



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

**Washington State Pharmacy Quality Assurance Commission
Review/Approval Process
Tamper Resistant Prescription Paper or Pads
RCW 18.64.500**

Starting July 1, 2010, all medication prescriptions written by licensed practitioners in this state must be on Pharmacy Quality Assurance Commission approved tamper-resistant prescription paper or pads.

Companies submitting their paper for approval by the commission and to received authorization to apply the "Pharmacy Quality Assurance Commission's" seal of approval must provide the following information and paper/pads samples.

Please respond to all items.

I. Demographics/Vendor Profile

1. Business name, mail and email addresses, telephone number and Web site address.
2. Name of primary contact person, his/her title and contact information, fax and telephone numbers, and email address.
3. Type of business structure: corporation, sole proprietor/individual owner or partnership.
4. Federal Tax Identification Number.
5. Secretary of State Identification Number or UBI# (indicate state if different from location of facility).
6. Name and contact information of agent for process service (non-resident vendors only).

II. Policies and Procedures – must include but not limited to the following:

1. Does the company conduct background checks of any individuals under the company's control who has direct access, management, or control of the tamper resistant paper, pads or raw material production, storage and/or distribution?
2. Method used to maintain readily retrievable records of sales and deliveries of prescription forms and/or paper or pads for a minimum of three years.
3. Process to safeguard electronic files.
4. Process used to establish and maintain effective controls and security procedures to prevent loss or theft of prescription forms, paper or pads, and/or raw materials.
5. Method used for securing production and facilities.
6. Process used to notify the Pharmacy Quality Assurance Commission within 24 hours of any changes of location, loss or theft of product. Include the process for internal investigation.
7. Method used for recording and destruction of discarded or waste material.
8. If the company will use distributors to market its product, policies and procedures must include the ordering process and distributor's responsibilities. {A company that has received authority to apply

the commission's seal to the approved paper may distribute blank stock with the seal directly to a legitimate requester. A legitimate requester is an eligible health care practitioner **or** a third party used by your company to distribute its product (printed or blank stock). Your company must affirm that you have agreements or policies/procedures in place that outline the responsibilities of all parties to ensure only legitimate requesters receive approved tamper resistant prescription paper or pads. }

9. Process used to verify the identity and eligibility of a prescriber to order and have prescription forms. You can verify licensure through the Washington State Department of Health, Provider Credential Search at <https://fortress.wa.gov/doh/providercredentialsearch/> . Further verification may be necessary with the appropriate licensing board, commission or program. Contact the department customer service office at 360.236.4700.

III. Commission-Approved Tamper-Resistant Prescription Pads or Paper

Tamper-Resistant Prescription Paper or Pads – Designed to prevent:

- Category One** - Unauthorized copying of a completed or blank prescription form; *
- Category Two** - Erasure or modification of information written on the prescription form by the practitioner; and
- Category Three** - Use of counterfeit prescription forms

Applicants must include sample prescription paper or pads with your request. Give a detailed description of all security features used in each sample by category. All vendors of commission-approved tamper-resistant prescription paper or pads **must** have at least one industry-recognized feature for each category listed above.

* If using a pantograph watermark to meet **Category One**, it is strongly suggested that the words **“Copy” or “Copy/Fax”** be used rather than “Void” or “Illegal.”

IV. Approval Process

Mail the policies, procedures and supporting documents to the Washington State Pharmacy Quality Assurance Commission, PO Box 47852, Olympia WA 98504-7852 or Washington State Pharmacy Quality Assurance Commission, 111 Israel Rd SE, Tumwater WA 98501.

Failure to provide any of the requested information will delay the approval process and may result in an incomplete request.

Material misrepresentation in the answer of any question or in the written submissions is a crime punishable under the Revised Code of Washington.

When your tamper-resistant prescription paper and pads are approved, the Washington State Pharmacy Quality Assurance Commission will provide guidelines for the use of the “seal of approval”.

Note: prescription forms on commission-approved tamper-resistant prescription paper and pads must include two signature lines at opposite ends of the bottom of the form. Under the line on the right side the words “DISPENSE AS WRITTEN” must clearly be printed. Under the line on the left side the word “SUBSTITUTION PERMITTED” must clearly be printed. (RCW 69.41.120)

Contact Doreen E. Beebe, Program Manager at 360.236.4834 or wspqac@doh.wa.gov if you have questions.