system, or medical group, as well as within their specialty. Understanding where their prescribing patterns are relative to peers forces critical thinking and conversations around improving pain management.
- **Opioid Management Coaching Program:** In partnership with the University of Washington Six Building Blocks program, the WSMA offers coaching services on improving systems in primary care clinics to deliver more evidence-based chronic pain care and opioid management.
- **CMO Reports:** The collaborative disseminates reports to chief medical officers who want to understand the prescribing practices of their staff and implement focused plans to improve outcomes for patients.

The initiative encompasses 11,000+ prescribers with 60 hospitals, health systems, and medical groups in the state.

Collectively, opioid prescriptions above guidelines have been reduced by 46% since 2018. Pediatric above guideline acute opioid prescribing has reduced from 34% (2018) to 18% (2021), adults from 14% (2018) to 6% (2021) and adults 65 years/>, 19% (2018) to 9% (2021).



Despite the proven success of this collaborative, the SAO does not recommend to the Legislature that it fund the work to sustain and expand a program that seeks to reduce inappropriate prescribing while maintaining access for patients that need them.

Instead, the SAO includes a recommendation to the DOH that it create a work group to explore how to expand the program to include more provider types in more settings, and work on co-prescribing of controlled substances, and chronic pain management. These are goals the collaborative shared with the SAO and have been working toward for several years. The barrier to expanding the program is not the lack of a work group; it is a lack of funding. WSMA urges the Legislature to fund this patient-centered approach to improving pain management outcomes.

<u>The epidemic is evolving</u>

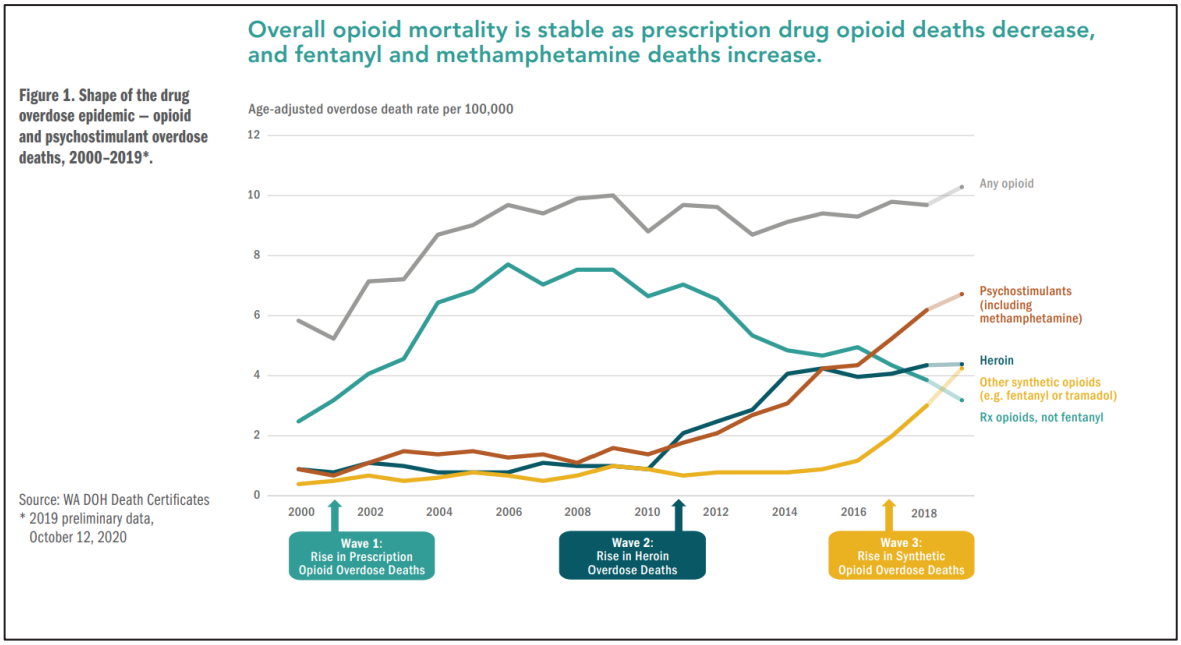
State efforts going forward should acknowledge the evolving nature of the opioid epidemic and pinpoint effective policies that reduce inappropriate opioid prescribing without creating barriers for patients who benefit from appropriate pain management that may include the use of opioids.

