



PROPOSED RULE MAKING

CR-102 (June 2024) (Implements RCW 34.05.320)

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DATE: December 11, 2024

TIME: 4:53 PM

WSR 25-01-067

Agency: Department of Health – Pharmacy Quality Assurance Commission

Original Notice

Supplemental Notice to WSR

Continuance of WSR

Preproposal Statement of Inquiry was filed as WSR 24-13-061; or

Expedited Rule Making--Proposed notice was filed as WSR ____; or

Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1); or

Proposal is exempt under RCW ____.

Title of rule and other identifying information: Permanent Closure Reporting Requirements for pharmacies, health care entities, hospital pharmacy associated clinics, wholesalers, and manufacturers. The Pharmacy Quality Assurance Commission (commission) is proposing to amend WAC 246-945-480 to require additional reporting requirements provided to customers and the commission in advance of permanent closures. The commission is proposing to add WAC 246-945-231 to consolidate the reporting requirement for pharmaceutical firms to report disciplinary action to the commission and add WAC 246-945-592 to establish reporting requirements for permanently closing manufacturers and wholesalers.

Hearing

location(s):

Date: Time: Location: (be specific)

Comment:

02/06/2024

10:30
am

Physical Location:

Department of Labor & Industries
7273 Linderson Way SW
Tumwater, WA 98501

Virtual Location:

Virtual:
To access the meeting on February 6,
2025
at 9:30 am, go to
<https://us02web.zoom.us/j/86309299195> or
<https://zoom.us/join> and use the Webinar
ID
863 0929 9195
The access options include one tap
mobile:
+12532158782,,86309299195# US
(Tacoma)
+12532050468,,86309299195# US
Or Telephone: Dial (for higher quality, dial
a
number based on your current location):
+1 253 215 8782 US (Tacoma)
+1 253 205 0468 US

The commission will hold a hybrid hearing. Attendees are welcome to attend either in-person at the physical location or virtual via Zoom.

Date of intended adoption: 02/06/2024 (Note: This is NOT the effective date)

Submit written comments to:

Name: Julia Katz

Address: PO Box 47852, Olympia, WA 98504-7852

Assistance for persons with disabilities:

Contact: Julia Katz

Phone: 360-236-4946

Email: None	Fax: 360-236-2260
Fax: 360-236-2260	TTY: 711
Other: https://fortress.wa.gov/doh/policyreview/	Email: PharmacyRules@doh.wa.gov
Beginning (date and time): The date and time of this filing	Other: None
By (date and time): January 23, 2025 at 11:59 pm	By (date): January 23, 2025

Purpose of the proposal and its anticipated effects, including any changes in existing rules:
 The commission is proposing rule amendments to provide customers earlier and more detailed notification of permanent facility closures. "Facility" includes pharmacies, health care entities, and hospital pharmacy associated clinics. The anticipated effect of the proposal is to provide customers additional time to transfer prescriptions and plan accordingly prior to a facility permanently closing.

The proposed rules also revise reporting requirements for pharmaceutical firms and require additional reporting requirements, within specified time frames, prior to permanent facility, manufacturer, and wholesaler closures.

Reasons supporting proposal: This rulemaking is in response to a rules petition filed by an interested party and approved by the commission during the December 2023 business meeting. The objective of the additional notification and reporting requirements for facilities, manufacturers, and wholesalers prior to permanently closing is to increase communication with the public and commission to benefit continuity of care. Providing timelines for notification of closures will allow customers timely notice to transfer prescriptions. Increased regulation on the accounting for and inventory of legend drugs and controlled substances helps to ensure accountability and prevent diversion. Enhancing facility, manufacturer, and wholesaler permanent closure requirements will allow the commission better oversight in the event of permanent facility, manufacturer, and wholesaler closures.

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

Statute being implemented: RCW 18.64.005

Is rule necessary because of a:

Federal Law?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
Federal Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No
State Court Decision?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No

If yes, CITATION:

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters: None

Name of proponent: Pharmacy Quality Assurance Commission
Type of proponent: Private. Public. Governmental.

