

Significant Legislative Rule Analysis (SA)
Chapter 246-470 WAC
A rule concerning
The Prescription Monitoring Program (PMP)

Section 1. What is the scope of the rule?

The Washington State Legislature passed Engrossed Second Substitute Senate Bill (ESSSB) 5930 in 2007, authorizing the Washington State Department of Health (department) to develop a prescription monitoring program (PMP).

PMP Overview:

The PMP is a program designed to deter prescription drug abuse by providing a tool for patient care and safety. In Washington State, licensed practitioners who can prescribe scheduled drugs are also allowed to dispense the drugs they prescribe. The proposed rule outlines the requirements for “dispensers” to report these transactions to a centralized database. Dispensers (i.e., pharmacists and licensed practitioners who can prescribe and dispense Schedule II, III, IV, and V drugs out of their office) include:

- pharmacists;
- physicians;
- physician assistants;
- osteopathic physicians;
- certified and non-certified osteopathic physician assistants;
- naturopaths;
- podiatric physicians;
- dentists;
- nurse practitioners;
- optometrists; and
- veterinarians

Once the data is entered and stored, practitioners who can prescribe and dispense drugs, law enforcement, licensing boards, and others can query the database and use this information to help prevent prescription drug misuse and diversion. It is important to note that access to this database, which will be available 24 hours a day, seven days a week, requires special permission and cannot be used for data mining.

The department will also be able to review the information in the database to alert prescribers if a patient has a perceived dangerous dosage level. This allows the program to proactively work to prevent misuse, abuse, overdose, and other health risks associated with the use of controlled substances.

Background: Opiate Abuse - a Serious Problem

More and more patients are being injured or killed by prescription drugs, according to the Institute for Safe Medication Practices. Data from the Centers for Disease Control and Prevention (CDC) shows a rapid rise in deaths and emergency room visits from drug poisoning. Unintentional drug poisoning death rates jumped five-fold from 1990 to 2006. "Drug overdose death rates in the United States have never been higher," the CDC report concluded. The increase in overdose death rates is mostly because of prescription opioid painkillers.¹

In Washington State specifically, the following problems from misuse and abuse exist.

- Washington State has a higher prevalence of non-medical use of prescription pain relievers compared to the nation.
- In Washington State from 1997-2005, the sales of methadone increased 1,042% and sales of oxycodone increased 500%.²
- Since 2003 in Washington State, four times more people are receiving substance abuse treatment for prescription pain medicine. From 1995 to 2008 in Washington, hospitalizations for overdoses involving prescription opioids increased 7 fold.
- From 1995 to 2008 in Washington State, overdose deaths involving prescription opioids increased 17 fold.
- One in eight high school seniors in schools in Washington State report using prescription opioids to get high.

These problems could continue to exist or get worse without a uniform regional response. Washington's border state, Idaho, has had an operational PMP since 1969 and has been collecting data electronically since 1997. Washington's other border state, Oregon, will have an operational program in 2011. The department expects that Washington will see an increase in patients seeking prescriptions for non-therapeutic reasons. Based on the experiences of other states, it is likely that those seeking drugs for non-therapeutic purposes will try to get those drugs in Washington because a monitoring system is not in place. This adds to the urgency to launch a program in Washington.

Currently, 34 states have an operational PMP and 9 states have enacted PMP legislation and are working towards starting their respective programs.

¹ Centers for Disease Control and Prevention. (2010). Unintentional drug poisoning in the United States. <http://www.cdc.gov/HomeandRecreationalSafety/pdf/poison-issue-brief.pdf>

² Washington State Department of Health. (2008). <http://www.doh.wa.gov/hsqa/emstrauma/injury/pubs/icpg/DOH530090Poison.pdf>

In response to the above concerns, the 2007 Legislature passed ESSSB 5930, authorizing the department to develop a PMP for Washington State.

Section 2. What are the general goals and specific objectives of the proposed rule's authorizing statute?

The general goal of chapter 70.225 RCW is to promote public health and welfare through detection and prevention of prescription drug abuse.

The statute's objectives the rule implements are:

1. The department shall establish and maintain a PMP to monitor the prescribing and dispensing of all Schedules II, III, IV, and V controlled substances.
2. The program shall be designed to improve health care quality and effectiveness by reducing abuse of controlled substances, reducing duplicative prescribing and overprescribing of controlled substances, and improving controlled substance prescribing practices.
3. The program shall eventually establish an electronic database that is available in real time to dispensers and prescribers of controlled substances.
4. Prescription information submitted to the department shall be confidential.

Section 3. What is the justification for the proposed rule package?

