COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor **(804) 367-4456 (Tel)**
Henrico, Virginia 23233 **(804) 527-4472(Fax)**

Tentative Agenda of Work Group for Translated Directions for Use of Prescriptions

September 28, 2023

9AM

TOPIC	**PAGES**

Call to Order: Dale St. Clair, PharmD, Chairman

- Welcome & Introductions

Review Charge: Evaluate challenges and barriers to requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy.

Call for Public Comment: The work group will receive public comment at this time. The work group will not receive comment on any Board regulation process for which a public comment period has closed or any pending disciplinary matters.

Discussion

Adjourn

Materials included in agenda packet:

****The work group will have a working lunch at approximately 12pm.****

Work Group for Translated Directions for Use of Prescriptions

Work Group Members

- Dale St.Clair, PharmD, Board of Pharmacy, Chairman
- Cheri Garvin, RPh, Board of Pharmacy, Member
- Kris Ratliff, DPh, Board of Pharmacy, Member
- Patricia Richards-Spruill, RPh, Board of Pharmacy, Member
- Joanne Dial, PharmD, Kaiser Permanente Mid-Atlantic States
- James Satterfield, PharmD, Virginia Association of Chain Drug Stores
- Tana Kaefer, PharmD, Virginia Pharmacy Association
- Cinthia Coffey, PharmD, Virginia Society of Health-System Pharmacists

CHAPTER 630

An Act to direct the Board of Pharmacy to convene a work group to evaluate the provision of translated directions for use of prescriptions; report.

[H 2147]

Approved March 26, 2023

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy (the Board) shall convene a work group of interested stakeholders to evaluate challenges and barriers to requiring or providing translated directions for the use of prescriptions, including the possibility of model directions and necessary changes within pharmacies to ensure patients are aware of the language services available at the pharmacy. The Board shall report the findings of the work group to the Governor and the Chairmen of the House Committee on Health, Welfare, and Institutions and the Senate Committee on Education and Health by December 1, 2023.*

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August 31, 2023

Caroline Juran, RPh, Executive Director
Virginia Board of Pharmacy
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Henrico, Virginia 23233
caroline.juran@dhp.virginia.gov

Dear Dr. Juarn and Members of the Board:

This letter is to provide testimony for the Virginia HB2147 workgroup on challenges and barriers to providing translated directions for use.

When it comes to language access in the pharmacy, there are four main questions to consider: What do patients need? What is possible with current technology? What role will emerging technologies play? What can we reasonably expect pharmacies to provide?

Legislatures and Boards of Pharmacy in California, New York, Oregon, Washington (and here) and Nevada have all spent a considerable amount of time asking these questions. There has also been health literacy related research in this area that can be drawn upon. Some research is listed here: https://www.staysaferx.org/p/research-and-articles-on-prescription.html Here is a summary of what we have learned:

What do patients need?

- Translation and interpretation have a variety of formats: from one spoken language to another, from a spoken language to a visible language like sign language, and visual interpretation from a printed language into audible language as for the blind.
- Counseling at the pharmacy counter allows patients to ask important questions surrounding polypharmacy, side effects, insurance and other critical medication management information. However counter counseling should never be considered a replacement for a legible label on the container itself. Both need to be translated and/or interpreted.
- Patients need to be able to access the directions for use, warnings, and indication at home. They need to be affixed to the bottle in the language and format that they can access whether in written or audible format. Separate sheets of paper get lost, damaged, or separated from the container they describe.

- If the bottle is only labeled in non-English, EMS, medical personnel, and caregivers may not be able to read it either, therefore dual language labels are necessary.

What is possible with current technology?

- There are several current API technologies that allow for pharmacies to place translated data on any form or label including multipage, wrap around, peel back and flagged style labeling.
- Standard SIGs use a combination of about 600 different words which means it is possible to use a hybrid of AI and human translations to create translated SIGs that are accurate and culturally appropriate in that language.
- ScripTalk even allows pharmacists to create audible translated labels for those who never learned to read in their native language.

What role will emerging technologies play?

- At this point in time AI translations alone are not reliable enough to be the sole source for culturally appropriate translations of critical medication information. Human training and oversight still play a crucial role in the translation process.
- Though there may be limited solutions currently, the more statutes and rules that require these services, the more technologies, ideas and languages will rise to meet the demand.

What can we reasonably expect pharmacies to provide?

- Before we answer this question, let us first ask if it is reasonable to continue to expect patients to safely manage medications if the prescription label is unreadable to them? Learning a new language takes time, but health issues will not wait.
- The technology and translation services are available and already being put into practice by five states so we know it can and is being done. Though USP <17> sets out a few standards, it is up to states to create, regulate and enforce prescription labeling standards.
- Though cost will always be considered a factor, long term there are cost savings when there is greater conformity to medication regimes and less hospital recidivism. Providing accommodations for those with a disability or limited ability to read English are considered a cost of doing business.

Other factors to consider:

- Currently the FDA has proposed rules for a new format for Patient Medication Guides and is seeking feedback in part on translation and accessibility issues. Some of the comments people have provided may be insightful. https://www.federalregister.gov/documents/2023/05/31/2023-11354/medication-guides-patient-medication-information

- In addition to interpreting and translating prescription labels into other languages, including sign language for the hearing impaired, pharmacies should also be prepared to provide accessible formats for visual interpretation for the blind, visually impaired and deaf-blind which may include audible, Braille or large print formats.

For more information on accessible and dual language prescription labeling standards and policies I put together these resources: https://mailchi.mp/envisionamerica/pharmacist_education_tool and also suggest www.StaySafeRx.org

En-Vision America is happy to answer any other questions you have about dual language labeling in general or our solutions in particular.

Kind Regards,

Sharla Glass
Public Policy and Community Outreach Liaison
En-Vision America
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Dual Language Prescription Labeling Best Practices

Pharmacy Barriers to Patients with Limited English Proficiency

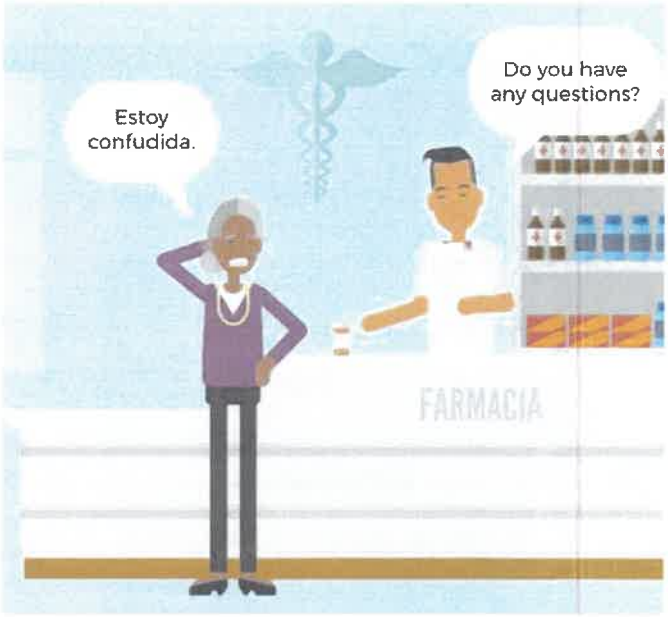
- Limited English proficiency is not always obvious. Some patients have enough basic English skills to navigate a prescription pick up transaction but not able to fully understand instructions or explanations given during an appointment or counter counseling. Therefore, part of counter counseling should include asking if the patient has any trouble reading the prescription labels. This should include asking consumers using mail order, delivery service and customers who are picking up for someone else.

- A pharmacy cannot require a person to bring someone to interpret for the patient or assume that a family member or caretaker will read prescription label information at home. The ADA places responsibility for providing effective communication directly on the public accommodation/pharmacy.

- Signage should clearly indicate which languages you are able to accommodate with dual language prescription labeling and/or translation.

- Even if an interpreter is provided during a doctor visit or during a pharmacy transaction, the person may not be able to commit all the information relayed to memory especially if multiple medications are involved. Providing a dual language prescription label allows patients to access their prescription information at any time.

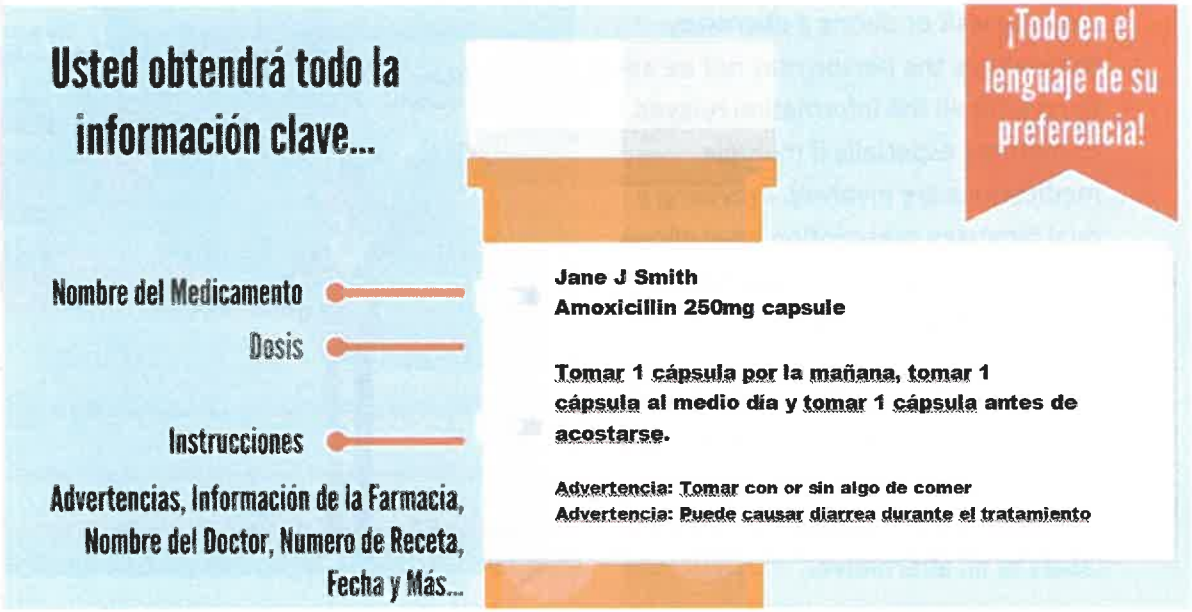
- In circumstances where a patient with limited English proficiency is also not literate in their native print language, provide audible translated prescription labels as an alternative.



