WSR 24-17-046
PROPOSED RULES
DEPARTMENT OF HEALTH
(Pharmacy Quality Assurance Commission)
[Filed August 14, 2024, 7:44 a.m.]

Original Notice.

Preproposal statement of inquiry was filed as WSR 23-13-035.

Title of Rule and Other Identifying Information: Prescription drug label accessibility standards. The pharmacy quality assurance commission (commission) is proposing amendments to WAC 246-945-015 and adding four new sections to chapter 246-945 WAC establishing prescription label accessibility standards. The proposed accessibility program focuses on ensuring meaningful access to prescription information for patients with visual impairments or print disabilities, and for limited English proficient (LEP) patients. This rule making is in response to two separate rule-making petitions approved by the commission.

Hearing Location(s): On October 4, 2024, at 9:00 a.m., at the Department of Labor and Industries, 7273 Linderson Way S.W., Tumwater, WA 98501; or virtual. To access the meeting on October 4, 2024, at 9:00 a.m., go to https://us02web.zoom.us/j/87143495001 or https://zoom.us/join and use the Webinar ID 871 4349 5001. The access options include One-tap mobile +12532158782,,87143495001# US (Tacoma), +12532050468,,87143495001# US; or telephone: Dial (for higher quality, dial a number based on your current location) +1 253-215-8782 US (Tacoma), +1 253 205 0468 US.

Date of Intended Adoption: October 4, 2024.

Submit Written Comments to: Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, email https://fortress.wa.gov/doh/policyreview/, fax 360-236-2901, beginning the date and time of filing, by October 3, 2024, by 11:59 p.m.

Assistance for Persons with Disabilities: Contact Joshua Munroe, phone 360-503-5058, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov, by September 27, 2024.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The proposed rule addresses the "protection and promotion of the public health, safety, and welfare" per RCW 18.64.005(7) 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, 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 proposed rule creates four new sections, WAC 246-945-026, 246-945-027, 246-945-028, and 246-945-029, 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 regulated entities with prescriptive authority 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 disability or language barriers.

Reasons Supporting Proposal: Existing minimum labeling requirements described in chapter 246-945 WAC lack the detail needed to accommodate patients who require alternative prescription drug labels. Rule making is necessary to establish drug label accessibility standards in chapter 246-945 WAC, and to provide clear guidance for both patients requesting alternative prescription drug labels and the dispensing facilities and dispensing practitioners fulfilling those requests.

The main alternative to rule making is to defer regulation to various federal laws addressing the provision of accessibility services. Those federal laws focus on private enterprises providing accessibility services in public spaces to individuals who are print disabled, visually impaired, or do not speak or understand English. However, they do not set specific prescription labeling standards for those same patient populations.

If the commission does not adopt the proposed rule then the commission and department of health (department) anticipates visually impaired, print disabled, and LEP individuals will be harmed from not being able to accurately comprehend information for prescribed medications. Patients face consequences such as emergency room visits, injury, or death resulting from not being able to accurately comprehend information for prescribed medications. Adopting the proposed rule would help reduce these consequences.

Statutory Authority for Adoption: RCW 18.64.005, 69.41.240, and 69.50.301.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: Pharmacy quality assurance commission, governmental.

Name of Agency Personnel Responsible for Drafting and Implementation: Joshua Munroe, 111 Israel Road S.E., Tumwater, WA 98501, 360-502-5058; Enforcement: Marlee O'Neil, 111 Israel Road S.E., Tumwater, WA 98501, 360-480-9108.

A school district fiscal impact statement is not required under RCW 28A.305.135.

A cost-benefit analysis is required under RCW 34.05.328. A preliminary cost-benefit analysis may be obtained by contacting Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-503-5058, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov.

This rule proposal, or portions of the proposal, is exempt from requirements of the Regulatory Fairness Act because the proposal:

Is exempt under RCW 19.85.025(3) as the rules only correct typographical errors, make address or name changes, or clarify language of a rule without changing its effect.

Explanation of exemptions: Proposed WAC 246-945-015 is exempt from analysis under RCW 34.05.310 (4)(d) because the proposed amend-

ments in this section clarify the rule by pointing to another section of the rule. WAC 246-945-026 is exempt from analysis under RCW 34.05.310 (4)(d) because the defined terms in this section clarify the meaning of the terms and are not intended to set standards.

Scope of exemption for rule proposal:

Is partially exempt.

The proposed rule does impose more-than-minor costs on businesses.

Small Business Economic Impact Statement (SBEIS)

SBEIS – Section 1: A brief description of the proposed rule, including the current situation/rule, followed by the history of the issue and why the proposed rule is needed. A description of the probable compliance requirements and the kinds of professional services that a small business is likely to need in order to comply with the proposed rule.

The proposed accessible labeling rules would require all dispensing facilities (i.e., pharmacies) and dispensing practitioners, health professionals with prescriptive authority in the state of Washington, to be able to provide meaningful access to prescription information for medications dispensed to patients. Accessible labeling services would be provided at the patient's request, and patients must be made aware of such services by the entity that would dispense their prescribed medications.