It should also be noted that emerging data is challenging the long held popular narrative of people starting on prescription drugs and then moving to heroin. According to a 2017 study released by Addictive Behaviors in 2005 only 8.7% of opioid initiators started with heroin, but this sharply increased to 33.3% ($p<0.001$) in 2015, with no evidence of stabilization. The use of commonly prescribed opioids, oxycodone and hydrocodone, dropped from 42.4% and 42.3% of opioid initiators, respectively, to 24.1% and 27.8% in 2015, such that heroin as an initiating opioid was now more frequently endorsed than prescription opioid analgesics.

The authors concluded as *the most prescribed opioids -hydrocodone and oxycodone - became less accessible due to supply-side interventions, the use of heroin as an initiating opioid has grown at an alarming rate. Given that opioid novices have limited tolerance to opioids, a slight imprecision in dosing inherent in heroin use is likely to be an important factor contributing to the growth in heroin-related overdose fatalities in recent years.*

This trend is supported by Washington DOH data:

Figure 1. Shape of the drug overdose epidemic – opioid and psychostimulant overdose deaths, 2000–2019*.



Source: WA DOH Death Certificates
* 2019 preliminary data, October 12, 2020

Inappropriate utilization of opioids is still a contributing factor to the epidemic that must be addressed by leveraging data, continued education, and improved pain management techniques the state currently supports. The intervention recommended by the SAO does not consider recent trends and mischaracterizes the epidemic as it exists today. At this stage in the epidemic, attention and resources must be allocated to stemming the supply of illicit opioids.

We understand the SAO's desire to help address the challenges created by the opioid epidemic. However, we believe the recommendation to give the SAO access to clinical data in the PMP and allowing the agency to "identify trends" without disclosing metrics or methods, with no access to the medical record, and referring physicians and other practitioners to their respective disciplinary body is the wrong approach. Enacting such a recommendation does not heed any of the lessons policy makers and the physician community have learned trying to address the opioid epidemic over the past decade.

Our continued success as a community at ensuring pain is treated appropriately in our state is contingent on adequately supporting and funding the programs and strategies currently in place, such as the BPBT collaborative. We urge the Legislature to fund these initiatives and reject the SAO's request for access to clinical data.

Thank you for the opportunity to provide comment. Should you have any questions, please never hesitate to reach out to WSMA Director of Policy Jeb Shepard at jeb@wsma.org.

Sincerely,

Jennifer Hanscom
Executive Director/CEO
Washington State Medical Association

State Auditor's Response

As part of the audit process, our Office provides a final draft of reports to audited entities and offers management an opportunity to respond. For this audit, these organizations were:

- The Department of Health, including the prescribing boards and commissions
- The Washington State Hospital Association
- The Washington State Medical Association

Those responses are included in every published audit report. In this case, the responses expressed some areas of concern and disagreement, which are included on pages 42-64 of this report. We summarize these concerns below, with our responses.

Granting SAO access to identifiable PMP data

In response to Recommendation No. 1, management from each of the entities involved in the audit stated they have concerns about the State Auditor's Office obtaining access to identifiable PMP data.

Auditor's Response

We appreciate and acknowledge the concerns each organization raised about the sensitivity of identifiable PMP data. We have a statutory mandate to conduct performance audits of government programs. This often requires us to access sensitive and confidential data from a variety of government agencies. In this audit, we identified two types of analyses that we could not conduct because we could not access the necessary data. First, we could not assess some system controls or fully identify pharmacy processes used to comply with PMP mandates. Second, we could not assess data trends to identify potential cases of overprescribing and doctor shopping. When auditors have access to such data, the public is assured of an independent review of government systems that are essential to supporting public health and safety.