RCW 70.225.020 requires the department to "establish and maintain a prescription monitoring program" and to adopt rules to implement the statute. The proposed rules will satisfy the statutory requirement by developing and implementing a PMP. The department has no alternative but to develop rules as required. If this rule is not adopted, the department would be out of compliance with the legislation.

Section 4. What are the costs and benefits of each rule included in the rules package? What is the total probable cost and total probable benefit of the rule package?

1. The proposed rule package includes eleven individual rules. The table below provides basic information on the rules that the department has determined are non-significant. The seven significant rules are analyzed in the next section.

2. Table: Non-Significant Rule Identification

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#	WAC Section	Section Title	Reason
1	WAC 246-470-001	Purpose	This section incorporates a portion of RCW 70.225.020 (without material change)
2	WAC 246-470-010	Definitions	This section defines terms used throughout the chapter and does not contain substantive provisions.
3	WAC 246-470-020	Adding additional drugs to the program	This section incorporates a portion of RCW 70.225.020 (without material change).
4	WAC 246-470-090	Confidentiality	This section incorporates a portion of RCW 70.225.040 (without material change)

3. Significant Rule Analysis

Method Used to Assess Impact of the Proposed Rule:

Department staff contacted various departmental groups (e.g., Board of Pharmacy, Medical Quality Assurance Commission, Nursing Quality Assurance Commission, Dental Quality Assurance Commission, Board of Osteopathic Medicine and Surgery, Podiatric Medical Board, Board of Optometry, Naturopath Advisory Committee, and the Veterinarian Board of Governors) to discuss the potential impact of the reporting requirements of the PMP rules. Staff developed and emailed a survey to a sample of Washington State dispensers to gather cost impact information. The information obtained in these discussions and results from the survey are included in the analysis below.

A.WAC 246-470-030 Data submission requirements for dispensers

Rule Overview:

Section 030 of the proposed rules incorporates the intent of RCW 70.225.020 and outlines the requirements for businesses and licensed practitioners who can legally dispense scheduled drugs to report their transactions to a centralized database³. The estimated cost of the rule is included in three subsections, estimated cost of rule for 1) pharmacies, 2) practitioners who prescribe and dispense drugs out of their office who have software to track their dispensing and 3) practitioners who have prescription and dispensing authority, but generally do not dispense out of their office and do not have software to track their dispensing.

The rule outlines the following requirements for dispensers:

- Which drugs must be reported

³ In Washington State, practitioners licensed to prescribe scheduled drugs can also dispense these drugs.

- How often data submissions must be made
- Which data fields must be reported

Estimated cost of rule for pharmacies:

In regard to pharmacies, there are two types to consider: large chain pharmacies and small independent pharmacies.

Large chain pharmacies comprise 73% of all Washington state pharmacies and dispense approximately 80% of all patient prescriptions⁴. The department's assumption is that large chain pharmacy stores within the state will not incur any new costs when complying with these rules. Large chain pharmacies typically have their reporting tasks completed by their central office. That is, pharmacists working in individual stores within a given chain do not run reports – the central office prepares the reports. These central offices are setup to run various types of reports and are already reporting prescription transactions to other states with active PMP programs. The department's assumption is that once Washington's PMP become active, chain pharmacies will simply add Washington State to their list of other PMP states and by doing so will automatically prepare the reports for Washington State. The result is that pharmacists working in these chain pharmacies will not have to prepare these reports and thus will not incur any additional cost.

Small independent pharmacies comprise the remaining 27% of all Washington state pharmacies and dispense approximately 20% of all patient prescriptions⁵. According to interviews with PMPs in other states, department board of pharmacy staff, direct conversations with several known software vendors, and results from a survey to pharmacies, the department's assumption is that small pharmacies already use a prescription tracking software that is compatible with the PMP. Furthermore in discussion with 6 out of the 21 known software vendors (see Appendix A for additional information on our vendor survey) that offer services, they indicated that they are already providing these services to customers in some of the 34 states that currently have an operational PMP and that their position was that if a data function for a PMP is required by statute or state rule that they would provide the required update at no cost to the pharmacy.

Estimated cost of rule for practitioners who dispense out of their office:

Practitioners, who have the authority to dispense scheduled drugs, will periodically prescribe and dispense scheduled drugs out of their offices. The department assumes that these practitioners will generally dispense drugs infrequently (e.g., less than 20 transactions per month). Furthermore, the department assumes that some of these practitioners maintain some type of software or data tracking mechanism to fulfill recording keeping requirements. The department, however, recognizes that the software or data tracking mechanisms may not be compatible with the PMP platform. Thus, these practitioners will have one of two options for complying with the PMP data reporting requirement. First, they may elect to purchase software that is compatible with the PMP system, which will automatically complete the PMP data submission process. For low volume practices, three software vendors (see Appendix A for additional information on our vendor survey) indicated that these software packages range from monthly licensing fee of \$25 to \$150 to purchase, install and learn how to use.

