WSR 26-19-097
PROPOSED RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed September 21, 2026, 9:22 a.m.]

Supplemental Notice to WSR 26-12-047.

Preproposal statement of inquiry was filed as WSR 25-23-064.

Title of Rule and Other Identifying Information: Prescription labeling accessibility rules. The pharmacy quality assurance commission (commission) proposes amending WAC 246-945-015 and 246-945-026 through 246-945-029 to refine the standards for dispensing practitioners and dispensing facilities subject to the commission's prescription labeling accessibility rules.

This supplemental filing further amends the rules to expand exemptions outlined in WAC 246-945-027, [update] a labeling requirement in WAC 246-945-028, and clarify when dispensing practitioners or dispensing facilities must offer accessible labeling services in WAC 246-945-028 and 246-945-029.

Hearing Location(s): On November 5, 2026, at 10:00 a.m., at Capitol Region ESD 113, 6005 Tyee Drive S.W., Tumwater, WA 98512; or virtually via Zoom at https://zoom.us/join or https://us02web.zoom.us/j/86309299195, Webinar ID 863 0929 9195; or One-tap mobile +12532158782,,86309299195# or +16699009128,,86309299195#; or phone: Dial (for higher quality, dial a number based on your current location) US: +1 253 215 8782 or +1 669 900 9128 or +1 346 248 7799 or +1 669 444 9171 or +1 386 347 5053 or +1 564 217 2000 or +1 646 558 8656 or +1 646 931 3860 or +1 301 715 8592 or +1 312 626 6799, Webinar ID 861 1495 8466. International numbers available at https://us02web.zoom.us/u/kdLNo6unOZ.

Date of Intended Adoption: November 5, 2026.

Submit Written Comments to: Joshua Munroe, P.O. Box 47850, Olympia, WA 98504-7850, email PharmacyRules@doh.wa.gov, fax 360-236-2260, web https://fortress.wa.gov/doh/policyreview, beginning the date and time of filing, by October 22, 2026, at 11:59 p.m.

Assistance for Persons with Disabilities: Contact Joshua Munroe, phone 360-502-5058, fax 360-236-2260, TTY 711, email PharmacyRules@doh.wa.gov, by October 15, 2026.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The commission adopted amended and new rules (WAC 246-945-015 and 246-945-026 through 246-945-029) for prescription labeling accessibility standards under WSR 25-04-003 on January 22, 2025. Those amended and new rules require dispensing facilities and dispensing practitioners to provide a means of access to patients with visual impairments or print disabilities, and patients with limited English proficiency (LEP) by supplying accessible prescription labels upon request. Acknowledging the need to give regulated practitioners and facilities time to implement the rules, the commission set an effective date of January 22, 2027.

Following the adoption of these rules, the commission received feedback from facilities and practitioners regarding the technological and fiscal challenges for providing the accessibility tools and methods listed in the adopted rules due to changes in the health care landscape that have occurred since the adoption of the rules. In addition, the rules did not clearly allow for the adaptation of newer technology that may assist in providing a means of access to prescription information. The commission determined at its October 16, 2025,

business meeting that the accessible labeling rules necessitated review to consider how to best address implementation burdens while still fulfilling the original goal of ensuring meaningful access to accurate prescription information for all patients receiving prescribed medications in Washington.

In response, the commission proposed rule amendments to the current rule, WSR 26-12-047, and held a rules hearing on July 23, 2026. The proposed rules revised the accessible labeling program to provide access to both individuals with print disabilities or visual impairments and individuals with LEP. Key changes included:

- Visual accessibility: Removing the requirement for dispensers to make specific methods, such as large print, Braille, QR codes, or prescription readers, available upon request. Instead, dispensers must provide an appropriate means of access based on the patient's needs.
- Definitions: Removing several definitions that are no longer necessary because the rule no longer requires specific accessibility methods.
- Flexibility: Eliminating the prescriptive list that allows facilities and practitioners to choose methods that best meet their patients' needs and adapt more easily as technology changes.
- LEP access: Reduces the languages required for written translation and oral interpretation from all languages to the 10 most common non-English languages, based on the office of financial management (OFM) estimates. This was intended to make it easier for facilities and practitioners to identify and use third-party language service vendors.

Comments received at the public hearing expressed that practitioners and facilities that dispense medications intended for short-term use, typically in periods of 72 hours or fewer, by a patient would experience logistic and fiscal obstacles to comply with the accessible labeling requirements and dispense those medications in a timely manner. In order to create an exemption applicable to all dispensing practitioners and dispensing facilities, the commission voted to amend the exemptions list in WAC 246-945-027 to add a new exemption to cover short-term medications for acute care needs.

The commission also voted to amend an exemption in WAC 246-945-027 (1)(e) for mobile health care teams as a part of a public health outreach program, and to update the term "self-evident" in WAC 246-945-028(2) and 246-945-029(2). Both of these changes were deemed to be nonsubstantive.