The commission initiated rule making in response to two petitions submitted by interested parties on the topic of prescription information accessibility. On October 22, 2021, the commission approved a rule petition requesting pharmacies provide accessible medication label options for patients with visual impairments or print disabilities. Minimum requirements for outpatient prescription labeling are described in WAC 246-945-015 and 246-945-016, but do not reference accommodations for patients who are visually impaired, blind, or have other disabilities requiring additional prescription label options.

The commission also received and approved a rule petition in January 2022 requesting that translations of prescription information on prescription labels be made available in multiple languages for ambulatory (community based) patients. The petition included an additional request to amend WAC 246-945-417 in order to establish a deadline by which pharmacy outpatient dispensing systems must comply with a requirement to translate prescription medication directions. Between the two petitions, the commission decided only to amend WAC 246-945-015 and instead address the petitions' requests by proposing four new sections in chapter 246-945 WAC.

Clear comprehension of prescription drug label information is a matter of public health and safety for all persons, regardless of ability or language, and the commission determined that opening chapter 246-945 WAC would help align state regulatory standards with patient needs.

The compliance requirements for small businesses to provide accessibility services to patients are described in WAC 246-945-027, 246-945-028, and 246-945-029.

- WAC 246-945-027 Accessible prescription information.
  - Each office of a dispensing practitioner and dispensing facility must develop policies and procedures (P&P) for the accessibility program as it applies to their respective offices or businesses.

- All staff designated for providing accessible labeling services must receive regular training in order to understand how to provide those services to patients.

- WAC 246-945-028 Accessible prescription information for visually impaired or print disabled individuals.
  - The entity must acquire hardware (e.g. large-print printers, Braille printers, and/or prescription readers) necessary to comply with accessible labeling standards if it does not already have such hardware.
  - There is also present a per-label cost for most accessible labels.
- WAC 246-945-029 Translation and interpretation of accessible prescription information for LEP individuals.
  - Offices of dispensing practitioners and dispensing facilities must be able to translate printed prescription information for LEP patients. This would likely be addressed through the use of a third-party vendor providing translation services.
  - Oral interpretation services must also be provided on LEP patient request. This would likely be addressed through the use of a third-party vendor providing oral interpretation services.

SBEIS – Section 2: Identification and summary of which businesses are required to comply with the proposed rule using the North American Industry Classification System (NAICS).

SBEIS Table 1. Summary of Businesses Required to Comply to the Proposed Rule

NAICS Code (4, 5 or 6 Digit)	NAICS Business Description	Number of Businesses in Washington State	Minor Cost Threshold
621111	Offices of Physicians (except Mental Health Specialists)	2,779	$11,301.68
621210	Offices of Dentists	3,111	$3,721.99
621391	Offices of Podiatrists	94	$1,820.71
541940	Veterinary Services	942	$5,412.78
621399	Offices of All Other Miscellaneous Health Practitioners*	5,023	$927.25
621320	Offices of Optometrists	454	$2,447.87
456110	Pharmacies and Drug Stores	267**	$19,161.74

* The offices of all other miscellaneous health practitioners category includes the remaining professions capable of having prescriptive authority in the State of Washington: Nurse practitioners, physician assistants, and naturopaths.

** The employment security department (ESD) reported 267 businesses categorized as pharmacies and drug stores, but department of health staff reported the number of pharmacies as of April 2024, with 1,283 facilities being standalone pharmacies and 110 facilities being hospital pharmacies.

SBEIS – Section 3: Analysis of probable costs of businesses in the industry to comply to the proposed rule and includes the cost of equipment, supplies, labor, professional services, and administrative costs. The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue.

General note: The proposed rules apply to both dispensing practitioners and dispensing facilities and therefore the range of implementation costs will be presented separately for each group. Per RCW 69.41.010(17), the definition for "practitioner" encompasses occupations with prescriptive authority in the state of Washington including but not limited to physicians, veterinarians, and dentists. Average wage information for each practitioner is provided below in SBEIS Ta-

ble 2. Dispensing facilities are defined as pharmacies, nonresident pharmacies, health care entities, or hospital pharmacy associated clinics that dispense and deliver prescriptions to the ultimate user or the ultimate user's authorized representative. Costs pertaining to facilities are estimated by the commission and department using average wage information from traditional pharmacy staff including, but not limited to, pharmacists, pharmacy technicians, and pharmacy assistants that is pulled from the United States Bureau of Labor Statistics as a primary source and other secondary sources, if needed.

***NEW SECTION* WAC 246-945-027 Accessible prescription information.**

Description: WAC 246-945-027 establishes the general provisions that dispensing facilities and offices of dispensing practitioners must comply with in order to provide accessible prescription information services to patients and individuals.

Subsection (1) outlines the types of medications and packaging types (e.g., prepackaged medications in an emergency department or drug samples as defined in RCW 69.45.010) that are exempt from accessibility requirements. Subsection (2) requires regulated entities to develop and implement P&P for compliance purposes and must provide accessibility services at no additional cost to the patient per subsection (3). Subsection (4) allows for a dispensing practitioner, an employee working in the office of a dispensing practitioner or dispensing facility, or a third party to provide accessibility services to the patient, provided that the provision of accessible prescription information occur "at the time of delivery of the filled prescription," in accordance with requirements in subsection (5). The last subsection of WAC 246-945-027 states that nothing in the 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 and state law."

