

Pharmacy Quality Assurance Commission
Accessible Labeling Rule Language Draft – June 15, 2023
PharmacyRules@doh.wa.gov

WAC 246-945-AAA 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-AAA through WAC 246-945-DDD:

(1) “Accessible prescription information” means the provision of prescription information that enables a visually impaired, print disabled, or LEP individual to accurately comprehend prescription information regardless of the individual’s visual impairment, print disability, or language barrier.

(2) “Competent oral interpretation” means oral 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 an LEP individual to receive all necessary information in the LEP individual's preferred language.

(3) “Complete directions for use” means instructions intended for the individual patient to use in order to understand the intended administration of the dispensed prescription. Elements include the verb (such as, but not limited to take, place, instill), the dosage form (such as, but not limited to tablet, capsule, drops), quantity of the medication, strength of the medication, route of administration, frequency of administration, additional contextual information for administration (such as, but not limited to “as needed,” “when tired”), and the reason or indication of the prescription (such as, but not limited to for insomnia, for blood pressure, for anxiety).

(4) “Dispensing facility” or “dispensing facilities” means a pharmacy, nonresident pharmacy, health care entity, or hospital pharmacy associated clinic that dispenses and delivers medications to the ultimate user or the ultimate user’s authorized representative. It does not include medications dispensed by a pharmacy, nonresident pharmacy, health care entity, and hospital pharmacy associated clinic that are administered by a licensed health care professional.

(5) “Dispensing practitioner” or “dispensing practitioners” means a practitioner authorized to prescribe legend drugs and who dispenses and delivers medications directly to the ultimate user or the ultimate user’s authorized representative.

(6) "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.

(7) “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.

(8) “Means of access” means providing a mechanism to enable a visually impaired or print disabled individual to accurately comprehend prescription information.

(9) “Prescription information” means drug name, patient name/species, complete directions of use, and drug quantity.

(10) "Prescription drug reader" means a dedicated electronic device that is able to obtain information from a QR code, or equivalent, affixed to a prescription drug container and provide the 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 conversion of a written text from one language into an equivalent written text in another language by an individual competent to do so and utilizing all necessary pharmaceutical and health-related terminology. Such translation may occur, where appropriate, in a separate document provided to an LEP individual or authorized representative that accompanies the prescribed medication.

(14) “Visually impaired” means:

- (a) 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;
- (b) Having a severe loss of visual acuity ranging from 20/70 to 20/200 while retaining some visual function; or
- (c) Having inoperable visual impairments including, but not limited to: albinism, aniridia, aphakia, cataracts, glaucoma, macular degeneration, or other similar diagnosed disease or disorder.

WAC 246-945-BBB Accessible Prescription Information.

(1) Dispensing facilities and dispensing practitioners shall comply with the requirements in WAC 246-945-BBB through WAC 246-945-DDD to provide accessible prescription information unless the prescribed medication is:

- (a) A prepackaged medication delivered pursuant to WAC 246-945-435; or
- (b) An opioid overdose reversal medication as defined in RCW 69.41.095.

(2) Dispensing facilities and dispensing practitioners shall develop and implement policies and procedures to implement the requirements in WAC 246-945-BBB through WAC 246-945-DDD to provide accessible prescription information.

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

(4) The accessible labeling services required by WAC 246-945-BBB through WAC 246-945-DDD may be provided by an employee of the dispensing facility or dispensing practitioner, the dispensing practitioner, or an independent contractor of the dispensing facility or dispensing practitioner. The use of an independent contractor does not diminish the responsibility of the dispensing facility or dispensing practitioner to comply with this subsection.

(5) The provision of accessible labeling services required by WAC 246-945-BBB through WAC 246-945-DDD shall be provided immediately 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. Pt. 36).

WAC 246-945-CCC Accessibility of Prescription Information for Visually Impaired or Print Disabled Individuals.

(1) Every dispensing facility and dispensing practitioner shall provide means of access to prescription information 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 means of access to prescription information 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) If the dispensing facility or dispensing practitioner offers to provide a means of access to prescription information pursuant to subsection (2) of this section but the visually impaired or print disabled individual refuses that service, then the dispensing facility or dispensing practitioner shall document this refusal in the individual's health record.

(4) 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 in a minimum of 12-point font size, including the ability to affix the printed prescription information to the prescription drug container in a minimum of 12-point font size;
- (b) Prescription information in Braille;
- (c) A QR code, or equivalent, affixed to the prescription drug container that transmits prescription information to an individual's external accessible device; or
- (d) A prescription drug reader that is able to obtain prescription information from the label affixed to the prescription drug container and provide the prescription information in an audio format accessible to the individual.

(5) When dispensing facilities or dispensing practitioners provide prescription information 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.

WAC 246-945-DDD Translation and Interpretation for Prescription Information for LEP individuals.

(1) Every dispensing facility and dispensing practitioner shall provide competent oral interpretation and translation services of the complete directions of use to LEP individuals upon the request of the LEP individual, their prescriber, or their authorized representative.

(2) Every dispensing facility and dispensing practitioner shall offer to provide competent oral interpretation and translation services of the complete directions of use to LEP individuals when it is self-evident the person to whom the prescription is being prescribed or delivered is an LEP individual.

(3) If the dispensing facility or dispensing practitioner offers to provide competent oral interpretation and translation services of the complete directions of use pursuant to subsection (2) of this section but the LEP individual refuses those services, then the dispensing facility or dispensing practitioner shall document this refusal in the individual's health record.

(4) Dispensing facilities and dispensing practitioners who dispense and deliver medications at a fixed physical location shall conspicuously post at, or adjacent to each counter over which prescription drugs are sold, a notification of an individual's right to competent oral interpretation and translation services of the complete directions of use . The notification shall:

- (a) Identify that competent oral interpretation and translation services of the complete directions of use will be provided at no additional cost upon request;
- (b) Be in at least 20-point bold face font;
- (c) Be in a color that sharply contrasts with the background color of the sign;
and
- (d) Be in each language spoken by at least one percent of the population in Washington as determined by the most recent decennial census

conducted by the Bureau of the Census of the United States Department of Commerce.

(5) Dispensing facilities and dispensing practitioners who dispense and deliver medications through the mail shall notify individuals of the individual's right to competent oral interpretation and translation services of the complete directions of use when delivering the individual's medication. The notification shall:

- (a) Identify that competent oral interpretation and translation services of the complete directions of use will be provided at no additional cost upon request;
- (b) Be in at least 20-point bold face font;
- (c) Be in a color that sharply contrasts with the background color of the notification; and
- (d) Be in each language spoken by at least one percent of the population in Washington as determined by the most recent decennial census conducted by the Bureau of the Census of the United States Department of Commerce.

(6) 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 when providing translation services of the complete directions of use to LEP individuals.