The commission determined that a supplemental hearing was necessary to obtain feedback from interested parties on the revised proposal.

Supplemental proposal: This supplemental filing further amends the rules to expand exemptions outlined in WAC 246-945-027 and a labeling requirement in WAC 246-945-028, and clarifies when dispensing practitioners or dispensing facilities must offer accessible labeling services in WAC 246-945-028 and 246-945-029.

The word "prepackaged" was removed from WAC 246-945-027 (1)(e) regarding medications delivered by a mobile health care team as a part of a public health outreach program in order to expand the types of medications exempt under such programs.

The exemptions list was also expanded to accommodate dispensing practitioners and facilities dispensing short-term medications or therapies. The new proposed exemption applies to medications or thera-

pies that are in a quantity of no greater than a 72-hour supply or is packaged directly by the manufacturer and cannot be altered to limit the quantity to a 72-hour supply. In order to use this exemption, the dispensing practitioner or dispensing facility must also determine that pharmacy services are not available, an individual has no ability to reach a community pharmacy or outpatient pharmacy, or the individual is identified as needing human immunodeficiency virus post-exposure prophylaxis drugs or therapies.

The supplemental amendment to the language in WAC 246-945-028(3) requires that the label mechanism to provide a means of access to visually impaired or print-disabled patients must be affixed to the medication container, if applicable. An additional supplemental amendment is made in WAC 246-945-028 and 246-945-029 to update the "self-evident" provision in both sections to clarify when dispensing practitioners or dispensing facilities must offer accessible labeling services.

Reasons Supporting Proposal: The proposed rule amends the requirements for which accessibility methods must be used by a practitioner or facility to best accommodate the patient's needs. The modified conditions for compliance would address expressed concerns over an entity's ability to implement and comply with the commission's prescription label accessibility rules. However, the goal remains that a means of access as defined in the rule must be provided to all patients and, per WAC 246-945-027, accessibility services must still be supplied to the patient at no additional cost.

Clear comprehension of prescription drug label information is a matter of public health and safety for all persons, regardless of disability or language barriers.

Supplemental proposal: As a result of the public hearing, the commission determined that exemptions to the accessible prescription label program needed adjustment to help dispensing practitioners and dispensing facilities comply with the rules. The commission focused on the logistical challenges faced by mobile health care teams as a part of a public health outreach program relating to the types of medications they provide to their patient populations. The commission concluded that, based on the conditions under which those medications are dispensed, it was not reasonable to require those health care teams to also bring accessible labeling hardware to their patients, many of whom would not otherwise be able to access their medications, to satisfy the conditions in the rules.

The commission also discussed comments received from dispensing entities that provide short-term medications and therapies to patients, deciding to add a new exemption category that encompasses medications that are intended for short-term use until the patient is able to obtain them from a dispensing practitioner or dispensing facility that can provide accessible labeling services. The reason given for the proposed supplemental change was to ease compliance requirements for the entities subject to the accessible prescription label regulations that would experience logistical and fiscal challenges in providing medications or therapies that are needed for a short period but are often also needed on an immediate basis. These would include medications needed for acute care such as those provided at an urgent care when pharmacy services are not available, for example.

Lastly, the commission chose to make nonsubstantive language changes based on received public comments. The commission received a comment that expressed concern over the missing requirement to affix the accessible label to the prescription container, and the commission

agreed that the "affixing" requirement was always intended as an element to the rule language and would be clarified by amending the rule language. The language around the "self-evident" determination of accessibility needs in WAC 246-945-028 and 246-945-029, referenced in another public comment, is also updated to provide clarity for when a dispensing practitioner or dispensing facility must offer accessible labeling services. For these supplemental changes, the commission maintains that clear comprehension of prescription drug label information is a matter of public health and safety for all persons, regardless of disability or language barriers.

Statutory Authority for Adoption: RCW 18.64.005, 69.41.240, and 69.50.301.

Statute Being Implemented: RCW 18.64.005(7), 69.41.240, and 69.50.301.

Rule is not necessitated by federal law, federal or state court decision.

Agency Comments or Recommendations, if any, as to Statutory Language, Implementation, Enforcement, and Fiscal Matters: The original accessible prescription labeling rules will go into effect on January 22, 2027. The goal is to adopt newly revised rules with the same effective date.

Name of Proponent: Pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Joshua Munroe, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058; Enforcement: Marlee 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 Joshua Munroe, P.O. Box 47850, Olympia, WA 98504-7850, phone 360-502-5058, fax 360-236-2260, 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 only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of exemptions: The proposed amendments of WAC 246-945-015 and 246-945-026 align terms used through the rules and remove defined terms relating to accessibility methods for individuals with print disabilities or visual impairments that are no longer used in the rules.

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.

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: Original proposal: The commission proposes amending WAC 246-945-015 and 246-945-026 through 246-945-029 to refine the standards for dis-

pensing practitioners and dispensing facilities subject to the commission's prescription labeling accessibility rules.

