

WSR 24-17-002

PROPOSED RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed August 8, 2024, 8:06 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-23-051.

Title of Rule and Other Identifying Information: Prescription transfers. The pharmacy quality assurance commission (commission) is proposing to amend WAC 246-945-345 and add new WAC 246-945-346 in chapter 246-945 WAC to establish the expectations of pharmacies related to noncontrolled and controlled substance prescription transfers upon patient request.

Hearing Location(s): On October 10, 2024, at 1:30 p.m., at the Department of Labor and Industries, Room S117/118, 7273 Linderson Way S.W., Tumwater, WA 98501; or virtually via Zoom https://us02web.zoom.us/webinar/tZwvcu-orjooGdL0uce3WWkJLsRorLzko_bx/ics?icsToken=98tyKuGgrD4sGtSUshqBRpw-AI_4M_TziH5BjadxzArmJnNkVQjcGvFwPaBTCTPf. To access the meeting on August 22, 2024, at 9:00 a.m., go to <https://zoom.us/join> or <https://us02web.zoom.us/j/87143495001> and use the Webinar ID 871 4349 5001. The access options include One-tap mobile: US +12532158782,,86114958466# or +16699009128,,86114958466#; or by 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 +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799, Webinar ID 861 1495 8466. International numbers available at <https://us02web.zoom.us/u/kdLNo6unOZ>.

Date of Intended Adoption: October 10, 2024.

Submit Written Comments to: Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, email <https://fortress.wa.gov/doh/policyreview/>, fax 360-236-2901, beginning date and time of this filing, by September 25, 2024, at midnight.

Assistance for Persons with Disabilities: Contact Julia Katz, phone 360-502-5058, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov, by October 3, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The purpose of the amended WAC 246-945-345 is to make the fulfillment of patient-requested noncontrolled prescription transfers enforceable by the commission and occur within a set time frame. Revising "may" to "shall" in WAC 246-945-345(1) will make prescription transfers upon patient request enforceable. Additionally, the time parameter added to WAC 246-945-345(2) will encourage prescription transfers to be conducted in a timely manner. The anticipated effect of the commission's rule is to increase the timeliness of patient access to medication therapy.

The proposed new WAC 246-945-346 applies the same enforceability and time parameters to patient-requested *controlled substance* prescription transfers. Its anticipated effect is also to increase the timeliness of patient access to medication therapy.

Reasons Supporting Proposal: The commission received feedback from interested parties about challenges obtaining requested prescription transfers permitted by WAC 246-945-345(2) in a timely manner and voted to address the concerns at the March 2, 2023, business meeting. The commission could not hold facilities accountable for the expressed

challenges due to the permissive language in WAC 246-945-345. The proposed language will compel compliance among facilities, reducing the challenges faced by some patients requesting a prescription transfer.

Statutory Authority for Adoption: RCW 18.64.005, 69.41.075, and 69.50.301.

Statute Being Implemented: RCW 18.64.005, 69.41.075, and 69.50.301.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Julia Katz, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058; and Enforcement: Marlee O'Neill, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2901, email PharmacyRules@doh.wa.gov.

Scope of exemption for rule proposal from Regulatory Fairness Act requirements:

Is not exempt.

The proposed rule does impose more-than-minor costs on businesses.

Small Business Economic Impact Statement (SBEIS)

SECTION 1: 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 commission is proposing this rule to regulate the fulfillment of patient-requested prescription transfers in a timely manner. Currently, WAC 246-945-345(2) states that upon patient request, prescriptions "may be transferred." The term "may" makes the provision difficult to enforce. The proposed rule aims to protect and promote public health and safety by ensuring patients' prescriptions are transferred upon request.

The proposed rule stems from feedback the commission received from interested parties about challenges obtaining requested prescription transfers permitted by WAC 246-945-345(2). On March 2, 2023, the commission voted to address the expressed concerns. The commission filed a CR-101 as WSR 23-23-051 on November 7, 2023. On May 2, 2024, the commission voted to approve the filing of the CR-102.