⁴ DOH Board of Pharmacy

⁵ Ibid

The second option is for these practitioners to submit the required data manually. The PMP website will have a secure connection for dispensers to log on and enter the required information (see Appendix B for a sample manual reporting form from the Michigan PMP). Based on input received from various parties, the department's assumption is that this task will take between 15 to 30 minutes each week. Assuming a maximum of 30 minutes per week, the cost for this ongoing reporting would be approximately \$9 each week for ½ hour of an office manager's time or other staff person to complete the data submission function.

Estimated cost of rule for practitioners who have prescription and dispensing authority, but generally do not dispense out of their office:

Prescribers are not currently required to receive a license or to register as a dispenser. Consequently, the department is unable to estimate the number of practitioners (nurse practitioners, physicians, physician assistants, podiatrists, optometrists, naturopaths, dentists, or veterinarians) who dispense. Therefore, for the purposes of this analysis, the data submission options, and associated costs, are the same as the one described in the section above.

A member of the Medical Commission was interviewed regarding the dispensing of controlled substances. His office does occasionally dispense samples out of their office for controlled substances. In a typical month there is no dispensing for controlled substances. Currently they do not have software for tracking the dispensing of these drugs. The member indicated that a medical assistant, nurse or office manager would likely be asked to report the information if they continued to dispense controlled substances.

Rule benefit analysis:

The PMP offers benefits to prescribers, dispensers and patients by allowing free access to the data collected. This allows prescribers to provide better care to their patients by being able to review a prescription history and check for duplicative prescriptions or dangerous drug interactions. It also helps dispensers identify possible forgeries, fraud, and other illegal activity that in turn could result in fewer problems associated with prescription misuse and abuse.

- B. WAC 246-470-050 Pharmacist, prescriber or other health care practitioner access to information from the program.
- WAC 246-470-060 Law enforcement, prosecutorial officials, coroners, and medical examiners' access to information from the program
- WAC 246-470-070 Other prescription monitoring program's access to information from the program
- WAC 246-470-080 Access by public or private research entities' to information from the program

Rule Overview:

Sections 050, 060, 070, and 080 of the proposed rules incorporate the intent of RCW 70.225.040 and describe the process approved groups will have to use in order to receive prescription reports from the PMP system. Access by all groups is voluntary and not required.

These sections describe the process for registration to access the program data and for making requests for the data once a user is registered.

Rule Cost:

The department assumes there are some minor costs associated with these groups registering to receive prescription reports. The groups include prescribers, pharmacists, law enforcement, prosecutors, medical examiners/coroners, other state PMP personnel, health researchers and other local government, state and federal agencies.

In order for these individuals to register they must complete a form, have it notarized, and send it by mail to the department for processing. The department anticipates that the form will likely be one page for information on the individual and a one page confidentiality statement they must sign. The department assumes it will take approximately 15 minutes or less to complete and notaries are available for free at many businesses. Assuming a maximum of 15 minutes to complete the form, the cost for an office manager to register for the practitioner they work for would be approximately \$4.50 (assuming an office assistant makes \$18 an hour. This analysis does not include the cost for mailing the form. Mailing the form and confidentiality statement to the department will require purchasing a stamp and envelope. Once approved by the department, the party can make individual requests for data using the prescribed process.

The only other impact on these individuals approved to obtain PMP data will be the time it takes them to login and request reports, which is estimated to be approximately 5 minutes, based on information received from other state programs. The web reporting system will be free for these individuals to use and available 24/7. Users will need to install a small security certificate on their computer that will be given to them at no cost.

Rule benefit analysis:

The PMP offers benefits to prescribers, pharmacists, law enforcement, prosecutors, and medical examiners/coroners by allowing free electronic access to the prescription data collected. The ability to appropriately review a patient's up to date prescription history for duplicative prescriptions or dangerous drug interactions will immediately translate into better care for that patient. The ability to appropriately review a patient's prescription history will also help the user to identify possible forgeries, fraud, and other illegal activity and avoid dispensing further drugs.

