PROPOSED RULE MAKING

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

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FILED

DATE: August 29, 2025
TIME: 8:43 AM

WSR 25-18-070

Agency: Department of Health – Pharmacy Quality Assurance Commission

☒ **Original Notice**
☐ **Supplemental Notice to WSR**
☐ **Continuance of WSR**

☒ **Preproposal Statement of Inquiry was filed as WSR** 23-20-115**; 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) Alternate distribution models for a dispensed prescription drug for the purpose of re-dispensing or subsequent administration to a patient. The Pharmacy Quality Assurance Commission (commission) is proposing a new section, WAC 246-945-416 Alternate Distribution Models, related to how alternate distribution models for prescribed and dispensed medications may be used by dispensing facilities and receiving facilities regulated by the commission that choose to use such models.

Hearing location(s):

Date:	**Time:**	**Location:** (be specific)	**Comment:**
10/16/2025	1:30 pm	**Physical location:** Labor & Industries Building 7273 Linderson Way SW Tumwater, WA 98501 **Virtual**: To access the meeting on October 16, 2025 at 9:00 am, go to https://zoom.us/join or https://us02web.zoom.us/j/86309299195 and use the Webinar ID 863 0929 9195 The access options include one tap mobile: US: +12532158782,,86309299195# or +16699009128,,86309299195# Or Telephone: Dial(for higher quality, dial a number based on your current location): US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or	The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

		+1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799 Webinar ID: 861 1495 8466 International numbers available: https://us02web.zoom.us/u/kdLNo6unOZ	

Date of intended adoption: 10/16/2025 (Note: This is **NOT** the **effective** date)

Submit written comments to:	**Assistance for persons with disabilities:**
Name Joshua Munroe	Contact Joshua Munroe
Address PO Box 47852, Olympia, WA 98504-7852	Phone 360-502-5058
Email PharmacyRules@doh.wa.gov	Fax 360-236-2901
Fax 360-236-2901	TTY 711
Other https://fortress.wa.gov/doh/policyreview	Email PharmacyRules@doh.wa.gov
Beginning (date and time) The date and time of filing	Other None
By (date and time) October 2, 2025 by 11:59 pm	By (date) October 2, 2025

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

The commission initiated rulemaking in 2023 on the topic of drug transfer practices such as “white bagging” and “brown bagging,” now referred to in rulemaking documents as “alternate distribution models” (ADM). These models outline the delivery method of filled prescriptions such as a specialty medication from the dispensing facility that produces or compounds it to a receiving facility at which the medication is administered to the patient.

Following ADM discussions held at commission business and task force meetings, the commission determined that it needed to consider adding more robust regulatory standards to ensure product integrity and patient safety in its rules chapter. Commission staff drafted rule language for a new section WAC 246-945-416 that establishes definitions relating to ADM, allows and prohibits actions for facilities that choose to utilize ADM, and sets a requirement for dispensing facilities and receiving facilities utilizing such models with one another to create a contract or agreement between both parties.

The anticipated effect of the proposed rules is to establish regulatory standards for alternate distribution models so that dispensing facilities and receiving facilities regulated by the commission can guarantee greater patient safety and product integrity should those facilities choose to use such models. This would be accomplished through limiting the types of distribution models dispensing and receiving facilities are allowed to use, and by requiring a contract or agreement between parties to reduce miscommunications that lead to distribution, storage, and handling errors for medications for which alternate distribution models would apply.

Reasons supporting proposal:

According to a 2018 report prepared by the National Association of Boards of Pharmacy, white bagging refers to “the distribution of patient-specific medication from a pharmacy . . . to the physician’s office, hospital, or clinic for administration” and brown bagging refers to “the dispensing of a medication from a pharmacy . . . directly to the patient, who then transports the medication(s) to the physician’s office for administration.”[1] Certain drugs are often the subject of white bagging and brown bagging practices. In 2015, 28% of medical benefit drugs—drugs that are injected or infused by a healthcare professional in an infusion center—were distributed to physician offices via brown bagging.[2] As of 2016, 28% of oncology drugs were distributed through white bagging and brown bagging practices.[3]

Alternate distribution models represent a different approach to the traditional chain-of-custody for prescribed medications. Concerns have been raised over ensuring the integrity and quality of these medications is maintained if such practices are used by prescribers, hospitals, or patients because these practices can create an unknown chain of custody. The commission cited a lack of clear regulatory standards on these distribution models in Washington as justification for rulemaking, and later explained that the intent of the rulemaking was to establish a clear understanding of what types of distribution models are allowed and to reduce potential miscommunication between dispensing and receiving facilities that could result in loss of product and delayed care to patients.

