

# **Significant Legislative Rule Analysis**

Chapter 246-872 WAC (Repeal) and Proposed  
New Chapter 246-874 WAC  
New chapter concerning Pharmacy and  
Technology, and rules regarding Automated  
Drug Distribution Devices

April 26, 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 chapter in rule that would create standards for the use of technology in the practice of pharmacy. In 2012 the Commission identified the rule issues needing action. Revising outdated pharmacy technology rules was chosen among the top two priorities. A Commission Technology Workgroup, formed in 2015, identified 5 pharmacy technology rule subject areas, and in November 2015 recommended updating the automated drug dispensing devices (ADDD) rules as its highest priority. The Commission further proposes this chapter be separated into parts to address different technologies and standards for those technologies. The first part addresses requirements for the use of ADDDs.

In creating this new chapter, the Commission is repealing chapter 246-872 WAC which sets current standards for the use of automated drug distribution devices. The standards set forth in chapter 246-872 WAC were developed and adopted in 2006 in response to pharmacy technology used at the time. Great improvement in technology has occurred in the last 10 years prompting the Commission to reevaluate the standards around the use of ADDDs. The current rules lack clear standards and require pharmacies and health care facilities to present their ADDD policies and procedures before the full Commission for approval prior to the placement of an ADDD in the pharmacy or facility. Additionally, current Commission practice requires updates to these policies and procedures be presented to the full Commission for approval.

The proposed new rule incorporates concepts found in current WAC. The proposed rule builds upon those concepts and adds clarity. The proposed rule also incorporates current practices used by the Commission to approve policies and procedures. In addition to repealing chapter 246-872 WAC, the commission decided to rename the new chapter as Automated Drug Dispensing Devices, replacing “distribution” with “dispensing”. The commission did so to make clear the requirements applied to dispensing devices not devices that incorporate other activities that are seen as distribution by the commission and the regulated community.

Proposed new chapter 246-874 WAC provides clearer requirements for installing and operating an ADDD. The proposed rules describe minimum supervision, access, security, recordkeeping, accountability, and quality assurance standards for an ADDD. The rule states that if a facility installs and operates an ADDD according to these proposed standards, then no prior Commission approval is required. Removing the approval requirement will provide pharmacies and facilities with greater flexibility in the practice of pharmacy, and assist the Commission in workload balance.

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## **SECTION 2:**

**Is a Significant Analysis required for this rule?**

Yes. As defined in chapter 34.05 RCW, the Commission has determined that portions of the proposed rules would result in significant amendments to a policy or regulatory program, and so

require a significant analysis. Violation of the proposed rules may also result in a possible penalty or sanction.

The Commission, however, has determined that WAC 246-874-010 – Definitions does not require significant analysis because it does not meet the definition of a legislatively significant rule.

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### **SECTION 3:**

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

RCW 18.64.005(7) requires the Commission to adopt rules for the dispensing, distribution, wholesaling, and manufacturing of drugs, devices, and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare. The proposed rule provides specific standards for the use of technology in the practice of pharmacy to improve medication safety, appropriate access to medications, and accountability, particularly for controlled substances.

Other sections of chapter 18.64 RCW require pharmacies to maintain and reproduce drug and prescription records for inspection by the Commission. These key elements of recordkeeping and security are necessary to ensure that drugs provided through an ADDD are monitored, stocked, dispensed and disposed of in a manner that protects the public health, safety and welfare.

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### **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.**

In 2012, the Commission did a full review of all pharmacy rules. They determined rules related to technology needed to be revisited to align with advances that had taken place since certain rules were adopted. There are no alternatives to rulemaking because the subject matter of this proposed rule was already in rule and the current chapter 246-872 WAC creates burdensome requirements for health facilities seeking to install ADDDs. Initially it was discussed to merely amend the current WAC, but upon further review it was determined a significant overhaul of chapter 246-872 was needed.