It is possible that some offices of dispensing practitioners or dispensing facilities may already be in partial or full compliance with the accessibility program requirements described in this section, such as providing prescription readers or printing prescription labels in Spanish. This may mitigate implementation costs incurred by these entities, but the commission is unable to say which practitioners and facilities already comply to some degree with the proposed sections on accessible labeling services.

Cost(s): The department estimated the time it takes to train practitioners and dispensing facility staff and the time taken to develop P&P in SA Table 2. Total costs will depend on how required actions are divided up among facility staff with different reported average wages.

One-time costs: The one-time cost incurred for the purpose of complying with WAC 246-945-027 is developing P&P. Commission staff estimate, based on consultation with pharmacists and comparison to similar processes, that developing the P&P will take between 10 and 30 hours of staff time depending on how the practitioner or facility intends to provide accessibility services to their patients.

Per WAC 246-945-027(2), offices of dispensing practitioners and dispensing facilities must develop P&P to implement the requirements of WAC 246-945-027 through 246-945-029. The commission and department assume that the responsibility to develop the P&P will be given to assistants, technicians, or equivalent staff (hereafter named assistant professions), with final approval of the P&P given either by the relevant practitioner or by a pharmacist for facilities. It is expected

that the practitioner or pharmacist would take an additional one to two hours to review and approve the drafted P&P.

Using the above time estimates, the lower-cost scenario would include 10 hours of development time by assistant professions and one hour of review time by the appropriate practitioner or pharmacist. The higher-cost scenario is based off 30 hours of development time by assistant professions and two hours of review time by the appropriate practitioner or pharmacist. While it is possible that costs could be higher should the practitioner or pharmacist choose to develop the P&P by themselves, this circumstance was deemed unlikely. The following formula is used to calculate the cost range for developing P&P:

- P&P development cost = (# hours to write P&P * average assistant profession hourly wage) + (# hours to review P&P * average practitioner or pharmacist hourly wage)

For the purpose of this formula, an average assistant profession wage[1] of **$23/hour** is used for both offices of dispensing practitioners and dispensing facilities to assess development costs based on the profession. The cost associated with review time is based on average wage figures for practitioners reported in SA Table 2 and the average wage figure for pharmacists is reported in SA Table 3. For example, a physician (with an average **$122/hour** wage) would have a one-time cost for developing P&P for an accessible labeling program fall within the following range:

- Low (10 hours development + 1 hour review): **$352**
- Median (20 hours development + 1.5 hours review): **$643**
- High (30 hours development + 2 hours review): **$934**

Recurrent/Ongoing costs: Ongoing costs associated with this section are encompassed by staff time associated with annual training in providing and supporting accessibility services proposed in rule. The purpose of the training includes developing and maintaining patient interaction skills, and how to utilize hardware, software, and third-party services associated with accessible labeling. The commission and department estimate that two hours of such training are needed each year to maintain and refresh the skills needed to support the proposed accessible prescription labeling program. This requirement applies to each office of a dispensing practitioner and each dispensing facility tasked with providing accessibility services to patients.

The commission and department estimate that training costs for offices of dispensing practitioners includes both the dispensing practitioners working in that office as well as any assistant professions tasked with aiding in the provision of accessible label services. The average profession assistant hourly wage is used for nonpractitioner roles when calculating training costs. Therefore, the training cost per year for each office of a dispensing practitioner was estimated by multiplying the time estimated to receive necessary training, two hours annually, by the wage of any practitioners and nonpractitioner employees in patient-facing professions, as expressed by the following formula:

- Training cost per office of a dispensing practitioner per year = (# hours of training per year * practitioner hourly wage) + (# hours of training per year * average assistant profession hourly wage)

Training costs for a dispensing facility also include accessibility program training for all patient-facing professions that work in that facility. This includes pharmacists, pharmacy technicians, and pharmacy assistants, and the annual cost is estimated by the following formula:

- Training cost per dispensing facility per year = # hours of training per year * [(average pharmacist wage * # of pharmacists) + (average pharmacy technician wage * # of pharmacy technicians) + (average pharmacy assistant wage + # of pharmacy assistants)]

The per person training costs for offices of dispensing practitioners is reported in SBEIS Table 2 and the per person training costs for dispensing facilities is reported in SBEIS Table 3. For example, a larger dispensing facility (i.e., pharmacy) with seven pharmacists, 16 pharmacy technicians, and two pharmacy assistants on staff would have approximately **$1,778** in training costs each year, assuming staffing levels remain the same. This figure could act as a high-end cost estimation, but training costs incurred by dispensing facilities are dependent on the number of staff and distribution of profession types unique to each facility.

SBEIS Table 2. Average Wage Data and Training Costs, Offices of Dispensing Practitioners

Occupation	Average Hourly Wage*	Annual Training (2 Hours)
Physician	$122	$244
Dentist**	$88	$176
Podiatric Physician	$94	$186
Veterinarian	$60	$120
Nurse Practitioner	$65	$130
Optometrist	$60	$120
Physician assistant	$70	$140
Naturopath	$46	$92
Profession Assistant***	$23	$46

* The average hourly wage for practitioners—excluding dentists—is derived from the 2022 wage statistics reported by the U.S. Bureau of Labor and Statistics. Average hourly wages rounded up to the next whole number.[2]

** The average hourly wage for dentists is derived from the 2021 wage statistics reported by the U.S. Bureau of Labor and Statistics. Average hourly wage rounded up to the next whole number.[3]

*** The profession assistant category represents all non-practitioner employees in an office of a dispensing practitioner tasked with aiding in the provision of accessible labeling services.