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Implementation Julia Katz	111 Israel Rd SE, Tumwater, WA 98501	360-236-4946
Enforcement Marlee B. O'Neill	111 Israel Rd SE, Tumwater, WA 98501	360-480-9108

Is a school district fiscal impact statement required under [RCW 28A.305.135](#)? Yes No
 If yes, insert statement here:

The public may obtain a copy of the school district fiscal impact statement by contacting:

- Name
- Address
- Phone
- Fax
- TTY
- Email
- Other

Is a cost-benefit analysis required under [RCW 34.05.328](#)?

Yes: A preliminary cost-benefit analysis may be obtained by contacting:

- Name Julia Katz
- Address PO Box 47852, Olympia, WA 98504-7852

Phone 360-236-4946
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

No: Please explain:

Regulatory Fairness Act and Small Business Economic Impact Statement

Note: The [Governor's Office for Regulatory Innovation and Assistance \(ORIA\)](#) provides support in completing this part.

(1) Identification of exemptions:

This rule proposal, or portions of the proposal, **may be exempt** from requirements of the Regulatory Fairness Act (see [chapter 19.85 RCW](#)). For additional information on exemptions, consult the [exemption guide published by ORIA](#). Please check the box for any applicable exemption(s):

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.061](#) because this rule making is being adopted solely to conform and/or comply with federal statute or regulations. Please cite the specific federal statute or regulation this rule is being adopted to conform or comply with, and describe the consequences to the state if the rule is not adopted.

Citation and description:

This rule proposal, or portions of the proposal, is exempt because the agency has completed the pilot rule process defined by [RCW 34.05.313](#) before filing the notice of this proposed rule.

This rule proposal, or portions of the proposal, is exempt under the provisions of [RCW 15.65.570\(2\)](#) because it was adopted by a referendum.

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(3\)](#). Check all that apply:

[RCW 34.05.310](#) (4)(b)
(Internal government operations)

[RCW 34.05.310](#) (4)(e)
(Dictated by statute)

[RCW 34.05.310](#) (4)(c)
(Incorporation by reference)

[RCW 34.05.310](#) (4)(f)
(Set or adjust fees)

[RCW 34.05.310](#) (4)(d)
(Correct or clarify language)

[RCW 34.05.310](#) (4)(g)
(i) Relating to agency hearings; or (ii) process requirements for applying to an agency for a license or permit)

This rule proposal, or portions of the proposal, is exempt under [RCW 19.85.025\(4\)](#). (Does not affect small businesses).

This rule proposal, or portions of the proposal, is exempt under RCW _____.

Explanation of how the above exemption(s) applies to the proposed rule:

(2) Scope of exemptions: *Check one.*

The rule proposal: Is fully exempt. (*Skip section 3.*) Exemptions identified above apply to all portions of the rule proposal.

The rule proposal: Is partially exempt. (*Complete section 3.*) The exemptions identified above apply to portions of the rule proposal, but less than the entire rule proposal. Provide details here (consider using [this template from ORIA](#)):

The rule proposal: Is not exempt. (*Complete section 3.*) No exemptions were identified above.

(3) Small business economic impact statement: *Complete this section if any portion is not exempt.*

If any portion of the proposed rule is **not exempt**, does it impose more-than-minor costs (as defined by RCW 19.85.020(2)) on businesses?

No Briefly summarize the agency's minor cost analysis and how the agency determined the proposed rule did not impose more-than-minor costs.

The costs of the proposed rule (\$117 per facility, \$12 per pharmaceutical firm, and \$98 to \$122 per manufacturer or wholesaler) are all less than the minor cost threshold (\$19,161.74 for pharmacies and drug stores and \$10,305.83 for drugs and druggists' sundries merchant wholesalers).

The minor cost analysis demonstrated that the estimated cost to pharmacies, health care entities, and hospital pharmacy associated clinics is \$117 per facility, \$12 per pharmaceutical firm, and \$98 to \$122 per manufacturer and wholesaler. Using the Governor's Office for Regulatory Innovation and Assistance's Minor Cost Threshold Calculator with NAICS Code Titles 446110 Pharmacies and Drug Stores and 424210 Drugs and Druggists' Sundries Merchant Wholesalers, the minor cost threshold is not met per RCW 19.85.020. A full SBEIS may not be required since the minor cost threshold is not met.

The following is 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 Washington State Pharmacy Quality Assurance Commission (commission) is proposing rule amendments to provide customers earlier and more detailed notification of permanent facility closures. "Facility" includes pharmacies, health care entities, and hospital pharmacy associated clinics.