If the proposed rule is not adopted, the Commission will remain burdened by the influx of applications to use these devices, and pharmacies and facilities will continue to be burdened by the process of gaining approval for this technology.

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### **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.**

During the rulemaking process the Commission collected input from stakeholders interested in the proposed rule. Detailed responses are included in the section analysis below.

**1. WAC 246-874-020 General Applicability (new)**

**Description of the proposed rule:** The rule replaces content currently in WAC 246-872-010 proposed for repeal. The proposed rule sets forth and clarifies the facilities that can use ADDDs devices, clarifies what the proposed rule does not apply to, and no longer requires pharmacies and facilities to obtain Commission approval prior to the use of ADDDs. The proposed rule removes medical facilities as defined by RCW 70.40.020(7), and lists out specific facilities that have previously gone before the Commission for approval, and facilities that may desire to take advantage of the security and accountability benefits of an ADDD. “Medical facilities” was removed from the applicability section because it caused confusion around certain facilities, specifically residential treatment facilities and how they qualify to use and ADDD. Additionally the definition of medical facilities referred to federal law and would incorporate outpatient clinics and nursing homes operated under a physician or in connection with a hospital. The Commission does not have jurisdiction to regulate physician practices, and nursing homes were already identified by state law.

**Cost/Benefit Analysis:** There is no cost associated with this proposed rule language. The current rule requires pharmacies and facilities to file an application with appropriate policies and procedures and present to the Commission with subsequent approval. Pharmacies and facilities often have long negotiations with Commission staff to ensure all policies and procedures comply with current rules. After the policies and procedures are vetted by Commission staff, pharmacies and facilities are required to attend a Commission meeting and request approval in person. Removing the requirement for Commission approval of policies and procedures will significantly save stakeholders time, money spent on travel, supplies, and labor costs required needed to prepare and present an application to the Commission.

Instead of presenting to the Commission, the proposed rule requires pharmacies and facilities to file a form with the department listing physical addresses of the facilities where ADDDs will be located. Minimal costs are associated with this requirement, as the form will be available on the Commission’s website and will be free to download.

The proposed rule simply puts current requirements from the Commission for prior approval into rule. The general applicability section lists the types of facilities that have previously gone before the Commission for approval. However, the proposed rule does not increase the burden these facilities would have if they were able to take advantage of ADDDs under the current WAC. Facilities like public health centers previously not included in the facilities allowed to use ADDDs under chapter 246-872 WAC will have to meet the requirements of the proposed rule. While this may require costs for the new facilities allowed to take advantage of ADDDs, it does not require a new or additional cost because the use of an ADDD is voluntary.

**2. WAC 246-874-025 Pharmacist-in-charge designation requirement for an ADDD (new)**

**Description of the proposed rule:** The proposed rule requires a pharmacy or facility wishing to use an ADDD to designate a pharmacist-in-charge as defined in WAC 246- 869-070, WAC 246-873-040, WAC 246-865-060, and WAC 246-904-030.

**Cost/Benefit Analysis:** There is no additional cost for pharmacies and facilities. Pharmacies and facilities are currently required to identify a responsible manager pharmacist under the identified WACs and provide that information to the Commission on their pharmacy license application and renewal. The benefit of the proposed rule is it reaffirms who will be responsible for compliance with state and federal rules and regulations.

**3. WAC 246-874-030 General requirements for an ADDD (new)**

Description of the proposed rule: The rule proposes repeal and replacement of content currently in WAC 246-872-030 and WAC 246-872-040. The current rule needs better organization of the requirements for pharmacy technology. The proposed rule groups appropriate subjects and requirements together and clarifies what the requirements mean. The proposed rule:

- Reiterates the necessity for policies and procedures to be developed and implemented.
- Clarifies what the policies and procedures must address and where the policy and procedures are located. Reiterates standard record keeping retention of two years.
- Clarifies the transaction information an ADDD must be able to collect and maintain.
- Sets requirements for the packaging of medications placed in an ADDD.
- Sets requirements for the storage of patient owned medications in an ADDD.
- Reiterates a pharmacist-in-charge may designate tasks but not ultimate legal responsibility to a pharmacist designee.

