RULE-MAKING ORDER
PERMANENT RULE ONLY

CR-103P (December 2017)
(Implements RCW 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 18, 2025
TIME: 2:26 PM

WSR 25-07-097

Agency: Department of Health – Pharmacy Quality Assurance Commission

Effective date of rule:

Permanent Rules

☒ 31 days after filing.

☐ Other (specify) _____ **(If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)**

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: Permanent Closure Reporting Requirements for Pharmacies, Health Care Entities, Hospital Pharmacy Associated Clinics, Wholesalers, and Manufacturers. The Pharmacy Quality Assurance Commission (commission) adopted amendments to WAC 246-945-480 to require additional reporting requirements to customers and the commission in advance of pharmaceutical firms permanently closing. The commission adopted WAC 246-945-231 to consolidate the reporting requirement for pharmaceutical firms to report disciplinary action to the commission and WAC 246-945-592 to establish reporting requirements for permanently closing manufacturers and wholesalers.

Citation of rules affected by this order:

New: WAC 246-945-231 and 246-945-592
Repealed: None
Amended: WAC 246-945-480
Suspended: None

Statutory authority for adoption: RCW 18.64.005, 69.41.075, and 69.50.301

Other authority: None

PERMANENT RULE (Including Expedited Rule Making)

Adopted under notice filed as WSR 25-01-067 on December 11, 2024.

Describe any changes other than editing from proposed to adopted version: None

If a preliminary cost-benefit analysis was prepared under RCW 34.05.328, a final cost-benefit analysis is available by contacting:

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Other:

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The number of sections adopted in order to comply with:

Federal statute:	New	0	Amended	0	Repealed	0
Federal rules or standards:	New	0	Amended	0	Repealed	0
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	2	Amended	1	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	0	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	2	Amended	1	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	2	Amended	1	Repealed	0

Date Adopted: March 14, 2025

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

NEW SECTION

WAC 246-945-231 Reporting disciplinary action. Any pharmaceutical firm credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.

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

WAC 246-945-480 Facility reporting requirements. (1) The outgoing and incoming responsible pharmacy manager must report in writing to the commission a change in a responsible manager designation within ((~~ten~~)) 10 business days of the change.

(2) Unless otherwise specified, when permanently closing a facility, the facility must:

(a) Report to the commission in writing, no later than ((~~thirty~~)) 30 calendar days prior to closing:

(i) The date the facility will close;

(ii) The names and addresses of the ((~~persons~~)) person(s) who shall have custody of the prescription files, bulk compounding records, repackaging records, invoices and controlled substances inventory records of the ((~~pharmacy~~)) facility to be closed; ((~~and~~))

(iii) The names, credential numbers, and addresses of ((~~any~~)) the person(s) who ((~~will~~)) shall acquire any legend drugs from the facility to be closed, if known at the time the notification is filed; and

(iv) The names, credential numbers, and addresses of persons who shall acquire any controlled substances from the facility to be closed, if known at the time the notification is filed.

(b) Provide notification to customers ((~~noting~~)) beginning no later than 30 calendar days prior to closing which includes the last day the pharmacy will be open((~~, name and address of the pharmacy to which prescription records will be transferred and instructions on how patients can arrange for transfer of their prescription records to a pharmacy of their choice~~)) and the last day a transfer may be initiated. Notification ((~~should~~)) shall include:

(i) ((~~Distribution by direct mail; or~~)) Posting a closing notice in a conspicuous place in the public area of the pharmacy;

(ii) ((~~Public notice in a newspaper of general circulation in the area served by the pharmacy~~)) Informing patients of the closure during prescription pick-up or delivery including a notice with dispensed prescriptions informing patients of their right to request a prescription transfer, if applicable; and

(iii) ((~~Posting a closing notice sign in a conspicuous place in the public area of the pharmacy.~~)) Public notice in at least one legal newspaper of general circulation in the area served by the pharmacy that meets the qualifications of RCW 65.16.020. The public notice must appear in both the print and digital versions of the legal newspaper, if available.

(c) No later than ((~~fifteen~~)) 15 calendar days after closing:

(i) Return the facility license to the commission;

(ii) Confirm to the commission that all legend drugs were transferred ((~~or destroyed. If the legend drugs were transferred,~~)) appropriately and provide the names, credential numbers, and addresses of the person(s) to whom ((~~they~~)) the legend drugs were transferred;

(iii) Confirm ((~~if~~)) to the commission that all controlled substances were transferred((~~, including the date of transfer, names, addresses, and a detailed inventory of the drugs~~)) appropriately and provide a detailed inventory of the drugs transferred and the names, credential numbers, and addresses of the person(s) to whom the controlled substances were transferred;

(iv) Confirm ((~~return of~~)) that the DEA registration and all unused DEA 222 forms were returned to the DEA;

(v) Confirm all pharmacy labels and blank prescriptions were destroyed; and

(vi) Confirm all signs and symbols indicating the presence of the pharmacy have been removed.

(3) The commission may conduct an inspection to verify all requirements in subsection (2) of this section have been completed.

(4) ((~~The~~)) A facility shall immediately report to the commission any disasters, accidents and emergencies which may affect the strength, purity, or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness, and disease.

((~~(5) Any facility credentialed by the commission must report to the commission any disciplinary action, including denial, revocation, suspension, or restriction to practice by another state, federal, or foreign authority.~~))

NEW SECTION

WAC 246-945-592 Wholesaler and manufacturer reporting requirements. (1) Unless otherwise specified, when permanently closing a wholesaler or manufacturer, the wholesaler or manufacturer must:

(a) Provide notification to customers in writing, no later than 30 calendar days prior to closing, which includes the last day the wholesaler or manufacturer will be open and the last day the customer may place an order to be fulfilled.

(b) Report to the commission in writing, no later than 30 calendar days prior to closing:

(i) The date the wholesaler or manufacturer will close; and

(ii) The names, credential numbers, and addresses of the person(s) who shall receive any legend drugs or controlled substances from the wholesaler or manufacturer to be closed, if known at the time the notification is filed.

(c) No later than 15 calendar days after closing:

(i) Return the wholesaler or manufacturer license to the commission;

(ii) Confirm to the commission that all legend drugs were transferred appropriately and provide the names, credential numbers, and addresses of the person(s) to whom the legend drugs were transferred;

(iii) Confirm to the commission that all controlled substances were transferred appropriately and provide a detailed inventory of the drugs transferred and the names, credential numbers, and addresses of each person(s) to whom the controlled substances were transferred;

(iv) Confirm that the DEA registration and all unused DEA 222 forms were returned to the DEA; and

(v) Confirm all signs and symbols indicating the presence of the wholesaler or manufacturer have been removed, if applicable.

(2) A wholesaler or manufacturer shall immediately report to the commission any disasters, accidents, and emergencies which may affect the strength, purity, or labeling of drugs, medications, devices or other materials used in the diagnosis or the treatment of injury, illness, and disease.