The commission adopted new and amended rules (WAC 246-945-015 and 246-945-026 through 246-945-029) for prescription labeling accessibility standards under WSR 25-04-003 on January 22, 2025. Those amended and new rules require dispensing facilities and dispensing practitioners to provide a means of access to patients with visual impairments or print disabilities, and patients with LEP by supplying accessible prescription labels upon request. Acknowledging the need to give regulated practitioners and facilities time to implement the rules, the commission set an effective date of January 22, 2027.

Following the adoption of the prescription labeling accessibility rules, the commission received feedback from facilities and practitioners regarding the technological and fiscal challenges for providing the accessibility tools and methods listed in the adopted rules due to changes in the health care landscape that have occurred since the adoption of the rules. In addition, the rules inadvertently restricted the use of newer technology that may assist in providing a means of access to prescription information. The commission determined at its October 16, 2025, business meeting that the accessible labeling rules necessitated review to consider how to best address implementation burdens while still fulfilling the original goal of ensuring meaningful access to accurate prescription information for all patients receiving prescribed medications in Washington.

The proposed rule amends both primary goals to the accessible labeling program: Providing a means of access to individuals with print disabilities or visual impairments, and providing a means of access to LEP individuals. The print and visual accessibility language in WAC 246-945-028 is amended to remove the requirement to make available a specified list of methods, large-print, Braille print, QR code or equivalent, and prescription reader or equivalent, to patients upon request. Dispensers must instead ensure they provide a means of access in any manner necessary. As a result of this removal, a number of definitions in WAC 246-945-026 are also removed.

The language accessibility section, WAC 246-945-029, is also amended to replace the requirement to translate or interpret the complete directions for use in any language upon patient request with the requirement for dispensing facilities and dispensing practitioners to instead be able to provide those same translation and interpretation services in the 10 most common non-English languages in Washington. The list of the 10 most common languages is based on OFM's LEP estimates. Facilities and practitioners subject to the accessible labeling rules shall review the OFM estimates annually in March and update the 10 non-English languages they make available as necessary. The commission must also annually review the OFM estimates to update the signage template it makes available to dispensing facilities and dispensing practitioners.

Lastly, an exemption is added to WAC 246-945-027 for prepackaged medications delivered to an individual by a mobile health care team as a part of a public health outreach program, and an editorial amendment has been made to WAC 246-945-015 to align the use of terms "drugs and devices" throughout the rules.

Supplemental proposal: The supplemental proposal amends the list of exemptions outlined in WAC 246-945-027 and a labeling requirement in WAC 246-945-028. The word "prepackaged" was removed from WAC 246-945-027 (1)(e) regarding medications delivered by a mobile health care team as a part of a public health outreach program in order to

expand the types of medications exempt under such programs. The exemptions list was also expanded to accommodate dispensing practitioners and facilities dispensing short-term medications or therapies. The new proposed exemption applies to medications or therapies that meet a number of enumerated conditions, including that the dose is in a quantity of no greater than a 72-hour supply or is packaged directly by the manufacturer and cannot be altered to limit the quantity to a 72-hour supply.

The supplemental amendment to the language in WAC 246-945-028(3) requires that the label mechanism to provide a means of access to visually impaired or print-disabled patients must be affixed to the medication container. The commission determined this amendment is not substantive as it is intended to address an unintentional removal of the affixing requirement in the rule language approved by the commission for this project.

The commission held a public hearing on July 23, 2026, for the CR-102 rules proposal package on this topic, filed as WSR 26-12-047. In its discussion of and response to the received comments from the public comment period and the hearing, the commission determined that exemptions to the accessible prescription label program needed adjustment to help dispensing practitioners and dispensing facilities comply with the program. The commission focused on the logistical challenges faced by mobile health care teams as a part of a public health outreach program relating to the types of medications they provide to their patient populations and concluded that, based on the conditions under which those medications are dispensed and the mobile health care teams conduct their patient outreach, it was not reasonable to require those health care teams to also bring accessible labeling hardware to their patients.

The commission also discussed comments received from dispensing entities that provide short-term medications and therapies to patients, deciding to add a new exemption category that encompasses medications that are intended for short-term use, or as a stop-gap until the patient is able to obtain a full prescription, which would still be subject to accessible labeling regulations, from their dispensing practitioner or dispensing facility. The reason given for the proposed change was to ease compliance requirements for the entities subject to the accessible prescription label program regulations that would experience logistical and fiscal challenges in providing medications or therapies that are needed for a short period but are often also needed on an immediate basis.

The commission responded to a patient advocate concern over the missing requirement to affix the accessible label to the prescription container. The commission agreed that the "affixing" requirement was always intended as an element to the rule language and moved to amend the language to include the affixing requirement in WAC 246-945-028 where appropriate. The commission also addressed the phrase "self-evident" in WAC 246-945-028 and 246-945-029, choosing to amend the language in both sections to make it easier to understand for dispensing practitioners and dispensing facilities how and under what circumstances to offer accessible prescription labeling services to individuals. The "affixing" and "self-evident" changes were determined to be nonsubstantive.

