Significant Legislative Rule Analysis
Chapter 246-470 WAC
Prescription Monitoring Program
December 23, 2015

Describe the proposed rule, including a brief history of the issue, and explain why the proposed rule is needed.

The Washington State Department of Health (department) is proposing amendments to the Prescription Monitoring Program (PMP), chapter 246-470 WAC. The department is proposing amendments per House Bill 1637 (chapter 49, Laws of 2015) adding tribal officials to the list of appropriate law enforcement or prosecutors who can access the PMP for bona fide specific investigations. The proposed rules authorize tribal officials to have access to PMP data.

In addition, the proposal includes updates and revisions per stakeholders' feedback and recommendations. These proposed updates are intended to enhance the PMP process and procedures to establish clearer standards for dispensers and prescribers participating in PMP in order to better protect the health and safety of the public.

The proposed amendments comprise the following seven topics:

1. Include law enforcement and prosecutorial officials of federally recognized tribes to the existing list of law enforcement groups with authority to access PMP.
2. Change data submission frequency from weekly to daily to improve timeliness of our data.
3. Revise language to make explicit the requirement to submit zero reports to the program within seven days.
4. Add additional fields for reporting in order to enhance system accuracy and offerings.
5. Clarify that a legal guardian of a minor child may obtain the child's PMP record.
6. Include pharmacists as one of the provider groups currently allowed in rule to delegate system access to licensed staff.
7. Provide clarification that PMP information may be retained in the provider's patient healthcare records at which point it is considered and treated as patient healthcare record.

Is a Significant Analysis required for this rule?

Yes, as defined in RCW 34.05.328, portions of the proposed rule require a significant analysis.

Clearly state in detail the general goals and specific objectives of the statute that the rule implements.

The proposed rule implements two statutes—RCW 70.225.020 and RCW 70.225.040. The proposed rules also respond to HB 1637 (Chapter 49, Laws of 2015) that amended RCW 70.225.040.

RCW 70.225.020 requires the department to "establish and maintain a prescription monitoring program" and to adopt rules to implement the statute. The goal of the PMP is to improve health care quality and effectiveness. The objectives of the proposal are to reduce abuse of controlled substances, reduce duplicative prescribing and overprescribing of controlled substances, and improve controlled substance prescribing practices by establishing an electronic database that is available in real time to dispensers and prescribers of controlled substances.

RCW 70.225.040 - The intent of RCW 70.225.040 is to specify which prescribers, individuals, health professional licensing entity, local, state, or federal enforcement or prosecutorial officials may be provided data in the PMP. HB 1637 (2015) amended RCW 70.22.040 to authorize law enforcement and prosecutorial officials of federally recognized Indian tribes access to PMP data for bona fide specific investigations. The proposed rule meets the intent of this underlying statute by including law enforcement and prosecutorial officials of federally recognized tribes to have access to data in the PMP.

Explain how the department determined that the rule is needed to achieve these general goals and specific objectives. Analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed amendments will enable the department to administer the PMP in a more efficient manner. If the department did not adopt these amendments, the rules would be inconsistent with House Bill 1637 passed in the 2015 legislative session. Collectively, the proposed changes will increase the data offerings, the timeliness of the data, improve the data value, and enhance the overall efficiency of the program.

Explain how the department determined that the probable benefits of the rule are greater than the probable costs, taking into account both the qualitative and quantitative benefits and costs and the specific directives of the statute being implemented.

The proposed rules package contains the following legislatively significant rules.

WAC 246-470-030--Data submission requirements for dispensers
(Each description of the proposed change and cost/benefit analysis is listed by the affected subsection)

Subsection (3) Revision - Description of the proposed rule:
Reporting frequency change - Proposed language intends to increase the frequency of reporting to the PMP. Current rule language requires records of dispensed controlled substances to be

reported to the PMP within seven days. The delay between dispensing and reporting creates considerable data lag for patient record availability on the system and is at odds with one of the program objectives defined in RCW 70.225.020, "…with the intent of eventually establishing an electronic database available in real time to dispensers and prescribers of controlled substances." By narrowing the allowable window of time between dispensing and reporting to one business day, patient records will be available to providers on the system up to six days sooner where they can be used in making healthcare decisions in meeting intent of RCW 70.225.020 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…".

Pharmacies are to submit zero reports to the PMP within seven days. In the absence of having received records of dispensing, program must contact each pharmacy to verify no controlled substances were dispensed during the compliance period. These direct communications require staff and often pharmacist time. Zero reports are a means by which pharmacies can submit this verification of no controlled substances activity electronically and often automatically. Pharmacies that do not fill controlled substances may submit a "No Dispensing of Controlled Substances" waiver, which will meet all of their reporting requirements for a licensing period.

Cost/Benefit Analysis:

During the comment period and in stakeholder meetings, respondents said that the rule change would not require any additional professional services and that the increase in reporting sessions for small businesses, including those not contracted with vendors for reporting, may require a slight increase in the total amount of time spent each week preparing data for reporting to the system. The increase is associated with logging in and logging off their computers each day instead of weekly. The time spent uploading the data, because it is the same data, is essentially the same amount of time. The impact of daily reporting versus weekly reporting in many cases is non-significant because chain pharmacies have had to meet daily reporting requirements in a number of states already; some have elected to report daily for Washington as well. Likewise, a majority of pharmacies contract with vendors to do their reporting and the vendors have already had to meet similar daily reporting requirements in other states.