The proposed rules also require additional and revised reporting requirements, within specified time frames prior to permanent facility, manufacturer, and wholesaler closures.

This proposed rule package is in response to a rule petition filed by an interested individual requesting pharmacies provide clear communication and a timeline for prescription transfers to patients ahead of a facility closure in December 2023. On December 14, 2023, the commission voted to approve the request and consider rulemaking.

Small facilities, manufacturers, and wholesalers that permanently close must fulfill reporting and notification requirements to the commission and customers. Commission reporting requirements for closing facilities, manufacturers, and wholesalers consist of communicating in writing planned and actualized logistics pertaining to closure plans. Customer notification requirements for closing facilities include informing customers verbally of the closure, informing employees of the rule adoptions, creating a notice to include with dispensed prescriptions, and advertising in a print and digital version of the newspaper, if available. Manufacturers and wholesalers must notify customers in writing of the closure date and the last day to place orders for fulfillment. Compliance with the proposed reporting requirements will involve time of the manager in charge.

SBEIS Table 1 identifies and summarizes 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 with the Proposed Rule

NAICS Code (4, 5 or 6 digit)	NAICS Business Description	Number of businesses in Washington State	Minor Cost Threshold
446110	Pharmacies and Drug Stores	267	\$19,161.74
424210	Drugs and Druggists' Sundries Merchant Wholesalers	388	\$10,305.83

The following is an 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 246-945-231(1) Reporting Disciplinary Action.

Description: Only three license types the commission regulates are currently required by state rule to report to the commission disciplinary action taken by another state, federal, or foreign authority. The commission is proposing to amend the term "facility" to "pharmaceutical firm" in WAC 246-945-480(5) and replace WAC 246-945-480(5) with WAC 246-945-231(1) thereby requiring all 15 licensee types the commission regulates to report disciplinary action taken by authorized entities to the commission. "Facility" includes pharmacies, health care entities, and hospital pharmacy associated clinics per WAC 246-945-405. "Pharmaceutical firm" refers to any business engaged in the dispensing, delivering, distributing, manufacturing, or wholesaling of prescription drugs or devices within or into Washington state per WAC 246-945-001. All pharmaceutical firms are also listed in WAC 246-945-990. This proposed reporting requirement applies to pharmaceutical firms at any time.

Cost(s): Pharmaceutical firms will need to report to the commission when a disciplinary action occurs.

The estimated probable total cost is \$12 per incident for a pharmaceutical firm to report to the commission of a disciplinary action by another state, federal, or foreign authority. The department is unable to estimate how many times this will happen per year.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
 - Each pharmaceutical firm is required to designate a responsible person whose responsibilities include accountability for transferred drugs and substances per the FDA Drug Quality and Security Act.¹
 - For the purpose of this estimate, the commission assumes that the closest probable job title is a general operations manager.
 - Commission staff estimate based on experience that reporting an applicable disciplinary action will require 10 minutes of a general operations manager's time (\$69.43/hour).²

Calculations for estimate:

- Calculations for commission reporting costs:
 - \$11.57 for 10 minutes of the general operations manager's time to report an applicable disciplinary action.

WAC 246-945-480(1) Facility Reporting Requirements.

Description: The proposed WAC 246-945-480(1) amendment is to replace the "ten" with "10." Per RCW 34.05.310(4)(d), this amendment is exempt from analysis as it exclusively corrects a typographical error.

WAC 246-945-480(2) Facility Reporting Requirements.

Description: Currently, when a facility (i.e., pharmacy, health care entity, or hospital pharmacy associated clinic) is closing permanently, 30 days prior they must notify the commission of the name and address of the person(s) who will acquire legend drugs from the facility to be closed. The commission is proposing to amend WAC 246-945-480(2)(a) to require permanently closing facilities to additionally report to the commission during this time frame the credential number of the people who are anticipated to acquire the facility's legend drugs and the name, address, and credential number of the people anticipated to acquire the facility's controlled substances. Pharmacy managers will need to apprise the commission of the credential number of the people who shall acquire the legend drugs and the name, address, and credential number of the people who shall acquire the controlled substances, if known at the time. The information may be included with an existing communication.