Best Practices For Dual Language Prescription Labeling

Standard Text Dual Language Labels

- **On the Vial** Ensure that the translation and English are printed on the prescription label. This is vital for caretakers and emergency personnel.
- **Warnings** Include the information on warning labels added to the container at the pharmacist's discretion.
- **Durability** Ensure the durability of labels until the expiration date specified on the prescription drug container label.
- **Time Frame** Provide prescription medication with an accessible prescription drug label within the time frame the same prescription would be provided to patients not in need of translation.
- **Free** Per ADA regulations pharmacies cannot impose a surcharge or extra fee to an individual to cover the cost of providing an accessible drug container label and equipment dedicated for prescription drug container label access.
- **Posting Requirement** Many states require a poster in the languages available letting customers know about translation and dual language label options.
- **Digital Access** If pharmacy websites and applications (apps) are made available to patients, ensure website and app translations are available
- **HIPPA** Maintain patient privacy in accordance with the Health Insurance Portability and Accountability Act (HIPAA) rules when preparing accessible prescription drug container labels, e.g., record audible labels in a location where patient information cannot be overheard by unauthorized persons.



Audible Translated Prescription Labels

- Select devices that provide independent, easy to use, start/stop operation, with volume control, and ear bud jack for private access to information.
- If using a voice recorder, speak in a clear voice and record information in a setting that minimizes background noise and maintains patient privacy.

Large Print Dual Language Labels for those with Low Vision

- Print label in 18-point bold font.
- Use non-glossy paper or other material that is durable and a size that is easy to manipulate.
- Use print with highest possible contrast between text and background color (ideally black text on a white or pale-yellow background). If printing on both sides, use material that does not allow print bleed-through from one side to the other.
- Use sentence case, with the initial capital letter followed by lower-case characters.
- Use non-condensed, San-Serif font, such as Arial.
- Provide 1.5 line spacing.
- Use horizontal text only.
- Securely affix the large print label to the prescription drug container.
- When covering a large print label with protective tape, use non-glossy, transparent tape.

Laws and Regulations

Federal Legislation

- **The Patient Protection and Affordable Care Act** (2010) Section 1557 prohibits discrimination on the basis of race, color, national origin, age, disability, or sex (including pregnancy, sexual orientation, and gender identity), in covered health programs or activities, including pharmacies that participate in Medicare programs. https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/hhs-continues-to-improve-access-for-lep-individuals/index.html

State and Local Legislation

- 2007 California SB472 Patient Centered Labels for Prescription Drug Containers (to be implemented by 2011 and review of implementation in 2013)
- 2009 New York City Council requires Prescription Label Translation
- 2012 New York State S6257E Pharmacy Translation Requirements
  Final Rules: http://www.op.nysed.gov/prof/pharm/article137.htm#sect6829
- 2015 California AB1073 Requires pharmacies to provide translated SIGs directly on the prescription label
- 2016: Affordable Care Act Section 1557 Nondiscrimination in Health Programs and Activities final rule issued. § 92.202 Effective communication for individuals with disabilities. A covered entity must provide translation services free of charge and in a timely manner to ensure an equal opportunity to participate and benefit from the entity's health programs or activities.
- 2019 Oregon SB 698 Requires pharmacies to provide dual language prescription labels in 14 languages. Enacted into Law.
- 2021 Nevada AB 177 – Dual Language Prescription label law passed.
- 2022 Washington HB1852 & SB5340 – Dual language and accessible prescription labeling bill did not pass. However, the Washington Pharmacy Quality Assurance Commission decided to work on revising rules to assure patient safety.

One System, Multiple Solutions

Script Ability™

Accessible Rx Labels

Talking Labels

- Meet the needs of customers who are blind, visually or print impaired

The Patient will hear the entire label read aloud, including:

- Drug Name, Dosage and Instructions
- Warnings and Contraindications
- Pharmacy Information
- Doctor Name
- Prescription Number and Date

Software/Hardware Features:

- Windows Compatible Software
- RFID and Text-to-Speech Technology
- Fast Production and Verification
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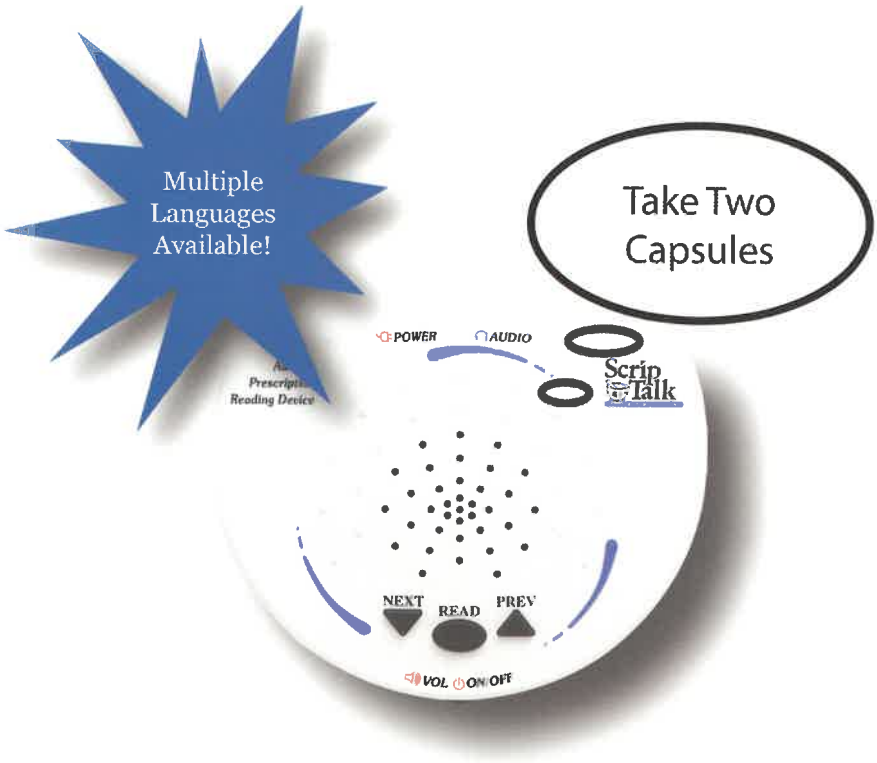

Script View

LARGE PRINT LABELS

Large Print Labels

ScriptView improves medication adherence for blind, visually impaired and print-impaired patients.

ScriptView features a booklet-style design for easy reading.

ScriptView features a large-print label affixed to the medication bottle.

ScriptView Includes Three Solutions:

Solution 1: Large-Print Label

Solution 2: Dual Language

Solution 3: Controlled Substance Safety Label (CSSL)

Scan for Safety Video

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Braille Labels

- Easy-to-access Grade 2 Braille label
- Meets guidelines of U.S. Access Board
- Select data to emboss
- Clear adhesive goes over pharmacy label
- Ideal for blind Braille readers

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Introducing...

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Script View® FLIP

What can you do with ScriptView Flip?

- *Translated Label (25 languages)*
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These labels are designed to help ensure patient compliance and adherence and can be created right in the ScriptAbility system.

Print these easy-to-use labels on our small footprint ScriptView SV208 printer.

A revolutionary way to add more space onto your prescriptions!

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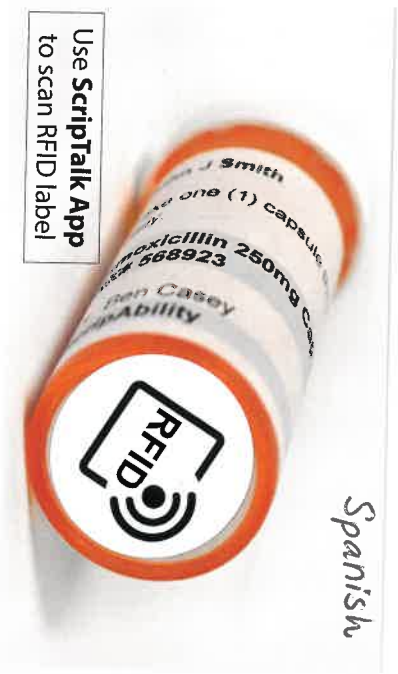
Greek • Haitian Creole • Hindi • Italian • Korean
Myanmar (Burmese) • Nepali • Pashto • Polish
Portuguese (Brazil) • Romanian • Russian • Somali
Spanish • Swahili • Tagalog • Vietnamese



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Nevada 2023 Bill

2023 Nevada bill (AB251) passed by the legislature but vetoed by Governor. Below is from the Governor Veto Journal.

Bill read. Assemblywoman Jauregui moved that Assembly Bill No. 235 be placed on the Chief Clerk's Desk. Motion carried. Vetoed Assembly Bill No. 251 of the 82nd Session. Governor's message stating his objections read. OFFICE OF THE GOVERNOR June 1, 2023 THE HONORABLE STEVE YEAGER, SPEAKER OF THE NEVADA STATE ASSEMBLY, Nevada Legislature, 401 South Carson Street, Carson City, Nevada 89701 Re: Assembly Bill 251 of the 82nd Legislative Session DEAR SPEAKER YEAGER:

I am forwarding to you, for filing within the time limit set forth in the Nevada Constitution and without my approval, Assembly Bill 251 ("AB 251"), which is titled as follows: AN ACT relating to pharmacy; revising requirements governing the language in which certain information relating to a prescription must be provided to a patient; and providing other matters properly relating thereto. AB 251 is well-intended in that it aims to increase the accessibility of pharmacy services for those who are more comfortable using a language other than English. That said, requiring every pharmacy in Nevada–from independently owned establishments to Fortune 10 companies–to provide information in each of the ten of the most spoken languages at-home in the State is an unnecessarily onerous burden. Not only is this law burdensome, it also provides no clarity about whether and how pharmacists should provide verbal instructions regarding certain prescriptions as may otherwise be required by law. Since AB 251 creates an unnecessary burden on pharmacies across our State, I cannot support it. For these reasons, I veto this bill and return it to without my signature or approval. Respectfully submitted, JOE LOMBARDO Governor of Nevada

Assembly Bill No. 251–Assemblymen Nguyen, Mosca, González, Brittney Miller; D'Silva and Torres

Joint Sponsor: Senator Nguyen

CHAPTER.....

