



PROPOSED RULE MAKING

CR-102 (June 2024)
(Implements RCW 34.05.320)
Do **NOT** use for expedited rule making

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STATE OF WASHINGTON
FILED

DATE: October 22, 2024

TIME: 3:59 PM

WSR 24-21-154

Agency: Department of Health and Pharmacy Quality Assurance Commission

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 22-02-015 ; 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); or

Proposal is exempt under RCW _____.

Title of rule and other identifying information: (describe subject) Medication assistance. The Pharmacy Quality Assurance Commission (commission) and the Department of Health (department) are jointly proposing adding five new sections—WACs 246-945-710, 246-945-712, 246-945-714, 246-945-716, and 246-945-718—to establish standards for the practice of medication assistance. The proposed rules describe definitions, actions, and restrictions pertaining to the provision of medication assistance in accordance with chapter 69.41 RCW.

Hearing location(s):

Date:	Time:	Location: (be specific)	Comment:
12/12/2024	9:30 am	<p>Physical location: Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501</p> <p>Virtual: To access the meeting on December 12, 2024, at 9:30 am, go to https://zoom.us/join or https://us02web.zoom.us/j/87143495001 and use the Webinar ID 871 4349 5001</p> <p>The access options include one tap mobile: US: +12532158782,,87149465001# or +16699009128,,87149465001#</p> <p>Or Telephone: Dial (for higher quality, dial a number based on your current location): US: +1 253 215 8782 US (Tacoma) or +1 253 205 0468 US</p> <p>International numbers available: https://us02web.zoom.us/j/87143495001</p>	The commission and department will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: December 12, 2024 (Note: This is **NOT** the effective date)

Submit written comments to:

Name Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Email <https://fortress.wa.gov/doh/policyreview/>
Fax 360-236-2901

Assistance for persons with disabilities:

Contact Joshua Munroe
Phone 360-503-5058
Fax 360-236-2901
TTY 711

Other None	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of filing	Other None
By (date and time) November 25, 2024 at 11:59 pm	By (date) November 25, 2024

Purpose of the proposal and its anticipated effects, including any changes in existing rules: The purpose of the proposed rule is to re-establish and update regulatory guidelines around the practice of medication assistance under the commission's jurisdiction. The proposed rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, handing an individual their prefilled insulin syringe, transferring an individual's medication from one container to another in order to prepare an individual dose, and medication alteration, provided the individual is aware their medication is being altered.

Reasons supporting proposal:

The commission conducted a rule consolidation project resulting in the formation of a new chapter—chapter 246-945 WAC—which went into effect in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking was conducted to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department began work on permanent rulemaking. The CR-101 Preproposal Statement of Inquiry was filed on December 27, 2021, under WSR 22-02-015.

The commission largely retained the medication assistance rule language formerly in chapter 246-888 WAC as its emergency rule language while the standard rulemaking process is ongoing. Each filing of the emergency rules remained the same while the goal of the standard rulemaking was to update and streamline the language. The purpose for doing so was so individuals involved in providing medication assistance services would not need to regularly change their standards of practice around medication assistance regularly with each filing of a new emergency rule. The commission worked in collaboration with and received feedback from the Washington State Board of Nursing (WABON), the Department of Social and Health Service (DSHS), and interested parties such as the Washington Health Care Association as it drafted updated rule language for this proposal. The proposed rule is different than the current emergency rules. This collaboration allowed the commission to craft language within its jurisdiction that meets the needs of the impacted community and will not disrupt the existing practice of medication assistance in Washington State when the proposed rule language is enacted.

Statutory authority for adoption: RCW 18.64.005, 69.41.010(15), and 69.41.075

Statute being implemented: RCW 18.64.005, 69.41.010(15), and 69.41.075

Is rule necessary because of a:

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

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

Name of agency personnel responsible for:

	Name	Office Location	Phone
Drafting	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Implementation	Joshua Munroe	111 Israel Rd SE, Tumwater, WA 98501	360-502-5058
Enforcement	Marlee O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No
 If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

Name
Address
Phone
Fax
TTY
Email
Other

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

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

Name Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

- | | |
|---|--|
| <input type="checkbox"/> RCW 34.05.310 (4)(b)
(Internal government operations) | <input type="checkbox"/> RCW 34.05.310 (4)(e)
(Dictated by statute) |
| <input type="checkbox"/> RCW 34.05.310 (4)(c)
(Incorporation by reference) | <input type="checkbox"/> RCW 34.05.310 (4)(f)
(Set or adjust fees) |
| <input checked="" type="checkbox"/> RCW 34.05.310 (4)(d)
(Correct or clarify language) | <input type="checkbox"/> RCW 34.05.310 (4)(g)
((i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit) |

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#). (Does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule: The proposed rule section WAC 246-945-710 provides definitions for key terms used in clarifying the practice of medication assistance in community-based and in-home care facilities without materially changing how those practices are allowed or restricted in rule.