SBEIS Table 3. Average Wage Data and Training Costs, Dispensing Facilities

Occupation	Average Hourly Wage*	Training Costs (2 Hours Annually)
Pharmacist	$67	$134
Pharmacy Technician	$24	$48
Pharmacy Assistant/ Pharmacy Aide	$18	$36

* Average hourly wage rounded up to the next whole number.

***NEW SECTION* WAC 246-945-028 Accessibility of prescription information for visually impaired or print disabled individuals.**

Description: WAC 246-945-028 focuses on providing means of access for patients who are visually impaired or print disabled. The prescription information that must be made accessible for such patients

is defined in WAC 246-945-026(9), containing information elements such as the name of the drug, name of the patient, drug quantity, and the complete directions for use.

Subsection (3) lists the means of access that may be provided for patients upon request. At least one, or a combination of one or more, of the following means of access are required and must be affixed to the prescription container in order to comply with the proposed rule:

- Printed text of a minimum 12-point font size;
- Printed text in Braille;
- A QR code or equivalent that can transmit prescription information to an external accessible device; and
- A prescription drug reader or equivalent device able to deliver the required information in an audio format for the patient.

Cost(s): *One-time costs:* Accessible labeling options for visually impaired or print disabled patients can be made available through one or more methods listed in subsection (3): Large print, Braille, a QR code or equivalent, and a prescription drug reader or equivalent device.

Printed text of a minimum 12-point font size or a QR code or equivalent that can transmit prescription information to an external accessible device: If providing large print or QR code options best fits a patient's needs, there are no expected one-time costs as those options could be provided through existing printing hardware. The department and commission reasonably believe that all entities have a printer already that can provide this functionality. Should a practitioner or facility choose to acquire a new printer capable of printing large print labels, the cost is estimated at **$240** (minimum) or more[4] but is excluded from this analysis.

Printed text in Braille: Providing Braille labels would likely require the acquisition of a printer capable of printing labels in Braille. Braille printers are classified as either "small-volume" or "high-volume" based on the number of labels that can be printed over a period of time. Small-volume printers are priced between **$1,800** and **$5,000** while high-volume printers range from **$10,000** to **$80,000.**[5] For typical patient service, the commission and department do not expect that offices of dispensing practitioners or dispensing facilities would have a large enough patient population requiring Braille printing to justify the use of a high-volume printer. Therefore, the commission and department reasonably estimate a one-time cost for those that choose to provide Braille as an accessible labeling option would be between **$1,800** and **$5,000.**

Audio Labeling: The commission and department estimate one-time costs for providing audio labeling options such as a prescription reader or equivalent range between **$700** and **$4,000** based on estimates received directly from third party vendors Envision America, AccessaMed, and Spoken Rx.[6] The costs are largely attributed to the acquisition of individual prescription readers by the practitioner or facility, which are then loaned to the patient at no additional charge.

It is possible that an office of a dispensing practitioner or dispensing facility could comply with the requirements established in WAC 246-945-028 at **no additional cost** provided they already have a printing system that can accommodate one or more methods listed in subsection (3). Pharmacy representatives relayed to commission staff that some pharmacies more commonly provide large-print, QR code, audio labeling services, or a combination of these services. Braille is the

least likely of the four, but it is possible to procure hardware to provide this option should the pharmacy choose to do so.

Recurrent/Ongoing costs: Any ongoing costs associated with WAC 246-945-028 come from the number of labels printed in the preferred accessibility method. The following costs would arise in addition to existing label printing costs, since the entity will also provide a prescription container label with standard formatting.

Service provider representatives provided an estimate of between **$0.30** and **$0.50** for each label requiring either large-print information as described in WAC 246-945-026(9) or a QR code. For Braille labels, printing each label would cost around **$0.30** per label, with the price fluctuating depending on the volume printed per day. Lastly, prescription label information presented in an audio format would cost between **$2.28** and **$4.00** per label.[7] The commission and department are **unable to estimate the total cost of accessible labeling to comply with the rule per entity** because the total is dependent on the volume of requests.

***NEW SECTION* WAC 246-945-029 Translation and interpretation for accessible prescription information for LEP individuals.**

Description: This section of rule establishes requirements for providing means of access for LEP patients when fulfilling prescriptions. Any language requested by the patient must be provided by the dispensing facility or office of the dispensing practitioner. The only element required for written translation is the complete directions for use, and the translated portion must be affixed to the prescription container per subsection (2).

Offices of dispensing practitioners and dispensing facilities must post signage developed and made available by the commission to notify individuals of the right to oral interpretation and written translation services. The signs will be translated in the ten most common written languages in Washington state and the commission will review the list of languages on the signs every five years. Signage developed and reviewed by the commission is exempt from analysis under RCW 34.06.328 (5)(b)(ii), as that rule relates only to internal government operations. Dispensing facilities and offices of dispensing practitioners that dispense and deliver prescriptions through the mail are required to provide notification to patients about the availability of accessibility services since the patient would not see a sign when interacting with that practitioner or facility.