[1] National Association of Boards of Pharmacy (2018). *White and Brown Bagging Emerging Practices, Emerging Regulation*. https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf

[2] Fein, Adam J. (April 16, 2016). *New Data: How Outrageous Hospital Markups Hike Drug Spending*. https://www.drugchannels.net/2016/04/new-data-how-outrageous-hospital.html

[3] Genentech (2016). *The 2016 Genentech Oncology Trend Report: Perspectives From Managed Care, Specialty Pharmacies, Oncologists, Practice Managers, and Employers.* https://www.gpbch.org/docs/2016_genentech_oncology_trend_report.pdf

Statutory authority for adoption: RCW 18.64.005

Statute being implemented: 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:

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:

- ☐ RCW 34.05.310 (4)(b) (Internal government operations)
- ☐ RCW 34.05.310 (4)(c) (Incorporation by reference)
- ☒ RCW 34.05.310 (4)(d) (Correct or clarify language)
- ☐ RCW 34.05.310 (4)(e) (Dictated by statute)
- ☐ RCW 34.05.310 (4)(f) (Set or adjust fees)
- ☐ 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: WAC 246-945-416(1) includes definitions for specific terminology used throughout the new chapter and exempt from the significant analysis because it proposes clarifying language.

(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):

	Proposed WAC Sections and Title	This proposed rule section is not exempt. Analysis is required	This proposed rule section is exempt. Provide RCW to support this exemption.
1.	*WAC 246-945-416(1) Definitions*		*RCW 34.05.310 (4)(d) because the proposed rule language clarifies terms used throughout the rule language without changing its effect of the rule.*

☐ 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.

☐ 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:

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 Pharmacy Quality Assurance Commission (commission) initiated rulemaking in 2023 on the topic of drug transfer practices such as "white bagging" and "brown bagging," now referred to in rulemaking documents as "alternate distribution models." These models outline the delivery method of filled prescriptions such as a specialty medication from the dispensing facility that produces or compounds it to a receiving facility at which the medication is administered to the patient. The commission cited a lack of clear regulatory standards on these distribution models in Washington state as justification for rulemaking.

According to a 2018 report prepared by the National Association of Boards of Pharmacy, white bagging refers to "the distribution of patient-specific medication from a pharmacy... to the physician's office, hospital, or clinic for administration" and brown bagging refers to "the dispensing of a medication from a pharmacy... directly to the patient, who then transports the medication(s) to the physician's office for administration."[4] Certain drugs are often the subject of white bagging and brown bagging practices. In 2015, 28% of medical benefit drugs—drugs that are injected or infused by a healthcare professional in

[4] National Association of Boards of Pharmacy (2018). *White and Brown Bagging Emerging Practices, Emerging Regulation*. https://nabp.pharmacy/wp-content/uploads/2018/04/White-Bagging-and-Brown-Bagging-Report-2018_Final-1.pdf

an infusion center—were distributed to physician offices via brown bagging.[5] As of 2016, 28% of oncology drugs were distributed through white bagging and brown bagging practices.[6]

These distribution models represent a different approach to the traditional chain-of-custody for prescribed medications. Concerns have been raised over ensuring the integrity and quality of these medications is maintained if such practices are used because these practices can create an unknown chain of custody.

Following discussions held at commission business and task force meetings, the commission determined that it needed to consider adding more robust regulatory standards for dispensing facilities and receiving facilities that may utilize alternate distribution models to ensure product integrity and patient safety in its rules chapter.

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
446110	Pharmacies	267**	$19,161.74

*As explained in the Significant Analysis, pharmacies are not required to engage with alternate distribution models as described in WAC 246-945-416. For pharmacies that could be classified as a dispensing facility or a receiving facility and choose to utilize such models, they would need to comply with any cost or regulatory elements described in the proposed rule.

**The Employment Security Department (ESD) reported 267 businesses categorized as Pharmacies and Drug Stores, but Department of Health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

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 246-945-416 Alternate distribution models.

Description: The proposed rule establishes definitions in subsection (1) relating to alternate distribution models, defining the types of facilities that dispense or receive medications under such models. The subsection also describes what qualifies as a "filled prescription" and an "injectable medication," for purposes of this rule. As indicated above this subsection is exempt from analysis as it only clarifies the use of terms uses throughout the section.

