WSR 26-19-069
PROPOSED RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed September 15, 2026, 12:00 p.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 25-21-079.

Title of Rule and Other Identifying Information: Tamper-resistant prescription pads and paper. The pharmacy quality assurance commission (commission) is proposing to establish new WAC 246-945-009, and amend WAC 246-945-010 to regulate tamper-resistant prescription pads and paper information, including industry-recognized security features and their approval process.

Hearing Location(s): On November 5, 2026, at 2:00 p.m., at Capital Region ESD 113, 6005 Tyee Drive S.W., Tumwater, WA 98512; or via Zoom at https://us02web.zoom.us/j/86309299195, Webinar ID 863 0929 9195; or join via telephone +1 253 215 8782 US (Tacoma), +1 253 205 0468 US, +1 669 444 9171 US, Webinar ID 863 0929 9195.

Date of Intended Adoption: November 5, 2026.

Submit Written Comments to: Julia Katz-Ukropina, P.O. Box 47850, Olympia, WA 98504-7850, email PharmacyRules@doh.wa.gov, web https://fortress.wa.gov/doh/policyreview/, beginning the date and time of this filing, by October 22, 2026, at 11:59 p.m.

Assistance for Persons with Disabilities: Contact Julia Katz-Ukropina, phone 360-236-4946, TTY 711, email PharmacyRules@doh.wa.gov, by October 22, 2026.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The commission is proposing to establish WAC 246-945-009 and amend WAC 246-945-010 to establish regulations on commission-approved tamper-resistant prescription pads and paper.

On August 14, 2025, the commission authorized rule making on tamper-resistant prescription pads and paper to replace a guidance document, "Tamper Resistant Prescription Paper or Pads Approval Process" with rules. Codifying the guidance document into rules will establish enforceable regulations which is beneficial to the prevention of prescription tampering. Also, the guidance document explains the commission's initial approval process, but does not address seeking commission approval of revisions to commission-approved tamper-resistant prescription pads and paper. The proposed rules serve to replace the guidance document with enforceable and comprehensive regulations.

Reasons Supporting Proposal: The commission has received inquiries from interested parties about the guidance document and the commission's approval process. The commission has also received inquiries from interested parties regarding potential changes to vendors' business structures. The proposed rules will provide additional context to what currently exists in the guidance document and additional oversight to prevent prescription tampering by clarifying reapproval is needed when there are changes to an approved prescription pad.

The proposed rules are needed to codify the guidance document with comprehensive and enforceable regulations on commission-approved tamper-resistant prescription pads and paper and establish processes for notifying the commission of changes to vendors' information and the tamper-resistant prescription pads and paper.

Statutory Authority for Adoption: RCW 18.64.005 and 18.64.500.

Statute Being Implemented: RCW 18.64.500.

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-Ukropina, 111 Israel Road S.E., Tumwater, WA 98501, 360-236-4946; Enforcement: Marlee B. O'Neill, 111 Israel Road S.E., Tumwater, WA 98501, 360-480-9108.

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-Ukropina, P.O. Box 47850, Olympia, WA 98504-7852[7850], phone 360-236-4946, TTY 711, email PharmacyRules@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules are adopting or incorporating by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule.

Explanation of exemptions: RCW 34.05.310 (4)(c) applies to the proposed amendment to WAC 246-945-010 as subsection (4)(i) incorporates by reference the proposed new WAC 246-945-009, which is analyzed below.

Scope of exemption for rule proposal:

Is partially exempt:

Explanation of partial exemptions: See above for exemptions.

The proposed rule does not impose more-than-minor costs on businesses. Following is a summary of the agency's analysis showing how costs were calculated. The estimated cost of $121.76 imposed by the proposed rule is *less than* the minor cost threshold ($2,680.79 for printing and related support establishments).

The proposed rule only requires a vendor of tamper-resistant prescription pads and paper to seek commission approval in the event of initial approval or an applicable change. The proposed rule outlines procedures for vendors to seek commission approval if they have a new or revised tamper-resistant prescription pad or paper or the vendor has an operational change.