The proposed rules are needed to ensure patient-requested prescription transfers are transferred by pharmacies. Amending WAC 246-945-345(2) to state that prescriptions "shall be transferred" and applying the same language to the new section makes the provision enforceable. The addition of time frames to both chapter 246-945 WAC sections provides a guidance to determine compliance with the rules.

Pharmacies must transfer prescriptions, upon patient request, and must do so within three business days or a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

SECTION 2: 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
456110	Pharmacies and Drug Stores	267*	\$19,161.74

*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.

SECTION 3: 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 246-945-345 Noncontrolled prescription transfers: Description: Currently, pharmacies are not required to fulfill noncontrolled prescription transfers requested by patients and while most do, approximately 15 percent of prescription transfers requested by patients are believed to be unfulfilled. The commission is proposing to amend WAC 246-945-345 to require pharmacies to transfer all noncontrolled prescriptions upon patient request and to do so within three business days of receiving the request or a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

Pharmacy managers will need to apprise pertinent staff of the rule adoption. The content may be supplemental to an existing communication.

The commission assumes that all pharmacies dispensing noncontrolled prescriptions have a fax machine, but should they have to purchase one the cost could be \$200 to \$1,000.¹

Pharmacies will need to fulfill all patient-requested noncontrolled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost (s): Pharmacies will need to communicate with staff the requirement that they must transfer noncontrolled prescriptions upon request and that the transfer must happen within three days of receiving the request, or in a time frame that does not adversely impact the medication therapy. The following cost estimate applies to communications for both WAC 246-945-345 and WAC 246-945-346.

Estimate: The estimated average probable cost is \$150.51 per pharmacy to communicate with its employees these new requirements.

Cost assumptions for estimate:

- In 2024, there are 1,393 active pharmacies and in 2023, there were 5,106 licensed pharmacies and other pharmaceutical firms meaning pharmacies and hospital pharmacies compose 27 percent of pharmaceutical firms in Washington.^{2,3}
- The average pharmacy in Washington employs eight pharmacy staff total - one pharmacy manager, three pharmacists, two pharmacy technicians, and two pharmacy assistants.⁴ Therefore, licensed pharmaceutical professions among pharmacies and hospital pharma-

cies in 2023 included 3,044 pharmacists, 2,703 pharmacy assistants, and 2,507 pharmacy technicians.⁵

- Commission staff estimate based on consultation with a pharmacist that the communication will require one hour of the pharmacy manager's time (\$73.50/hour) to prepare and deliver the content.⁶
- Commission staff estimate based on consultation with a pharmacist that the communication will require 15 minutes of time from pharmacists (\$71.42/hour), pharmacy technicians (\$26.63/hour), and pharmacy assistants (\$20.29/hour) to review the communication.^{7,8,9}

Calculations for estimate:

- One hour of a pharmacy manager's time (\$73.50/hour) = \$73.50.
- Fifteen minutes of one pharmacist's (\$71.42/hour) time = $\$71.42/4 = \17.85 .
- Fifteen minutes of one pharmacy technician's (\$26.63/hour) time = $\$26.63/4 = \6.66 .
- Fifteen minutes of one pharmacy assistant's (\$20.29/hour) time = $\$20.29/4 = \5.07 .
- One hour of the pharmacy manager's time plus 15 minutes of time from three pharmacists, two pharmacy technicians, and two pharmacy assistants = $\$73.50 + (17.85 \times 3) + (6.66 \times 2) + (5.07 \times 2) = \150.51 .

Estimate: \$0 to \$1,303.05 total estimated average probable annual cost per pharmacy to transfer currently unfulfilled noncontrolled prescription transfers requested by patients.