**Cost/Benefit Analysis:** The proposed rule would not create additional costs compared to the repealed rules and is expected to result in savings. It provides greater clarity about written policies and procedures and recordkeeping standards for housing and operating an ADDD. The rule will no longer require prior Commission review or approval of the policies and procedures. The pharmacies and facilities ADDD policies and procedures would be subject to review during a site inspection. Facilities are currently required to have policies and procedures on-site which is confirmed in the inspection process, however, compliance with those policies and procedures is the focus; this inspection practice would continue. Currently, a facility must present and have its ADDD policies and procedures, as well as updates, approved at a Commission meeting. As a result, the proposed rules represent a time, labor, travel and supply savings to pharmacies and facilities compared to the current rules.

**4. WAC 246-874-040 Security and safety requirements for ADDD (new)**

**Description of proposed rule:** The rule proposes repeal and replacement of content currently in WAC 246-872-030 and WAC 246-872-040. The current rule needs better organization of the requirements for pharmacy technology. The proposed rule groups appropriate subjects and requirements together and clarifies what the requirements mean. The proposed rule:

- Reiterates the requirement for preventing unauthorized access to the ADDD. The proposed rule, however, requires this prevention to be accomplished by having secure technology, i.e. biometrics, logins, and requires specific timelines for removal of former employees and discharged patients.
- Reiterates the replenishment of an ADDD is reserved to a pharmacist, pharmacy intern, or pharmacy technician.
- Reiterates requirements around technician specialized functions, and the use of electronic verification system checking.
- Clarifies that the pharmacist-in-charge is responsible for access controls.
- Requires prospective drug utilization review, and clarifies when prospective review does not need to occur.
- Clarifies standards regarding medications on override lists, return of meds to an ADDD, and breach of security.
- Requires assisted living facilities to use a double lock system for an ADDD, consistent with guidance from Centers for Medicare and Medicaid Services.

**Cost/Benefit Analysis:** The proposed rule would not create additional costs compared to the repealed rules, and is expected to result in savings. It provides greater clarity about written policies and procedures and recordkeeping standards for housing and operating an ADDD. The rule does not require prior Commission review or approval of the policies and procedures. The licensee's ADDD policies and procedures would be subject to review during a site inspection. Currently, a facility must present and have its ADDD policies and procedures, as well as updates, approved at a Commission meeting. As a result, the proposed rules represent a time, labor, travel and supply savings to pharmacies and facilities compared to the current rules.

## **5. WAC 246-874-050 Accountability requirements for ADDD (new)**

**Description of proposed rule:** The rule proposes repeal and replacement of content currently in WAC 246-872-030 and WAC 246-872-040. In the different sections of the current rule, there are requirements that need to be grouped together. The proposed rule groups appropriate subjects and requirements together and clarifies what the requirements mean. The proposed rule sets the requirements around the tracking, handling, and inventory of medications, specifically controlled substances and reporting requirements for discrepancies.

**Cost/Benefit Analysis:** The proposed rule does not add costs for pharmacies and facilities compared to the repealed rule. The proposed rule provides greater clarity about the drug handling, accountability and inventory tracking, specific stocking requirements for controlled substances, discrepancy monitoring and drug wastage controls. The current rules require the licensee to have an accountability system, but without clear information about the standards the accountability system must achieve. This has led to variable systems among

approved ADDDs, and greater need for Commission review of a licensee's accountability system. Facilities that have already been approved to use an ADDD will have one year to come into compliance with the proposed rule. The proposed rule focuses on the requirements for facilities policies and procedures; the rule does not require facilities to purchase certain technology or devices. Facilities previously approved will not have to purchase new technology or devices to come into compliance because of the rules focus on adequate policies and procedures.