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
621111	Offices of Physicians (except Mental Health Specialists)	2,779	$12,206.76
621210	Offices of Dentists	3,111	$4,929.21
621391	Offices of Podiatrists	94	$2,131.32
541940	Veterinary Services	942	$6,265.81
621399	Offices of All Other Miscellaneous Health Practitioners*	5,023	$1,428.08
621320	Offices of Optometrists	454	$3,760.94
456110	Pharmacies and Drug Stores	267**	$70,682.56

* The offices of all other miscellaneous health practitioners category includes the remaining professions capable of having prescriptive authority in the state of Washington: Nurse practitioners, physician assistants, and naturopaths.

** The employment security department reported 267 businesses categorized as pharmacies and drug stores, but department of health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

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: **EXEMPT SECTIONS:** WAC 246-945-015 Minimum requirements for dispensing practitioners, and 246-945-026 Accessible prescription information—Definitions, are exempt from analysis under RCW 34.05.310 (4)(d) because they clarify the rule and do not substantively change the existing duties or responsibilities of practitioners.

WAC 246-945-027 ACCESSIBLE PRESCRIPTION INFORMATION:

Description: Original proposal: WAC 246-945-027 establishes the general provisions that dispensing facilities and dispensing practitioners must comply with in order to provide accessible prescription information services to patients and individuals.

Subsection (1) outlines the types of medications and packaging exempt from accessibility requirements (e.g., prepackaged medications in an emergency department and drug samples as defined in RCW 69.45.010). The section is amended to include prepackaged medications delivered to an individual by a mobile health care team as a part of a public health outreach program.

Supplemental proposal: The commission moved to amend WAC 246-945-027 in two ways for the supplementary rules proposal. The first change removes the word "prepackaged" from WAC 246-945-027 (1)(e) regarding medications delivered by a mobile health care team as a part of a public health outreach program in order to expand the types of medications exempt under such programs. The commission agreed with feedback from public health representatives that it would be untenable to satisfy the accessible labeling requirements for medications that mobile health care teams bring to patient populations that can only be reached on foot and cannot otherwise access their medications.

The second supplemental change adds an exemption to accommodate dispensing practitioners and facilities dispensing short-term medications or therapies. The new proposed exemption applies to medications or therapies that must meet multiple conditions. The first set of conditions require that the drug or therapy must either be dispensed in a

quantity of no greater than a 72-hour supply or is packaged directly by the manufacturer in a quantity larger than a 72-hour supply and cannot be altered to limit the quantity to a 72-hour supply. The second set of conditions necessitate that either the dispensing practitioner or dispensing facility determined that community or outpatient pharmacy services are not available within 15 miles by road within Washington, the patient cannot reasonably reach the local community or outpatient pharmacy, or the individual patient is identified as needing human immunodeficiency virus post-exposure prophylaxis medications or therapies. Unless both sets of conditions are satisfied, the drug or therapy is not exempt from the accessible prescription labeling requirements unless covered by one of the other exemptions in WAC 246-945-027(1).

Cost(s): Original proposal: The change made by the proposed rule is the addition of the exemption category of "prepackaged medications delivered to an individual by a mobile health care team as a part of a public health outreach program" in WAC 246-945-027 (1)(e). It is estimated that creating an exemption for such prepackaged medications represents **no additional cost** to those programs because adding this exemption removes potential costs.

Supplemental proposal: For the first amendment to the section, the commission determined that removing the term "prepackaged" from WAC 246-945-027 (1)(e) would incur **no costs** to the mobile health care teams affected by the exemption category. Expanding the types of medications exempt from the accessible labeling requirements for mobile health care teams would not require any changes to the existing one-time and ongoing compliance costs for public health outreach programs that provide services in brick-and-mortar locations.

The addition of the new exemption in WAC 246-945-027 (1)(f) is also intended to ease compliance conditions for the dispensing practitioners and dispensing facilities providing immediate and acute care to patients when pharmacy services may not be available. The only change in implementation strategy that the commission foresees is the adjustment to training so that those providing accessibility services understand the conditions under which medications may be exempt from the accessibility requirements when dispensed. The commission does not feel that this would add to any planned training costs for the entities that must comply with the accessibility regulations, and therefore **no additional cost** is associated with the new proposed exemption category.

However, it is possible that a dispensing practitioner or dispensing facility, in preparation for the January 22, 2027, implementation date of the original accessible labeling rules, already incurred costs beyond that required under the proposed rule in order to obtain hardware and software associated with the four visual or print accessibility methods. Commission staff believe this scenario is unlikely based on feedback received from regulated entities.

There is also a consideration needed for patients being treated by mobile health care teams or patients that receive dispensed medications that might still need accessibility considerations. Despite the intended effect of easing of compliance requirements for the discussed practitioners and facilities, nothing in the existing accessible prescription labeling rules prevents dispensing facilities and dispensing practitioners from complying with other federal and state accessibility requirements.