Cost assumptions for estimate:

- An average pharmacy in Washington employs eight pharmacy staff, three of whom are pharmacists.¹⁰
- Commission staff estimate based on consultation with a pharmacist that pharmacies are fulfilling 85 percent of patient-requested noncontrolled prescription transfers. There may be pharmacies dispensing noncontrolled prescriptions that receive zero prescription transfers requested by patients annually.
- Commission staff estimate based on consultation with a pharmacist that each noncontrolled prescription transfer will require three to 10 minutes of a pharmacist's time (\$71.42/hour) and that each pharmacy dispensing noncontrolled substances transfers two patient requests per workday or 730 transfers annually.^{11,12} Therefore, it is estimated that an average pharmacy in Washington dispensing noncontrolled prescriptions spends 36.5 to 121.7 hours of pharmacist time annually fulfilling patient-requested noncontrolled prescription transfers which is \$2,606.83 to \$8,691.81 in pharmacist time.¹³

Calculations for estimate:

- One hundred percent requested prescription transfers - 85 percent fulfilled prescription transfers = 15 percent of prescription transfers go unfulfilled.
- Fifteen percent unfulfilled prescription transfers x estimated 730 annual transfers = 109.5 unfulfilled noncontrolled prescription transfers.
- Three to 10 minutes of a pharmacist's (\$71.42/hour) time per prescription transfer = \$3.57 (three minutes) to \$11.90 (10 minutes)

cost of a pharmacists' time per noncontrolled prescription transfer.

- \$3.57 to \$11.90 cost of a pharmacists' time per noncontrolled prescription transfer x 0 to 109.5 estimated annual unfulfilled noncontrolled prescription transfers = \$0 to \$1,303.05 for pharmacist time to fulfill estimated unfulfilled prescription transfers.

Estimate: The commission estimates a negligible annual cost to pharmacies for fulfilling patient-requested noncontrolled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost assumptions for estimate:

- No additional staff time nor equipment were identified as necessary to comply with the time frame of the proposed rule. However the commission acknowledges that there may be unforeseen negligible administrative costs in this space.

WAC 246-945-346 Controlled substance prescription transfers: Description: Pharmacies are not currently required to fulfill controlled prescription transfers requested by patients and while most do, approximately 15 percent of prescription transfers requested by patients are believed to be unfulfilled. The commission is proposing to add WAC 246-945-346 to require pharmacies to transfer all controlled substance prescriptions upon patient request and to do so within three business days of receiving the request or a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

Pharmacy managers will need to apprise pertinent staff of the rule adoption. The content may be supplemental to an existing communication. See cost estimate above.

The commission assumes all pharmacies transferring controlled prescriptions have electronic medical record systems in accordance with 21 C.F.R. § 1306.08 and 21 C.F.R. § 1306.25.

Pharmacies will need to fulfill all patient-requested controlled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost(s): Pharmacies will need to fulfill all controlled prescription transfers requested by patients.

Estimate: \$0 to \$11,141.52 total estimated average probable annual cost per pharmacy to transfer currently unfulfilled patient-requested controlled prescriptions in accordance with 21 C.F.R. § 1306.08 and 21 C.F.R. § 1306.25. Controlled prescription transfers must be communicated via electronic medical record system by licensed pharmacists.¹⁴

Cost assumptions for estimate:

- Assumes an average pharmacy in Washington employs eight pharmacy staff, three of whom are pharmacists based on a calculation vetted by a pharmacist of active pharmacy facility licenses and active pharmacy profession licenses.¹⁵
- Assumes all pharmacies transferring controlled prescriptions have electronic medical record systems in accordance with 21 C.F.R. §§ 1306.08 and 1306.25.
- Commission staff estimate based on consultation with a pharmacist that pharmacies are fulfilling 85 percent of patient-requested controlled prescription transfers.

- There may be pharmacies dispensing controlled prescriptions that receive zero prescription transfers requested by patients annually.
- Commission staff also estimate based on consultation with a pharmacist that each controlled prescription transfer will require five to 10 minutes of a pharmacists' time (\$71.42/hour) and that each pharmacy dispensing controlled substances transfers three patient-requested controlled prescription transfers an hour or 6,240 transfers annually.^{16,17} Therefore, it is estimated that an average pharmacy in Washington dispensing controlled prescriptions spends 520 to 1,040 hours of pharmacist time fulfilling patient-requested controlled prescription transfers which is \$37,138.40 to \$74,276.80 in pharmacist time annually.