Finally, the department assessed the amount of additional time and cost this proposed rule would impose on pharmacies. The department researched the average hourly rate for pharmacy technicians in Washington State and calculated the standard hourly rate times the additional amount of time daily reporting would require of pharmacy technicians. This net amount would have minimal cost impact to participating dispensers.

Receipt of zero reports in the system saves time for both program and pharmacies by eliminating the need for time intensive direct communications. The expected impact on small pharmacies is either none or provides the benefit of saving time and labor by reducing direct communication time with program.

Subsection (3) (a) (ii) through (xvi) Revision -Description of the proposed rule:
The proposed rules adds additional fields for reporting in order to enhance system accuracy and offerings. Adding additional fields to PMP reports will enhance the accuracy and offerings of the PMP system making the system more valuable to prescribers when making prescribing decisions. The fields in question are already captured on the pharmacy record; however they have not been included on reports to the PMP. Many pharmacies have their reports submitted by a third party. Under typical agreements for maintenance and operation these adjustments to include new data fields are included.

Cost/Benefit Analysis:
The impact to businesses, both large and small, will be a marginal amount of time to adjust reporting structure. Once this one-time adjustment is made, reports will be submitted in the current manner with no additional workload.

WAC 246-470-040--Patient access to information from the program

Description of the proposed rule:
This section defines how patients may obtain their own PMP records, and how parents or legal guardians of minor children may obtain the records of children in their care. The proposed language clarifies that a legal guardian of a minor child may obtain the child's PMP record. The original language was unclear regarding this. The proposed revision also removes reference to federal statute that was unclear and replaced this language with "parent or legal guardian".

Cost/Benefit Analysis:
There is no cost associated with this proposed change. The current reference to the federal statute makes unclear that legal guardians may receive records for children in their legal care. The benefit of the proposed rule is that it will remove the reference that was hard for parents and legal guardians to understand.

WAC 246-470-050--Pharmacist, prescriber or other health care practitioner access to information from the program

Description of the proposed rule:
This section defines which health care providers have access to the PMP and what level of access (master or delegate) they are authorized. The department has the authority to designate access to entities, and this proposed language is just clarifying this current authority per RCW 70.225.020. Proposed language intends to include pharmacists as one of the provider groups currently allowed in rule to delegate system access to licensed staff.

Cost/Benefit Analysis:
The benefit of the proposal is that by adding pharmacists to the list of providers able to delegate PMP access, pharmacists will be able to delegate the task of PMP query to subordinate pharmacy staff, which will result in cost savings. This proposed revision does not create additional cost or

workload to pharmacies and is anticipated it will decrease time/cost associated with PMP query as this function will no longer have to be the responsibility of only the pharmacist.

WAC 246-470-060--Law enforcement, prosecutorial officials, coroners, and medical examiners access to information from the program

Description of the proposed rule:
This section authorizes state, county and federal law enforcement, prosecutorial officials, coroners and medical examiners access to PMP. Proposed language intends to include law enforcement and prosecutorial officials of federally recognized tribes to the existing list of law enforcement groups with authority to access PMP per HB 1637 (2015).

Cost/Benefit Analysis:
This proposed rule has no impact on pharmacies. The benefit of the proposed rule is that it will include law enforcement and prosecutorial officials of federally recognized tribes in the list of those authorized to access PMP data.

WAC 246-470-090--Confidentiality

Description of the proposed rule:
Proposed language clarifies that access to the full PMP database is restricted by RCW 70.225.040 security requirements and once a patient's PMP record has been appropriately retrieved and made part of the patient's healthcare record, the security requirements for access to the full PMP database no longer apply. A patient's PMP information may be retained in the patient's healthcare record at which point it is considered and treated as part of the patient healthcare record.

Cost/Benefit Analysis:
This proposed rule has no impact on pharmacies. The benefit of the rule is that it will state more clearly that healthcare providers may retain PMP data for their patients in the patient's healthcare record without maintaining separate security standards.

Cost Benefit Summary

The proposed rules make several changes to the existing PMP system. Collectively, the proposed changes will increase the data offerings, timeliness of the data, data value, and efficiency of the program. Although these proposed rules will have a nominal impact to pharmacies, as described in the analysis above, the benefits of improved efficiency and effectiveness of the PMP will outweigh these costs. Therefore, the total probable benefits of the rule exceed the total probable costs.

Identify alternative versions of the rule that were considered, and explain how the department determined that the rule being adopted is the least burdensome alternative for those required to comply with it that will achieve the general goals and specific objectives state previously.

In considering changing data submission frequency from weekly to daily to improve timeliness of PMP data, program and stakeholders considered alternatives including time frames that were less than one week but greater than one day, as well as real-time and reporting multiple times daily. Real time reporting was quickly determined to be too costly as an option both for pharmacies as well as for program. Program then evaluated how to maximize benefit while minimizing costs. Daily reporting was determined to offer the greatest benefit while holding costs to a minimum for both pharmacies and program. Additionally, this was further confirmed by the national trend of state PMPs that are also moving to daily reporting frequency.

Determine that the rule does not require those to whom it applies to take an action that violates requirements of 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.

Determine that the rule does not impose more stringent performance requirements on private entities than on public entities unless required to do so by federal or state law.

The rule does not impose more stringent performance requirements on private entities than on public entities.

Determine if the rule differs from any federal regulation or statute applicable to the same activity or subject matter and, if so, 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.

Demonstrate that the rule has been coordinated, to the maximum extent practicable, with other federal, state, and local laws applicable to the same activity or subject matter.

There are no other applicable laws.