C. WAC 246-470-100 Penalties and sanctions

Rule Overview:

Section 100 of the proposed rules incorporates the intent of RCW 70.225.060. The rules let dispensers know that failure to submit prescription transactions to the department, knowingly submitting incorrect information to the department, or inappropriate disclosure of accessed PMP information, will result in disciplinary action or civil penalties. This section also adds department actions when it has determined inappropriate use of the PMP including: termination of access to the system, filing complaints with appropriate licensing entities, and reporting violations to law enforcement.

Rule Cost:

The section does not impose a regulatory compliance cost. The penalties and sanction process only applies to practitioners that do not follow a prescribed process. These steps to address non-compliance are reasonable and appropriate for helping ensure the protection of the information contained by the system.

Rule Benefit Analysis:

The legislation directs the department to ensure the privacy and confidentiality of patients and patient information collected, recorded, transmitted, and maintained. These steps are necessary to ensure that system access does not continue when inappropriate access or use of the data has occurred. The department is also responsible for ensuring that penalties are levied according to RCW 70.225.060 when inappropriate access or use of the data has occurred. RCW 70.225.040 also directs the department to use data submitted to the program for administration and enforcement of chapter 70.225 RCW.

4. Rule Package Cost/Benefit Conclusion

Cost/Benefit summary

The overall cost burden to dispensers to submit transaction data (i.e., either no cost if they have compatible software or minor costs associated with weekly data submission if they do not have compatible software) is minimal. The benefits of the PMP are numerous and include:

- 24/7 Access by prescribers and dispensers to patient history information so they can make better decisions before prescribing or dispensing a drug.
- The ability to proactively review the information to look for dangerous levels of dispensing and alert practitioners who have been prescribing to the patient(s) identified.
- Allow prescribers to review all prescriptions listed for their DEA number so they can look for fraudulent scripts or to review their own prescribing history.
- Improve the efficiency of investigations by law enforcement and licensing by providing the prescription they need for an investigation in one report. Currently investigators have to call pharmacies to search for the records they need. The PMP can provide a single report that identifies all the records they will need.
- Licensing entities can use the data to monitor compliance with a licensee who is on probation and has limits on their prescribing.
- Improve the efficiency and information available to medical examiners and coroners when they are investigating a death that might involve a prescription drug.

- Potential to create cost savings in Medicaid and Workers Compensation by providing data to Medicaid and the Department of Labor and Industry regarding their clients. Fraud may be found from clients who are receiving drugs paid for by Medicaid or Workers Compensation as well as additional drugs paid for by cash or other insurances that Medicaid/Worker's Compensation are not aware of.
- De-identified data can be used to inform policy makers regarding prescription drug prescribing and dispensing patterns by age, gender, or geographic location.
- Potential way of monitoring prescribers to ensure compliance with the new pain management law and rules.

Several studies, identified below, are available that demonstrate the effectiveness of PMPs and the value they add to a prescriber's ability to treat patients regarding controlled substances. The department will be designing the program to operate in a manner to achieve these types of results.

- Carnevale Associates Information Brief: [State Prescription Drug Monitoring Programs Highly Effective](#)
- PMP Center of Excellence: [Notes from the Field: Trends in Wyoming PMP Prescription History Reporting: Evidence for a Decrease in Doctor Shopping?](#)
- Annals of Emergency Medicine: A Statewide Prescription Monitoring Program Affects Emergency Department Prescribing Behaviors
- American Public Health Association: RADARS® System Poison Center Opioid Abuse and Misuse Rates over Time in States with and without Active Prescription Monitoring Programs
- Simeone Associates: [Evaluation of Prescription Drug Monitoring Programs, 2006](#)
- Alliance of States with Prescription Monitoring Programs: [An Assessment of State Prescription Monitoring Program Effectiveness and Results, Version 1, 11.30.07](#)
- Kentucky PMP: [KASPER Evaluation Executive Summary 10-15-2010](#)
- Kentucky PMP: [2010 KASPER Satisfaction Survey Executive Summary](#)
- Maine PMP: [Impact Evaluation of Maine's PMP](#)
- Virginia PMP: [Executive Summary Report of the PMP](#)

Conclusion

The numerous benefits of implementing the PMP for Washington State, as outlined above, far outweigh the costs of implementing the program.

Section 5. What alternative versions of the rule did we consider? Is the proposed rule the least burdensome approach?

The requirement to submit data to the department is part of the authorizing statute. The rule does not create any additional burden that is not contained within the statute. The law requires the department to create these rules to implement the program.

Department staff worked closely with constituents to minimize the burden of the rule. In preparation for the development of draft rules, the department recognized that 34 states currently have operational PMPs. The department decided to use PMP rules from the state of Maine as a starting point for its draft rules. Similar to Washington States' collaborative rulemaking process, Maine partnered with stakeholders (dispensers, prescribers, licensing, law enforcement, patient advocacy, etc...) to develop and refine their PMP rules. Maine's involvement of stakeholders in the rule development process not only produced a better rule set, but also contributed to an overall support of the rules by affected parties.