Calculations for estimate:

- One hundred percent requested prescription transfers - 85 percent fulfilled prescription transfers = 15 percent of uncontrolled prescription transfers go unfulfilled.
- Fifteen percent unfulfilled prescription transfers x 6,240 estimated annual transfers = 936 unfulfilled controlled prescription transfers.
- Five to ten minutes of a pharmacists' time per prescription transfer x \$71.42 pharmacist hourly wage = \$5.95 (five minutes) to \$11.90 (10 minutes) cost of a pharmacists' time per controlled prescription transfer.
- \$5.95 to \$11.90 cost of a pharmacists' time per prescription transfer x 0 - 936 estimated annual unfulfilled controlled prescription transfers = \$0 to \$11,141.52 for pharmacist time to fulfill estimated unfulfilled controlled prescription transfers.

Estimate: The commission estimates a negligible annual cost to pharmacies for fulfilling patient-requested controlled prescription transfers within three business days of receiving the request or a time frame that does not adversely impact medication therapy.

Cost assumptions for estimate: No additional staff time nor equipment are necessary to comply with the time frame of the proposed rule. However, the commission acknowledges that there may be unforeseen negligible administrative costs in this space.

Summary of all Cost(s):

SBEIS Table 2. Summary of Section 3 Probable Cost(s):

WAC Section	Description of Cost	Probable Estimated Cost(s)
WAC 246-945-345 and 246-945-346	Employee notification	\$151 (one-time)
WAC 246-945-345	Employee time	\$0-\$1,303.05 (annually)
WAC 246-945-346	Employee time	\$0-\$11,141.52 (annually)
Total First Year Costs (Range) ^{18,19}		\$151-\$12,595.57

SECTION 4: 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: While the commission has no reason to believe that the cost for business to comply with the proposed rule would exceed the minor cost threshold at the maximum probable cost, the commission was only able to calculate a scenario that produced the average cost of compliance per business. Because the estimate did not include a potential maximum cost of compliance per businesses, the commission decided it was most protective to determine that:

Yes, the costs of the proposed rule could be more than the minor cost threshold (\$19,161.74).

Summary of how the costs were calculated: The average probable costs were calculated for pharmacies to comply with the proposed rule under what the commission believes to be a likely scenario for an average pharmacy to comply with the proposed rule. Probable costs affiliated with compliance primarily pertain to staff time and equipment. Average staff wages in Washington state were sourced from data produced by the United States Bureau of Labor and Statistics. Additional resources were used to estimate employee quantities and equipment costs. Commission staff, including a pharmacist consultant, determined the estimated time and equipment requirements.

SECTION 5: Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule: No, the commission believes the proposed rule does not have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

The commission believes that there is not a disproportionate impact because costs to comply with the rule are based on number of staff and volume of businesses. The commission anticipates that all businesses will have a scaled impact because the cost will vary depending on size of the business (number of employees) and volume of service.