AN ACT relating to pharmacy; revising requirements governing the language in which certain information relating to a prescription must be provided to a patient; and providing other matters properly relating thereto.

Legislative Counsel's Digest:

Existing law requires a prescription be dispensed in a container with a label or other device that provides certain information about the prescription, including the specific directions for use given by the prescribing practitioner. (NRS 639.2801) Existing law requires a pharmacy, other than an institutional pharmacy, to provide the directions for use in English and, upon the request of the prescribing practitioner, a second language. Existing law requires the State Board of Pharmacy to adopt regulations prescribing every language, other than English, in which a pharmacy must provide such information, based on demographic trends and projections. (NRS 639.28013) This bill removes the requirement for the Board to adopt such regulations and instead requires each pharmacy to provide the information in the 10 languages mostly commonly spoken at home in this State, as determined by the most recent decennial census. This bill also authorizes a pharmacy to provide the required information in a separate document if it is impractical to include the information in English on the label or other device affixed to the container of the prescription.

EXPLANATION – Matter in ***bolded italics*** is new; matter between brackets **[**~~omitted material~~**]** is material to be omitted.

THE PEOPLE OF THE STATE OF NEVADA, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. NRS 639.28013 is hereby amended to read as follows:

639.28013 1. Each pharmacy, except for an institutional pharmacy, shall, upon the request of a prescribing practitioner, a patient or an authorized representative of a patient, provide the information required by subsection 6 of NRS 639.2801 in English and any language in which the information is required to be provided pursuant to subsection 3.

2. Each pharmacy subject to the requirements of subsection 1 shall post in a conspicuous place:

(a) Notice of the rights of a patient to request information in a language other than English pursuant to subsection 1; and

(b) A list of every language in which such information is available.

3. ~~[The Board]~~ ***Each pharmacy*** shall ~~[adopt regulations prescribing every language in which a pharmacy is required to]~~ provide ***the*** information required by ***subsection 6 of*** NRS 639.2801 ~~[. The]~~ ***in any of the 10*** languages ~~[in which a pharmacy is required to provide such information must be specified by the regulations adopted by the Board pursuant to this section based on demographic trends and projections.]~~ ***most commonly spoken at home in this State, as determined by the most recent decennial census conducted by the Bureau of the Census of the United States Department of Commerce. If it is impractical to include the information required by subsection 6 of NRS 639.2801 on the label or other device which is affixed to the container of the prescription in English only, a pharmacy may provide the information in English and the other language in a separate document. If it is practical to include the information in English on such a label or other device, the pharmacy must also include the information in the other language on the label or other device.***

4. The Board may adopt such ~~[other]~~ regulations as are necessary to carry out the provisions of this section.

5. 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.

20 ~~~~~ **23**

To Whom It May Concern,

The Washington Council of the Blind Advocacy and Governmental Affairs Committees are requesting that the Washington Pharmacy Compliance Board create rules to require pharmacies in Washington State to offer accessible labeling on medication bottles. The Food and Drug Administration Safety Innovation Act of 2012, section 904, tasked the US Access Board to develop Best Practices for Accessible Medication Labels. The National Council on Disability along with the American Council of the Blind put together an online information site (www.ncd.gov) and brochure highlighting best practices for pharmacies who serve low-vision and blind persons. However, these were only recommendations. Therefore, many pharmacies, including pharmacies based in Washington state either do not follow these recommendations or only offer large print but no other accessible labeling options.

Over 25 million Americans age 65 and older have low-vision or are blind. This makes reading labels impossible without accommodations. I am legally blind and cannot see or read medication labels. When I asked my local Costco pharmacy for large print labels, I was told they did not offer that service. I then asked how was I, as a legally blind person, supposed to read the small print on my medication bottle? I was told I needed to find someone to read the label to me. This is insulting. My privacy and independence are being taken away due to lack of understanding, professionalism and a failure to follow basic best practices guidelines for accessible medication labels. This is only one example of many such stories throughout Washington state involving other visually impaired persons. There is no consistency and therefore, patient safety is affected depending the pharmacy a person uses. In some areas of Washington, there are very few pharmacy choices. So, if you have to use a pharmacy that does not offer accessible labeling you are at risk for an avoidable medication error.

With the advances that En-Vision has made with Script Talk labeling, accessible medication labels are now available to other patient populations. Those who are reading impaired (dyslexia, low reading comprehension, English as a second language and others) now have a way to have way to know what the label says in an easy to use manner. This means many more patients could be positively impacted with this technology. Patient/consumer safety will increase.

Patient caused medication errors is a major reason for emergency room visits and, at times, hospitalization. The CDC estimates that non-adherence to medication treatments cause 30 to 50% of the chronic disease treatment failures. Furthermore, medications are not taken as prescribed about 50% of the time. While non-adherence to medication regimens has several causes, one major cause is understanding or being able to properly read the label.

Patient caused medication errors are avoidable. Communication is a key component is stopping these errors. Offering accessible medication labels will go a long way in improving medication communication.

Thank you for considering this request. Please feel free to contact me with any questions.

Judy Brown, RN, BSN
Washington Council of the Blind
Co-Chair Advocacy Committee
Member Governmental Affairs Committee
Jeibrown726@gmail.com
207-944-1837
Shoreline, WA 98133

Highlighted portions have been added since last presented to the commission.

Accessible Label Rule References

Translated Labels

California

- CA Law 4076.6 - California
  - 4076.6(a) – Dispenser shall provide translated directions for use on patient request
    - Printed on container label
  - 4076.6(b) – Dispensers may use translations provided by the board of pharmacy
  - 4076.6(c) – Dispenser don't need to use languages beyond those that the board provides
  - 4076.6(d) – Dispensers may use their own translation services to comply with the section
  - 4076.6(e) – Dispensers are responsible for the accuracy of English-language directions for use provided to the patient
  - 4076.6(f) – Veterinarians are not considered dispensers for this section
- The California Board of Pharmacy received funding from a third party to create original translations of the SIGs and pharmacists cut out those SIGs from prepared sheets and attach them to the prescription bottle.

New York

- NY Law 6829 – New York
  - 6829(1) – Definitions provided for:
    - 6829(1)(a): "Covered pharmacy"
    - 6829(1)(b): "Limited English proficient individual"
    - 6829(1)(c): "Translation"
    - 6829(1)(d): "Competent oral interpretation"
    - 6829(1)(e): "Pharmacy primary languages"
    - 6829(1)(f): "Mail order pharmacy"
  - 6829(2)(a) – Pharmacies must provide free, competent oral interpretation services on patient request
  - 6829(2)(b) – Pharmacies must printed translated medication labels, warning labels, and other written material on patient request
  - 6829(2)(c) – Pharmacies may use staff or third-party contractors to provide translations
  - 6829(3) – Signage advertising translation services must be conspicuously posted
  - 6829(4) – The pharmacy commission is responsible for rulemaking in order to establish translation services
    - 6829(4)(a): Rules must state how to determine if patient is LEP
    - 6829(4)(b): Determine which languages are considered
    - 6829(4)(c): Manner and circumstances by which oral interpretation services are provided
    - 6829(4)(d): Which information is eligible for oral interpretation

        - 6829(4)(e): Anticipate how service is utilized, which resources used and what costs are incurred
        - 6829(4)(f): Establish compliance/monitoring standards
    - 6829(5) – Covered pharmacies are not liable for injuries resulting from third-party contractor translations
    - 6829(6) – Must establish a process by which pharmacies may apply to receive a waiver from compliance
    - 6829 (7) – Commissioner must coordinate with the commissioner of health to "effectuate" requirements of the section
- NY Rule Section 63.11 – Interpretation and translation requirements for prescription drugs
    - This rule was filed in 2014 following the passage of associated legislation regarding the translation of prescription information.
        - Final rule filed in the New York State Register, Volume XXXVI, Issue 11 (March 19, 2014).
        - New York State Register, Volume XXXVI, Issue 27, effective 7/9/2014
    - 63.11(a) – Definitions for:
        - 63.11(a)(1): "Covered pharmacy"
        - 63.11(a)(2): "Corporate entity"
        - 63.11(a)(3): "Limited English proficiency individual"
        - 63.11(a)(4): "Translation"
        - 63.11(a)(5): "Competent oral interpretation"
        - 63.11(a)(6): "Pharmacy primary languages"
        - 63.11(a)(7): "Mail order pharmacy"
    - 63.11(b) – How competent oral interpretations are provided
        - 63.11(b)(1) – Covered pharmacies must provide oral translation services for patient counseling for free on request
        - 63.11(b)(2) – Covered pharmacies must provide oral translation services of medication/warning labels or other written materials for free on patient request
        - 63.11(b)(3) – Translations must be provided on site unless list of languages exceed seven
        - 63.11(b)(4) – Staff or third-party contractors are allowed to provide translated information
    - 63.11(c) – Notification requirements
        - 63.11(c)(1) – Conspicuous signage for advertising translation services
        - 63.11(c)(2) – Font size and type, design element requirements
        - 63.11(c)(3) – Placement of signage
    - 63.11(d) – Waivers for translation services
        - 63.11(d)(1) – One application per pharmacy
        - 63.11(d)(2) – Waiver applications must describe financial/physical constraints and impact on other services
        - 63.11(d)(3) – Reasons to deny waiver application
        - 63.11(d)(4) – Applicants must identify nearby services that can provide translation services
        - 63.11(d)(5) – Post notice of alternative services if waiver granted

        - 63.11(d)(6) – Waiver duration and renewal conditions
    - 63.11(e) – This section preempts local laws/ordinances, though cities of 100,000 or more may impose stricter regulations

Nevada

- NV Law 639.28013 – Requirement to provide prescription info in English and certain other languages on request
    - All pharmacies must comply except institutional pharmacies
    - Signage required:
        - Notice of the rights of a patient to request information in another language
        - A list of languages available for translation
    - Board responsible for adopting regulations prescribing each language required
    - Pharmacy/employees not liable in any civil action for injury if the pharmacy uses a third-party vendor to provide translation services
- Rules are ongoing following the enactment of NRS 639.28013, as the labeling requirements described under their section of rule (NAC 639.397) was last updated in 2014.
    - Proposed regulation language: R119-21P
    - Workshop document: R119-21I
    - Adopted regulation language: R119-21A
    - Proposed Revised regulation language: R119-21RA

Oregon

- Oregon filed a rule adding the requirement to use interpreters and modify patient records to reflect the patient's preferred language (LINK)
- OR Law 689.564 – Prescription drug labels
    - 689.564(1) – Board of pharmacy responsible for rules establishing pharmacy printing of prescription drug labels in English and language requested by LEP individual. Rules must also:
        - 689.564(1)(a) – Define "limited English proficiency"
        - 689.564(1)(b) – Determine which sections with which pharmacies must comply
        - 689.564(1)(c) – Determine list of drugs eligible for translation
        - 689.564(1)(d)(A) – Minimum list length of 14 languages other than English
        - 689.564(1)(d)(B) – Board must reassess/update list every 10 years
    - 689.564(2)(a) – Third-party contractors may be used
        - 689.564(2)(b) – Liability exemptions for injury resulting from errors in third-party translations
    - 689.564(3) – Not applicable to institutional drug outlets
    - 689.564(4) – Grants board of pharmacy rulemaking authority
    - 689.564(5) – Signage posting requirements

Texas

- TX Rule 291.3 – Required notifications

    - 291.3(h)(2)(B)(viii) – Pharmacies must provide in their profile the type of language translation services, including translating services for persons with impairment of hearing
        - No requirements for services themselves, but that they need to announce any services pharmacies choose to use
- While the board of pharmacy was required in statute to establish a pharmacy profile system including the above information by January 1, 2005, the historical records on file only go as far back as 2007.