(2) Scope of exemptions: Check one.

- The rule proposal: Is fully exempt. (*Skip section 3.*) Exemptions identified above apply to all portions of the rule proposal.
- The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):
- The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

(3) Small business economic impact statement: Complete this section if any portion is not exempt.

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

The following is a brief description of the proposed rule including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The purpose of the proposed rule is to re-establish and update regulatory guidelines around the practice of medication assistance under the Pharmacy Quality Assurance Commission's (commission) jurisdiction. This rule establishes criteria for medication assistance in community-based and in-home care settings in accordance with chapter 69.41 RCW. The definition for medication assistance provided in RCW 69.41.010(15) states:

"Medication assistance" means assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or in-home care setting to facilitate the individual's self-administration of a legend drug or controlled substance. It includes reminding or coaching the individual to take their medication, handing the medication container to the individual, opening the individual's medication container, using an enabler, or placing the medication in the individual's hand, handing an individual their prefilled insulin syringe, transferring an individual's medication from one container to another in order to prepare an individual dose, and medication alteration, provided the individual is aware their medication is being altered.

The commission conducted a rule consolidation project resulting in the formation of a new chapter—chapter 246-945 WAC—which went into effect in July 2020. The old rules, including the former rules on medication assistance (chapter 246-888 WAC), were repealed in March 2021. The commission's repeal of chapter 246-888 WAC resulted in unintended disruptions for medication assistance in the community-based and in-home care settings permitted under chapter 69.41 RCW. Emergency rulemaking was conducted to immediately restore medication assistance regulations to preserve patient safety and welfare while the commission and the department began work on permanent rulemaking. The CR-101 Rules Inquiry package was filed on December 27, 2021 under WSR 22-02-015.

The commission largely retained the medication assistance rule language formerly in chapter 246-888 WAC as its emergency rule language while the standard rulemaking process is ongoing. Each filing of the emergency rules remained the same while the goal of the standard rulemaking was to update and streamline the language. The purpose for doing so was so individuals involved in providing medication assistance services would not need to regularly change their standards of practice around medication assistance regularly with each filing of a new emergency rule. The commission worked in collaboration with and with feedback from the Washington State Board of Nursing (WABON), the Department of Social and Health Service (DSHS), and interested parties such as the Washington Health Care Association as it drafted updated rule language for the CR-102 Rules Proposal package. This collaboration allowed the commission to craft language within its jurisdiction that meets the need of the impacted community and will not disrupt the existing practice of medication assistance in Washington State when the proposed rule language is enacted.

Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to comply to the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
623312	Assisted living facilities for the elderly without nursing care	1869	\$3,244.87

The following is an analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

WAC 246-945-714 MEDICATION ASSISTANCE BY NONPRACTITIONERS.

Description: Per RCW 69.41.010, nonpractitioners—individuals who do not fall into the category of practitioner defined in RCW 69.41.010(17)—may provide medication assistance to individuals. The proposed rule outlines the actions that qualify as medication assistance. Nonpractitioners may only provide medication assistance in circumstances where a practitioner

determines that it is “necessary and appropriate.” Lastly, medication assistance involving intravenous or injectable medications, except prefilled insulin syringes, may not be provided by nonpractitioners.

Cost(s): As WAC 246-945-714 describes who may provide medication assistance and under what circumstances that assistance may be provided, there are no measurable financial costs associated with the requirements outlined in the proposed section of rule. This rule is permissive and does not require these settings to utilize nonpractitioners for medication assistance. The proposed parameters for medication assistance would not require entities such as community-based or in-home care settings to incur additional costs to comply with the medication assistance rules.

WAC 246-945-716 SELF-ADMINISTRATION IN LICENSED ASSISTED LIVING FACILITIES.

Description: The proposed rule allows “self-administration” under circumstances in which an individual in a licensed assisted living facility is physically unable to administer their own medications but is able to accurately direct others to do so.

Cost(s): WAC 246-945-716 is also a permissive rule and there are no known costs of compliance with the rule. Assisting in self-administration per this proposed section of rule would be included in existing duties performed by the nonpractitioner or facility personnel in the care setting in which medication assistance occurs.

WAC 246-945-718 MEDICATION ASSISTANCE — RESTRICTIONS.

