



# RULE-MAKING ORDER PERMANENT RULE ONLY

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

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STATE OF WASHINGTON  
FILED

DATE: January 22, 2025

TIME: 2:12 PM

WSR 25-04-003

**Agency:** Department of Health - Pharmacy Quality Assurance Commission

**Effective date of rule:**

**Permanent Rules**

- 31 days after filing.  
 Other (specify) 1/22/2027 (If less than 31 days after filing, a specific finding under RCW 34.05.380(3) is required and should be stated below)

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

- Yes  No If Yes, explain:

**Purpose:** Establishing prescription drug label accessibility standards. The adopted accessible labeling rules establish requirements for all dispensing facilities [i.e., pharmacies, nonresident pharmacies, healthcare entities (HCE), hospital pharmacy associated clinics (HPAC)] and dispensing practitioners (i.e., health professionals with prescriptive authority in the State of Washington). The adopted rule addresses the protection and promotion of the public health, safety, and welfare by ensuring that all practitioners and facilities in the state of Washington dispensing prescription medications provide information to the patient on the prescription container in a format that can be accurately comprehended by the patient. There are two methods to achieve this goal:

1. Provide the complete directions for use for the prescription medication on the container label in the language with which the patient is most comfortable.
2. Provide the complete directions for use, patient name, patient species (for veterinary prescriptions), drug name, and drug quantity for the prescription medication on the container label in at least one visually accessible format. These formats are large print, Braille, a QR code or equivalent tool, and a prescription reader that delivers the necessary information in an audible format.

Both accessibility methods must be used for the same prescription if doing so best accommodates the patient's needs to comprehend the prescription information. Dispensing practitioners and dispensing facilities must inform patients about the availability of accessibility services through the use of posted signage and direct communication with the patient or patient's representative. Accessibility services must also be provided to the patient at no additional cost.

The adopted rule creates four new sections—WACs 246-945-026, 246-945-027, 246-945-028, and 246-945-02 - describing what dispensing practitioners and dispensing facilities must do to provide accessible labeling services to patients. WAC 246-945-015 is also amended to inform dispensing practitioners that they must comply with the new sections of rule.

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

**Citation of rules affected by this order:**

New: WACs 246-945-026, 246-945-027, 246-945-028, and 246-945-029  
Repealed: None  
Amended: WAC 246-945-015  
Suspended: None

**Statutory authority for adoption:** RCW 18.64.005, 69.41.240, and 69.50.301

**Other authority:** None

**PERMANENT RULE (Including Expedited Rule Making)**

Adopted under notice filed as WSR 24-17-046 on 8/14/2024 (date).

Describe any changes other than editing from proposed to adopted version:

The commission approved three changes to the accessible labeling rule language. None of the requested changes were considered substantive.

- Changed instances of “LEP individuals” to “individuals with LEP” throughout the rule language to prioritize referencing the patient over their language-speaking status.
- Removed the word “obtain” from WAC 246-945-028(3)(d) and replaced it with “provide,” and further removed a phrase later in the same subsection starting with “and provide...” It was determined that “provide” encompassed the action of obtaining, rendering the use of the word “obtain” redundant.
- Amended WAC 246-945-029(5) to clarify that the complete directions for use need not be printed in English for translated labels, as long as the complete directions for use are printed in the language of the patient’s need.

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

Name: Joshua Munroe  
 Address: PO Box 47852, Olympia, WA 98504-7852  
 Phone: 360-502-5058  
 Fax: N/A  
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 Other:

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

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

**The number of sections adopted in order to comply with:**

Federal statute:	New	<u>4</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Federal rules or standards:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Recently enacted state statutes:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>

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

New	<u>4</u>	Amended	<u>1</u>	Repealed	<u>0</u>
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**The number of sections adopted on the agency’s own initiative:**

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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**The number of sections adopted in order to clarify, streamline, or reform agency procedures:**

New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
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**The number of sections adopted using:**

Negotiated rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Pilot rule making:	New	<u>0</u>	Amended	<u>0</u>	Repealed	<u>0</u>
Other alternative rule making:	New	<u>4</u>	Amended	<u>1</u>	Repealed	<u>0</u>

**Date Adopted:** January 22, 2025

**Name:** Hawkins DeFrance, PharmD

**Title:** Pharmacy Quality Assurance Commission Chair

**Signature:**

A handwritten signature in cursive script, appearing to read "Hawkins DeFrance". The signature is written in black ink on a white background.

**WAC 246-945-015 Minimum requirements for dispensing practitioners.** (1) A practitioner authorized to prescribe or administer a legend drug including a controlled substance, other than a pharmacy, ~~((ean))~~ 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 who dispense ~~((legend))~~ 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.

NEW SECTION

**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 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, healthcare 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, healthcare entity, and hospital pharmacy associated clinic that are administered by a licensed healthcare professional acting within their scope of practice.

(4) "Dispensing practitioner" or "dispensing practitioners" means a practitioner authorized to prescribe legend drugs 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) "Means of access" means provision of a mechanism to enable a visually impaired or print disabled individual to receive accurate prescription information.

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

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

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

#### NEW SECTION

**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 or device dispensed and partially administered to an individual by a healthcare 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.

(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).

#### NEW SECTION

**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 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 prescription information, as defined in WAC 246-945-026(9), in

one or more accessible means to visually impaired or print disabled individuals, the dispensing facility or dispensing practitioner must still 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.

NEW SECTION

**WAC 246-945-029 Translation and interpretation for prescription information for individuals with LEP.** (1) Every dispensing facility and dispensing practitioner shall 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.

(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 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 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 to evaluate whether there has been a change to the 10 most common 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 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. 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 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 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.