**6. WAC 246-874-060 Quality Assurance requirements for ADDD (new)**

**Description of proposed rule:** The rule replaces content currently in WAC 246-872-040 and 050 proposed for repeal. The proposed rule changes the requirement for compliance audits to annual review rather than quarterly. This change aligns the rules with current practice, and another requirement in the rule for annual review of policies and procedures. Additionally, the proposed rule moves the requirement for monitoring controlled substance discrepancies into a separate accountability section.

**Cost/Benefit Analysis:** The proposed rule contains similar requirements to the current rule, and does not add costs for pharmacies and facilities compared with the repealed rule. Pharmacies and facilities will have greater clarity about the types of quality assurance measures that must be in place for safe and secure operation of an ADDD.

**7. WAC 246-874-070 Nursing student ADDD access (new).**

**Description of proposed rule:** The section of the proposed rule sets the requirements negotiated between the Nursing Care Quality Assurance Commission and the Pharmacy Quality Assurance Commission, regarding the use and access of nursing students and ADDDs.

**Cost/Benefit Analysis:** The cost of this rule is negligible as it only sets parameters for the use of ADDDs by nursing students enrolled in Washington state nursing Commission approved nursing programs. The addition of the proposed rule language will provide a benefit to patient safety and care by providing nursing students with additional training and clarity about student access to an ADDD.

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## **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.**

Requirements determined as unnecessary for the rule were eliminated based on input from pharmacies and facilities.

Not changing the current rules was considered, but was rejected because of their lack of clarity and the requirement for pharmacies and facilities to present their ADDD, policies and procedures (and updates) before the Commission for approval in open session. This requirement created an overly burdensome rule with unnecessary licensee and Commission time and expense to implement.

The Commission's Technology Workgroup first attempted to amend chapter 246-872 WAC within its existing structure. But the current rule was determined to be too outdated. The Commission decided to propose an entire new WAC chapter with more clearly organized standards that reflect current practice.

The workgroup also considered drafting rules with requirements tailored to the type of health care facility where the ADDD would be located, such as hospitals, nursing homes, residential treatment facilities and others. This rule organization was rejected because the separation no longer made sense once general requirements were proposed. Additionally stakeholders rejected one draft they found to be too prescriptive even without the separate facility distinctions.

The workgroup contemplated having the rule apply to automated emergency kits and supplemental dose kits. This idea was rejected because long term care stakeholders felt these proposed rule requirements were too burdensome and not functional for their setting or the use of emergency kits. It was determined rules regarding automated emergency kits would be best handled under different rulemaking.

The proposed rules were determined to provide an acceptable balance between the Commission dictating in rule specific operation, security, accountability, and other standards, and allowing pharmacies and facilities to develop their standards under broader parameters in the rule. The rule also does not require Commission pre-approval before an ADDD is installed, provided it meets the requirements of the proposed new rules. Compliance will be monitored through regular Commission inspection of ADDDs and the licensee's written ADDD standards, policies and procedures. Overall, the proposed rules represent the least burdensome alternative, by clarifying requirements and removing the pre-approval requirement in the current rules. As a result, the proposed rules would reduce costs and administrative burdens on pharmacies and facilities, as well as allowing the Commission to reallocate resources currently dedicated to reviewing and approving ADDDs.

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## **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 rule does not require those to whom it applies to take an action that violates requirements of federal or state law. The rules require pharmacies and facilities to follow applicable state and federal laws and rules.

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## **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 rule does not impose more stringent performance requirements on private entities than on public entities. Both publicly and privately-owned health care facilities must follow the same requirements for using an ADDD.

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## **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 proposed rules do not differ from any federal regulation or statute applicable to the same activity or subject matter.

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## **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.**

The proposed rules require pharmacies and facilities using an ADDD to comply with all applicable state and federal laws and rules applicable to their use with controlled substances and other legend drugs, as well as labeling, recordkeeping and security requirements. The rules cite the specific state laws that must be followed regarding an ADDD.