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 to establish WAC 246-945-009 and amend WAC 246-945-010 to establish regulations on commission-approved tamper-resistant prescription pads and paper.

In 2009, HB 2014 (chapter 328, Laws of 2009) codified RCW 18.64.500 to define tamper-resistant prescription pads and paper, require all written prescriptions in Washington state be written on tamper-resistant prescription paper approved by the commission, and au-

thorized the commission to adopt rules. The purpose of the statute is to prevent prescription tampering. At the time the statute was codified, the commission decided to explain the commission's approval process in a guidance document instead of adopting rules.

On February 5, 2026, the commission decided to undertake a process to replace policy, procedure, and guidance documents with rules where possible. The commission's guidance document on tamper-resistant prescription pads and paper, "Tamper Resistant Prescription Paper or Pads Approval Process" was one of the guidance documents identified to replace with rules. Codifying the guidance document into rules will establish enforceable regulations, which is beneficial to the prevention of prescription tampering and the commission's ability to promote the delivery of high quality healthcare to Washington residents. Also, the guidance document explains the commission's initial approval process, but does not address seeking commission approval of revisions to commission-approved tamper-resistant prescription pads and paper. The proposed rules serve to replace the guidance document with enforceable and comprehensive regulations.

The commission has received inquiries from interested parties about the guidance document's content. Applicants have inquired about the commission's approval process as they are more familiar with seeking similar instruction from the commission's rule chapter, chapter 246-945 WAC, than guidance documents on the commission's website. Similarly, applicants have inquired about references to sections of pertinent rules on the topic for additional detail about the commission's approval process. The commission has also received inquiries from interested parties regarding the commission's awareness of changes to vendors' business structures. The proposed rules will provide more context than exists currently in the guidance document and additional oversight to prevent prescription tampering.

The proposed rules are needed to codify the guidance document with comprehensive and enforceable regulations on commission-approved tamper-resistant prescription pads and paper and establish processes for notifying the commission of changes to vendors' information and the tamper-resistant prescription pads and paper.

To comply with the proposed rule, an applicable small business will need to become familiar with the new rule and follow applicable processes when seeking initial approval from the commission or apprising the commission of a change. Applicable small businesses are small vendors of tamper-resistant prescription pads and paper, commonly printing service establishments. Professional services likely needed for compliance are communicating with the vendor's employees and the commission, and a technological device to edit the vendor's tamper-resistant prescription pads and paper.

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

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
3231	Printing or Support Activities	1,052	$2,680.79

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 246-945-009 Tamper-resistant prescription pads and paper.

Description: The proposed rule provides current and future vendors of tamper-resistant prescription pads and paper clarification of the commission's approval process, notification process for changes to vendor information, and permitted security features of the pads and paper. Vendors must report and submit materials to the commission for: Changes to the vendor's name, ownership, distributors, or location, and closure or ceasing to manufacture or distribute commission-approved tamper-resistant prescription pads and paper. Vendors of approved tamper-resistant prescription pads and papers [applying] by the effective date of the rule need not reapply for initial approval.

Vendor managers will need to update their staff on the rule. The content may be supplemental to an existing communication.

Vendors of tamper-resistant prescription pads and paper applying for commission approval will need to follow the approval process.

Vendors of commission-approved tamper-resistant prescription pads and paper encountering an applicable change will need to notify the commission appropriately.

Cost(s): Vendor communication to staff regarding rules: The commission estimates a one-time total probable cost of **$102.32** per vendor of commission-approved tamper-resistant prescription pads and paper for 3.5 hours of staff time to disseminate a communication to employees to inform them of the new rule. Most of the vendors of which the commission has approved their tamper-resistant prescription pads and paper are printing press companies. As such, the following cost estimates assume the vendor is a printing press company and include:

