

DEPARTMENT OF HEALTH PHARMACY QUALITY ASSURANCE COMMISSION PROCEDURE

Title:	Nonresident Pharmacy Report Guidelines
Reference:	<u>Chapter 18.64 RCW</u> Pharmacist/Interns & Pharmaceutical Firms
Contact:	Lauren Lyles-Stolz, PharmD., Executive Director
Effective Date:	September 30, 2016 (reaffirm August 28, 2020)
Approved:	Tim Lynch, PharmD, MS, FABC, FASHP, Pharmacy Quality Assurance Commission Chair

POLICY STATEMENT:

This procedure establishes appropriate guidelines for reports received against nonresident pharmacy licensees and ensures consistent processing of all reports against nonresident pharmacy licensees under the authority of the Washington State Pharmacy Quality Assurance Commission (PQAC).

DEFINITION:

Reciprocal discipline: When a nonresident pharmacy receives enforcement action in one state and another state(s) subsequently takes enforcement action based solely on the first state's enforcement action.

PROCESS FOR HANDLING REPORTS AGAINST NON-RESIDENT PHARMACIES:

- 1. Reports against nonresident pharmacies typically fall into two categories: administrative violations and standard of care violations.
- 2. For administrative violations:
 - a. If the violation in the report is not a violation of Washington State law, close the matter as otherwise resolved by the other state's action, no violation of Washington State law, or other applicable closure code.
 - b. If the violation in the report is a violation of Washington State law, open the matter for investigation or close the matter as otherwise resolved by the other state's action or other applicable closure code.
 - The panel will need to make a determination whether the violation in the report warrants investigation and possible enforcement action by the Commission.
 - Things to consider are the following:
 - o severity of the violation;
 - o whether any Washington State patients were affected; and
 - o whether the other state's action was sufficient to resolve the matter for Washington residents.

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- c. If the violation in the report is reciprocal discipline by another entity and the Commission has already reviewed this action, close the matter as otherwise resolved by the other state's action or other applicable closure code.
- 3. For standard of care violations such as the following, the panel should open the matter to determine if the non-resident pharmacy shipped any product(s) to patients in Washington State:
 - misfill;
 - improper compounding;
 - adulterated, misbranded, or mislabeled prescriptions; or
 - other standard of care violations.
 - a. The panel may pre-authorize that if products were shipped to Washington State residents, the investigator shall complete a full investigation.
 - b. If no products were shipped to Washington State residents, the matter will return to a panel who can determine whether to close or complete a full investigation.
 - The panel may consider closing the matter as otherwise resolved by the other state's action or other applicable closure code.

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