Due to the level of their concern, we want to provide further clarity on certain areas.

1. **SAO will not publicly disclose any confidential health or clinical information received through the PMP program**

   When the Auditor's Office works with sensitive data such as health records, it is not added to the public record because such data is already protected health information under the Healthcare Insurance Portability and Accountability Act and Washington's data classification system. Consequently, this information would not be released to the public nor to any other unauthorized personnel within our agency or state government. Additionally, public records request protections for PMP data that are in place for DOH also apply to our Office: we cannot disclose any PMP data that DOH cannot disclose. Furthermore, while our audit activities require examining confidential data, we report only summary results that protect confidentiality. We have protocols in place to ensure we safeguard any data provided for audit, following the Office of the Chief Information Officer standards and properly disposing of it after the required records retention period.

2. **SAO would hire a subject matter expert with clinical expertise to assist with an analysis of overprescribing and doctor shopping**

   SAO has a practice of ensuring audits are informed by professionals with expertise in their fields, and have done so in the past when auditing medical or other highly technical fields. For any future audit of prescription monitoring records, for example, we would anticipate hiring a subject matter expert (SME) with clinical expertise to help inform our analysis and interpretation of the data.

3. **SAO could use the data to evaluate DOH oversight and identify concerning prescribing and dispensing patterns in the data**

   How we use the data in the future would depend on the audit's objectives. Access to this data would allow us or another outside auditor to examine issues such as potential instances of doctor shopping, unusually high quantities of opioids prescribed, or dangerous combinations of drugs prescribed.

   At the end of such an audit, we would review the results of this analysis with DOH. Audits are time-bound, so any audit review of the data would not be ongoing. The State Auditor's role is to identify issues and make recommendations for the Legislature and audited agency to consider. It is possible the Legislature or audited agency could determine that monitoring PMP data in this way would be an effective approach to improving patient and public safety.

4. **SAO was not able to examine the outcomes of audits in other states due to how recently they had been conducted**

   This audit did not examine the outcomes of other states' audit recommendations related to opioid prescription monitoring because the audits were conducted quite recently. The other states' audit results themselves, however, indicate potential areas for examination that Washington could benefit from.

Establishing a workgroup to discuss the needs of the Better Prescribing, Better Treatment Collaborative

In response to Recommendation No. 14, management from each audited organization disagree with the recommendation for the Department of Health (DOH) to establish a workgroup to discuss the needs of the Better Prescribing, Better Treatment Collaborative and to serve in an advisory role.

Auditor's Response

We understand each organization's perspective about the clear delineation of roles in that DOH is the lead state health agency. As we envisioned this workgroup, DOH's role would be limited to coordinating the workgroup and consulting with members when needed to help it achieve its goals. The Collaborative would lead the workgroup discussions and decide when to seek out advice or state-level resources from DOH. One of the workgroup's key functions would be to involve other professions to help expand the reports to other health care providers. We think not moving forward with this recommendation would be a missed opportunity to help expand and further enhance the opioid prescribing reports that help prescribers reflect on and adjust their prescribing behaviors.

Reviewing a pharmacy's uploading history before approving a waiver

In response to Recommendation No. 10, management from DOH disagrees with the recommendation that agency staff should review a pharmacy's uploading history before it approves a waiver.

Auditor's Response

We understand DOH's concerns and agree that having a system solution in place would supersede the need for staff to look at a pharmacy's uploading history. However, because such a solution does not currently exist, we recommend the agency implement the process until such time as an automated system is in place.

Providing reports to pharmacies so they can perform a reconciliation and the Pharmacy Commission can review them during their inspections

In response to Recommendations No. 13, 16 and 17, management from DOH disagree with the recommendation to provide reports to pharmacies so they can perform a reconciliation between the records submitted to the PMP system and their own records. In addition, the Pharmacy Commission disagrees with the recommendations to review in its inspections whether pharmacies have completed this reconciliation and to assess the resources needed for this review.