Visual/print Accessibility

Arkansas

- Arkansas Rule 054.00.75-6
    - November 1, 2019
    - Font size for data elements in prescription drug card: 8 points or greater (no font type listed in this section of rule)

California

- California Rule 1707.5 – Patient-centered labels for prescription drug containers
    - The following elements, clustered together, must comprise at least 50 percent of the label:
        - Name of patient
        - Name of drug/strength of drug
        - Directions for use
        - The condition/purpose for which the drug was prescribed
    - Font: At least 12-point font in sans serif typeface
    - Provides suggested phrasing to accommodate compliance
    - Amendment to subsection 1707.5(a)(1) filed on January 8, 2015 and went into effect on April 1, 2015.

Massachusetts

- MA Law MGLA 94C-21
    - Title XV, Chapter 94C, Section 21
    - November 1, 2019
    - On request, prescription label must be printed in a size "allowing no more than ten characters per inch."
- 247 CMR
    - Board of pharmacy's rules chapter. As of yet, have not found accessibility language.

Nevada

- NV Law 639.28015 – Notice of prescription readers
  - Pharmacies must let patients know about availability of prescription readers and provide them on request
  - Definitions provided for "prescription reader" and what applies as a "retail community pharmacy"
- NAC 639.756
  - Proposed regulation language: R131-17P
  - Information Statement: R131-17NI
  - Workshop document: R131-17I
  - Revised proposed regulation language: R131-17RP1
  - Approved regulation language: R131-17AP
  - Adopted regulation language: R131-17A

New Jersey

- New Jersey Rule 13-39-7.12 – Labeling
  - 54 N.J.R. 88(a).
  - Amended by R.2022 d.004, filed December 6, 2021 and effective January 3, 2022.
  - Font size directions for warning label/sticker only
    - Must be at least 10-point font (not cursive) that is "clear and readable" per subsection (2)(iii)

New York

- New York Rule Section 63.12 – Standardized patient-centered data elements to be used on all drug labels
  - Levels of information importance
    - Critical: Patient name, directions of use, drug name/strength
    - Important: Name/address/phone of pharmacy, patient's address, name of prescriber, filling date, prescription/identifying number
  - Critical elements must be at least 12-point font, with highlighting/bolding used for emphasis
    - No highlighting/bolding of "Important" info

Oregon

- Oregon Revised Statute (ORS) 689.561
  - November 1, 2019
  - Definitions for "blind" and "prescription reader"
  - Notification of prescription readers to patients except for drugs dispensed by "an institutional drug outlet"
    - Readers must last duration of prescription and meet needs of identified impairment
  - Labels must be compatible with prescription readers
- OR Rule 855-041-1131 – Prescription reader accessibility

- Pharmacies must notify each person receiving a prescription that a prescription reader is available, and provide that reader if requested
- The final rule was approved by the agency on June 18, 2020 and went into effect on June 23, 2020.
- A Temporary rule was put in place while standard rulemaking was ongoing.
- Filing document for -1131

Texas

- Texas Rule 291.33 – Operational Standards
  - Subsection TAC 291.33(c)(1)(B)(v)(I) includes language for "easily readable font size," though later subsections describe this as at least ten-point Times New Roman.
  - Subsections with font size references:
    - TAC 291.33(a)(7)(A) – Dispensing container label
      - **NOTE:** There is also language in TAC 562.006(f) for the board to adopt rules requiring dispensing container labels be printed in an "easily readable font size"
    - TAC 291.33(7)(A)(ii) – Prescription drug ID number
    - TAC 291.33(7)(A)(vii) – Name of patient (or animal name/species if prescribed for animal)
    - TAC 291.33(7)(A)(viii) – Instructions for use
  - Last amendment went into effect December 14, 2020
    - The filing for the amending language was published in the Texas Register (Volume 45, issue 50, page 8852).

Washington State Department of Health

Commission SBAR Communication

Agenda Item/Title: Review of Title VI and Other Federal Regulations Related to Accessibility

Date SBAR Communication Prepared: February 24, 2023

Reviewer: PQAC Staff

Link to Action Plan:

☐ **Action** ☒ **Information** ☒**Follow-up** ☐**Report only**

Situation: At the January business meeting, the Pharmacy Quality Assurance Commission (commission) discussed a conceptual draft of the accessible labeling rule. This discussion included identifying a possible intersection between this rulemaking and various federal laws, including Title VI of the Civil Rights Act.

Background:

Title VI of the Civil Rights Act 1964 (42 U.S.C. 2000d)

- Title VI provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance" (42 U.S.C. § 2000d). This includes a prohibition against national origin discrimination affecting limited English proficiency (LEP) persons, *see Lau v. Nichols*, 414 U.S. 563, 94 S. Ct. 786, 39 L. Ed. 2d 1 (1974).
- Title VI applies to "any program or activity receiving Federal financial assistance" (42 U.S.C. § 2000d). HHS has confirmed that this definition of a "program or activity" includes health care providers and facilities who receive Medicaid or Medicare reimbursement are subject to Title VI.
- In 2000, Bill Clinton issued Executive Order 13166: Improving Access to Services for Persons with Limited English Proficiency (recently reaffirmed by Attorney General Merrick Garland on November 12, 2022), which required federal agencies to publish guidelines on how recipients of federal financial assistance can provide meaningful language access under the requirements in Title VI.
- HHS has guidance on its website for federal financial assistance recipients regarding Title VI's prohibition against national origin discrimination affecting LEP persons. The goal of the guidance is to ensure recipients conduct an individualized assessment of their operation to ensure "meaningful access by LEP persons to critical services while not imposing undue burdens on small business, small local governments, or small nonprofits." As a result, what amounts of "meaningful access" has the potential to vary greatly based on the recipient.

- Title VI is enforced by the Department of Justice and the agencies who provide federal financial assistance to recipients. There is no private cause of action for individual persons to enforce disparate impact regulations promulgated under Title VI, such as those related to language accessibility (*Alexander v. Sandoval*, 532 U.S. 275, 121 S. Ct. 1511, 149 L. Ed. 2d 517 (2001)).

Section 504 of the Rehabilitation Act (29 U.S.C. § 794)

- Generally speaking, the Rehabilitation Act protects individuals from discrimination on the basis of disability. In particular, Section 504 of the Rehabilitation Act of 1973 provides that no otherwise qualified individual with a disability in the United States can, solely by reason of his or her disability, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under: (1) any program or activity receiving federal financial assistance; or (2) any program or activity conducted by any executive agency or by the United States Postal Service (29 U.S.C. § 794(a)).
- Similar to Title VI, "program or activity" is defined broadly in the Rehabilitation Act to include all of the operations of "an entire corporation, partnership, or other private organization, or an entire sole proprietorship . . . which is principally engaged in the business of providing education, health care, housing, social services, or parks and recreation."
- Section 504 can be enforced by a private citizen or by the Department of Justice. In order to prevail on a Section 504 claim, a plaintiff must establish that "(1) [they are] an individual with a disability; (2) [they are] otherwise qualified to receive [a certain] benefit; (3) [they were] denied the benefits of [a certain] program solely by reason of [their] disability; and (4) the program receives federal financial assistance" (*Updike v. Multnomah* County, 870 F.3d 939, 949 (9th Cir. 2017)).
- Whether the conduct of a program or activity amounts to a violation of Section 504 is highly fact specific. For example, in *Bax v. Drs. Med. Ctr. of Modesto*, Inc., 48 F.4th 1008 (9th Cir. 2022), the 9th Circuit Court of Appeals considered an appeal related to a Section 504 claim and made clear, on multiple occasions, that whether Section 504 was violated is a fact-intensive exercise (*Bax* at 1016 and 1018) and that ultimately the district court in this matter had engaged in "precisely the sort of fact-intensive exercise our precedent requires" by hearing testimony from nine witnesses and considering 132 exhibits (*Id.* at 1014 and 1018).

Title III of the American with Disabilities Act (42 U.S.C. §§ 12181 to 12189; 28 C.F.R. Pt. 36)

- Title III of the ADA provides that no individual can be discriminated against on the basis of disability in the full and equal enjoyment of the goods, services, facilities, privileges, advantages, or accommodations of any place of public accommodation by any person, or private entity, who owns, leases (or leases to), or operates a place of public accommodation. A place of public accommodation includes a pharmacy (42 U.S.C. § 1281(7)).

- Title III regulations identify three broad principles that underlie the nondiscrimination requirements. These include: (1) equal opportunity to participate; (2) equal opportunity to benefit; and (3) receipt of benefits in the most integrated setting appropriate (28 C.F.R. §§ 36.202-203).
- In addition to these three broad principles, there are also federal requirements that address specific factual situations. For example, 28 C.F.R. § 36.303 addresses the requirement that a public accommodation "shall take those steps that may be necessary to ensure that no individual with a disability is excluded, denied services, segregated or otherwise treated differently than other individuals ***because of the absence of auxiliary aids and services***, unless the public accommodation can demonstrate that taking those steps would fundamentally alter the nature of the goods, services, facilities, privileges, advantages, or accommodations being offered or would result in an undue burden, i.e., significant difficulty or expense." According to the ADA Technical Assistance Manual, "if a specific requirement applies, it controls over the general requirement".
- The ADA can be enforced either by private suits by individuals who are subjected to discrimination or have reasonable grounds for believing they are about to be subjected to discrimination (28 C.F.R. § 36.501); or by the Department of Justice if a person or persons have engaged in a pattern or practice of discrimination or a person has been discriminated against and the discrimination raises an issue of general public importance (28 C.F.R. § 36.503).