Description: The proposed rule limits medication assistance to only be provided if the individual is cognitively aware they are receiving the medication and must occur immediately prior to the individual’s self-administration of the medication. Only persons legally authorized to administer medication to an individual may do so, and only if the individual is not able to administer their medication independently or with assistance. The proposed rule also clarifies that WACs 246-945-710 through 246-945-718 do not limit the rights of people with functional disabilities to self-direct care in accordance with chapter 74.39 RCW.

Cost(s): There are no anticipated financial costs to entities that must comply with WAC 246-945-718. Commission staff believe that facilities already have persons available to provide the medication assistance services described in rule.

Analysis on if the proposed rule may impose more than minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

The proposed rules do not impose any probable costs and therefore are less than the minor cost threshold of \$3,244.87 for assisted living facilities. The proposed rules potentially save money for entities providing medication assistance services should an entity choose to employ a nonpractitioner in place of a registered nurse.

Summary of how the costs were calculated

None of the proposed changes described in WAC 246-945-714, 246-945-716, and 246-945-718 have probable costs associated with them.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-502-5058
Fax 360-236-2901
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Signature:

Date: October 22, 2024

Name: Hawkins DeFrance, PharmD and Kristin Peterson,
JD for Umair A. Shah, MD, MPH

Title: Pharmacy Quality Assurance Commission Chair and
Chief of Policy for Secretary of Health



PART 5 - MEDICATION ASSISTANCE

NEW SECTION

WAC 246-945-710 Scope and applicability. WAC 246-945-710 through 246-945-718 only apply to medication assistance rendered by a nonpractitioner to an individual residing in a community-based care setting or an in-home care setting.

NEW SECTION

WAC 246-945-712 Definitions. The definitions in this section apply to WAC 246-945-710 through 246-945-718 unless the context clearly requires otherwise:

(1) "Community-based care settings" has the same meaning as RCW 69.41.010.

(2) "Enabler" means a physical device or devices used to facilitate an individual's self-administration of a medication including, but not limited to, a medicine cup, glass, cup, spoon, bowl, prefilled insulin syringe, a specially adapted table surface, straw, piece of cloth, fabric, or the individual's hand.

(3) "Hand-over-hand administration" means a person is providing total physical assistance to an individual when administering the individual's medication.

(4) "In-home care settings" has the same meaning as RCW 69.41.010.

(5) "Individual" means a person residing in a community-based setting or in-home care setting.

(6) "Medication" means legend drugs, including controlled substances, prescribed to an individual residing in a community-based care setting and an in-home care setting. Medication does not include oxygen.

(7) "Medication alteration" means alteration of a medication by a nonpractitioner to prepare a medication for an individual's self-administration and includes, but is not limited to, crushing tablets, cutting tablets in half, opening capsules, mixing powdered medications with foods or liquids, mixing tablets or capsules with foods or liquids, or altering an oral medication for administration via enteral tube.

(8) "Practitioner" has the same meaning as RCW 69.41.010.

NEW SECTION

WAC 246-945-714 Medication assistance by nonpractitioners. (1)

An individual may receive medication assistance from nonpractitioners. Medication assistance only includes:

- (a) Reminding or coaching the individual to take their medication;
- (b) Handing the individual their medication container;
- (c) Opening the individual's medication container;
- (d) Using an enabler, except if a nonpractitioner uses the individual's hand as an enabler, the nonpractitioner may only steady or guide an individual's hand while the individual administers a medication to themselves and may not engage in "hand-over-hand" administration;
- (e) Placing the individual's medication in their hand;
- (f) Handing an individual their prefilled insulin syringe;
- (g) The transfer of an individual's medication from one container to another container for the purpose of preparing an individual dose; or
- (h) Medication alteration. An individual must be aware that their medication has been altered.

(2) A nonpractitioner shall only perform the medication assistance described in subsection (1)(g) and (h) of this section, where a practitioner has determined and communicated orally or by written direction that such medication preparation assistance is necessary and appropriate.

(3) A nonpractitioner shall not provide medication assistance to individuals that involves intravenous medications or injectable medications, except handing an individual their prefilled insulin syringes.

NEW SECTION

WAC 246-945-716 Self-administration in licensed assisted living facilities. In licensed assisted living facilities, self-administration may include situations in which an individual cannot physically self-administer medications but can accurately direct others.

NEW SECTION

WAC 246-945-718 Medication assistance—Restrictions. (1) Medication assistance must only be provided if the individual is cognitively aware they are receiving medications.

(2) Medication assistance must occur immediately prior to the individual's self-administration of the medication.

(3) If an individual is not able to administer a medication to themselves independently or with assistance, then the medication must be administered to the individual by a person legally authorized to do so.

(4) WAC 246-945-710 through 246-945-718 do not limit the rights of people with functional disabilities to self-direct care according to chapter 74.39 RCW.