Cost(s): Subsections (1) and (2) outline the necessity to provide the complete directions for use for a prescribed medication to an LEP patient upon request or if it is self-evident that the patient would require such accommodations. The signage requirement described in subsection (3) also represents a cost to the regulated entity, even though it is the commission's responsibility to create and update the sign template and to make it available to those entities (which is exempted from the analysis).

Offices of dispensing practitioners and dispensing facilities may utilize staff to provide interpretation services for patients, but those costs are included in the estimate for staff job functions described in the ongoing costs section for WAC 246-945-027. Translation and interpretation service costs mentioned below result from using third-party vendor services.

Recurrent/Ongoing costs: The commission takes responsibility for designing and updating the signage; the office of the dispensing practitioner or dispensing facility must print and conspicuously post the

sign at the location where patient interaction occurs. This cost could be as low as **$0 or negligible** if the regulated entity already has printing capabilities for such signage and can absorb the single printing action as part of routine procedure. If the practitioner or facility chooses to use a professional printing service, the commission and department estimate costs ranging between **$0.20**[8] and **$48.96.**[9] The commission plans to review the list of languages every five years but could be more frequently if issues are brought to the commission's attention; therefore, this printing cost interval is unknown. Lastly, regulated entities might incur an ongoing cost for the signage requirement in WAC 246-945-029(3) should the commission need to update the accessibility sign template. Such costs would occur about once every five years, with the same expecting low-end printing cost of **$0 or negligible** for offices and facilities capable of printing the sign in-house, with **$48.96** as the high-end estimate for using an external printing service.

Translation services from third-party vendors are estimated using service price quotes from vendors for print translation ranging from **$5/month** to **$100/month**, depending on the volume of translations needed and the types of languages requested for translation.

For oral interpretation services, a third-party vendor representative provided an estimate for oral interpretation services provided via phone or video range from **$89/month** ($0.89 per minute for 100 minutes per month) to **$6,250/month** ($1.25 per minute for 5,000 minutes per month). Another third-party vendor quoted a rate of $2.00 per minute for interpretation services but estimated only 2,000 minutes per month in the provision of those services which is why high-end estimate is based off a lower per minute rate. Overall, the price point depends on the number of patients requiring/requesting interpretation services but based on those conversations with third-party vendor representatives, it is expected that the ongoing cost for offices of dispensing practitioners and dispensing facilities will be closer to the low-end estimate.

Compliance Cost Determination: The analysis considers if compliance with the proposed rule will cause businesses in the industry to lose sales or revenue. The compliance costs presented in this section are necessary for the implementation and maintenance of an accessible prescription labeling program. The probable one-time costs of the rule are developing P&P and purchasing accessible labeling hardware such as printers and audio prescription reader devices, and the probable ongoing costs are staff training, monthly third-party vendor fees, and per-label printing fees.

Because a major goal of the accessible labeling rules is to make accurate prescription information available to all patients, the commission and department determined that compliance costs associated with the program will not result in the loss of sales or revenue for businesses in the industry.

SBEIS – Section 4: Analysis on if the proposed rule may impose more-than-minor costs for businesses in the industry. Includes a summary of how the costs were calculated.

The proposed rule for accessible prescription labeling standards may impose costs **greater than** the minor cost thresholds. This determination was made based on total costs produced under different service volume scenarios (SBEIS Table 4) for the following entities:

Business Description/Minor Cost Threshold:

- Offices of physicians (except mental health specialists): $11,302

- Dentist's office: $4,060
- Podiatric physician's office: $1,821
- Veterinarian's office: $7,930
- Nurse practitioner's office: $1,355
- Optometrist's office: $3,004
- Physician assistant's office: $1,355
- Naturopath's office: $1,355
- Pharmacy: $63,205

SBEIS Table 4. Total Estimated Cost of Compliance for Regulated Entities Using Service Volume Scenarios

Cost Categories	Regulated Entity	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule after the First Year
Developing Policies and Procedures and Training	Office of Dispensing Practitioner	$ 352 to $934 (+ indeterminate training)	$0 (+ indeterminate training)
Developing Policies and Procedures and Training	Dispensing Facility	$381 to $2,452	$134 to $1,778
Equipment Acquisition	Both	$342 to $10,174	$0
Provision of Accessible Labels and Services (Scenario A)	Office of Dispensing Practitioner	$0 - $2,868	$0 - $2,868
Provision of Accessible Labels and Services (Scenario B)	Dispensing Facility	$0 - $172,650*	$0 - $172,650*
Total for an Office of a Dispensing Practitioner based on assumed scenario		**$694 to $13,573 (+ indeterminate training)**	**$134 to $2,468 (+ indeterminate training)**
Total for a Dispensing Facility based on assumed scenario		**$723 to $183,758**	**$0 to $174,428**

Summary of how costs were calculated: The department and commission separated the cost estimates into categories (equipment costs, costs for developing P&P and training, and costs based on volume of service) and are reflected below.

Costs for Developing PP and Training: SBEIS Table 5 reflects costs that the department and commission were able to estimate to comply with the rule for both the first year and subsequent years.