Assessment:

In addition to the commission's future accessible labeling rules, there are several federal laws covering the same or similar subject matter that may also be applicable to facilities licensed by the commission.

Recommendation:

Staff recommends ensuring that the commission's rules on accessible labeling make clear that its rules do not in any way restrict the application of the federal laws mentioned here or any other applicable federal laws.

Follow-up Action:

Staff will proceed as directed.

Prescription Label Accessibility Requirements	LEP Patients *Written Translation*		LEP Patients *Oral Interpretation*		Visually Impaired Patients		Print Disabled Patients	
	Commission Decision*	Federal Statute**	Commission Decision	Federal Statute	Commission Decision	Federal Statute	Commission Decision	Federal Statute
Name of the Dispensing Pharmacy RCW 18.64.246(1)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Name of the Prescriber RCW 18.64.246(1) & RCW 69.41.050(1)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Prescription Number RCW 18.64.246(1)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Drug Name RCW 69.41.050(1)	Not Required	Maybe	Not Required	Maybe	**Required**	Maybe	**Required**	Maybe
Drug Strength per Unit Dose RCW 69.41.050(1)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Complete Directions of Use RCW 69.41.050(1)	**Required**	Maybe	**Required**	Maybe	**Required**	Maybe	**Required**	Maybe
Patient Name/Species WAC 246-945-016(1)(d) & RCW 69.41.050(1)	Not Required	Maybe	Not Required	Maybe	**Required**	Maybe	**Required**	Maybe
Date Provided RCW 69.41.050(1)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe

***The commission determined its accessibility stance on the described prescription label elements at its May 5, 2023 business meeting.

****Federal statutes relating to accessibility services for entities such as pharmacies include Title III of the Americans with Disabilities Act (ADA), Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973. **This is not an exhaustive list of federal law that guides the provision of accessibility options.**

Prescription Label Accessibility Requirements (cont.)	LEP Patients *Written Translation*		LEP Patients *Oral Interpretation*		Visually Impaired Patients		Print Disabled Patients	
	Commission Decision*	Federal Statute**	Commission Decision	Federal Statute	Commission Decision	Federal Statute	Commission Decision	Federal Statute
Number of Refills WAC 246-945-016(1)(b)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Warning Statement WAC 246-945-016(1)(c)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Expiration/BUD Date RCW 18.64.246(1)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Patient Authorization WAC 246-945-016(1)(e)	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Drug Quantity WAC 246-945-016(1)(a)	Not Required	Maybe	Not Required	Maybe	**Required**	Maybe	**Required**	Maybe
Auxiliary Directions	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Miscellaneous Warning Labels	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
Counseling Info WAC 246-945-325	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe	Not Required	Maybe
WAC 246-945-016(2) Special Note: Compounded product must meeting labeling requirements in USP <795>, <797>, <800>, and <825>								

*The commission determined its accessibility stance on the described prescription label elements at its May 5, 2023 business meeting.

Federal statutes relating to accessibility services for entities such as pharmacies include Title III of the Americans with Disabilities Act (ADA), Title VI of the Civil Rights Act of 1964, and Section 504 of the Rehabilitation Act of 1973. **This is not an exhaustive list of federal law that guides the provision of accessibility options.

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.

From California Board of Pharmacy Website at
https://www.pharmacy.ca.gov/publications/translations.shtml

Translations of Pill Directions as Specified in 16 California Code of Regulations Section 1707.5

Requirement

Being able to read a prescription label is an essential element of being able to understand how to take medication appropriately.

In January 2016 new California requirements for prescription labels took effect that establish a mechanism by which patients with limited English skills may often obtain translated directions on their prescription container labels or as a supplement to the label.

This law was authored by Assembly Member Ting as AB 1073, and amends Business and Professions Code sections 4076 and 4199 and creates new section 4076.6.

4076.6. Patient-Centered Prescription Labels; Translated Directions for Use; Requirements
(a) Upon the request of a patient or patient's representative, a dispenser shall provide translated directions for use, which shall be printed on the prescription container, label, or on a supplemental document. If translated directions for use appear on a prescription container or label, the English-language version of the directions for use shall also appear on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. When it is not possible for the English-language directions for use to appear on the container or label, it shall be provided on a supplemental document.
(b) A dispenser may use translations made available by the board pursuant to subdivision (b) of Section 1707.5 of Title 16 of the California Code of Regulations to comply with this section.
(c) A dispenser shall not be required to provide translated directions for use beyond the languages that the board has made available or beyond the directions that the board has made available in translated form.
(d) A dispenser may provide his or her own translated directions for use to comply with the requirements of this section, and nothing in this section shall be construed to prohibit a dispenser from providing translated directions for use in languages beyond those that the board has made available or beyond the directions that the board has made available in translated form.
(e) A dispenser shall be responsible for the accuracy of the English-language directions for use provided to the patient. This section shall not affect a dispenser's existing responsibility to correctly label a prescription pursuant to Section 4076.
(f) For purposes of this section, a dispenser does not include a veterinarian.
(Added by Stats. 2015, Ch. 784, Sec. 2. Effective January 1, 2016.)

The law recognizes that many dispensers already provide translations on prescription containers. The enacted legislation allows this practice to continue.
The requirements of the new law implement three concepts:

1. A pharmacist shall use professional judgment when selecting the wording of directions that appear on a prescription container label in any language.

The specific requirement is:

4076(e) A pharmacist shall use professional judgment to provide a patient with directions for use that enhance the patient's understanding of those directions, consistent with the prescriber's instructions.

2. A dispenser shall provide translated directions for use on a prescription container when requested by the patient or a patient's representative, provided:

a)The appropriate direction is among the 15 standardized directions for use that have been translated and made available on the board's website in Spanish, Vietnamese, Korean, Russian and Chinese [see the translations below.], and the pharmacist believes the direction for use is appropriate.
Translations into additional languages or translations of additional directions are not required.

b)The dispenser may provide its own translations in place of the translations available from the board, And

c)The dispenser is responsible for the accuracy of the English directions provided to the patient.

3. The translated direction should, whenever possible, appear in the patient-centered area of the prescription container label. When this occurs, the English version should appear whenever possible on the prescription container label outside the patient-centered area. When the English translation cannot be printed on the prescription container, the English translation may be provided on a supplemental sheet.

A translated direction may be provided on a supplemental sheet when it cannot be added to the prescription container label. In this case, the patient-centered area of the label shall contain the English version of the direction.

Press Release Announcing the New 2016 Requirement for Prescription Labels

Disclaimer

The California Endowment, in an effort to support quality labels for those who do not read English, funded a project with national patient literacy researchers to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. While every effort was made to ensure accuracy and reliability of these translations, the Board cannot ensure that a particular translation is appropriate for a particular patient. The

Board recommends that each pharmacy and pharmacist confirm the validity and the medical appropriateness of any given translation for a particular patient before using it for the patient's drug label.

Translations

- Chinese
- Farsi
- Korean
- Russian
- Spanish
- Vietnamese

From: ***https://www.pharmacy.ca.gov/publications/labels_press_release.shtml***

Patients Can Now Request Translations on the Directions for Use on Certain Prescription Labels

On February 10, 2016, the board released the press release announcing the new 2016 requirement for prescription labels. The press release was translated into Chinese, Korean, Russian, Spanish and Vietnamese. The press release was sent to over 800 media outlets including:

- 499 media outlets received the English and translated press releases
- 272 media outlets received the Spanish translated press release
- 33 media outlets received the Chinese translated press release
- 17 media outlets received the Vietnamese translated press release
- 12 media outlets received the Korean translated press release
- 3 media outlets received the Russian translated press release

NEWS RELEASE
February 10, 2016
CONTACT: Debbie Damoth
(916) 574-7935

Translations on Prescription Drug Labels Patients Can Now Request Translations on the Directions for Use on Certain Prescriptions Labels

Being able to read a prescription label is an essential element of being able to understand how to take medication appropriately.

In January 2016 new California requirements for prescription labels took effect that establish a mechanism by which patients with limited English skills may often obtain translated directions on their prescription container labels or as a supplement to the label.

This law was sponsored by the California Board of Pharmacy and authored by Assembly Member Ting as AB 1073.

The law recognizes that many dispensers already provide translations on prescription containers and the enacted legislation allows this practice to continue. This law creates another opportunity for consumers to receive translations. Consumers interested in receiving such translations should request this service from their pharmacy.

In some cases, a translation may not be available for the pharmacy to provide. In such cases, the board strongly encourages consumers to use the free interpreter services available at the pharmacy to ensure they understand how to safely take medications.

