

Significant Legislative Rule Analysis

WAC 246-869-105 (New)

A Rule Concerning Continuity of Care
Prescription Refills in a Proclaimed Emergency

May 31, 2016

SECTION 1:

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

The Pharmacy Quality Assurance Commission (Commission) is proposing a new rule to address patient's access to their current medications during a governor-proclaimed emergency. The rule would allow licensed pharmacists to provide prescription refills for legend drugs and certain controlled substances to patients who are displaced and whose access to their medications are disrupted in a declared emergency such as an earthquake, flood, landslide, tsunamis, or wildfire.

In 2014, the Commission-by policy- allowed pharmacists to provide patients with temporary prescription refills in areas hard hit by wildfires that resulted in evacuations of all or parts of some towns. However, the policy could not be enforced if a pharmacist violated its provisions.

In 2015, wildfires in Washington State again displaced entire communities and forced the evacuation of at least one hospital, the entire town of Conconully, and portions of other communities in Eastern Washington. At one point, in June 2015 the governor issued Proclamation 15-11 which declared a wildfire emergency in all 39 counties in the state.

The Commission has determined that rulemaking is needed to provide consistent and enforceable standards, and that a permanent rule would alleviate the need to adopt emergency rules each time patients are displaced from their medications and usual pharmacy services during a governor-proclaimed emergency. The proposed rule would be activated automatically when there is a governor-declared emergency that displaces patients from their usual community pharmacy services.

Currently there is no permanent rule regarding pharmacists issuing temporary prescription refills during a governor-proclaimed emergency.

SECTION 2:

Is a Significant Analysis required for this rule?

Yes. Violations of the proposed rule could result in penalties or sanctions on a licensed pharmacist. So, as defined in RCW 34.05.328, a significant analysis is required.

SECTION 3:

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

The statute associated with new WAC 246-869-105 is RCW 18.64.005 entitled "Commission-Powers and Duties". Specifically, RCW 18.64.005(7) states that, "The Commission shall

promulgate rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. Violation of any such rules shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the commission”.

Thus, the general goals and specific objectives outlined in RCW 18.64.005(7) allow the Commission to initiate rulemaking to develop a permanent rule for the protection and promotion of the public’s health, safety and welfare. By adopting the permanent rule language in proposed new WAC 246-869-105, the statute’s objectives will have been met and the need to adopt emergency rules each time patients are displaced from their medications and usual pharmacy services during a governor-proclaimed emergency will have been alleviated.

SECTION 4:

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.

Existing WAC 246-869-100 only allows pharmacists to provide up to a 72- hour emergency prescription refill in certain circumstances, but does not address refills when patients are displaced from their homes or pharmacy services for longer periods during a major declared emergency such as an earthquake, flood, wildfire, or other disaster.

By adopting the new rule section WAC 246-869-105, pharmacist’s would an additional means of providing patients with larger quantities of necessary medications to meet their needs and help prevent the potential loss of life, suffering, or interruption of medication therapy.

Alternatives to rulemaking can be categorized into only two options. The first option would be to make no changes to the existing process which would consist of filing emergency rules using the proposed rule language in WAC 246-869-105 or similar language during a governor-proclaimed emergency. This option is not feasible and would not be in the best interest of the patient’s health and well-being, particularly during an emergency event that occurs without warning such as a major earthquake.

The second option would be to make changes to the existing WAC 246-869-100 by a proposing an increase in the amount of emergency medication supply allowed to be given to the patient under the circumstances outlined in the rule. This option is not feasible as well because not all emergency refill requests involve patient displacement or extended interruptions of medication therapy. This was not the intent of WAC 246-869-100.

Two separate rule sections – WAC 246-869-100 and the proposed rule - are needed within Chapter 246-869 WAC in order to adequately provide uninterrupted medication therapy to all patients under varying emergency circumstances.

The consequences of not adopting WAC 246-869-105 would be detrimental to the health of all patients affected by a declared state of emergency that involved displacement from their homes

and usual pharmacy services for extended periods of time. In many cases, a 72-hour emergency refill would not provide enough treatment to cover the emergency period and result in worsening of patient health conditions, hospitalizations or even death. A patient would potentially have to visit multiple pharmacies, attempt to acquire numerous 72 hour supplies, in order to obtain enough medication to sustain them over a potential emergency displacement period.

If this type of access or activity were possible, it could endanger the patient or other family members in the process. Under WAC 246-869-100, when an emergency need for medication has been demonstrated by the patient and the prescriber is not available, the pharmacist may dispense enough medication, not exceeding a 72 hours' supply, including controlled substances, to last a patient until a prescriber can be contacted.

SECTION 5:

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.

Essentially, there are minimal to no costs associated with this rule.

The steps necessary for a pharmacist to comply with the proposed rule would be minimal, if any, and comparable to the steps followed in processing a normal prescription for a patient who has never received medications or visited the pharmacy before. The pharmacist would spend the same amount of time writing up the prescription information, attempting to contact a prescriber by phone and filling the prescription(s) with existing stock. If the patient was not be able to provide or produce insurance information for drug coverage, then more time might need to be spent by the pharmacy staff in determining which insurer to bill for the medications being filled.

