

## **Accessible Labeling Rule Concepts Draft**

**PLEASE NOTE:** This is a preliminary outline intended to guide a draft for the rule language. This is not draft rule language. There will be further opportunities to provide comment once the draft rule language is complete.

Compliance with the proposed sections does not eliminate the need for patient counseling or any other requirement in any applicable law or rule.

### **WAC 246-945-(AAA) Visual Accessibility Requirements for Prescription Information and Prescription Labeling.**

#### **Subsection 1: Definitions**

(1) Proposed terms for definition in this section:

- (a) “Visually impaired”
- (b) “Print impaired”
- (c) “Prescription reader”
- (d) *Other definitions deemed relevant to visually accessible labeling and information*

*standards...*

#### **Subsection 2: Accessible Info Requirements**

(2) Prescription drug containers dispensed to outpatients under this section shall contain all of the required information in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050. The following options must be provided in a timely manner upon request by a prescribing practitioner, a patient, or an authorized representative of a patient.

(a) *Accessible print/audio methods on patient request provided in a timely manner to be printed on the prescription container label:*

- (i) Larger type font (can specify size requirement); and,

(ii) *Braille; or,*

(iii) *Prescription reader provided through a technological device.*

(a) If a prescription reader is provided, it must be provided for at least the duration of the drug therapy. The device must be capable of conveying all required information listed in WAC 246-945-016;

(b) The pharmacy must also provide directions or advice to the person on obtaining a prescription reader appropriate to his or her visual or print impairment.

(b) *An element to consider:* Should it not be reasonably possible to put the required information on the container label, can it be printed on a separate information sheet?

**Subsection 3: Patient notification requirements**

(3) A pharmacy shall notify each person to whom a drug is dispensed that prescription readers, larger print labels, and braille labels are available.

**Subsection 4: Implementation Timeframe**

(4) Implementation timeframe

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## **WAC 246-945-(BBB) Translation and interpretation requirements for prescription drug**

### **information and standardized medication labeling.**

#### **Subsection 1: Definitions**

(1) For the purposes of this section:

(a) "Limited English proficient individual" or "LEP individual"

(b) "Translation"

(c) "Interpretation"

(d) *Other definitions may be considered specific to this section...*

#### **Subsection 2: Translation Service Directive**

(2) Each pharmacy that dispenses to outpatients shall, upon the request of a prescribing practitioner, a patient, or an authorized representative of a patient, provide free, competent translations services and interpretation services to each LEP individual of the information required by WAC 246-945-016 in English and any language in which the information is required to be provided pursuant to subsection 4. If a label on a prescription container is provided in a language other than English, the same information must also be included on the prescription container in English.

(a) *Other elements to consider here:* Can these services be provided by a staff member of the pharmacy or a third-party contractor. If provided by a staff member, is it written, verbal, or both?

#### **Subsection 3: Translated Info Requirements**

(3) Labels on prescription drug containers dispensed to patients and separate sheets packaged with prescription drug containers dispensed under this section shall include all required elements in WAC 246-945-016, RCW 18.64.246, and RCW 69.41.050.

(a) Information described in subsection 3(a) and printed on a prescription container label or separate sheet packaged with the prescription container must comply with the visual accessibility requirements described in WAC 246-945-(AAA).

#### **Subsection 4: Language Selection**

(4) Pharmacies must make available a minimum of [placeholder number] languages other than English in the provision of translation services and interpretation services.

(a) The number of languages made available for translation services and interpretation services are based on:

(i) *Factors needed to determine a list of languages...*

#### **Subsection 5: Notification Requirement**

(5) Each pharmacy shall provide conspicuously posted notices and oral notifications to inform LEP individuals of their rights to free, competent oral interpretation services and translation services.

(a) The printed notice shall:

(i) Be posted in a conspicuous location to which both pharmacy staff and patients may reference; and

(ii) 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."

(b) Pharmacy staff must also provide an oral notification to LEP individuals either by reference to the posted notice or a direct explanation of the translation services and interpretation services offered for prescription information.

#### **Subsection 6: Third-party Vendor Usage**

(6) If a pharmacy enters into a contract with a third party for the translation of the information that the pharmacy is required to provide pursuant to this section, the pharmacy and any employee of

the pharmacy are not liable in any civil action for any injury resulting from the translation by the third party which is not the result of negligence, recklessness or deliberate misconduct of the pharmacy or employee.

**Subsection 7: Implementation Timeframe**

(7) Implementation Timeframe

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