SBEIS Table 5. Elements, Assumptions, and Indeterminate Costs

Cost Elements/ Regulated Entity	Assumptions	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule (after the First Year)
Developing policies and procedures/ office of a dispensing practitioner	*Low-end scenario*: Ten hours of assistant staff time and one hour of practitioner review time *High-end scenario*: Thirty hours of assistant staff time and two hours of practitioner review time	$352 to $934	$0
Developing policies and procedures/ dispensing facility	*Low-end scenario*: Ten hours of assistant staff time and one hour of practitioner review time *High-end scenario*: Thirty hours of assistant staff time and two hours of practitioner review time	$247 to $674	$0
Training/office of a dispensing practitioner	Unable to estimate training costs for offices because of the unknown variance in staff size and types of practitioner and non-practitioner professions working in the same office	Indeterminate	Indeterminate

Cost Elements/ Regulated Entity	Assumptions	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule (after the First Year)
Training/dispensing facility	*Low-end scenario*: Annual staff training for one pharmacist *High-end scenario*: Annual staff training time per year for staff size of seven pharmacists, sixteen pharmacy technicians, and two pharmacy assistants	$134 to $1,778	$134 to $1,778
Total for an office of a dispensing practitioner		**$ 352 to $934 (+ indeterminate)**	**$0 (+ indeterminate)**
Total for a dispensing facility		**$381 to $2,452**	**$134 to $1,778**

Limitations: For an office of a dispensing practitioner the commission and department were unable to determine training costs as it is not known how these offices are comprised between practitioner and nonpractitioner employees, as well as an accurate range in staff size. However, training costs, which each office of a dispensing practitioner can calculate using the provided formulas in SBEIS Section 3, do not affect exceeding respective minor cost thresholds because the department and commission have already anticipated that costs may be greater than the threshold.

The costs for dispensing facility training increase based on staff size. As explained in SBEIS Section 3, the higher-end costs are represented by a pharmacy with 25 people on staff: Seven pharmacists, 16 pharmacy technicians, and two pharmacy assistants. The lower-end costs are represented by a single pharmacist requiring training.

Equipment Acquisition Costs: The SBEIS Table 6 reflects costs that the department and commission were able to estimate to comply with the rule for both the first year and subsequent years.

SBEIS Table 6. Elements, Assumptions, and Costs

Cost Elements	Assumptions Used for Estimate	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule (after the First Year)
Large-print or QR-code-capable printer	New purchase of hardware - if needed	$0 to $240	$0
Braille printer	New purchase of hardware - if needed	$0 to $5,000	$0
Prescription readers or audio devices	New purchase of hardware - if needed	$0 to $4,000	$0
Total		**$0 to $9,240***	**$0**

* Total low-end cost estimate assumes the entity already has a printer capable of producing large-print or QR-code labels, a printer capable of producing Braille labels, or audio device readers on hand. The high-end estimate assumes the entity procures one of each hardware at the highest estimated rate.

Provision of Accessible Label and Service Costs based on Volume of Service: The expected number of patients requiring and requesting accessible labeling services differs for each entity, resulting in wide ranges for most cost estimates. For this reason, the commission and department used two scenarios, one for offices of dispensing practitioners and one for dispensing facilities, to better understand costs dependent on service volume.

Scenario A: Office of Dispensing Practitioner: In this scenario, it is assumed that an office of a dispensing practitioner would provide, at most, one accessible label a week **(52 labels per year)**. For

this scenario, the estimated annual compliance costs for an office of a dispensing practitioner range from **$0 and $2,868** (SBEIS Table 7).

SBEIS Table 7. Scenario A: Elements, Assumptions and Costs for an Office of a Dispensing Practitioner

Cost Elements	Assumptions	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule (after the First Year)
Provision of accessible label (including large-print, QR code, Braille, or audio reader)	52 labels per year (one label per week) at the highest rate of $4 per audio label	$0 to $208	$0 to $208
Third-party translation services	52 labels per year (one label per week) at the highest rate of $5 per audio label	$0 to $260	$0 to $260
Third-party interpretation services	Oral interpretation services at 1,200 minutes per year (100 minutes per month) at the highest rate of $2 per minute	$0 to $2,400	$0 to $2,400
Total costs		**$0 to $2,868***	**$0 to $2,868***

* Total low-end cost estimate assumes no requests for accessible labeling or translation and interpretation. The high-end estimate assumes 52 labels at $4 per label plus third-party translation and interpretation services.

Scenario B: Dispensing Facility: In this scenario, practitioners would provide **3,795 visually accessible labels and 7,494 translated labels per year.** Determining a realistic number of accessible labels produced by dispensing facilities for visually impaired, print disabled, and LEP patients is based on the number of prescriptions issued daily by a pharmacy and the proportion of the patient population that would need accessible labeling services. According to the Centers for Disease Control and Prevention (CDC), approximately four percent of Washington residents have some form of vision impairment[10] and the Migration Policy Institute estimates that 7.9 percent of Washington residents are LEP individuals.[11] Per a 2021 estimate from the National Community Pharmacists Association, pharmacies have an average prescription volume of 63,228 prescriptions per store.[12] This means that, on average, about 2,530 labels could be produced annually for visually impaired patients and about 4,996 labels for LEP patients. The commission estimates that the highest expected volume could be 50 percent above the reported average, meaning that top-end volume would be 3,795 visually accessible labels and 7,494 translated labels per year.

For this scenario, the estimated annual compliance costs for a dispensing facility ranges from **$0 and $172,650** (SBEIS Table 8).