Subsection (2) prohibits the practice known as "brown bagging," in which a receiving facility takes possession of a filled prescription dispensed and delivered from a dispensing facility that was previously received, stored, and handled by the patient or patient's representative.

Subsection (3) allows for a receiving facility to take possession of filled prescriptions delivered to it by the dispensing facility if certain conditions are met. This action is allowed only if the receiving facility cannot directly procure the filled prescription through standard distribution channels, or if the receiving facility cannot compound the filled prescription at the health care facility where that prescription would be administered to the patient by a health care professional.

Subsection (4) requires a written contract or agreement between the receiving and dispensing facilities that describes procedures such as a delivery system and the responsibilities of each party.

Subsection (5) identifies the filled prescriptions to which the rule does not apply. Exempt prescriptions are filled prescriptions sent from a dispensing facility to a receiving facility where both facilities are under common ownership, filled prescriptions sent by a compounding pharmacy or registered outsourcing facility at the request and specification of the receiving facility, or filled prescriptions for home infusion patients.

The proposed rule is designed to establish a clear chain-of-custody for filled prescriptions and decrease instances of those prescriptions becoming unusable due to delivery method or miscommunication between facilities resulting in incorrect prescriptions being sent to the receiving facility.

[5] Fein, Adam J. (April 16, 2016). *New Data: How Outrageous Hospital Markups Hike Drug Spending*. https://www.drugchannels.net/2016/04/new-data-how-outrageous-hospital.html

[6] Genentech (2016). *The 2016 Genentech Oncology Trend Report: Perspectives From Managed Care, Specialty Pharmacies, Oncologists, Practice Managers, and Employers.* https://www.gpbch.org/docs/2016_genentech_oncology_trend_report.pdf

Cost(s): The purpose of WAC 246-945-416 is to establish enforceable regulatory guidelines for alternate distribution models that are already in use by dispensing and receiving facilities regulated by the commission in Washington. The use of such distribution models is also optional for facilities identified in the proposed section of rule, so any reported costs and benefits are not a requirement for all regulated facilities but only those that choose to engage with alternate distribution models. Both one-time and ongoing costs for the proposed rule are associated.

***One-time costs*:** The one-time cost incurred for the purpose of complying with the proposed rule is the development of a contract or agreement between the dispensing facility and receiving facility, per WAC 246-945-416(4). Commission staff estimate, based on consultation with pharmacists and comparison to similar processes, that developing a contract or agreement would require between one and three hours of staff time depending on how the facilities structure the core elements such as delivery system procedures and party responsibilities, and whether legal counsel would be required to review a drafted contract.

The commission and department assume that the responsibility to develop the policies and procedures will be given to pharmacy assistants, pharmacy technicians, or equivalent administrative staff, with final approval of the policies and procedures given either by a pharmacist or attorney. It is expected that the practitioner or pharmacist would take an additional one to two hours to review and approve the drafted policies and procedures.

SBEIS Table 2. Average Wage Data and Training Costs, Dispensing Facilities

Occupation	Average Hourly Wage*
Pharmacist	$75
Pharmacy Technician	$28
Pharmacy Assistant/ Pharmacy Aide	$22
Office and Administrative Support Occupations	$28
Lawyer	$83

*The average hourly wage for practitioners—excluding dentists—is derived from the 2024 wage statistics reported by the U.S. Bureau of Labor and Statistics. Average hourly wage rounded up to the next whole number.[7]

Using the above time estimates, the lower-cost scenario would include one hour of contract or agreement development time by a pharmacy assistant or pharmacy aide and one hour of review time by a pharmacist. Applying the wage data from SBEIS Table 2, a receiving facility or dispensing facility would expect to incur **$97** as a low-end cost.

The higher-cost scenario is based off three hours of contract or agreement drafting time by a pharmacist working in the dispensing or receiving facility and an additional two hours of review time by an attorney. Therefore, a facility that would need to comply with WAC 246-945-416 would expect to incur **$391** as a one-time cost. While it is possible that costs could be higher should an attorney be asked to both draft a contract and help with the review of the document, this circumstance was deemed unlikely.