- Commission staff estimate that preparing and delivering the communication will require one hour of the vendor manager's time. The average hourly rate in Washington for a general manager is **$76.40.**[1]
- Commission staff estimate that reading and understanding the communication will require 0.25 hours of vendor employees' time. The average hourly rate in Washington for a prepress worker is **$25.92.**[2]
- As of January 2026, there were 1,052 printing and related services establishments in Washington and 4,618 employees of those establishments.[3] Commission staff estimate the average printing establishment in Washington employs four employees.[4] Given the average hourly rate for a prepress worker in Washington, 0.25 hours for four employees is equivalent to **$25.92.**[5]

1 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Washington State Table May 2025, Prepress Technicians and Workers (51-5111), https://www.bls.gov/oes/current/oes119111.htm; https://www.bls.gov/oes/current/oes119111.htm (visited June 25, 2026).

2 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Washington State Table May 2025, Prepress Technicians and Workers (51-5111), https://www.bls.gov/oes/current/oes119111.htm (visited June 25, 2026).

3 Governor's Office for Regulatory Innovation & Innovation, Minor-Cost Threshold Calculator https://www.oria.wa.gov/site/alias__oria/3192/minor-cost-threshold-calculator.aspx (visited June 25, 2026).

4 4,618 (Washingtonians employed by printing establishments)/1,052 (printing establishments in Washington)=4.39 Washingtonians on average per printing establishment.

5 4 (Washingtonians on average per printing establishment)*0.25 (hours)*$25.92 (hourly mean wage)=$25.92

Applying for the commission's initial approval process: The department and commission reasonably believe vendors of tamper-resistant prescription pads and paper are already applying to the commission for initial approval consideration per the guidance document. To date, the commission has approved over 70 tamper-resistant prescription pads and

paper. No additional cost is anticipated to incur for the commission's initial approval process.

Notification process for changes: The commission estimates a cost of $19.44 per vendor, per change of approved tamper-resistant prescription pads or paper notifying the commission of a change to the tamper-resistant prescription pads or paper or a change in the vendor's information for 1.75 hours of staff time to complete the notification process. There is no way to estimate the number of changes that will be needed in any given time period, therefore the commission has estimated the cost on a per notification basis and will be incurred each time a change notification is needed. Most of the vendors of which the commission has approved their tamper-resistant prescription pads and paper are printing press companies. As such, the following cost estimates assume the vendor is a printing press company and include:

- Commission staff estimate the application will require one hour of a prepress worker's time. The average hourly rate in Washington for a prepress worker is **$25.92.**[6]
- Commission staff estimate providing a sample copy of the vendor's tamper-resistant prescription pad or paper will require 0.25 hours of a prepress worker's time. Given the average hourly rate for a prepress worker in Washington, 0.25 hours is equivalent to **$6.48.**
- Commission staff estimate providing any other information requested by the commission will require 0.5 hours of a prepress worker's time. Given the average hourly rate for a prepress worker in Washington, 0.5 hours is equivalent to **$12.96.**

6 Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Washington State Table May 2025, Prepress Technicians and Workers (51-5111), https://www.bls.gov/oes/current/oes119111.htm; https://www.bls.gov/oes/current/oes119111.htm (visited June 25, 2026).

Summary of all cost(s):

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

WAC Section and Title	Probable Cost(s)
WAC 246-945-009 Notifications	$102.32 one-time cost per vendor
WAC 246-945-009 Approval process	No additional cost
WAC 246-945-009 Notification process	$19.44 per vendor per change notification

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 ($121.76) are *less than* the minor cost threshold ($2,680.79).

Summary of how the costs were calculated: The proposed rule only requires a vendor of tamper-resistant prescription pads and paper to seek commission approval in the event of initial approval or an applicable change. The proposed rule outlines procedures for vendors to seek commission approval if they have a new or revised tamper-resistant prescription pad or paper or the vendor has an operational change. The commission is unable to estimate the number of changes that will require the notification process (WAC 246-945-009) from a vendor in any given time period. Therefore, in calculating the cost per vendor, the commission analyzed the cost per change notification ($19.44) and the commission reasonably believes that the total costs of the proposed rule will not exceed the minor cost threshold ($2,680.79), even in a given time period with multiple change notifications.