WAC 246-945-028 ACCESSIBILITY OF PRESCRIPTION INFORMATION FOR VISUALLY IMPAIRED OR PRINT DISABLED INDIVIDUALS:

Description: Original proposal: WAC 246-945-028 focuses on providing means of access for patients who are visually impaired or print disabled. The prescription information that must be made accessible for such patients is defined in WAC 246-945-026, containing information elements such as the name of the drug, name of the patient, drug quantity, and the complete directions for use. The proposed rule removes subsection (3) and amends subsection (4) with clarifying language regarding the responsibilities of dispensing practitioners and dispensing facilities to provide a means of access for print disabled or visually impaired patients.

Supplemental proposal: Subsection (2) is amended to replace the phrase "when it is self-evident" with the phrase "upon request, demonstration of need, or other indicator that" the person being prescribed a medication is visually impaired or print disabled. It was determined that the adjustment of the "self-evident" term also constituted a change that clarifies the language for those responsible for implementing the accessible labeling requirements which is exempt from analysis under RCW 34.05.328 (5)(b)(iv).

Subsection (3) is amended to specify that "the mechanism to provide a means of access must be affixed" to a prescription container for medication dispensed to a visually impaired or print disabled individual. The change to this section of rule is clarifying and is exempt from analysis under RCW 34.05.328 (5)(b)(iv). The commission stated that the original intent of the accessible labeling rules was that labels provided as a means of access to patients must be affixed to the prescription container.

Cost(s): Original proposal: The proposed rule removes a subsection that required each dispensing practitioner and dispensing facility to acquire and maintain four methods of visual and print accessibility: Large-print labels, Braille labels, QR codes or equivalent, and audio prescription readers or equivalent. While the entities that must comply with the accessible labeling rules will still need to acquire and maintain a method or methods that provide their patients a means of access to their prescription information, the expenditure will be less than or equal to the prior requirements.[1] As such, there are **no new costs** estimated for this proposed section of rule.

[1] Hardware acquisition for complying with WAC 246-945-028 was estimated at between $0 and $9,240, and ongoing label printing costs for the section was estimated at between $0 and $15,180 based on patient volume and type of entity required to comply with those rules. Further information about cost estimates associated with the original accessible prescription labeling rules may be found with the CR-102 rules proposal package filed with the Washington state office of the code reviser on August 14, 2024, under WSR 24-17-046.

However, it is possible that a dispensing practitioner or dispensing facility, in preparation for the January 22, 2027, implementation date of the original accessible labeling rules, already incurred costs beyond that required under the proposed rule in order to obtain hardware and software associated with the four visual or print accessibility methods. Commission staff believe this scenario is unlikely based on feedback received from regulated entities.

Supplemental proposal: The proposed changes are clarifying and therefore there is nothing additional to add to the cost.

WAC 246-945-029 TRANSLATION AND INTERPRETATION FOR PRESCRIPTION INFORMATION FOR INDIVIDUALS WITH LEP:

Description: Original proposal: This section of rule establishes requirements for providing means of access for LEP patients when fulfilling prescriptions. The current rule requires dispensing practitioners and facilities to be able to provide oral interpretation and written translation services in any language. The amended rule requires the dispensing facility or office of the dispensing practition-

er to be able to make available to LEP patients written translation or oral interpretation in the 10 most common non-English languages in Washington based on OFM's estimates. Facilities and practitioners subject to the accessible labeling rules must check the OFM's website annually during the month of March to evaluate whether there is a change to the 10 most common non-English languages, and adjust the languages they provide in response. The only element required for written translation is the complete directions for use, and the translated portion must be affixed to the prescription container per subsection (2).

Offices of dispensing practitioners and dispensing facilities must post signage developed and made available by the commission to notify individuals of the right to oral interpretation and written translation services. The signs will be translated in the 10 most common written non-English languages in Washington state and the commission will review the list of languages on the signs annually. Signage developed and reviewed by the commission is exempt from analysis under RCW 34.05.328 (5)(b)(ii), as that rule relates only to internal government operations. Dispensing facilities and offices of dispensing practitioners that dispense and deliver prescriptions through the mail are required to provide notification to patients about the availability of accessibility services since the patient would not see a sign when interacting with that practitioner or facility.

Supplemental proposal: Subsection (2) is amended to replace the phrase "when it is self-evident" with the phrase "upon request, demonstration of need, or other indicator that" the person being prescribed a medication is a person with LEP.

Cost(s): Original proposal: The proposed rule amends the number of languages that dispensing facilities and dispensing practitioners must make available to LEP patients upon request, from all languages down to the 10 most common non-English languages in Washington state. The department of health (department) and commission reasonably assumes that the costs for providing 10 languages for translation and interpretation are less burdensome than finding a third-party vendor that can provide all languages and paying for that service; it is estimated that the change to the language requirements in WAC 246-945-029 represents **no additional cost** to regulated entities.