The department held four rules workshops in different locations throughout the state. At these workshops, stakeholders were able to review the draft PMP rules and were encouraged to comment on areas that they felt needed to be changed. Aside from minor changes in wording and formatting, stakeholders did not suggest any significant revisions. The department also hosted several "webinars" in which stakeholders were given the opportunity to ask questions and comment on the proposed rules. Although rule comments were encouraged, no significant revisions were suggested.

Section 6. Did we determine that the rule does not require anyone to take an action that violates another federal or state law?

The rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 7. Did we determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

The department determined that the rule does not impose more stringent performance requirements on private entities than on public entities.

Section 8. Did we determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, did we determine that the difference is justified by an explicit state statute or by substantial evidence that the difference is necessary?

The rule does not differ from any applicable federal regulation or statute.

Section 9. Did we demonstrate that the rule has been coordinated, to the maximum extent possible, with other federal, state, and local laws applicable to the same activity or subject matter?

Yes, the rule is coordinated to the maximum extent practicable with other applicable laws, including chapter 70.225 RCW.

APPENDIX A: Survey of Pharmacy & Practitioner Dispensing Software

Based on conversations with the board of pharmacy the program learned that independent pharmacies will have software and computers in place to track their dispensing. The department surveyed 6 of 21 known vendors who provide software to independent pharmacies. The vendors were asked if they will charge their customers to provide the needed software update the program will require for data submission. All six vendors told the department that they would not charge customers for the software update or for training on how to submit the data. The vendors indicated that it is common practice to consider these updates as part of their standard maintenance agreement with their customers because the submissions are required by law. Two of the vendors indicated that their software could be updated to provide an automated approach so that the pharmacy would not have to create the file and upload it to the program. The software in this case would not only create the file to be uploaded, it would also automatically and securely send the file in.

Prescribers who do not have software to provide the required data submissions will have a secure online form available for submissions. This form will only require internet access and the time of office staff for data entry. If the prescriber chooses to, they could purchase software to track and report the dispensing of these drugs. The department surveyed 3 vendors who provide software to prescribers that would allow them to submit the necessary data to the program. The vendors had a small initial installation fee of free to \$500 and then an ongoing monthly service fee of \$25 to \$150 per month. They all indicated that their software could be used to submit the required data to the program.

APPENDIX B: Sample Single Record Data Submission Form (Michigan PMP)

Authority: P.A. 231 of 2001

State of Michigan
Department of Community Health
Bureau of Health Professions-Michigan Automated Prescription System (MAPS)
MAPS Claim Form

MAPS - Form 001 - 1A - 07/10

Dispenser Information		
DEA#:	Dispenser Name:	
Dispenser Address:	City/State:	Zip Code:
Dispenser Telephone:	Dispenser Email Address:	
Patient Information		
Patient ID: (Drivers License or State ID)	Patient (Human) First Name:	Patient Last Name:
Patient (Human) Date of Birth:	Patient Address:	Zip Code:
<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Animal <input type="checkbox"/> Unknown		
Date Issued:		Prescriber DEA#:
Date Filled:		
NDC Number:		Drug Name:
Quantity:		Method of Payment:
Days Supply:	Authorized Refills:	RX Number:
Date Issued:		Prescriber DEA#:
Date Filled:		
NDC Number:		Drug Name:
Quantity:		Method of Payment:
Days Supply:	Authorized Refills:	RX Number:
Date Issued:		Prescriber DEA#:
Date Filled:		
NDC Number:		Drug Name:
Quantity:		Method of Payment:
Days Supply:	Authorized Refills:	RX Number:

All dispensed controlled substances must be reported by the 1st and 15th of the month for the preceding period.

Dispenser: All controlled substance prescriptions dispensed may be entered electronically through MAPS Online. Instructions for registration to MAPS Online are listed on our website at www.michigan.gov/mimapsinfo. Upon registration, you will be able to submit your prescription records online using an electronic version of the above form. In addition to submitting prescription data online, MAPS Online also offers practitioners the ability to request patient-specific reports to review the patient's Schedules 2-5 controlled substance prescription records. Submit the above prescription data information to the following address:

State of Michigan - Department of Community Health
Bureau of Health Professions-Michigan Automated Prescription System
P.O. Box 30454 - Lansing, Michigan 48909
www.michigan.gov/mimapsinfo