- 1 Staples, Fax Machines, https://www.staples.com/fax+machine/directory_fax%2520machine?autoCompletesearchkey=fax%2520machine&algo=y (visited May 7, 2024).
- 2 L. Faelund (personal communication, April 3, 2024).
- 3 Washington State Department of Health, Licensee Counts by Year: Professions, <https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fdoh.wa.gov%2Fsites%2Fdefault%2Ffiles%2F2023-09%2F631106-LicenseeCountsbyProfession.xlsx&wdOrigin=BROWSELINK> (visited May 14, 2024).
- 4 3,044 (pharmacists)/1,393 = 2.2 = 3 average pharmacists per pharmacy; 2,507 (technicians)/1,393 = 1.8 = 2 average assistants per pharmacy; 2,703 (assistants)/1,393 = 1.9 = 2 average technicians per pharmacy; 3+2+2+1 (manager) = 8 employees
- 5 See source #2
- 6 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers, <https://www.bls.gov/oes/current/oes119111.htm> (visited May 6, 2024).
- 7 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacists, <https://www.bls.gov/oes/current/oes291051.htm> (visited May 7, 2024).
- 8 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacy Technicians, <https://www.bls.gov/ooh/healthcare/pharmacy-technicians.htm#tab-5> (visited May 7, 2024).
- 9 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacy Aides, <https://www.bls.gov/oes/current/oes319095.htm> (visited May 7, 2024).
- 10 3,044 (pharmacists)/1,393 = 2.2 = 3 average pharmacists per pharmacy; 2,507 (technicians)/1,393 = 1.8 = 2 average assistants per pharmacy; 2,703 (assistants)/1,393 = 1.9 = 2 average technicians per pharmacy; 3+2+2+1 (manager) = 8 employees
- 11 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacists, <https://www.bls.gov/oes/current/oes291051.htm> (visited May 7, 2024).
- 12 2 (average number of patients requesting transfers per day) x 365 work days per year = 730 average patient transfers per year
- 13 730 (average patient transfers annually) x 3 (minutes per transfer) = 2190 minutes annually for transfers; 2190/60 (minutes per hour) = 36.5 hours annually for transfers; \$71.42 (pharmacist average wage) x 36.5 (hours annually for transfers) = \$2,606.83 for annual pharmacist time transferring patient-requested noncontrolled prescriptions
- 14 § 1306.25 - Transfer between pharmacies of prescription information for Schedules III, IV, and V controlled substances for refill purposes, <https://www.govregs.com/regulations/21/1306.25> (visited on May 23, 2024).
- 15 3,044 (pharmacists)/1,393 = 2.2 = 3 average pharmacists per pharmacy; 2,507 (technicians)/1,393 = 1.8 = 2 average assistants per pharmacy; 2,703 (assistants)/1,393 = 1.9 = 2 average technicians per pharmacy; 3+2+2+1 (manager) = 8 employees
- 16 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Pharmacists, <https://www.bls.gov/oes/current/oes291051.htm> (visited May 7, 2024).
- 17 3 (average prescription transfer requests an hour) x 40 hour work week = 120 average prescription transfers per week; 120x 52 (weeks/per) = 6,240 prescription transfers per pharmacy per year
- 18 The total reflects a pharmacy that dispenses both controlled and noncontrolled prescriptions.
- 19 The low end of the range is calculated by the one-time cost (\$151) plus neither of the annual costs which is applicable to a pharmacy that does not receive prescription transfer requests from patients in the first year. The high end of the range (\$8,448.41) is calculated by adding the one-time cost with the high end costs of each annual cost which is indicative of a pharmacy that currently does not fulfill 15% of prescription transfers requested by patients, all of which take the maximum anticipated time to transfer.

A copy of the statement may be obtained by contacting Julia Katz, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2901, email PharmacyRules@doh.wa.gov.

August 7, 2024
Hawkins DeFrance, PharmD, Chair

OTS-5466.1

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-345 Noncontrolled prescription transfers. (1)

~~((Subsections (2) through (5) of this section apply to the transfer of prescription information for noncontrolled drugs. The transfer of controlled substance prescription information must conform to the requirements of 21 C.F.R. Sec. 1306.25.~~

~~(2)) Upon request by a patient (~~(request)~~) or an authorized representative of a patient, a noncontrolled prescription (~~(may)~~) shall be transferred within the limits of state and federal law.~~

(2) Pharmacies shall transfer noncontrolled prescription information within three business days of receiving the request or within a time frame that does not adversely impact the provision of medication therapy, whichever comes first.

(3) Sufficient information needs to be exchanged in the transfer of a noncontrolled prescription to maintain an auditable trail, and all elements of a valid prescription.

(4) Pharmacies sharing a secure real-time database are not required to transfer noncontrolled prescription information for dispensing.

(5) Noncontrolled prescriptions must be transferred by electronic means or facsimile, except in emergent situations.

NEW SECTION

WAC 246-945-346 Controlled substance prescription transfers.

(1) Upon request by a patient or an authorized representative of the patient, a controlled substance prescription shall be transferred within the limits of state and federal law including, but not limited to, the requirements of 21 C.F.R. Secs. 1306.08 and 1306.25.

(2) Pharmacies shall transfer controlled substance prescription information within three business days of receiving the request or within a time frame that does not adversely impact the provision of medication therapy, whichever comes first.