Additional information about this new law as well as other changes to pharmacy law can be found on the board's website via the following link
- https://www.pharmacy.ca.gov/laws_regs/new_laws.pdf

From California Rules:
https://www.pharmacy.ca.gov/laws_regs/pharmacy_lawbook.shtml

1707.5. Patient-Centered Labels for Prescription Drug Containers; Requirements
(a)Labels on drug containers dispensed to patients in California shall conform to the following format:
(1) Each of the following items, and only these four items, shall be clustered into one area of the label that comprises at least 50 percent of the label. Each item shall be printed in at least a 12point sans serif typeface, and listed in the following order:
(A) Name of the patient
(B) Name of the drug and strength of the drug. For the purposes of this section, "name of the drug" means either the manufacturer's trade name of the drug, or the generic name and the statement "generic for _____" where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist,
(i)If the brand name is no longer widely used, the label may list only the generic name of the drug, and
(ii)The manufacturer's name may be listed outside of the patient-centered area.
(C)The directions for the use of the drug.
(D)The condition or purpose for which the drug was prescribed if the condition or purpose is indicated on the prescription.
(2)For added emphasis, the label shall also highlight in bold typeface or color, or use blank space to set off the items listed in subdivision (a)(1).
(3)The remaining required elements for the label specified in section 4076 of the Business and Professions Code, as well as any other items of information appearing on the label or the container, shall be printed so as not to interfere with the legibility or emphasis of the primary elements specified in paragraph (1) of subdivision (a). These additional elements may appear in any style, font, and size typeface.
(4) When applicable, directions for use shall use one of the following phrases:
(A)Take 1 [insert appropriate dosage form] at bedtime
(B)Take 2 [insert appropriate dosage form] at bedtime
(C)Take 3 [insert appropriate dosage form] at bedtime
(D)Take 1 [insert appropriate dosage form] in the morning
(E)Take 2 [insert appropriate dosage form] in the morning
(F)Take 3 [insert appropriate dosage form] in the morning
(G)Take 1 [insert appropriate dosage form] in the morning, and Take 1 [insert appropriate dosage form] at bedtime
(H)Take 2 [insert appropriate dosage form] in the morning, and Take 2 [insert appropriate dosage form] at bedtime
(I)Take 3 [insert appropriate dosage form] in the morning, and Take 3 [insert appropriate dosage form] at bedtime
(J)Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, and l [insert appropriate dosage form] in the evening
(K)Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, and 2 [insert appropriate dosage form] in the evening

(L)Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, and 3 [insert appropriate dosage form] in the evening
(M)Take 1 [insert appropriate dosage form] in the morning, 1 [insert appropriate dosage form] at noon, 1 [insert appropriate dosage form] in the evening, and 1 [insert appropriate dosage form] at bedtime
(N)Take 2 [insert appropriate dosage form] in the morning, 2 [insert appropriate dosage form] at noon, 2 [insert appropriate dosage form] in the evening, and 2 [insert appropriate dosage form] at bedtime
(O)Take 3 [insert appropriate dosage form] in the morning, 3 [insert appropriate dosage form] at noon, 3 [insert appropriate dosage form] in the evening, and 3 [insert appropriate dosage form] at bedtime
(P)If you have pain, take __ [insert appropriate dosage form] at a time. Wait at least __ hours before taking again. Do not take more than __ [appropriate dosage form] in one day
(b)By October 2011, and updated as necessary, the board shall publish on its Web site translation of the directions for use listed in subdivision (a)(4) into at least five languages other than English, to facilitate the use thereof by California pharmacies.
(c)The board shall collect and publish on its Web site examples of labels conforming to these requirements, to aid pharmacies in label design and compliance.
(d)The pharmacy shall have policies and procedures in place to help patients with limited or no English proficiency understand the information on the label as specified in subdivision (a) in the patient's language. The pharmacy's policies and procedures shall be specified in writing and shall include, at minimum, the selected means to identify the patient's language and to provide interpretive services and translation services in the patient's language. The pharmacy shall, at minimum, provide interpretive services in the patient's language, if interpretive services in such language are available, during all hours that the pharmacy is open, either in person by pharmacy staff or by use of a third-party interpretive service available by telephone at or adjacent to the pharmacy counter.
(e) As used in this section, “appropriate dosage form” includes pill, caplet, capsule or tablet. Authority cited: Sections 4005 and 4076.5, Business and Professions Code. Reference: Sections 4005, 4076, and 4076.5, Business and Professions Code.

1707.6. Notice to Consumers

(a)In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as: (1) The video screen is at least 24 inches, measured diagonally; (2) The pharmacy utilizes the video image notice provided by the board; (3) The text of the notice remains on the screen for a minimum of 60 seconds; and (4) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays. The pharmacy may seek approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval.

(b)The notice shall contain the following text:

NOTICE TO CONSUMERS

California law requires a pharmacist to speak with you every time you get a new prescription.

You have the right to ask for and receive from any pharmacy prescription drug labels in 12-point font. **Interpreter** services are available to you upon request at no cost. **Before** taking your medicine, be sure you know: the name of the medicine and what it does; how and when to take it, for how long, and what to do if you miss a dose; possible side effects and what you should do if they occur; whether the new medicine will work safely with other medicines or supplements; and what foods, drinks, or activities should be avoided while taking the medicine. Ask the pharmacist if you have any questions. **This** pharmacy must provide any medicine or device legally prescribed for you, unless it is not covered by your insurance; you are unable to pay the cost of a copayment; or the pharmacist determines doing so would be against the law or potentially harmful to health. If a medicine or device is not immediately available, the pharmacy will work with you to help you get your medicine or device in a timely manner. **You** may ask this pharmacy for information on drug pricing and use of generic drugs.
(c)Every pharmacy, in a place conspicuous to and readable by a prescription drug consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or furnished, shall post or provide a notice containing the following text:

Point to your language. Interpreter services will be provided to you upon request at no cost.

This text shall be repeated in at least the following languages: Arabic, Armenian, Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and Vietnamese. Each pharmacy shall use the standardized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. The pharmacy may post this notice in paper form or on a video screen if the posted notice or video screen is positioned so that a consumer can easily point to and touch the statement identifying the language in which he or she requests assistance. Otherwise, the notice shall be made available on a flyer or handout clearly visible from and kept within easy reach of each counter in the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches. Note: Authority cited: Sections 4005 and 4122, Business and Professions Code. Reference: Sections 733, 4005, 4076.5 and 4122, Business and Professions Code.

DISCLAIMER

The California Endowment, in an effort to support quality labels for those who do not read English, funded a project with national patient literacy researchers to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. While every effort was made to ensure accuracy and reliability of these translations, the Board cannot ensure that a particular translation is appropriate for a particular patient. The Board recommends that each pharmacy and pharmacist confirm the validity and the medical appropriateness of any given translation for a particular patient before using it for the patient's drug label.

ENGLISH	CHINESE
Take 1 pill at bedtime	睡前服一粒藥丸
Take 2 pills at bedtime	睡前服兩粒藥丸
Take 3 pills at bedtime	睡前服三粒藥丸
Take 1 pill in the morning	早上服一粒藥丸
Take 2 pills in the morning	早上服兩粒藥丸
Take 3 pills in the morning	早上服三粒藥丸
Take 1 pill in the morning and 1 pill at bedtime	早上服一粒藥丸和 睡前服一粒藥丸
Take 2 pills in the morning and 2 pills at bedtime	早上服兩粒藥丸和 睡前服兩粒藥丸
Take 3 pills in the morning and 3 pills at bedtime	早上服三粒藥丸和 睡前服三粒藥丸
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	早上服一粒藥丸 中午服一粒藥丸和 傍晚服一粒藥丸
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	早上服兩粒藥丸 中午服兩粒藥丸和 傍晚服兩粒藥丸
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	早上服三粒藥丸 中午服三粒藥丸和 傍晚服三粒藥丸
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	早上服一粒藥丸 中午服一粒藥丸和 睡前服一粒藥丸
Take 2 pills in the morning 2 pills at noon and	早上服兩粒藥丸 中午服兩粒藥丸和

2 pills at bedtime	睡前服兩粒藥丸
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	早上服三粒藥丸 中午服三粒藥丸和 睡前服三粒藥丸

English	Farsi
Take 1 pill at bedtime	وقت خواب 1 قرص مصرف کنید
Take 2 pills at bedtime	وقت خواب 2 قرص مصرف کنید
Take 3 pills at bedtime	وقت خواب 3 قرص مصرف کنید
Take 1 pill in the morning	صبح‌ها 1 قرص مصرف کنید
Take 2 pills in the morning	صبح‌ها 2 قرص مصرف کنید
Take 3 pills in the morning	صبح‌ها 3 قرص مصرف کنید
Take 1 pill in the morning and 1 pill at bedtime	1 قرص صبح و 1 قرص وقت خواب مصرف کنید
Take 2 pills in the morning and 2 pills at bedtime	2 قرص صبح و 2 قرص وقت خواب مصرف کنید
Take 3 pills in the morning and 3 pills at bedtime	3 قرص صبح و 3 قرص وقت خواب مصرف کنید
Take 1 pill in the morning, 1 pill at noon and 1 pill in the evening	1 قرص صبح، 1 قرص ظهر و 1 قرص شب مصرف کنید
Take 2 pills in the morning, 2 pills at noon and 2 pills in the evening	2 قرص صبح، 2 قرص ظهر و 2 قرص شب مصرف کنید
Take 3 pills in the morning, 3 pills at noon and 3 pills in the evening	3 قرص صبح، 3 قرص ظهر و 3 قرص شب مصرف کنید
Take 1 pill in the morning, 1 pill at noon and 1 pill at bedtime	1 قرص صبح، 1 قرص ظهر و 1 قرص وقت خواب مصرف کنید

DISCLAIMER

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ENGLISH	KOREAN
Take 1 pill at bedtime	취침 전 1 알을 복용하십시오
Take 2 pills at bedtime	취침 전 2 알을 복용하십시오
Take 3 pills at bedtime	취침 전 3 알을 복용하십시오
Take 1 pill in the morning	아침에 1 알을 복용하십시오
Take 2 pills in the morning	아침에 2 알을 복용하십시오
Take 3 pills in the morning	아침에 3 알을 복용하십시오
Take 1 pill in the morning and 1 pill at bedtime	아침에 1 알, 취침 전 1 알씩 복용하십시오
Take 2 pills in the morning and 2 pills at bedtime	아침에 2 알, 취침 전 2 알씩 복용하십시오
Take 3 pills in the morning and 3 pills at bedtime	아침에 3 알, 취침 전 3 알씩 복용하십시오
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	아침에 1 알, 정오에 1 알, 저녁에 1 알씩 복용하십시오
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	아침에 2 알, 정오에 2 알, 저녁에 2 알씩 복용하십시오
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	아침에 3 알, 정오에 3 알, 저녁에 3 알씩 복용하십시오
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	아침에 1 알, 정오에 1 알, 취침 전 1 알씩 복용하십시오
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	아침에 2 알, 정오에 2 알, 취침 전 2 알씩 복용하십시오
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	아침에 3 알, 정오에 3 알, 취침 전 3 알씩 복용하십시오

