



PROPOSED RULE MAKING

CR-102 (June 2012)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health- Pharmacy Quality Assurance Commission

- Preproposal Statement of Inquiry was filed as WSR 14-23-046 ; or
- Expedited Rule Making--Proposed notice was filed as WSR ; or
- Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

Chapter 246-872 WAC - Automated Drug Distribution Devices (Repeal); and creating a new chapter 246-874 WAC - Pharmacy and Technology. The new chapter will include several parts regarding different technologies; the first will be Automated Drug Dispensing Devices.

Hearing location(s): Department of Health
Center Point Corporate Park
20425 72nd Avenue S, Building 2, Suite 310
Kent, WA 98032

Date: 8/31/2016

Time: 2:30 PM

Submit written comments to:

Name: Tracy West
Address: Department of Health
Pharmacy Quality Assurance Commission
P.O. Box 47852
Olympia, WA 98504
e-mail: <https://fortress.wa.gov/doh/policyreview>
fax (360) 236-2260 by (date) 08/19/2016

Assistance for persons with disabilities: Contact

Doreen Beebe by 08/16/2016

TTY (800) 833-6388 or () 711

Date of intended adoption: 08/31/2016

(Note: This is NOT the effective date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The proposed new rules incorporate concepts found in the current WAC, build upon those concepts, and adds clarity. The proposed rules also incorporate current practices used by the commission to approve policies and procedures. The proposed new chapter 246-874 WAC provides clearer requirements for installing and operating an Automated Drug Dispensing Device (ADDD). The proposed rules describe minimum supervision, access, security, recordkeeping, accountability, and quality assurance standards for an ADDD. The proposed rules state that if a facility installs and operates an ADDD according to these proposed standards, then no prior commission approval will be 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.

Reasons supporting proposal:

Chapter 246-872 WAC is outdated and great improvement in technology has occurred in the last 10 years prompting the commission to reevaluate the standards around the use of ADDDs.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. Updated rules with clear standards will help streamline the process by eliminating full commission pre-approval.

Statutory authority for adoption:

RCW 18.64.005

Statute being implemented:

Chapter 18.64 RCW and RCW 18.64.005

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: July 18, 2016

TIME: 9:20 AM

WSR 16-15-058

DATE July 18, 2016

NAME (type or print)

Steve Saxe, RPh

SIGNATURE

TITLE

Executive Director

(COMPLETE REVERSE SIDE)

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

No comments or recommendations.

Name of proponent: (person or organization) Pharmacy Quality Assurance Commission Private
 Public
 Governmental

Name of agency personnel responsible for:		
Name	Office Location	Phone
Drafting..... Tracy West	Office of the Assistant Secretary, HSQA, 111 Israel Rd, Tumwater, WA 98501	(360) 236-4988
Implementation.... Steve Saxe	Pharmacy Quality Assurance Commission, 111 Israel Rd, Tumwater, WA 98501	(360) 236-4853
Enforcement..... Steve Saxe	Pharmacy Quality Assurance Commission, 111 Israel Rd, Tumwater, WA 98501	(360) 236-4853

Has a small business economic impact statement been prepared under chapter 19.85 RCW or has a school district fiscal impact statement been prepared under section 1, chapter 210, Laws of 2012?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Tracy West

Address: Office of the Assistant Secretary, HSQA
PO Box 47863, Olympia, WA 98504-7863

phone (360) 236-4988

fax (360)236-4626

e-mail tracy.west@doh.wa.gov

No: Please explain: