

Accessible Labeling Rule Language Draft

PLEASE NOTE: This is a preliminary rule language draft and is not finalized or concrete language. There will be further opportunities to provide comment once the draft rule language is complete.

WAC 246-945-(AAA) Accessible Labeling Definitions

- (1) For the purpose of sections WAC 246-945-(AAA) through WAC 246-945-(DDD):
 - (a) “Accessible labeling” means the act of labeling as defined by RCW 18.64.011(18) in a way that allows any patient to accurately comprehend prescription drug information regardless of visual impairment, print disability, or language barrier.
 - (b) “Visually impaired” means:
 - (i) Having a central visual acuity that does not exceed 20/200 in the better eye with corrective lenses, or the widest diameter of the visual field does not exceed twenty degrees; or
 - (ii) Having a severe loss of visual acuity ranging from 20/70 to 20/200 while retaining some visual function; or
 - (iii) Having inoperable visual impairments including, but are not limited to: Albinism, aniridia, aphakia, cataracts, glaucoma, macular degeneration, or other similar diagnosed disease or disorder.
 - (c) “Print disabled” means the inability to effectively read or access printed materials due to a visual, physical, perceptual, or cognitive disability, or other impairment.
 - (d) “Prescription reader” means a device or other technology that is designed to audibly convey the information contained on the label of a prescription drug.
 - (e) “QR” means a quick reference code.
 - (f) "Limited English proficient individual" or "LEP individual" 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.

- (g) "Translation" shall mean the conversion of a written text in another language by an individual competent to do so and utilizing all necessary pharmaceutical and health-related terminology.
- (h) "Interpretation" shall mean communication in which a person acting as an interpreter comprehends a message and re-expresses that message accurately in another language, utilizing all necessary pharmaceutical and health-related terminology, so as to enable a person to receive all necessary information in the person's preferred primary language. This includes, but is not limited to, interpretation from English to American Sign Language (ASL). message orally from one language into another.

WAC 246-945-(BBB) Accessible Labeling Applicability (placeholder title)

- (1) Nothing in WAC 246-945-(BBB) through WAC 246-945-(DDD) shall diminish or impair any requirement that any credential holder of the commission provide any accessibility service, language assistance, interpretation, or translation under any 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. Pt. 36).
- (2) Facilities must provide accessible labeling accommodations as described in WAC 246-945-(CCC) and WAC-246-945-(DDD) on request from a patient, prescriber, or the patient’s agent. If a patient, prescriber, or patient’s agent requests accessible labeling accommodations from both WAC 246-945-(CCC) and WAC-246-945-(DDD), the facility must provide both.
- (3) If an accessible labeling accommodation is provided on the label of a drug container, the label on the prescription drug container dispensed to a patient for patient administration under WAC 246-945-CCC or WAC 246-945-DDD must at least be in non-Braille English and contain all of the information required by WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.
 - (a) If a separate information sheet is used to provide prescription information, that sheet must contain all information required by WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.
- (4) The following are exempt from WAC 246-945-BBB and WAC 246-945-CCC:
 - (a) Pre-packaged emergency medications;
 - (b) Opioid reversal medications;
 - (c) Bubble packs; and,
 - (d) Medication packs dispensed in strip machines.
- (5) Compliance with WAC 246-945-AAA through WAC 246-945-DDD does not eliminate the need for

patient counseling or any other requirement in any applicable law or rule. Patient counseling must be provided in a visual or language accessible manner in accordance with patient circumstances.

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WAC 246-945-(CCC) Visual Accessibility Requirements for Prescription Information and

Prescription Labeling and Written Counseling

- (1) Each facility that dispenses and delivers to patients shall, upon the request of a prescriber, a patient, or the patient's agent, provide at least the following accessible labeling accommodations in a timely manner at no additional cost to the patient. Nothing in this section shall prevent a facility from providing additional options to promote visual accessibility.
 - (a) A minimum 12-point font size;
 - (b) Braille; or,
 - (c) A QR reference code, device, or other technology that can direct the patient to a separate print or digital resource that provides all required information for the dispensed prescription; or,
 - (d) A prescription reader provided as a device or other technology. The facility must provide a device that can be used as a prescription reader, but the patient may elect to use their own device or technology in place of that device.
 - (i) If a prescription reader is provided through a device supplied by the pharmacy, it must be provided for at least the duration of the drug therapy. The device or other technology used must be capable of conveying all required information in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050. The pharmacy must also provide directions for using the prescription reader appropriate to the patient's visual or print impairment.
 - (e) Additional information relevant to the patient's intended use of the prescription but not required in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050 must be provided in an accessible format on a separate print or digital resource accessible through a device or

other technology.

- (2) A pharmacy shall notify each patient to whom a drug is dispensed in a manner that fits the patient's needs and circumstances of the availability of accessibility accommodations as defined by subsection 1 of this section.
 - (a) Pharmacies shall make a good faith effort to communicate the availability of visually impaired and print disabled services to their community.
 - (b) Good faith communication efforts include but are not limited to signage, phone notification and messaging, inserts, advertisements, and websites.
- (3) Pharmacies must comply with the requirements of this section by [12 months after the rule goes into effect].

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WAC 246-945-(DDD) Translation and interpretation requirements for prescription drug

information and standardized medication labeling.

- (1) Each facility that dispenses to patients for patient administration shall, upon the request of an LEP individual, their agent or their prescriber, provide free translation services and interpretation of prescription information as described in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050 to each LEP individual.
- (2) Facilities that dispense and deliver to patients must provide translation services and interpretation services in a minimum of [XX] languages that address the needs of the community around the facility in addition to English.
 - (a) The facility shall choose languages to make available for translation by the identified needs of the community that facility serves.
- (3) Each facility that dispenses and delivers to patients shall provide conspicuously posted notices to inform LEP individuals of their rights to free, competent oral interpretation services and translation services of prescription information as described in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.
 - (a) The commission will make available a free downloadable notice for facilities to print and display.
 - (b) The printed notice shall include the following statement in English and in each language provided by the pharmacy: "Point to your language. Language assistance will be provided at no cost to you."
- (4) Pharmacies must comply with the requirements of this section by [12 months after the rule goes into effect].

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