- Low (1 hour drafting + 1 hour review): **$97**
- High (3 hours drafting + 2 hours review): **$391**

***Recurrent / Ongoing costs*:** Dispensing facilities and receiving facilities would need to review the existing contract or agreement. Commission staff estimate that, at most, one hour would be needed from a facility to conduct the review. This task could be assigned to a pharmacy technician, pharmacist, or attorney familiar with the existing contract or agreement. As a result, the annual ongoing cost associated with the alternate distribution model rule would fall into the following range:

- Low (1 hour review by an attorney): **$22**
- High (1 hour review by an attorney): **$83**

[7] Washington - May 2024 OEWS State Occupational Employment and Wage Estimates (bls.gov)

Summary of all Cost(s)

SBEIS Table 3. Summary of Section 3 probable cost(s)**

WAC 246-945-416, Alternate Distribution Models		
Regulated Entity	**One-Time Cost(s)**	**Ongoing Cost(s)**
Dispensing facility as defined in WAC 246-945-416(1)(a)	**$97 - $391**	**$22 - $83**
Receiving facility as defined in WAC 246-945-416(1)(d)	**$97 - $391**	**$22 - $83**

**The one-time and ongoing costs reported in this table reflect a single contract or agreement developed by a receiving or dispensing facility. A facility could encounter higher costs if it develops multiple contracts or agreements with additional facilities, but the commission determined this would be rare.

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.

No, the costs of the proposed rule—at most $391 one-time costs and $83 in annual ongoing costs per contract or agreement for each facility choosing to use alternate distribution models—are less than the minor cost threshold of $19,161.74 for pharmacies.

Summary of how the costs were calculated

The range of costs associated with drafting and reviewing a contract or agreement between a dispensing facility and a receiving facility is calculated by assessing the average wage amounts reported by the U.S. Bureau of Labor and Statistics for pharmacists, pharmacy technicians, pharmacy assistants/aides, administrative support occupations, and attorneys.

Low-end cost calculation: One hour of drafting time by a pharmacy assistant/aide and one hour review time by a pharmacist. One hour of review time by a pharmacy technician annually.

High-end cost calculation: Three hours of drafting time by a pharmacist and two hours review time by an attorney. One hour of review time by an attorney annually.

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 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other

Date: August 29, 2025 **Name:** Hawkins DeFrance, PharmD **Title:** Pharmacy Quality Assurance Commission Chair	**Signature:**

NEW SECTION

WAC 246-945-416 Alternate distribution models. (1) For the purpose of this section, the following definitions apply unless the context clearly requires otherwise:

(a) "Dispensing facility" or "dispensing facilities" means an entity that dispenses and delivers filled prescriptions to a patient, a patient's representative, or other third party for subsequent administration by a licensed health care professional acting within their scope of practice at a health care facility.

(b) "Filled prescription" or "filled prescriptions" means an injectable medication that has been dispensed and delivered pursuant to a prescription by a dispensing facility.

(c) "Injectable medication" means a drug or biological product approved by the FDA for administration by injection through the skin or other external boundary tissue to reach a blood vessel, organ, tissue, or lesion. Routes of administration include, but are not limited to:

(i) Intravenous;

(ii) Intramuscular;

(iii) Subcutaneous;

(iv) Intradermal;

(v) Intraocular; or

(vi) Intrathecal.

(d) "Receiving facility" or "receiving facilities" means a pharmacy, HCE, or HPAC that receives filled prescriptions from a patient, a patient's representative, or other third party for subsequent administration of the filled prescription by a licensed health care professional acting within their scope of practice at a health care facility.

(2) Receiving facilities may not take possession of filled prescriptions dispensed and delivered by a dispensing facility if the filled prescription has been previously received, stored, and handled by the patient or the patient's representative.

(3) Receiving facilities may not take possession of filled prescriptions, including filled prescriptions requiring manipulation, delivered to the receiving facility by a dispensing facility, unless:

(a) The receiving facility cannot directly procure the filled prescription through standard distribution channels such as a manufacturer, wholesaler, or outsourcing facility; or

(b) The receiving facility cannot compound the filled prescription at the health care facility where the filled prescription will be administered by a health care professional.

(4) A receiving facility may only take possession of filled prescriptions pursuant to subsection (3) of this section if the receiving facility has a written contract or agreement between the dispensing facility and the receiving facility. The written contract or agreement must describe the procedures for such a delivery system and the responsibilities of each party. The dispensing facility and receiving facility must verify that appropriate measures have been taken to ensure product integrity, security, accountability, and accuracy of delivery for the filled prescription.

(5) This section does not apply to:

(a) Filled prescriptions sent by dispensing facilities to receiving facilities that are under common ownership or control of a corporate entity via an intracompany transfer;

(b) Filled prescriptions sent by a compounding pharmacy or registered outsourcing facility based on an order made by the receiving facility; or

(c) Filled prescriptions for home infusion patients.