The only new element that might represent a new cost is the proposed requirement to check OFM estimates annually and adjust the 10 non-English languages provided in response. Since OFM does not issue new language estimates each year, it is unlikely that dispensing facilities and dispensing practitioners would need to spend more than a few minutes a year on this task. The department and commission reasonably believe that it is reasonably less to verify the languages each year and make adjustments as needed, and therefore there is **no additional cost**.

As with the visual and print accessibility changes in WAC 246-945-028, it is possible that a dispensing practitioner or dispensing facility, in preparation for the January 22, 2027, implementation date of the original accessible labeling rules, already incurred costs in order to provide every language for translation and interpretation to patients. Commission staff believe this scenario is also unlikely based on feedback received from regulated entities.

Supplemental proposal: The proposed changes are clarifying and therefore there is nothing additional to add to the cost.

Summary of all cost(s):

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

WAC Section and Title	Probable Cost(s)
WAC 246-945-027 Accessible Prescription Information	Original Proposal: No additional costs Supplemental Proposal: No additional costs
WAC 246-945-028 Accessibility of Prescription Information for Visually Impaired or Print Disabled Individuals	Original Proposal: No new costs Supplemental Proposal: The proposed changes are clarifying and therefore there is nothing additional to add to the cost
WAC 246-945-029 Translation and Interpretation for Prescription Information for Individuals with LEP	Original Proposal: No additional costs (potential for negligible costs) Supplemental Proposal: The proposed changes are clarifying and therefore there is nothing additional to add to the cost

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: Original proposal: The determination of "no new costs" or "no additional costs" (with potential for estimated negligible costs of annually checking the OFM's language estimates and adjusting the non-English languages offered to patients) are *less than* the minor cost threshold of the following dispensing practitioners and dispensing facilities ranging from $1,428.08 to $70,682.56.

Supplemental proposal: The costs of the proposed rule of no new or additional costs are *less than* the minor cost thresholds of any impacted businesses ranging from $1,428.08 to $70,682.56.

Summary of how the costs were calculated: The commission considered the fiscal impact of the amended and new exemptions in WAC 246-945-027(1) on dispensing practitioners and dispensing facilities and determined that the proposed changes would ease implementation and compliance requirements for those entities.

Business Description: Minor cost threshold:

- Offices of physicians (except mental health specialists): $12,206.76
- Dentist's office: $4,929.21
- Podiatric physician's office: $2,131.32
- Veterinarian's office: $6,265.81
- Nurse practitioner's office: $1,428.08
- Optometrist's office: $3,760.94
- Physician assistant's office: $1,428.08
- Naturopath's office: $1,428.08
- Pharmacy: $70,682.56

The public may obtain a copy of the small business economic impact statement or the detailed cost calculations by contacting Joshua Munroe, P.O. Box 47850, Olympia, WA 98504-7850, phone 360-502-5058, fax 360-236-2260, TTY 711, email PharmacyRules@doh.wa.gov.

September 21, 2026
Ann Wolken, PharmD, RPh, Chair
Pharmacy Quality Assurance Commission

RDS-7018.5

AMENDATORY SECTION (Amending WSR 25-04-003, filed 1/22/25, effective 1/22/27)

WAC 246-945-015 Minimum requirements for dispensing practitioners. (1) A practitioner authorized to prescribe or administer a leg-

end drug including a controlled substance, other than a pharmacy, may dispense a legend drug including a controlled substance directly to an ultimate user without a prescription.

(2) All practitioners authorized to prescribe legend drugs and devices, and who dispense drugs or devices directly to the ultimate user, shall affix a label to the prescription container that meets the requirements of RCW 69.41.050 and shall comply with WAC 246-945-026 through 246-945-029.

AMENDATORY SECTION (Amending WSR 25-04-003, filed 1/22/25, effective 1/22/27)

WAC 246-945-026 Accessible prescription information—Definitions. Unless the context clearly requires otherwise, the following definitions, as well as the definitions in WAC 246-945-001, apply for the purposes of WAC 246-945-026 through 246-945-029:

(1) "Accessible prescription information" means the provision of accurate prescription information to a visually impaired or print disabled individual, and means the provision of accurate complete directions for use to an individual with LEP.

(2) "Complete directions for use" means standard instructions intended to guide a patient on how to safely and effectively use a dispensed prescription. Minimum elements include:

(a) ((~~The~~)) A verb such as, but not limited to, take, place, instill;

(b) ((~~The~~)) Dosage form such as, but not limited to, tablet, capsule, and drops;

(c) Dosage quantity;

(d) Route of administration;

(e) Frequency of administration; and

(f) Additional contextual information for the safe and effective use of a dispensed prescription such as, but not limited to, "as needed," and "when tired."