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting Julia Katz[-Ukropina], P.O. Box 47850, Olympia, WA 98504-7852[7850], phone 360-236-4946, TTY 711, email PharmacyRules@doh.wa.gov.

September 10, 2026
Ann Wolken, PharmD, RPh, Chair
Pharmacy Quality Assurance Commission

RDS-7082.4

NEW SECTION

WAC 246-945-009 Tamper-resistant prescription pads and paper. (1) A vendor shall apply to the commission for approval of their tamper-resistant prescription pads or paper consistent with RCW 18.64.500 and this section.

(2) A vendor seeking initial commission approval of their tamper-resistant prescription pads or paper shall submit to the commission:

(a) A completed application on forms provided by the commission, that includes an attestation from the vendor that it has policies and procedures that require, at a minimum, the following:

(i) Background checks of any individual under the vendor's control who have direct access or management of the tamper-resistant prescription pads, paper, or raw material production, storage or distribution;

(ii) Maintenance of readily retrievable records of sales and deliveries of tamper-resistant prescription pads or paper for a minimum of two years;

(iii) The safeguarding of any hard-copy and digital files;

(iv) Loss and theft prevention of tamper-resistant prescription pads or paper, and raw materials;

(v) Methods to secure production and facilities;

(vi) Provision of notice to the commission within 24 hours of any loss or theft of tamper-resistant prescription pads or paper, to include the process for internal investigation;

(vii) Recordkeeping and destruction of discarded or waste material;

(viii) If the vendor uses distributors to market its tamper-resistant prescription pads or paper, the ordering process and distributor's responsibilities; and

(ix) The process and responsibilities of the vendor to ensure only legitimate requesters receive tamper-resistant prescription pads or paper, and the process used to verify the identity and eligibility of a prescriber to order and possess its tamper-resistant prescription pads or paper.

(b) A sample copy of the vendor's tamper-resistant prescription pad or paper that identifies a designated place in the bottom right hand corner for the commission's seal of approval that is next to the required signature lines; and

(c) Any other information requested by the commission.

(3) To be considered for approval by the commission, tamper-resistant prescription pads or paper must contain at least one feature for each of the following three characteristics:

(a) Feature(s) designed to prevent unauthorized copying of a completed or blank prescription, such as "Washington Security Prescription" or "Copy" appearing legibly when the prescription is photocopied or manually faxed;

(b) Feature(s) designed to prevent the erasure or modification of information written on the prescription by the prescriber, such as a solid color or consistent pattern background appearing legibly when the prescription is photocopied or manually faxed; and

(c) Feature(s) designed to prevent the use of counterfeit prescription forms, such as a complete list of the security features on the tamper-resistant prescription pads and paper.

(4) A vendor must report and submit the materials identified in subsection (2) of this section, as applicable, to the commission within 30 calendar days if one of the following occurs:

(a) The vendor changes its name;

(b) The vendor changes ownership;

(c) The vendor changes distributors;

(d) The vendor changes location;

(e) The vendor closes or otherwise ceases to manufacture or distribute its approved tamper-resistant prescription pads or paper.

(5) If a vendor makes changes to its approved tamper-resistant prescription pads or paper, they shall apply to the commission for approval under subsection (2) of this section prior to distributing the modified tamper-resistant prescription pads or paper.

(6) A vendor of tamper-resistant prescription pads and paper approved by the commission prior to the effective date of this rule does not need to submit an application for initial approval, but must comply with all other requirements of this rule.

AMENDATORY SECTION (Amending WSR 26-13-027, filed 6/9/26, effective 7/10/26)

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500 and WAC 246-945-009;

(4) A prescription for a controlled substance must include all the information listed in subsection (3) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of January 1, 2026.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R. Secs. 1300 through 1399 in effect as of January 1, 2026.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner shall deliver a signed prescription to the dispenser within seven days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the seven day period, and further the pharmacist shall note on the prescription that it was filled on an emergency basis.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(9) Copies of the reference material listed in this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.