Auditor's Response

We understand DOH's and the Pharmacy Commission's concerns and acknowledge that DOH does plan to work with the Pharmacy Commission to explore the feasibility of this recommendation in terms of Commission and individual pharmacy resources. In Washington, most pharmacies use an automated process to upload their prescription records to the PMP. Consequently, having a process in place to reconcile the number of controlled substance records in the pharmacy system to the PMP system would allow a pharmacy to detect and address any system issues early on.

Appendix A: Initiative 900 and Auditing Standards

Initiative 900 requirements

Initiative 900, approved by Washington voters in 2005 and enacted into state law in 2006, authorized the State Auditor's Office to conduct independent, comprehensive performance audits of state and local governments.

Specifically, the law directs the Auditor's Office to "review and analyze the economy, efficiency, and effectiveness of the policies, management, fiscal affairs, and operations of state and local governments, agencies, programs, and accounts." Performance audits are to be conducted according to U.S. Government Accountability Office government auditing standards.

In addition, the law identifies nine elements that are to be considered within the scope of each performance audit. The State Auditor's Office evaluates the relevance of all nine elements to each audit. The table below indicates which elements are addressed in the audit. Specific issues are discussed in the Results and Recommendations sections of this report.

I-900 element	Addressed in the audit
1. Identify cost savings	**No.** This audit focused on public health and safety, and did not identify cost savings directly related to the Prescription Monitoring Program (PMP).
2. Identify services that can be reduced or eliminated	**No.** This audit did not identify services that can be reduced or eliminated.
3. Identify programs or services that can be transferred to the private sector	**No.** The Department of Health (DOH) already contracts with Bamboo Health in the private sector to provide data-management software for the PMP system.
4. Analyze gaps or overlaps in programs or services and provide recommendations to correct them	**Yes.** This audit looked for gaps or overlaps in interactions between multiple agencies and organizations, including: DOH as the administrator of the PMP; the boards and commissions that are the regulatory authorities of the medical professions; the hospital and medical associations that oversee the Better Prescribing, Better Treatment Collaborative, which distributes opioid prescribing reports to some prescribers.

I-900 element	Addressed in the audit
5. Assess feasibility of pooling information technology systems within the department	**No.** The PMP system already connects to the Health Information Exchange at the Health Care Authority.
6. Analyze departmental roles and functions, and provide recommendations to change or eliminate them	**Yes.** This audit looked at the completeness, accuracy and timeliness of PMP data, which is designed to give health care providers the information they need to make good decisions about patient care. It also looked at whether opioid prescribing reports in the Better Prescribing, Better Treatment Collaborative can be expanded to other professions.
7. Provide recommendations for statutory or regulatory changes that may be necessary for the department to properly carry out its functions	**Yes.** The audit reviewed DOH's administrative rules to see if changes are needed to make the program more effective.
8. Analyze departmental performance data, performance measures and self-assessment systems	**No.** The audit did not review performance measures.
9. Identify relevant best practices	**Yes.** The audit looked at leading practices related to prescription monitoring programs.

Compliance with generally accepted government auditing standards

We conducted this performance audit under the authority of state law (RCW 43.09.470), approved as Initiative 900 by Washington voters in 2005, and in accordance with generally accepted government auditing standards as published in *Government Auditing Standards* (July 2018 revision) issued by the U.S. Government Accountability Office. 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, with one exception described below and on pages 31-35, provides a reasonable basis for our findings and conclusions based on our audit objectives.

As discussed in that section of our report, state law limited our access to data that included individual pharmacies, patients and prescribers. As a result, we were not able to fully perform audit testing to obtain evidence about whether the state's PMP system could be used to monitor opioid prescribing and dispensing patterns. In addition, we were not able to review whether some pharmacies were persistently late in our analysis of submission timeliness, nor could we review DOH's process for updating pharmacy contact information in the PMP system.

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To provide citizens with independent and transparent examinations of how state and local governments use public funds, and develop strategies that make government more efficient and effective. The results of our work are widely distributed through a variety of reports, which are available on our website and through our free, electronic subscription service. We take our role as partners in accountability seriously. We provide training and technical assistance to governments and have an extensive quality assurance program. For more information about the State Auditor's Office, visit www.sao.wa.gov.