The probable benefits would be the maintaining of patient health and safety by providing uninterrupted medication therapy to those patients needing their medications during these emergency situations. This new law would allow the pharmacist to provide those necessary medications in a legal and efficient manner and prevent a patient from going without their medication.

SECTION 6:

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.

An alternative version of proposed rule WAC 246-869-105 language was brought before the Commission for approval that removed the language in section (1) pertaining to allowing a seven-day supply of current prescriptions for controlled substance medications in Schedules III, IV and V to be provided to a patient under specific circumstances. The Commission rejected the alternative version and wanted the language to remain intact as original proposed in WAC 246-869-105. Their reasoning for the decision was focused on patient safety and determining that a patient needs their medications, controlled or non-controlled, in order to be appropriately treated and maintain uninterrupted current drug therapy.

The proposed rule is the least burdensome alternative compared to not adopting rules or limiting filling to no more than a 72-hour supply of controlled substances. The proposed rules provide an immediate and enforceable mechanism to refill patient medications when a declared emergency event displaces patients from their usual pharmacy services, and gives pharmacists and pharmacies clear criteria for legally refilling prescriptions during these situations in a manner that protects patient health and safety.

The Commission adopted an “Emergency/Disaster Prescription Refill Guideline” that was put into place in 2014. During the 2015 wild fire season that led to Proclamation 15-11, the Commission determined that the 2105 guideline was not an enforceable policy, and that a rule was needed. The Commission adopted emergency rules in September and December of 2015 (WSR 15-15-101 and 16-02-015 respectively). A subsequent third CR-103E was filed in May of 2016 (WSR 16-11-002) to keep WAC 246-869-105 in effect until the new permanent rule is adopted.

SECTION 7:

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 proposed rule does not require any person to violate a federal or state law.

When the initial emergency rule language was being discussed back in 2015, the Commission members at that time considered the limitations and emergency dispensing safeguards included within 21 CFR 1306.11 for Schedule II controlled substance dispensing, in its determination to allow and limit up to a thirty day supply of current prescriptions for legend drugs or a seven day supply of controlled substance medications in Schedules III, IV and V based on the presentation of a valid prescription container complete with a legible label indicating that valid refills remain in the emergency rule language that was drafted and put into law.

Also considered in this determination was the fact that when the Governor declares an emergency, in almost all instances, the Governor does so, in part, to seek federal assistance. If the event is a natural disaster or terrorist act, federal assistance is available via the Stafford Act, if the President declares an emergency. If the nature of the emergency or disaster, does not qualify for Stafford Act coverage, such as a naturally occurring disease event, the Secretary of

the Department of Health and Human Services can declare a public health emergency under the Public Health Services Act. Federal declarations under the Stafford Act or the PHS Act authorize waivers of various federal requirements and laws.

The proposed rule WAC 246-869-105 limits, in part, the dispensing to only those controlled substances within Schedules III, IV and V and no Schedule II dispensing. Based on the specific safeguards with in this proposed rule, the rule will be in compliance with other emergency activities and practices in place during a Governor declared emergency proclamation and allow a pharmacist to provide a patient their necessary medications uninterrupted.

SECTION 8:

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 proposed rule, WAC 246-869-105, will not impose more stringent performance requirements on private entities than on public entities. The rule language specifically and uniformly outlines the requirements that must be met by a pharmacist, regardless of practice setting, to legally fill a temporary prescription when an emergent event occurs that results in a governor's emergency proclamation displacing a patient from their pharmacy services.

SECTION 9:

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 Commission in its determination of rule language that would appropriately address the patients uninterrupted medication needs during a Governor declared emergency proclamation considered that when the Governor declares an emergency, in almost all instances, the Governor does so, in part, to seek federal assistance. If the event is a natural disaster or terrorist act, federal assistance is available via the Stafford Act, if the President declares an emergency. If the nature of the emergency or disaster, does not qualify for Stafford Act coverage, such as a naturally occurring disease event, the Secretary of the Department of Health and Human Services can declare a public health emergency under the Public Health Services Act. Federal declarations under the Stafford Act or the PHS Act authorize waivers of various federal requirements and laws.

Also, within the Ryan Haight Online Pharmacy Consumer protection Act, adopted by Congress in 2008, provides some leeway under the public health emergency declaration for the use and access to controlled substances for patients in areas subject to declarations of emergency.

Additionally, the Commission believes that during a governor's emergency proclamation, guidance would be provided either from the governor's office or D.E.A. potentially relaxing the requirements needed to allow a pharmacist to properly provide a patient their needed medications.

SECTION 10:

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.

Under RCW 18.64.005(7), the Commission has the authority to "Promulgate rules for the dispensing, distribution, wholesaling and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety and welfare". At the time of a governor declared emergency, other agencies, i.e. F.E.M.A., C.D.C. and Homeland Security, would mobilize and assist patients displaced from their homes providing necessary medical services. The legal counsel for FEMA region 10, verbally agreed with the intended rule language and believes that the rule parallels their objectives in helping those people affected by emergency events.