DISCLAIMER

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ENGLISH	RUSSIAN
Take 1 pill at bedtime	Принимать по 1 таблетке перед сном
Take 2 pills at bedtime	Принимать по 2 таблетки перед сном
Take 3 pills at bedtime	Принимать по 3 таблетки перед сном
Take 1 pill in the morning	Принимать по 1 таблетке утром
Take 2 pills in the morning	Принимать по 2 таблетки утром
Take 3 pills in the morning	Принимать по 3 таблетки утром
Take 1 pill in the morning and 1 pill at bedtime	Принимать по 1 таблетке утром и по 1 таблетке перед сном
Take 2 pills in the morning and 2 pills at bedtime	Принимать по 2 таблетки утром и по 2 таблетки перед сном
Take 3 pills in the morning and 3 pills at bedtime	Принимать по 3 таблетки утром и по 3 таблетки перед сном
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	Принимать по 1 таблетке утром, по 1 таблетке в полдень и по 1 таблетке вечером
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	Принимать по 2 таблетки утром, по 2 таблетки в полдень и по 2 таблетки вечером
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	Принимать по 3 таблетки утром, по 3 таблетки в полдень и по 3 таблетки вечером
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	Принимать по 1 таблетке утром, по 1 таблетке в полдень, по 1 таблетке перед сном
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	Принимать по 2 таблетки утром, по 2 таблетки в полдень, по 2 таблетки перед сном
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	Принимать по 3 таблетки утром, по 3 таблетки в полдень, по 3 таблетки перед сном

DISCLAIMER

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ENGLISH	SPANISH
Take 1 pill at bedtime	Tome 1 pastilla a la hora de acostarse
Take 2 pills at bedtime	Tome 2 pastillas a la hora de acostarse
Take 3 pills at bedtime	Tome 3 pastillas a la hora de acostarse
Take 1 pill in the morning	Tome 1 pastilla por la mañana
Take 2 pills in the morning	Tome 2 pastillas por la mañana
Take 3 pills in the morning	Tome 3 pastillas por la mañana
Take 1 pill in the morning and 1 pill at bedtime	Tome 1 pastilla por la mañana y Tome 1 pastilla a la hora de acostarse
Take 2 pills in the morning and 2 pills at bedtime	Tome 2 pastillas por la mañana y Tome 2 pastillas a la hora de acostarse
Take 3 pills in the morning and 3 pills at bedtime	Tome 3 pastillas por la mañana y Tome 3 pastillas a la hora de acostarse
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	Tome 1 pastilla por la mañana, 1 pastilla al mediodía y 1 pastilla al atardecer
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	Tome 2 pastillas por la mañana, 2 pastillas al mediodía y 2 pastillas al atardecer
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	Tome 3 pastillas por la mañana, 3 pastillas al mediodía y 3 pastillas al atardecer
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	Tome 1 pastilla por la mañana, 1 pastilla al mediodía, 1 pastilla a la hora de acostarse
Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	Tome 2 pastillas por la mañana, 2 pastillas al mediodía, 2 pastillas a la hora de acostarse
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	Tome 3 pastillas por la mañana, 3 pastillas al mediodía, 3 pastillas a la hora de acostarse

DISCLAIMER

The California Endowment, in an effort to support quality labels for those who do not read English, funded a project with national patient literacy researchers to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. While every effort was made to ensure accuracy and reliability of these translations, the Board cannot ensure that a particular translation is appropriate for a particular patient. The Board recommends that each pharmacy and pharmacist confirm the validity and the medical appropriateness of any given translation for a particular patient before using it for the patient's drug label.

ENGLISH	VIETNAMESE
Take 1 pill at bedtime	Uống 1 viên trước khi đi ngủ
Take 2 pills at bedtime	Uống 2 viên trước khi đi ngủ
Take 3 pills at bedtime	Uống 3 viên trước khi đi ngủ
Take 1 pill in the morning	Uống 1 viên vào buổi sáng
Take 2 pills in the morning	Uống 2 viên vào buổi sáng
Take 3 pills in the morning	Uống 3 viên vào buổi sáng
Take 1 pill in the morning and 1 pill at bedtime	Uống 1 viên vào buổi sáng và 1 viên trước khi đi ngủ
Take 2 pills in the morning and 2 pills at bedtime	Uống 2 viên vào buổi sáng và 2 viên trước khi đi ngủ
Take 3 pills in the morning and 3 pills at bedtime	Uống 3 viên vào buổi sáng và 3 viên trước khi đi ngủ
Take 1 pill in the morning 1 pill at noon and 1 pill in the evening	Uống 1 viên vào buổi sáng, 1 viên vào buổi trưa, và 1 viên vào buổi tối
Take 2 pills in the morning 2 pills at noon and 2 pills in the evening	Uống 2 viên vào buổi sáng, 2 viên vào buổi trưa, và 2 viên vào buổi tối
Take 3 pills in the morning 3 pills at noon and 3 pills in the evening	Uống 3 viên vào buổi sáng, 3 viên vào buổi trưa, và 3 viên vào buổi tối
Take 1 pill in the morning 1 pill at noon and 1 pill at bedtime	Uống 1 viên vào buổi sáng, 1 viên vào buổi trưa, và 1 viên trước khi đi ngủ

Take 2 pills in the morning 2 pills at noon and 2 pills at bedtime	Uống 2 viên vào buổi sáng, 2 viên vào buổi trưa, và 2 viên trước khi đi ngủ
Take 3 pills in the morning 3 pills at noon and 3 pills at bedtime	Uống 3 viên vào buổi sáng, 3 viên vào buổi trưa, và 3 viên trước khi đi ngủ

Oregon Law

ORS 689.564

Language requirements for prescription drug labels

(1)

The State Board of Pharmacy shall adopt rules to require that, if a patient is of limited English proficiency and the prescribing practitioner, patient or an authorized representative of the patient so requests, a prescription drug dispensed by a pharmacy bear a label in both English and in the language requested and, if authorized by the board by rule, include an informational insert in both English and the language requested. The rules adopted under this section must:

(a)

Define "limited English proficiency."

(b)

Determine the pharmacies to which the requirements of this section apply, and include at least retail drug outlets and other drug outlets that dispense prescription drugs.

(c)

Determine for which prescription drugs it is appropriate to include an informational insert in addition to the label. In adopting rules under this paragraph, the board shall consider the complexity and length of the directions for use of the prescription drug.

(d)

Intentionally left blank —Ed.

(A)

Require that labels and informational inserts be available in at least 14 languages other than English that are spoken in Oregon by individuals who are of limited English proficiency, as determined by the most recent American Community Survey from the United States Census Bureau and in consultation with the Oregon Health Authority and other necessary resources.

(B)

Require the board to reassess, and update as necessary, the languages described in this paragraph at least once every 10 years, in consultation with the authority and other stakeholders.

(2)

Intentionally left blank —Ed.

(a)

A pharmacy may contract with a third party for the translation of the labels and informational inserts required under subsection (1) of this section.

(b)

A pharmacy, pharmacist or pharmacy intern that dispenses a prescription drug in compliance with the requirements of subsection (1) of this section may not be held liable for injuries resulting from the actions of a third party if the pharmacy from which the label or informational insert was dispensed entered into a contract with the third party in good faith, and the pharmacy, pharmacist or pharmacy intern was not negligent with regard to the alleged misconduct of the third party.

(3)

This section does not apply to an institutional drug outlet.

(4)

The board may adopt other rules as necessary to carry out this section.

(5)

The board shall, in consultation with the Oregon Health Authority, adopt rules to require that a pharmacy post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency. Rules adopted under this subsection must comply with any relevant federal laws and regulations. [2019 c.465 §2]

Source: Section 689.564 — Language requirements for prescription drug labels; exceptions; interpretation and translation services; rules, https://www.oregonlegislature.gov/bills_laws/ors/ors689.html (last updated Jun. 16, 2023).

Chapter 855

Division 41
OPERATION OF PHARMACIES

855-041-1132
Limited English Proficiency and Accessibility

(1) Upon request of a prescriber, patient or a patient's agent, each drug dispensed by a pharmacy for a patient's self-administration must bear a label in both English and the language requested for an individual with limited English proficiency, defined as a person who is not fluent in the English language. This does not apply to a drug outlet dispensing a drug intended for administration by a healthcare worker.

(2) When dispensing a drug under (1), a pharmacy must provide labels and informational inserts in both English and one of the following languages:

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

(3) The board must reassess and update (2) as necessary and at least every ten years.

Statutory/Other Authority: ORS 689.564
Statutes/Other Implemented: ORS 689.205
History:
BP 99-2020, adopt filed 12/23/2020, effective 01/01/2021

Understanding Oregon's Dual-language Prescription Drug Labeling Law

Contact: Kristen Beiers-Jones, RN, MN 503-810-9059 or beiersjo@ohsu.edu

In 2019, the Oregon Legislature passed SB 698 to require pharmacies to provide dual- language prescription labels in both English and one of Oregon's 14 high-need languages for patients with Limited English Proficiency (LEP). The new law took effect Jan. 1, 2021 (ORS 689.564) and applies to all pharmacies except institutional drug outlets, where medications are not generally self-administered.

The goal was to provide medication instructions *on the bottle* in both English and a language the patient can understand so that it's not confused with other medications or lost. The dual translation allows patients with LEP, pharmacists, providers, and caregivers to all understand medication directions. This will help reduce medication errors and ensure patient and caregiver understanding of critical prescription information.

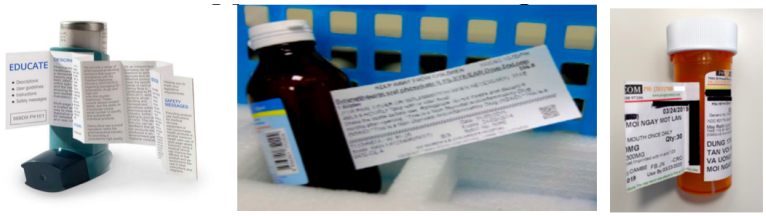
The Oregon Board of Pharmacy (OBOP), in consultation with the Oregon Health Authority (OHA), is tasked with identifying the 14 languages. They are also required to reevaluate the list at least once every 10 years. Currently, the law covers the following languages:

- Spanish (Español)
- Russian (русский)
- Somali (Soomaali)
- Arabic (عربعربي)
- Chinese (simplified) (简体中文)
- Vietnamese (Tiếng Việt)
- Farsi الفبای فارسی
- Korean (한국어)
- Romanian (Română)
- Swahili (Kiswahili)
- Burmese ဗမာစကား
- Nepali (**नेपाली**)
- Amharic **አማርኛ**
- Pashtu پښتو

Posting requirement: The law also requires pharmacies to post signage notifying clients of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency as well as the right to dual-language prescription labels. Pharmacies are responsible for creating and displaying this required signage.

Liability protection for pharmacists: Pharmacies are granted a measure of liability protection under the law. Pharmacies can't be held liable for harms or injuries resulting from a third party (i.e. a translation vendor) if the pharmacy has both a contract with the third party and was not negligent with regard to the alleged misconduct of the third party.