Facilities currently should notify customers of imminent permanent closures via direct mail, public notice in a newspaper, and signage in a conspicuous area of the pharmacy without a time parameter. Proposed WAC 246-945-480(2)(b) amends the patient notification requirements to mandate informing customers of the closure during prescription pick-up or delivery, include a notice with dispensed prescriptions informing them of their right to request a prescription transfer, and public notice in a legal newspaper of general circulation in both print and digital versions, if applicable, in addition to the signage in a conspicuous area of the pharmacy. These notifications must begin no later than 30 calendar days prior to closing. Pharmacy managers will need to apprise pertinent staff of the rule adoption, develop and print notices to be included in dispensed prescriptions to inform customers of their right to request a prescription transfer, and determine if the newspaper in which they are circulating the announcement has a digital version.

After a facility closes, they have 15 days to report several items to the commission, including the name and address of the person(s) to whom the legend drugs and controlled substances were transferred. The proposed WAC 246-945-480(2)(c) amends the post-closure requirements to require the facility closing to additionally report the credential numbers of the people who acquired both the legend drugs and controlled substances. The information may be included with an existing communication.

Cost(s): The probable costs only impact facilities that permanently close. Permanently closing facilities will need to report to the commission the credential numbers for the people anticipated to acquire the legend drugs, the name, address, and credential number of the people anticipated to acquire the controlled substances, if known at the time, and credential numbers of the people who ultimately acquired legend drugs and controlled substances. To communicate to the public, they will also need to apprise pertinent staff to inform customers upon prescription pick-up or delivery, include notices of prescription transfer rights in dispensed prescriptions, and, if available, publicize a notice of permanent closure in a digital version of the selected newspaper.

¹ H.R. 3204 – Drug Quality and Security Act, 113th Congress (2013-2014), <https://www.congress.gov/bill/113th-congress/house-bill/3204/text?s=10&r=1&q=%7B%22search%22%3A%22hr3204%22%7D> (visited September 23, 2024).

² Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

The commission assumes that all facilities dispensing prescriptions have a working computer and printer, but should they have to purchase one the cost could be \$300 to \$2,000 for a computer and \$100 to \$300 for a printer.^{3,4}

The estimated probable total cost is \$117 per permanently closing facility to communicate additional reporting and notification requirements to the commission and public.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
 - Assumes each facility has 1 pharmacy manager per WAC 246-945-410(5).⁵
 - Commission staff estimate based on experience that requesting a credential number for the people anticipated to acquire the legend drugs and communicating it in writing will take 5 minutes of a pharmacy manager's time (\$73.50/hour).⁶
 - Commission staff estimate based on experience that reporting the name, address, and credential number of the people anticipated to acquire the controlled substances will take 10 minutes of a pharmacy manager's time (\$73.50/hour).⁷
 - Communicating the name, address, and credential number of the people who ultimately acquired legend drugs and controlled substances will take 20 minutes of a pharmacy manager's time (\$73.50/hour) according to commission staff's estimate based on pharmacist consultation.⁸
- Customer notification cost assumptions:
 - Assumes each facility has 1 pharmacy manager per WAC 246-945-410(5).⁹
 - Commission staff estimate based on consultation with a pharmacist that apprising pertinent staff of the rule adoption and the need to inform customers of the permanent closure upon prescription pick-up or delivery will require 30 minutes of the pharmacy manager's time (\$73.50/hour) to prepare and deliver the communication.¹⁰
 - Commission staff estimate based on consultation with a pharmacist that creating a paper notice to include with dispensed prescriptions that informs the customer of their right to request a prescription transfer will require 30 minutes of the pharmacy manager's time (\$73.50/hour) to prepare and insert the notice.¹¹
 - Informing customers of the permanent closure will occur verbally and refer customers to the noticed inserted with the dispensed prescription. The time required to convey the information to the customer will vary greatly, depending on the number of questions received from the customer, but is anticipated to generally be a negligible amount of time.
 - The cost of notices inserted with dispensed prescriptions is minimal, about one to two reams of paper, depending on the facility's dispensing capacity. The commission considers this cost negligible for the purposes of this analysis.
 - The cost of an advertisement in a digital version of a newspaper does not impose an additional cost as print newspaper advertisements include digital publication.¹² Facilities currently have to advertise in a print newspaper when permanently closing.