(3) "Dispensing facility" or "dispensing facilities" means a pharmacy, nonresident pharmacy, health care entity, or hospital pharmacy associated clinic that dispenses and delivers prescriptions to the ultimate user or the ultimate user's authorized representative. It does not include prescriptions dispensed by a pharmacy, nonresident pharmacy, health care entity, and hospital pharmacy associated clinic that are administered by a licensed health care professional acting within their scope of practice.

(4) "Dispensing practitioner" or "dispensing practitioners" means a practitioner authorized to prescribe legend drugs and devices and who dispenses and delivers prescriptions directly to the ultimate user or the ultimate user's authorized representative.

(5) ((~~"External accessible device" means a commercially available computer, mobile phone, or other communications device that is able to receive electronic information transmitted from an external source and provide the electronic information in a form and format accessible to the individual.~~

~~(6)~~)) "Individual with limited-English proficiency" or "individual with LEP" means a person who does not speak English as their primary language and who has a limited ability to read, speak, write, or understand English.

((~~(7)~~)) (6) "Means of access" means provision of a mechanism to enable a visually impaired or print disabled individual to receive accurate prescription information.

((~~(8)~~)) (7) "Oral interpretation" means oral communication in which a person acting as an interpreter comprehends a message in one language and re-expresses all necessary information accurately in ((~~the individual with LEP's preferred~~)) another language.

((~~(9)~~)) (8) "Prescription information" means drug or device name, patient name, patient species if applicable, complete directions for use, and drug quantity.

((~~(10) "Prescription drug reader" means a device that provides information in an audio format accessible to the individual.~~

~~(11)~~)) (9) "Print disabled" means the inability to effectively read or access prescription information due to a visual, physical, perceptual, cognitive disability, or other impairment.

((~~(12) "QR code" means a two-dimensional barcode printed as a square pattern of black and white squares that encodes data.~~

~~(13)~~)) (10) "Translation" shall mean the accurate conversion of a written text from one language into an equivalent written text in another language.

((~~(14)~~)) (11) "Visually impaired" means an impairment that prevents an individual from effectively reading or accessing information, such as prescription information, without assistance.

AMENDATORY SECTION (Amending WSR 25-04-003, filed 1/22/25, effective 1/22/27)

WAC 246-945-027 Accessible prescription information. (1) Dispensing facilities and dispensing practitioners shall comply with the requirements in WAC 246-945-027 through 246-945-029 to provide accessible prescription information unless the prescription is for:

(a) A prepackaged medication delivered pursuant to WAC 246-945-435;

(b) An opioid overdose reversal medication as defined in RCW 69.41.095;

(c) A multiple dose ((~~drug~~)) medication or device dispensed and partially administered to an individual by a health care professional acting within their scope of practice and subsequently relabeled for that individual's use; ((~~or~~))

(d) A drug sample, as defined in RCW 69.45.010, delivered to an individual no more than twice within a 60-day period by the same dispensing practitioner or dispensing facility;

(e) Medication delivered to an individual by a mobile health care team as part of a public health outreach program; or

(f) Medication or therapy delivered to an individual under the following conditions:

(i) The medication or therapy is dispensed:

(A) In a quantity no greater than a 72-hour supply; or

(B) Packaged directly by the manufacturer in quantities larger than a 72-hour supply that cannot be altered to limit the quantity to a 72-hour supply; and

(ii) The dispensing facility or dispensing practitioner has determined one of the following:

(A) Community or outpatient pharmacy services are not available within 15 miles within Washington by road;

(B) Consistent with policies and procedures, an individual has no reasonable ability to reach a local community or outpatient pharmacy; or

(C) When an individual is identified as needing human immunodeficiency virus postexposure prophylaxis drugs or therapies.

(2) Dispensing facilities and dispensing practitioners shall develop and implement policies and procedures to implement the requirements in WAC 246-945-027 through 246-945-029.

(3) Dispensing facilities and dispensing practitioners shall provide accessible prescription information as required in WAC 246-945-027 through 246-945-029 at no additional cost.

(4) The services required by WAC 246-945-027 through 246-945-029 may be provided by an employee of the dispensing facility or dispensing practitioner, the dispensing practitioner themselves, or a third party. The use of a third party does not diminish the responsibility of the dispensing facility or dispensing practitioner to comply with the requirements in WAC 246-945-027 through 246-945-029.

(5) The provision of accessible prescription information, as required by WAC 246-945-027 through 246-945-029, shall occur at the time of delivery of the filled prescription to the individual or the individual's authorized representative, but need not be provided in-person.

(6) Nothing in this section shall diminish or impair any requirement that a dispensing facility or dispensing practitioner provide any accessibility service, language assistance, interpretation, or translation under applicable federal or state law, such as, but not limited to, Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.), Section 504 of the Rehabilitation Act (29 U.S.C. § 794), and Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189, 28 C.F.R. Part 36).