Appendix B: Objectives, Scope and Methodology

Objectives

The purpose of this performance audit was to identify potential improvements to the Prescription Monitoring Program (PMP) that would improve data quality and help reduce the risk of misuse and abuse of prescription opioids. The 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 PMP system be used to monitor opioid prescribing and dispensing patterns and help reduce opioid abuse and misuse

For reporting purposes, the audit results have been organized into key findings as follows:

1. The Department of Health (DOH) needs a more comprehensive process to ensure PMP data is sufficiently complete and timely to meet the needs of prescribers who are making decisions about patient care.
2. Improving and expanding opioid prescribing reports to more medical professionals could help provide better patient care.
3. State law does not allow DOH to share PMP identifiable data for the purpose of independent oversight of the program.

Scope

For objective 1, this audit examined issues of PMP data quality and completeness by assessing DOH's compliance activities, analyzing de-identified PMP data, and other activities.

- This audit could not determine how many prescription records were missing from the PMP or how accurate PMP records were because doing so would require comparing PMP records to pharmacies' records. We had limited access to the former, and no access to the latter.
- We analyzed PMP data to determine the overall timeliness of PMP submissions. However, we could not determine if late record submissions were concentrated among a small number of pharmacies or were a broader phenomenon because we could not obtain data with pharmacy identifiers, as described on pages 17-18 and 34.

- We could not confirm that DOH reviews the pharmacy table and fills in missing fields for pharmacies due to data restrictions. This review is a foundational aspect of the PMP system because the names and contact details in this table feed the system's automated messages that are sent to pharmacies (as described on page 34).
- We could not observe how pharmacists enter and upload prescription information to the PMP. This is because doing so would have required us to look at their computer screens, which contain identifiable information we were not authorized to view.

For objective 2, this audit examined ways that opioid prescribing reports can be improved or expanded, primarily through interviews with the Better Prescribing, Better Treatment Collaborative and DOH. The reports fit under objective 2 because they were designed to help medical professionals monitor their own prescribing practices and make safer prescribing decisions.

- We took this approach because we could not legally access PMP data with patient and prescriber identifiers, as described on pages 31-33, and so we could not conduct the analysis we had originally planned.

In addition, this audit did not look at general PMP usage or access. For example, we did not determine how many prescribers use the PMP with what frequency, or what systems prescribers use to access the PMP database. Nor did this audit look at DOH's compliance activities around requirements that prescribers check the PMP when prescribing controlled substances.

Methodology

We obtained the evidence used to support the findings, conclusions and recommendations in this report during fieldwork conducted during October 2021 through May 2022, with some additional follow-up work afterward. We have summarized the work performed to address the audit objectives in the following sections.

Objective 1: Is program data sufficiently complete, accurate and timely to meet the needs of prescribers and other users when making decisions about patient care?

To determine whether PMP data was complete, accurate and timely to meet the needs of prescribers and other users, we first evaluated the system controls in place. We interviewed staff at DOH and at Bamboo Health and had them demonstrate the system's operations to determine if it had controls in place to prevent problematic data entering the system. These controls serve to limit mistakes such as leaving required fields blank and duplicating patient information. We did not review any pharmacy systems in this audit to evaluate how they process information. We limited our review to examining what happens once the data is uploaded to the PMP system, and how the system processes records and sends automated notifications to pharmacists.

Next we interviewed staff at DOH and at the Pharmacy Commission to determine what processes were in place to ensure pharmacies were submitting data, correctly and on time. Then we obtained data from DOH and its PMP contractor to evaluate whether pharmacies submitted data on time, the number of uncorrected errors outstanding in the system, and the number of waivers granted to pharmacies.