SBEIS Table 8. Scenario B: Elements, Assumptions, and Costs for a Dispensing Facility

Cost Elements	Assumptions	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule (after the First Year)
Provision of accessible label (including large-print, QR code, Braille, or audio reader)	3,795 labels per year at the highest rate of $4 per audio label	$0 to $15,180	$0 to $15,180
Third-party translation services	7,494 labels at the highest rate of $5 per label	$0 to $37,470	$0 to $37,470

Cost Elements	Assumptions	First Year Total Probable Cost to Comply with the Rule	Annual Total Probable Cost to Comply with the Rule (after the First Year)
Third-party interpretation services	Oral interpretation services at 60,000 minutes per year (5,000 minutes per month) at the highest rate of $2 per minute	$0 to $120,000	$0 to $120,000
Total costs		**$0 to $172,650***	**$0 to $172,650***

* Total low-end cost estimate assumes no requests for accessible labeling or translation and interpretation services. The high-end estimate assumes 3,795 labels at $4 per label plus third-party translation for 7,494 labels at $5 per label and interpretation services at 60,000 minutes per year at $2 per minute.

Overall Limitations: Dispensing facilities could receive multiple requests for accessible labeling services daily, bringing up costs pertaining to per-label printing or third-party translation or interpretation vendor services. However, offices of dispensing practitioners could provide far fewer such labels directly to patients because the prescriptions they issue are typically sent to and filled by a dispensing facility.

Third-party vendor costs for interpretation and translation services could exceed the cost estimates per year if the practitioner used a higher per minute rate from the third-party vendor.

SBEIS – Section 5: Determination on if the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule: Yes, the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

SBEIS – Section 6: Explanation of the determination: The proposed accessible labeling rules apply to all offices of dispensing practitioners and dispensing facilities operating in the state of Washington and contain multiple compliance elements that represent costs to those entities. Rules of this type, broad application and complex compliance elements, tend to be regressive in nature, meaning that more obstacles exist for smaller businesses to comply with and implement the rules.

For example, developing P&P would represent a similar cost range to all facilities and offices of practitioners regardless of their respective office or business's staff size or revenue. The department and commission expect both smaller and larger business to take 10 to 30 hours to complete the P&P. It is also likely that larger businesses already have some or all of the hardware required to provide accessible labels to visually impaired or print disabled patients.

1. Reducing, modifying, or eliminating substantive regulatory requirements: The regulatory requirements for the accessible labeling rules cannot be reduced, modified, or eliminated for the entities to which the regulations apply because the requirements are necessary to provide meaningful access to all patients receiving prescribed medications.

2. Simplifying, reducing, or eliminating recordkeeping and reporting requirements: No additional recordkeeping or reporting requirements are described in the rule language.

3. Reducing the frequency of inspections: There are no plans to change the frequency of inspections.

4. Delaying compliance timetables: The commission plans to delay implementation for small businesses and other entities required to comply at least several months. Although the commission will not vote

on the implementation date until the CR-103 is authorized, they have expressed the intent to delay implementation for at least 12-18 months.

5. Reducing or modifying fine schedules for noncompliance: No new fines for noncompliance are added to the existing fining structure.

6. Any other mitigation techniques including those suggested by small businesses or small business advocates: Offices of dispensing practitioners and dispensing facilities have a number of options to reduce or mitigate the necessary compliance costs associated with the accessible labeling rules. The estimate examples provided in Section 4 of this document represent the highest-end of potential costs that regulated entities could incur. The mitigation strategies below are organized by the cost elements in each section of the rule language.

- Developing P&P
  - The cost range for developing P&P for each entity mostly depends on the time needed by staff to write and review the necessary documents. Development time could be around 10 hours or less, about a third of the high-end time estimated by staff, depending on the familiarity of the facility's or practitioner's respective business or office with developing P&P, as well as the complexity of the entity's internal operating structure.
- Staff training time (two hours per person annually)
  - The amount of time needed from each staff member to receive accessibility program training is not expected to change year-over-year, though training costs would be lower for regulated offices and businesses with smaller staff sizes.
- Visual accessibility hardware acquisition
  - Per WAC 246-945-028(3), a dispensing facility or office of a dispensing practitioner "shall provide one, or a combination" of the visual accessibility methods listed in rule: Large-print labels, Braille labels, QR codes, and prescription readers (audio devices). This means that a regulated entity may only need to acquire the hardware and pay the per-label printing costs for one of the four methods, provided the entity is able to provide accurate prescription information for their patient population.
- Large-print or QR-code-capable printer (if needed)
  - Costs could be mitigated in the acquisition of a large-print-capable printer by purchasing a lower cost device. Costs could also be negated entirely for entities that already have the capability to provide large-print labels or QR codes that link to the patient's prescription information.
- Braille printer (if needed)
  - Costs could be mitigated in the acquisition of a Braille printer by purchasing a lower cost device (around $1,800 as opposed to the higher cost range of around $5,000). Costs could also be negated entirely for entities that already have the capability to provide Braille labels.
- Prescription readers/audio devices (if needed)
  - The acquisition cost for prescription readers depends on both the cost of each device and the number of devices needed to serve the patient population. It is likely that smaller businesses or businesses with fewer patients needing accessible labeling services would not need to invest in as

many prescription readers as larger businesses. Costs could also be negated entirely for entities that already have the capability to provide prescription readers to their patient population.