AMENDATORY SECTION (Amending WSR 25-04-003, filed 1/22/25, effective 1/22/27)

WAC 246-945-028 Accessibility of prescription information for visually impaired or print disabled individuals. (1) Every dispensing facility and dispensing practitioner shall provide a means of access to prescription information, as defined in WAC 246-945-026((~~(7)~~)), to visually impaired or print disabled individuals upon the request of the visually impaired or print disabled individual, their prescriber, or their authorized representative.

(2) Every dispensing facility and dispensing practitioner shall offer to provide a means of access to prescription information, as defined in WAC 246-945-026((~~(7)~~)), to visually impaired or print disabled individuals ((~~when it is self-evident~~)) upon request, demonstration of need, or other indicator that the person to whom the prescription is being prescribed and delivered is visually impaired or print disabled.

(3) ((~~A dispensing facility or dispensing practitioner shall provide one, or a combination, of the following means of access for visually impaired or print disabled individuals upon the request of the visually impaired or print disabled individual, their prescriber, or their authorized representative:~~

~~(a) Printed prescription information, as defined in WAC 246-945-026(9), in a minimum of 12-point font size, which is affixed to the prescription container;~~

~~(b) Prescription information, as defined in WAC 246-945-026(9), in Braille affixed to the prescription container;~~

~~(c) A QR code, or equivalent, affixed to the prescription drug container that transmits prescription information, as defined in WAC 246-945-026(9), to an individual's external accessible device; or~~

~~(d) A prescription drug reader, or equivalent, that is able to provide prescription information, as defined in WAC 246-945-026(9), from the label affixed to the prescription container in an audio format accessible to the individual.~~

~~(4)~~)) When dispensing facilities or dispensing practitioners provide a means of access to prescription information, as defined in WAC 246-945-026((~~(9)~~)), ((~~in one or more accessible means~~)) to visually impaired or print disabled individuals, the mechanism to provide a means of access must be affixed to the container, if applicable. The dispensing facility or dispensing practitioner must ((~~still~~)) also affix their standard label to the prescription ((~~drug~~)) container that meets the requirements of WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities.

AMENDATORY SECTION (Amending WSR 25-04-003, filed 1/22/25, effective 1/22/27)

WAC 246-945-029 Translation and interpretation for prescription information for individuals with LEP. (1) Every dispensing facility and dispensing practitioner ((~~shall~~)) must be able to provide oral interpretation and written translation services of the complete directions for use ((~~to individuals with LEP upon the request of the individual with LEP, their prescriber, or their authorized representative. The translated complete directions for use must be affixed to the prescription container~~)) in the 10 most common non-English languages in Washington based on the Washington state office of financial management's (OFM) LEP estimates.

(a) Every dispensing facility and dispensing practitioner shall provide oral interpretation and written translation services as described in this subsection to individuals with LEP upon the request of the individual with LEP, their prescriber, or their authorized representative.

(b) The translated complete directions for use must be affixed to the prescription container.

(c) Dispensing facilities and dispensing practitioners shall review the OFM LEP estimates report annually during the month of March to evaluate whether there has been a change to the 10 most common non-English languages in Washington based on this data.

(2) Every dispensing facility and dispensing practitioner shall offer to provide oral interpretation and written translation services of the complete directions for use to individuals with LEP ((~~when it is self-evident~~)) upon request, demonstration of need, or other indicator that the person to whom the prescription is being prescribed or delivered is an individual with LEP. The complete directions for use must be affixed to the prescription container.

(3) Dispensing facilities and dispensing practitioners who dispense and deliver prescriptions at a fixed physical location shall, at

a minimum, conspicuously display a sign developed and made available by the commission that notifies individuals of the right to oral interpretation and written translation services of the complete directions of use.

(a) When creating the sign, the commission will include the 10 most common non-English languages in Washington based on the Washington state office of financial management's (OFM) LEP estimates.

(b) The commission shall review the OFM LEP estimates report ((~~once every five years~~)) annually during the month of March to evaluate whether there has been a change to the 10 most common non-English languages in Washington based on this data and update the signage template as necessary. ((~~During this review, the commission will determine whether other resources or methodologies provide more accurate LEP estimate information to determine the list of languages included on the sign.~~))

(4) Dispensing facilities and dispensing practitioners who dispense and deliver prescriptions through the mail shall notify individuals of the individual's right to oral interpretation and written translation services of the complete directions for use when delivering the individual's ((~~medication~~)) prescription. The commission will develop and make available the notification that dispensing facilities and dispensing practitioners will provide.

(a) When creating the notification, the commission will include the 10 most common non-English languages based on the Washington state office of financial management's (OFM) LEP estimates.

(b) The commission shall review the OFM LEP estimates report once every five years to evaluate whether there has been a change to the 10 most common non-English languages in Washington based on this data. During this review, the commission will determine whether other resources or methodologies provide more accurate LEP estimate information to determine the list of languages included on the notification.

(5) Dispensing practitioners and dispensing facilities must still affix a label that meets the requirements of WAC 246-945-015 for dispensing practitioners or WAC 246-945-016 for dispensing facilities in English, except the complete directions for use can be affixed in its translated form only.