³ Lenovo, new laptops range from \$300 to \$2,000,

https://www.lenovo.com/us/en/d/deals/business/?orgRef=https%253A%252F%252Fwww.bing.com%252F&sortBy=bestSelling&cid=us%3Asem%7Cse%7Cmsn%7Cnonbrand_pc%7C%7Coffice%20laptop%7Cp%7C506005685%7C1268838063590376%7Ckwd-79302875432137%3Aloc-190%7Csearch%7Cnonbrand%7Cconsumer&msclkid=cb523a8cb13f12b648eb5c602cb4e2f7&visibleDats=1014%3ALaptops (visited September 19, 2024).

⁴ Lenovo, new printers range from \$100 to \$300, <https://www.lenovo.com/us/en/search?fq=&text=printer&rows=20&sort=relevance> (visited September 19, 2024).

⁵ WAC 246-945-410(5) "The facility shall designate a pharmacy manager," <https://app.leg.wa.gov/WAC/default.aspx?cite=246-945-410> (visited September 19, 2024).

⁶ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, <https://www.bls.gov/oes/current/oes119111.htm> (visited September 20, 2024).

⁷ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, <https://www.bls.gov/oes/current/oes119111.htm> (visited September 20, 2024).

⁸ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, <https://www.bls.gov/oes/current/oes119111.htm> (visited September 20, 2024).

⁹ WAC 246-945-410(5) "The facility shall designate a pharmacy manager," <https://app.leg.wa.gov/WAC/default.aspx?cite=246-945-410> (visited September 19, 2024).

¹⁰ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, <https://www.bls.gov/oes/current/oes119111.htm> (visited September 20, 2024).

¹¹ Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment and Wage Statistics, Health Service Managers in WA in May 2023, <https://www.bls.gov/oes/current/oes119111.htm> (visited September 20, 2024).

¹² Phil Kearney, National Marketing Strategist at The Seattle Times, (phone call on September 20, 2024).

Calculations for estimate:

- Calculations for commission reporting costs:
 - \$6.13 for 5 minutes of a pharmacy manager's time to report a credential number for people anticipated to acquire legend drugs and communicate it in writing to the commission.
 - \$12.25 for 10 minutes of a pharmacy manager's time to report the name, address, and credential number for people anticipated to acquire controlled substances and communicate them in writing to the commission.
 - \$24.50 for 20 minutes of a pharmacy manager's time to report the name, address, and credential number for people who ultimately acquired legend drugs and controlled substances.
- Calculations for customer notification costs:
 - \$36.75 for 30 minutes of a pharmacy manager's time to prepare and deliver a communication apprising pertinent staff of the rule adoption and the need to inform customers of the closure.
 - \$36.75 for 30 minutes of a pharmacy manager's time to create and include a paper notice with dispensed prescriptions that informs customers of their right to request a prescription transfer.

WAC 246-945-480(3) Facility Reporting Requirements.

Description: There are no proposed amendments to WAC 246-945-480(3) making it exempt from analysis.

WAC 246-945-480(4) Facility Reporting Requirements.

Description: The proposed WAC 246-945-480(4) amendment is to replace the first "The" with "A." Per RCW 34.05.310(4)(d), this amendment is exempt from analysis as it exclusively corrects a typographical error.

WAC 246-945-592(1) Wholesaler and Manufacturer Reporting Requirements.

Description: Manufacturers and wholesalers that are permanently closing are not explicitly required in rule to inform the commission nor their customers. The commission is proposing to add WAC 246-945-592 to require manufacturers and wholesalers to notify the commission and their customers in the event of a permanent closure.

Proposed WAC 246-945-592(1)(a) includes a customer notification requirement in the form of a written communication which includes the last day the manufacturer or wholesaler will be open and the last day the customer may place an order to be fulfilled.

Reporting requirements to the commission are included in proposed WAC 246-945-592(1)(b) and WAC 246-945-592(1)(c). At least 30 calendar days prior to permanently closing, a manufacturer or wholesaler shall report to the commission in writing the date of the closure and the names, credential numbers, and addresses of the people who will receive any legend drugs or controlled substances, if known at the time. Within 15 calendar days from the closure date, the manufacturer or wholesaler will return their license, confirm the name, credential number, and address of the people who received any legend drugs and controlled substances, confirm U.S. Drug Enforcement Agency (DEA) registration and unused DEA 222 forms were returned to the DEA, and confirm all signs and symbols indicating the presence of the wholesaler and manufacturer have been removed, if applicable, to the commission.