- Visual accessibility printing
  - The per-label printing costs for the visual accessibility service tools listed in WAC 246-945-028(3) can be reduced through at least two methods. The first method is using same-type hardware (e.g., selecting one Braille printer over another) that can print accessible labels at a lower per-label cost, and the second method is to use an accessibility service tool, such as a large-print label instead of a prescription reader, that features lower per-label costs.
  - It is also important to note that, while the cost estimates discussed in Section 4 of this document estimate the number of accessible labels a dispensing facility might expect to produce each year, that number could be lower based on patient population size and the number of patients that ask for accessible labels for their medications. Not all visually impaired, print disabled, or LEP patients are expected to utilize the accessibility services, though it must be clear to each patient that such services are available.
- Third-party translation services for LEP patients
  - The label translation services provided by third-party vendors have no start-up costs, per staff discussion with vendor representatives. All associated costs are through monthly service fees, and costs could be mitigated through the use of certain vendors.
- Third-party interpretation services for LEP patients
  - Oral interpretation service costs are also expressed via monthly service fees, and costs could be mitigated through the use of certain vendors. Some vendors reported their monthly fees being based on interpretation fees between $0.89 and $2.00 per minute, meaning that costs to the regulated entity could be further reduced based on patient need.

In conclusion, department and commission staff believe that many options exist for small businesses to reduce accessibility program implementation costs while still complying with the accessible labeling rules and serving the needs of their patient community.

SBEIS – Section 7: Description of how small businesses were involved in the development of the proposed rule: Commission staff created and maintained a list of interested parties at the start of the CR-101 rule-making process and sent alerts to interested parties and licensees with any updates pertaining to listening sessions, draft outline workshops, and rule language workshops conducted at the commission's public meetings. The commission solicited and received feedback at these meetings from both small businesses that would be regulated by the proposed rules and representatives for small businesses such as the Washington state pharmacy association. The feedback received from small businesses helped in the formulation and editing of rule language drafts, such as adjusting defined terms and developing a list of medications that would be exempt from the accessibility rules.

An organization focused on language access invited commission staff to present on the accessible labeling rules project at one of their meetings. Attending staff discussed the scope of the proposed

rules and provided an overview of the rule-making process for those in attendance.

The commission also distributed a survey to all pharmacist licensees, many of whom worked in small businesses, in 2022 for the purpose of assessing the challenges and opportunities present in designing and tailoring an accessibility program with which dispensing facilities could comply. The data collected from this survey helped guide a draft outline for the accessible labeling program and eventual draft language.

SBEIS – Section 8: The estimated number of jobs that will be created or lost in result of the compliance with the proposed rule: Commission and department staff do not believe that compliance with the proposed rule will result in the creation or loss of any jobs associated with offices of dispensing practitioners and dispensing facilities.

1 The average assistant profession wage is based on an average of four assistant professions—pharmacy technicians, pharmacy aides, medical assistants, and medical secretaries/administrative assistants—from the 2022 wage statistics reported by the U.S. Bureau of Labor and Statistics. The average wage is rounded up to the next dollar.
2 Washington - May 2022 OEWS State Occupational Employment and Wage Estimates (bls.gov)
3 Washington - May 2021 OEWS State Occupational Employment and Wage Estimates (bls.gov)
4 U-LINE. (2023). Dymo Labelwriter 400 Series Printers. https://www.uline.com/BL_8650/Dymo-LabelWriter-400-Series-Printers?keywords=printer
5 American Foundation for the Blind. (Accessed October 2023). Braille Printers. https://www.afb.org/blindness-and-low-vision/using-technology/assistive-technology-products/braille-printers
6 American Foundation for the Blind. (Accessed October 2023). An In-Depth Look at the ScripTalk Station from En-Vision America. https://www.afb.org/aw/14/6/15685
7 Consultation with service provider representatives (August 2023).
8 Staples. (2023). Document Printing. https://www.staples.com/services/printing/copies-documents-printing/
9 Minuteman Press. (2023). Posters. https://minuteman.com/us/products/signs/posters?location=wa,chehalis
10 Centers for Disease Control and Prevention. (May 12 2023). Disability & Health U.S. State Profile Data for Washington (Adults 18+ years of age). Disability & Health U.S. State Profile Data: Washington | CDC
11 Migration Policy Institute. (2023). State Immigration Data Profiles - Washington. State Demographics Data | migrationpolicy.org
12 National Community Pharmacists Association (2022). NCPA Releases 2022 Digest Report. NCPA Releases 2022 Digest Report | NCPA

A copy of the statement may be obtained by contacting Joshua Munroe, P.O. Box 47852, Olympia, WA 98504-7852, phone 360-502-5058, fax 360-236-2901, TTY 711, email PharmacyRules@doh.wa.gov.

August 13, 2024
Hawkins Defrance, PharmD, Chair
Pharmacy Quality Assurance Commission

OTS-5127.1

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

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~~)) 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 LEP individual.

(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) "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.

(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 LEP individual'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 obtain prescription information, as defined in WAC 246-945-026(9), from the label affixed to the prescription container and provide the prescription information, as defined in WAC 246-945-026(9), 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 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 de-

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