Submission timeliness

To evaluate pharmacy submission timeliness, we obtained data from DOH that showed the date a prescription was filled, the date it was sold, the date the information was submitted to the PMP, the date the information was uploaded to the PMP, and the date of the prescription record's last update. The data had two limitations:

- First, the data did not include any direct or indirect pharmacy identifiers, so we had to make assumptions about when a pharmacy would be open.
- Second, about a quarter of the records did not include a "sold at" date. This is because Washington does not require pharmacies to include this date when submitting records to the PMP. We do not know if the pharmacies that did not include a "sold at" date used the "filled at" date to represent when they gave the prescription to the customer or when they filled it behind the counter. Further, a pharmacy could have submitted a prescription to the PMP prior to giving it to the customer. These are important distinctions because Washington law requires prescriptions to be submitted to the PMP within one business day of "distributing," which we understood to mean giving the prescription to the customer. Pharmacies can submit records before distributing prescriptions.

To address these limitations, we created a high-end range and a low-end range for submission timeliness. The number reported on page 17 is the median of these two ranges.

Low-end estimate: We excluded any record from our analysis that was missing data in the "date sold" field. The estimate also assumed most pharmacies were only open Monday through Friday. However, if the prescription was filled, sold or submitted to the PMP system on a Saturday or a Sunday, we considered these business days because the weekend activity indicated the pharmacy was open. Similarly, if we observed activity on a Sunday, we considered Saturday a business day as well. Because we did not have any pharmacy identifiers, we could not identify if a particular pharmacy had activity on a given day to indicate it was open, only if that specific prescription had activity. Therefore, this is an ***underestimate*** of late records.

To determine the reasonableness of the assumptions in the low end of the range, we sampled 50 pharmacies and used web searches to determine their operating hours. In our sample, only one pharmacy was closed on any regular weekday, and nearly 80 percent of pharmacies were open on Saturday. Sixty percent of pharmacies were open on Sunday, and all pharmacies that were open on Sunday were also open on Saturday.

High-end estimate: We included all records in the analysis, whether they had data in the "date sold" field or not. If the record was missing data in the "date sold" field, we treated the "date filled" date as the "date sold" date. We also considered all pharmacies to be open seven days a week, so one business day equalled one day. Since we know that only about 60 percent of pharmacies are open on Sunday, and that "date filled" does not always equal "date sold," this is an ***overestimate*** of the number of late records.

Using this approach, we determined that between 21 percent and 28 percent of records could be considered late because they were submitted to the PMP two or more days after the prescription was sold. On page 17, we use the median of these two numbers: 25 percent.

Waivers

DOH provided a report on the number of waivers applied for and granted. We used this report to determine the number of active PMP submission waivers in the state.

Interviews with other states

We interviewed prescription drug monitoring program administrators in ten other states (listed in **Figure 1**) to learn about their programs.

We selected this sample based on a targeted mixture of practices identified by nationwide studies, the existence of audit reports that were comparable to our own, and similarity to Washington in terms of population and severity of the opioid epidemic. We learned eight states will provide pharmacies that do not dispense controlled substances with a waiver from reporting. Three of these states perform some type of monitoring to see if the pharmacies should receive or maintain a waiver.

Figure 1: Interviewed state PMP programs

State	Issues waiver from reporting	Monitors to verify waiver status
Colorado	Yes	Yes
Connecticut	No	Not applicable
Iowa	Yes	No
Kentucky	Yes	No
Maryland	Yes	No
Massachusetts	Yes	Yes
Minnesota	Yes	Yes
New Jersey	Yes	No
Oregon	No	Not applicable
Wisconsin	Yes	No

System controls evaluation

We tested a selection of automated system controls with assistance from staff from Bamboo Health to determine if they were working effectively. These are automated system checks that provide some assurance that prescription records are complete and accurate, based on system specifications, before being uploaded to the PMP database with the exception of the patient consolidation process that occurs after it is uploaded. We conducted this work in a test environment set up by Bamboo Health. This allowed us to test different scenarios in the system to see if they were working as intended. We tested the following automated system checks:

- Error detection processes that identify and isolate missing or invalid data
- Data normalization tools that use lookup tables to populate provider and prescriber names and addresses based on their Drug Enforcement Agency number ensuring consistency of data
- Patient consolidation processes that combine records under one patient ID when certain criteria are met