Cost(s): The probable costs only impact manufacturers and wholesalers that permanently close. Permanently closing manufacturers and wholesalers will need to report to the commission the date of the closure and the names, credential numbers, and addresses of the people anticipated to receive any legend drugs or controlled substances, if known at the time. After the manufacturer or wholesaler location has closed, they will need to report to the commission the return of their license, the name, credential number, and address of the people who received any legend drugs and controlled substances, confirmation of returned U.S. Food and Drug Administration's (FDA) Drug Enforcement Agency (DEA) registration and unused DEA 222 forms, and, if applicable, confirmation of removal of all signs and symbols indicating the presence of the wholesaler and manufacturer.

The estimated probable total cost ranges from \$98 to \$110 per permanently closing manufacturer or wholesaler to fulfill reporting requirements to the commission and notify customers.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
 - Each pharmaceutical wholesaler or manufacturer is required to designate a responsible person whose responsibilities include accountability for transferred drugs and substances per the FDA Drug Quality and Security Act.¹³
 - For the purpose of this estimate, the commission assumes that the closest probable job title is a general operations manager.

¹³ H.R. 3204 – Drug Quality and Security Act, 113th Congress (2013-2014), <https://www.congress.gov/bill/113th-congress/house-bill/3204/text?s=10&r=1&q=%7B%22search%22%3A%22hr3204%22%7D> (visited September 23, 2024).

- Commission staff estimate based on experience that reporting the date of the closure will require 5 minutes of a general operations manager's time (\$69.43/hour).¹⁴
- Communicating the name, address, and credential number of people anticipated to acquire the legend drugs and controlled substances will take 20 minutes of a general operations manager's time (\$69.43/hour).¹⁵
- Communicating the name, address, and credential number of the people who ultimately acquired legend drugs and controlled substances will take 20 minutes of a general operations manager's time (\$69.43/hour) according to commission staff's estimate based on pharmacist consultation.¹⁶
- Commission staff estimate based on consultation with a pharmacist that reporting the return of their license will require 5 minutes of a general operation manager's time (\$69.43/hour).¹⁷
- Confirming that DEA registration and unused DEA 222 forms were returned to the DEA is estimated to require 5 minutes of a general operation manager's time (\$69.43/hour) per commission staff estimate based on consultation with a pharmacist consultant.¹⁸
- If there are signs and symbols indicating the presence of the manufacturer or wholesaler, commission staff estimate based on consultation with a pharmacist that confirming their removal will require 10 minutes of a general operation manager's time (\$69.43/hour).¹⁹ If the manufacturer or wholesaler does not have signs or symbols, there will be no confirmation and the cost would be \$0.
- Customer notification cost assumptions:
 - Commission staff estimate based on consultation with a pharmacist that notifying customers of the manufacturer or wholesaler's closure in writing and the last day to place an order to be fulfilled will require 30 minutes of the general operation manager's time (\$69.43/hour) to prepare and distribute the written notice.²⁰

Calculations for estimate:

- Calculations for commission reporting costs:
 - \$5.79 for 5 minutes of the general operations manager's time to report the date of closure.
 - \$23.14 for 20 minutes of the general operations manager's time to communicate the name, address, and credential number of people anticipated to acquire the legend drugs and controlled substances.
 - \$23.14 for 20 minutes of the general operations manager's time to communicate the name, address, and credential number of people who ultimately acquired the legend drugs and controlled substances.
 - \$5.79 for 5 minutes of the general operations manager's time to report the return of the license.
 - \$5.79 for 5 minutes of the general operations manager's time to confirm DEA registration and unused DEA 222 forms were returned to the DEA.
 - \$0 to \$11.57 range for 0 to 10 minutes of the general operations manager's time to confirm removal of identifying signs and symbols. This cost is only applicable to permanently closing manufacturers and wholesalers with signs and symbols indicating their presence.
- Calculations for customer notification costs:
 - \$34.72 for 30 minutes of the general operations manager's time to inform customers of the manufacturer or wholesaler's closure and the last day to place an order to be fulfilled.

WAC 246-945-592(2) Wholesaler and Manufacturer Reporting Requirements.