Fitting lengthy directions on the bottle: There are multiple options available when a dual-language label seemingly will not fit on the bottle. This includes using pull out tabs, a larger bottle or folding a second label in half, called "flagging," as seen below:



Cost of translation services: There are several translation service vendors that provide translation service in the 14 required languages. Without offering an endorsement of any vendor, approximate cost comparisons are as follows:

- Rx Tran: 14 languages for $70-$90/month
- IRCO Language Bank: 100 directions in 1 language: $250 one-time payment. This option is a medication translation bank that allows pharmacists to copy and paste translated instructions onto medication labels.
- ScriptAbility by En-Vision America: Starting at $960.00 annually/25 languages - Prices vary with options. Translated sigs and warnings. Unlimited labeling space and multiple font sizes using ScriptView labels. No integration required, but available.
- FDB's Meducation: Multilingual sigs and monographs in over 30 languages. Pricing varies by use and content. Standalone and native workflow integration(s) available.

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New York Law and Regulation

§6829. Interpretation and translation requirements for prescription drugs and standardized medication labeling.

1. For the purposes of this section, the following terms shall have the following meanings:
    a. "Covered pharmacy" means any pharmacy that is part of a group of eight or more pharmacies, located within New York state and owned by the same corporate entity. For purposes of this section, "corporate entity" shall include related subsidiaries, affiliates, successors, or assignees doing business as or operating under a common name or trading symbol.
    b. "Limited English proficient individual" or "LEP individual" means an individual who identifies as being, or is evidently, unable to speak, read or write English at a level that permits such individual to understand health-related and pharmaceutical information communicated in English.
    c. "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 that accompanies his or her medication.
    d. "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 pharmacy primary language.
    e. "Pharmacy primary languages" shall mean those languages spoken by one percent or more of the population, as determined by the U.S. Census, for each region, as established by regulations promulgated pursuant to this section, provided, however, that the regulations shall not require translation or competent oral interpretation of more than seven languages in any region.
    f. "Mail order pharmacy" shall mean a pharmacy that dispenses most of its prescriptions through the United States postal service or other delivery system.
2.
    a. Every covered pharmacy shall provide free, competent oral interpretation services and translation services to each LEP individual requesting such

services or filling a prescription that indicates that the individual is limited English proficient at such covered pharmacy in the LEP individual's preferred pharmacy primary language for the purposes of counseling such individual about his or her prescription medications or when soliciting information necessary to maintain a patient medication profile, unless the LEP individual is offered and refuses such services.

b. Every covered pharmacy shall provide free, competent oral interpretation services and translation services of prescription medication labels, warning labels and other written material to each LEP individual filling a prescription at such covered pharmacy, unless the LEP individual is offered and refuses such services or the medication label, warning labels and other written materials have already been translated into the language spoken by the LEP individual.

c. The services required by this section may be provided by a staff member of the pharmacy or a third-party contractor. Such services must be provided on an immediate basis but need not be provided in-person or face-to-face in order to meet the requirements of this section.

3. Every covered pharmacy shall conspicuously post, at or adjacent to each counter over which prescription drugs are sold, a notification of the right to free, competent oral interpretation services and translation services for limited English proficient individuals as provided for in subdivision two of this section. Such notifications shall be provided in the pharmacy primary languages. The size, style and placement of such notice shall be determined in accordance with rules promulgated pursuant to this section.

4. The commissioner, in consultation with the commissioner of health, shall promulgate regulations requiring that mail order pharmacies conducting business in the state provide free, competent oral interpretation services and translation services to persons filling a prescription through such mail order pharmacies whom are identified as LEP individuals. Such regulations shall take effect one year after the effective date of this section; provided, however, that they shall be promulgated pursuant to the requirements of the state administrative procedure act, address the concerns of affected stakeholders, and reflect the findings of a thorough analysis of issues including:

a. how persons shall be identified as an LEP individual, in light of the manner by which prescriptions are currently received by such mail order pharmacies;

b. which languages shall be considered;

c. the manner and circumstances in which competent oral interpretation services and translation services shall be provided;

d. the information for which competent oral interpretation services and translation services shall be provided;
e. anticipated utilization, available resources, and cost considerations; and
f. standards for monitoring compliance with regulations and ensuring the delivery of quality competent oral interpretation services and translation services.

The commissioner, in consultation with the commissioner of health, shall provide a report on implementation, utilization, unanticipated problems, and corrective actions undertaken and planned to the temporary president of the senate and the speaker of the assembly no later than two years after the effective date of this section.

5. Covered pharmacies shall not be liable for injuries resulting from the actions of third-party contractors taken pursuant to and within the scope of the contract with the covered pharmacy as long as the covered pharmacy entered into such contract reasonably and in good faith to comply with this section, and was not negligent with regard to the alleged misconduct of the third-party contractor.
6. The regulations promulgated pursuant to this section shall establish a process by which covered pharmacies may apply and receive a waiver from compliance with subdivisions two and three of this section upon a showing that implementation would be unnecessarily burdensome when compared to the need for such services.
7. The commissioner shall promulgate regulations in consultation with the commissioner of health to effectuate the requirements of this section.

§63.11 Interpretation and translation requirements for prescription drugs

a. Definitions. As used in this section:
    1. Covered pharmacy shall mean any pharmacy that is part of a group of eight or more pharmacies, located within New York State and owned by the same corporate entity.
    2. Corporate entity shall include related subsidiaries, affiliates, successors, or assignees doing business as or operating under a common name or trading symbol of the covered pharmacy.

3. Limited English proficient individual or LEP individual shall mean an individual who identifies as being, or is evidently, unable to speak, read or write English at a level that permits such individual to understand health-related and pharmaceutical information communicated in English.
4. 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 that accompanies his or her medication.
5. Competent oral interpretation shall mean an 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 pharmacy primary language.
6. Pharmacy primary languages shall mean those languages, up to a maximum of seven languages other than English, spoken by one percent or more of the population of the State, as determined by the U.S. Census. If more than seven languages other than English are spoken by one percent or more of the population, the pharmacy primary languages shall be limited to seven most spoken languages, as determined by the U.S. Census.
7. Mail order pharmacy shall mean a pharmacy that dispenses most of its prescriptions through the United States postal service or other delivery system.

b. Provision of competent oral interpretation services and translation services. Except as otherwise provided in subdivision (e) of this section:
    1. For purposes of counseling an individual about his or her prescription medications or when soliciting information necessary to maintain a patient medication profile, each covered pharmacy and mail order pharmacy shall provide free, competent oral interpretation services and translation services in such individual’s preferred pharmacy primary language to each LEP individual requesting such services or when filling a prescription that indicates that the individual is limited English proficient at such covered pharmacy or mail order pharmacy, unless the LEP individual is offered and refuses such services.
    2. With respect to prescription medication labels, warning labels and other written materials, each covered pharmacy and mail order pharmacy shall provide free, competent oral interpretation services and translation

services to each LEP individual filling a prescription at such covered pharmacy or mail order pharmacy in such individual's preferred pharmacy primary language, unless the LEP individual is offered and refuses such services or the medication labels, warning labels and other written materials have already been translated into the language spoken by the LEP individual.

3. Translation and competent oral interpretation shall be provided in the preferred pharmacy primary language of each LEP individual, provided that no covered pharmacy or mail order pharmacy shall be required to provide translation or competent oral interpretation of more than seven languages.
4. The services required by this subdivision may be provided by a staff member of the covered pharmacy or mail order pharmacy or a third-party contractor. Such services shall be provided on an immediate basis but need not be provided in-person or face-to-face.

c. Notification relating to language assistance services. Except as otherwise provided in subdivision (e) of this section:

1. In accordance with Education Law section 6829(3), each covered pharmacy shall conspicuously post a notice to inform LEP individuals of their rights to free, competent oral interpretation services and translation services. Such notice shall include the following statement in English and in each of the pharmacy primary languages: "Point to your language. Language assistance will be provided at no cost to you." With each initial transaction with patients seeking mail order services, mail order pharmacies shall provide printed materials in English and in each of the pharmacy primary languages, explaining the availability of competent oral interpretation services and translation services. In addition, mail order pharmacies that are nonresident establishments shall provide any required information pursuant to section 63.8(b)(6) of this Part in English and in each of the pharmacy primary languages.
2. The statement in each of the pharmacy primary languages shall be in 20 point bold face, Arial type in a color that sharply contrasts with the background color of the sign. Each such statement shall be enclosed in a box, and there shall be at least a ¼ inch clear space between adjacent boxes.
3. The statements in each of the pharmacy primary languages shall be printed on one sign that shall be conspicuously displayed at or adjacent to each counter where prescription drug orders are dropped off and where prescriptions are picked up, and near every cash register at which payment is received for prescription drugs. Such signs shall be positioned so that a

consumer can easily point to the statement identifying the language in which such person is requesting assistance.

d. Waivers. An application for a waiver of the provisions of subdivisions (b) and (c) of this section shall be made on a form prescribed by the Department. The burden of substantiating the validity of a request for a waiver shall be on the applicant.
    1. Each application shall be specific to a registered covered pharmacy, regardless of common ownership.
    2. The applicant shall clearly document the financial or physical constraints, threat to other services provided, or other circumstances upon which the request is based.
    3. No waiver shall be granted in the absence of a showing that implementation of the provisions of subdivisions (b) and (c) of this section would be unnecessarily burdensome when compared to the need for the translation and competent oral interpretation services.
    4. The applicant shall identify alternative sources of competent oral interpretation services or translation services available for LEP individuals within a reasonable distance.
    5. In the event a request for waiver is approved, the pharmacy shall post a notice in the pharmacy primary languages informing LEP individuals of alternative sources.
    6. The duration of a waiver shall be one year and may be renewed upon approval of a new waiver application by the department.
e. In accordance with part V of chapter 57 of the Laws of 2012, the provisions of this section shall preempt any contrary local law or ordinance; provided, however, that cities with a population of 100,000 or more may retain or promulgate such local laws or ordinances imposing additional or stricter requirements relating to interpretation services or translation services in pharmacies. Nothing in this section shall diminish or impair any requirement that any pharmacy or pharmacist provide any language assistance, interpretation, or translation under any applicable federal or state law, local law or ordinance (unless preempted by this section), consent decree, or judicial settlement, judgment or order.