Additionally, we confirmed that the system sends emails to notify pharmacies of the status of their submissions. The system has built-in alerts to ensure that pharmacists are notified about both the

status of the file they submitted or that no file has been received. We tested the following automated notifications related to the file submissions:

- File submission failure – This alerts the submitter that the entire file failed to process due to an incorrect file format.
- File status – This notifies the submitter that the file processed. It also includes a list of errors and the number of records received by the system.
- Delinquency in submitting prescription data – This notification is emailed when a pharmacy has not submitted a file within a 24-hour period.

Uncorrected errors

We received a report from DOH and its contractor, Bamboo Health, showing the number of errors that had not yet been corrected in the system at a given point in time. The system wipes records that are more than a year old, so the report only showed errors that remained uncorrected for up to one year. We used that report to determine the total number of uncorrected errors and the distribution of errors by date and pharmacy.

Objective 2: Could the state's PMP system be used to monitor opioid prescribing and dispensing patterns and help reduce opioid abuse and misuse?

To address this objective, we conducted three activities:

1. Interviews with key stakeholders
2. Conducted background research on the history and method of opioid prescribing reports in Washington
3. Examined information on the percentage of prescribers who receive opioid reports

Interviews with key stakeholders

We sought to understand the Better Prescribing, Better Treatment Collaborative, how it operates, and how many prescribers it serves. To do this, we interviewed staff at DOH, the Washington State Medical Association and the Washington State Hospital Association. To learn if other prescribing professions were receiving and valued opioid prescribing reports, we contacted several state associations and ultimately spoke with four: Advanced Registered Nurse Practitioners United of Washington, Washington State Dental Association, Washington State Podiatric Medical Association and Optometric Physicians of Washington. We also asked the regulatory licensing boards and commissions that oversee the professions that prescribe opioids (listed in the sidebar with the relevant RCWs) for their perspectives on opioid prescribing reports.

Washington boards and commissions overseeing health care professions with prescribing authority

Dental Quality Assurance Commission (RCW 18.32.800)

Medical Commission (RCW 18.71.800 and RCW 18.71A.800)

Nursing Care Quality Assurance Commission (RCW 18.79.800)

Board of Osteopathic Medicine and Surgery (RCW 18.57.800)

Podiatric Medical Board (RCW 18.22.800)

Additionally, we interviewed prescription drug monitoring program managers in 10 other states (listed in Figure 1) to determine whether they use provider reports and how beneficial they find them.

Conducted background research on the history and method of opioid prescribing reports in Washington

We reviewed documents on the internet about how opioid prescribing reports currently work, as well as their history.

Examined information on the percentage of prescribers who receive opioid prescribing reports

We requested data from the Washington State Hospital Association that showed the number of prescribers who received opioid prescribing reports compared to the number of prescribers who had prescribed opioids in our state. The data we received had some limitations, including that it is self-reported and covers a long timeframe (January 2018 through September 2021). We were not able to verify this data independently. For these reasons, we recognize there may be some variation in the numbers reported.

Work on internal controls

We evaluated the internal controls around pharmacy submissions in this audit that were significant to our first audit objective. First, we evaluated the system controls as discussed above to determine if the system was designed to effectively prevent erroneous or incorrectly formatted data from entering the PMP and also to send automated notifications to pharmacists. Then we interviewed representatives from the Pharmacy Commission and DOH to determine their monitoring practices over pharmacy submission compliance.

Appendix C: Percent of providers receiving opioid prescribing reports

Figure 2 presents the top 30 opioid prescribing professions in the state and the total number of opioid prescriptions written from January 2018 through September 2021. Across all professions, an average of 39 percent of prescribers received reports from the Better Prescribing, Better Treatment Collaborative, which includes specialties not listed in the table. Some specialties that have a high amount of opioid prescribing, including internal medicine, nurse practitioners and dentistry, receive opioid prescribing reports below the average rate of 39 percent.

