

Pharmacy Quality Assurance Commission
Accessible Labeling Rule Language Draft – July 25, 2023
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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 accurate prescription information to a visually impaired or print disabled individual, and means the provision of accurate complete directions for use to an LEP individual.
- (2) "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 LEP individual's preferred language.
- (3) "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 but are not limited to:
 - (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."
- (4) "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.

(5) "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.

(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 receive accurate prescription information.

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

(10) "Prescription drug reader" means a dedicated electronic device that provides 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 as self-identified by a patient.

(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 by an individual or technology.

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

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 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 drug or device administered within a health care facility and subsequently re-labeled for short-term continuation of therapy upon discharge from the health care facility; 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.

(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 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 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-BBB through WAC 246-945-DDD.

(5) The provision of accessible prescription information, as required by WAC 246-945-BBB through WAC 246-945-DDD, shall be provided 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. 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 a means of access to prescription information, as defined in WAC 246-945-AAA(X), 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-AAA(X), 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-AAA(X), in a minimum of 12-point font size, which is affixed to the prescription container;
- (b) Prescription information, as defined in WAC 246-945-AAA(X), 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-AAA(X), to an individual's external accessible device; or
- (d) A prescription drug reader that is able to obtain prescription information, as defined in WAC 246-945-AAA(X), from the label affixed to the prescription container and provide the prescription information, as defined in WAC 246-945-AAA(X), in an audio format accessible to the individual.

(4) When dispensing facilities or dispensing practitioners provide prescription information, as defined in WAC 246-945-AAA(X), 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 oral interpretation and written translation services of the complete directions for use to LEP individuals upon the request of the LEP individual, 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 LEP individuals when it is self-evident the person to whom the prescription is being prescribed or delivered is an LEP individual. 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 top ten 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 determine whether other resources or methodologies provide more accurate LEP estimate information to determine the list of languages included on the notification sign.

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(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 sign dispensing facilities and dispensing practitioners will use to provide this notification.

- (a) When creating the sign, the commission will include the top ten 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 determine whether other resources or methodologies provide

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more accurate LEP estimate information to determine the list of languages included on the notification sign.

(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 when providing written translation services of the complete directions for use to LEP individuals.

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, can 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 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-AAA through WAC 246-945-DDD.