Description: Manufacturers and wholesalers are not currently required by state rule to report to the commission any disasters, accidents, or emergencies. The commission is proposing to require wholesalers and manufacturers to report to the commission any disasters, accidents, or 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, or disease in new WAC 246-945-592. This proposed reporting requirement applies to manufacturers and wholesalers at any time.

¹⁴ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA in May 2023 <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

¹⁵ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA in May 2023 <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

¹⁶ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA in May 2023 <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

¹⁷ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA in May 2023 <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

¹⁸ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA in May 2023 <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

¹⁹ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

²⁰ Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

Cost(s): Manufacturers and wholesalers will need to report to the commission when a disaster, accident, or emergency which affects the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, or disease occurs.

The estimated probable total cost is \$12 per incident for a manufacturer or wholesaler to report to the commission of a disaster, accident, or emergency which affects the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of injury, illness, or disease. The department is unable to estimate how many times this will happen per year.

Cost assumptions for estimate:

- Commission reporting cost assumptions:
 - Each pharmaceutical wholesaler or manufacturer is required to designate a responsible person whose responsibilities include accountability for transferred drugs and substances per the FDA Drug Quality and Security Act.²¹
 - For the purpose of this estimate, the commission assumes that the closest probable job title is a general operations manager.
 - Commission staff estimate based on experience that reporting an applicable disaster, accident, or emergency will require 10 minutes of a general operations manager's time (\$69.43/hour).²²

Calculations for estimate:

- Calculations for commission reporting costs:
 - \$11.57 for 10 minutes of the general operations manager's time to report an applicable disaster, accident, or emergency.

Summary of all Cost(s)

SBEIS Table 2. Summary of Section 3 probable cost(s)

WAC Section and Title	Probable Cost(s)
WAC 246-945-231(1) Reporting Disciplinary Action	\$12 per pharmaceutical firm occurrence
WAC 246-945-480(2) Facility Reporting Requirements	\$117 per facility permanent closure
WAC 246-945-592(1) Wholesaler and Manufacturer Reporting Requirements	\$98 to \$110 per manufacturer or wholesaler permanent closure
WAC 246-945-592(2) Facility Reporting Requirements	\$12 per manufacturer or wholesaler occurrence
TOTAL	\$12 per pharmaceutical firm occurrence \$117 per facility permanent closure \$98 to \$122 per manufacturer or wholesaler permanent closure and occurrence

The following is an analysis on if the proposed rule may impose more than minor costs for businesses in the industry and a summary of how the costs were calculated.

The costs of the proposed rule (\$12 per pharmaceutical firm, \$117 per facility, and \$98 to \$122 per manufacturer or wholesaler) are less than the minor cost threshold (\$19,161.74 for pharmacies and drug stores or \$10,305.83 for drugs and druggists' sundries merchant wholesalers).

The probable costs were calculated for pharmaceutical firms, pertinent facilities, manufacturers, and wholesalers to comply with the proposed rule. Probable costs affiliated with compliance primarily pertain to staff time. Average staff wages in Washington state were sourced from data produced by the U.S. Bureau of Labor and Statistics. Commission staff, including staff licensed as pharmacists, estimated time requirements.

Yes Calculations show the rule proposal likely imposes more-than-minor cost to businesses and a small business economic impact statement is required. Insert the required small business economic impact statement here:

²¹ H.R. 3204 – Drug Quality and Security Act, 113th Congress (2013-2014), <https://www.congress.gov/bill/113th-congress/house-bill/3204/text?s=10&r=1&q=%7B%22search%22%3A%22hr3204%22%7D> (visited September 23, 2024).

²² Bureau of Labor Statistics, General and Operations Manager, \$69.43 Hourly mean wage in WA <https://www.bls.gov/oes/current/oes119111.htm> (visited September 23, 2024).

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting:

Name Julia Katz
Address PO Box 47852, Olympia, WA 98504-7852
Phone 360-236-4946
Fax 360-236-2260
TTY 711
Email PharmacyRules@doh.wa.gov
Other None

Date: December 4, 2024

Name: Hawkins DeFrance, PharmD

Title: Pharmacy Quality Assurance Commission Chair

Signature:

A handwritten signature in black ink, appearing to read "Hawkins DeFrance", written in a cursive style.

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.