Figure 2: Percent of providers receiving opioid prescribing reports

Specialty	Total opioid prescriptions	Percent of providers receiving reports	Total providers prescribing opioids
Family Medicine	5,039,474	49%	5,456
Internal Medicine	2,859,228	37%	7,335
Nurse Practitioner	2,662,480	32%	5,254
Physician Assistant	2,275,769	42%	3,646
Dentistry	1,073,736	1%	5,516
Emergency Medicine	752,895	52%	1,752
Pain Medicine	587,571	46%	147
Surgery Orthopedic	576,126	57%	948
Physical Medicine And Rehabilitation	416,614	48%	391
Obstetrics / Gynecology	280,936	67%	1,115
General Surgery	262,014	61%	777
Hematology Oncology	143,472	83%	187
Pharmacist	139,182	5%	305
Surgery Otolaryngology	132,046	59%	365

Figure 2: Percent of providers receiving opioid prescribing reports, *continued*

Specialty	Total opioid prescriptions	Percent of providers receiving reports	Total providers prescribing opioids
Podiatry	119,245	68%	397
Surgery Urologic	116,169	59%	346
Anesthesia	98,393	44%	268
Surgery Plastic	87,842	57%	183
Psychiatry	87,270	23%	595
Neurology	56,601	60%	343
Surgery Neurologic	40,108	59%	177
Pediatric Medicine	37,792	53%	1,222
Ophthalmology	37,315	64%	443
Other (Unable to Classify)	33,165	4%	553
Gastroenterology	25,070	69%	398
Surgery Vascular	24,088	50%	217
Dermatology	20,850	73%	313
Radiology	20,010	56%	284
Certified Nurse Midwife	17,646	64%	345
Cardiology	16,256	68%	459

Source: Washington State Hospital Association.

Appendix D: Audits in other states

We found that auditors in other states used PMP data to identify prescribing and dispensing patterns of concern. Audits conducted in Colorado, Louisiana and Oregon used prescription monitoring data to identify issues such as potential instances of doctor and pharmacy shopping and dangerous combinations of drugs prescribed. Please note that we did not examine the subsequent outcomes of these audits and whether their recommendations were implemented. Our Bibliography provides links to the original audit reports.

Three audits conducted in other states identified potential instances of doctor and pharmacy shopping. **Figure 3** shows the audit approach, findings and data required to conduct these analyses.

Figure 3: Audits in three states identified doctor and pharmacy shopping

State	Approach	Finding	Data required that is not available to SAO
Colorado	Looked at patients who received opioids from 10+ prescribers in two years	8,700 patients who filled opioid prescriptions	1. Prescriber identifiers 2. Patient identifiers
Louisiana	Looked at patients who received controlled substance prescriptions written by 4+ prescribers and filled by 4+ pharmacies in one month	1,393 patients with controlled substance prescriptions	1. Prescriber identifiers 2. Patient identifiers 3. Pharmacy identifiers
Oregon	Looked at patients who received controlled substance prescriptions from 30+ prescribers filled by 15+ pharmacies over 3 years	148 patients with controlled substance prescriptions	1. Prescriber identifiers 2. Patient identifiers 3. Pharmacy identifiers

Two audits conducted in other states identified potentially dangerous co-prescribing. **Figure 4** shows the audit approach, findings and the data required to conduct these analyses.

Figure 4: Audits in two states examined the frequency of co-prescribing with drugs that can be dangerous when mixed with opioids

State	Approach	Finding	Data required that is not available to SAO
Colorado	Looked at patients prescribed a benzodiazepine who already had an opioid from a different prescriber and patients prescribed an opioid who already had a benzodiazepine from a different prescriber	12,839 who were on an opioid prescribed a benzodiazepine 17,420 who were on a benzodiazepine prescribed an opioid	1. Prescriber identifiers 2. Patient identifiers
Oregon	Looked at patients who were prescribed opioids, benzodiazepines, and muscle relaxers within a one-month period	4,270 prescribed all three within a one-month period	1. Patient identifiers

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