Health Impact Review of ESHB 1852
Concerning language requirements for prescription drug labels
(2022 Legislative Session)

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Full review
The full Health Impact Review report is available at:

Acknowledgements

Contents

Executive Summary
ESHB 1852, Concerning language requirements for prescription drug labels
(2022 Legislative Session)

> Evidence indicates that ESHB 1852 has the potential to result in more pharmacies providing translated prescription drug labels and other prescription information, improving access to culturally and linguistically appropriate services for some people with limited English proficiency (LEP), which would likely improve health outcomes and decrease health inequities.

BILL INFORMATION

Sponsors: House Health Care & Wellness (originally sponsored by Representatives Thai, Cody, Gregerson, Macri, Santos, Slatter, Valdez, Pollet, and Riccelli)

Summary of Bill:
- Requires the Pharmacy Quality Assurance Commission (Pharmacy Commission) to adopt rules establishing the requirements for the translation of prescription drug labels and prescription information by July 1, 2024.
- Directs the Pharmacy Commission to determine at least 15 languages for which to provide translations.
- Requires the Pharmacy Commission to adopt rules establishing other accessibility requirements for people who are blind, low vision, or otherwise print disabled for prescription drug labels and prescription information by July 1, 2024.
- Requires the Pharmacy Commission to submit a report to the relevant legislative policy and fiscal committees on the rulemaking progress, including selection of languages and the process for procuring or providing the translations, by July 1, 2023.
- Establishes that the Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine (maximum $1,000) per violation for failure to comply with requirements.

HEALTH IMPACT REVIEW

Summary of Findings:
This Health Impact Review found the following evidence for relevant provisions in ESHB 1852:

- **Informed assumption** that requiring the Pharmacy Commission to adopt rules establishing requirements for the translation of prescription drug labels and other prescription information would result in the Commission undertaking rulemaking and establishing translation requirements. This assumption is based on information from Pharmacy Commission staff.
- **Informed assumption** that the Pharmacy Commission undertaking rulemaking and establishing requirements for the translation of prescription drug labels and other prescription information would likely result in more pharmacies providing translated materials in the languages determined in rule. This assumption is based on information from key informants

and research on New York State's implementation of prescription label translation requirements.

- **Informed assumption** that more pharmacies providing translated prescription drug labels and other prescription information would result in improved language access to pharmacy services and prescription information for some people with limited English proficiency (LEP). This assumption is based on U.S. Department of Health and Human Services standards, National Council on Interpreting in Health Care recommendations, and information from key informants.
- **A fair amount of evidence** that improving language access to pharmacy services and prescription information for some people with LEP would improve health outcomes.
- **Strong evidence** that improving health outcomes would decrease health inequities for people with LEP.

Introduction and Methods

A Health Impact Review is an analysis of how a proposed legislative or budgetary change will likely impact health and health disparities in Washington State (RCW 43.20.285). For the purpose of this review 'health disparities' have been defined as differences in disease, death, and other adverse health conditions that exist between populations (RCW 43.20.270). Differences in health conditions are not intrinsic to a population; rather, inequities are related to social determinants (e.g. access to healthcare, economic stability, racism, etc.). This document provides summaries of the evidence analyzed by State Board of Health staff during the Health Impact Review of Engrossed Substitute House Bill 1852 (ESHB 1852).

Staff analyzed the content of ESHB 1852 and created a logic model depicting possible pathways leading from the provisions of the bill to health outcomes. We consulted with experts and contacted key informants about the provisions and potential impacts of the bill. We conducted an objective review of published literature for each pathway using databases including PubMed, Google Scholar, and University of Washington Libraries. We evaluated evidence using set criteria and determined a strength-of-evidence for each step in the pathway. More information about key informants and detailed methods are available upon request.

The following pages provide a detailed analysis of the bill, including the logic model, summaries of evidence, and annotated references. The logic model is presented both in text and through a flowchart (Figure 1). The logic model includes information on the strength-of-evidence for each pathway. The strength-of-evidence has been established using set criteria and summarized as:

- **Very strong evidence:** There is a very large body of robust, published evidence and some qualitative primary research with all or almost all evidence supporting the association. There is consensus between all data sources and types, indicating that the premise is well accepted by the scientific community.

- **Strong evidence:** There is a large body of published evidence and some qualitative primary research with the majority of evidence supporting the association, though some sources may have less robust study design or execution. There is consensus between data sources and types.

- **A fair amount of evidence:** There is some published evidence and some qualitative primary research with the majority of evidence supporting the association. The body of evidence may include sources with less robust design and execution and there may be some level of disagreement between data sources and types.

- **Expert opinion:** There is limited or no published evidence; however, rigorous qualitative primary research is available supporting the association, with an attempt to include viewpoints from multiple types of informants. There is consensus among the majority of informants.

- **Informed assumption:** There is limited or no published evidence; however, some qualitative primary research is available. Rigorous qualitative primary research was not possible due to time or other constraints. There is consensus among the majority of informants.

- **No association:** There is some published evidence and some qualitative primary research with the majority of evidence supporting no association or no relationship. The body of evidence may include sources with less robust design and execution and there may be some level of disagreement between data sources and types.

- **Not well researched:** There is limited or no published evidence and limited or no qualitative primary research and the body of evidence has inconsistent or mixed findings, with some supporting the association, some disagreeing, and some finding no connection. There is a lack of consensus between data sources and types.

- **Unclear:** There is a lack of consensus between data sources and types, and the directionality of the association is ambiguous due to potential unintended consequences or other variables.

This review was completed during Legislative Session and was subject to the 10-day turnaround required in statute. This review was subject to time constraints, which influenced the scope of work for this review. The annotated references are only a representation of the evidence and provide examples of current research. In some cases, only a few review articles or meta-analyses are referenced. One article may cite or provide analysis of dozens of other articles. Therefore, the number of references included in the bibliography does not necessarily reflect the strength-of-evidence. In addition, some articles provide evidence for more than one research question, so are referenced multiple times.

Analysis of ESHB 1852 and the Scientific Evidence

Summary of relevant background information
- Washington State law requires that a label be fixed to every box, bottle, jar, tube, or other container of a prescription or legend drug dispensed in the state.[1,2]
    - [RCW 18.64.246](#) requires a prescription drug label include "the name and address of the dispensing pharmacy, the prescription number, the name of the prescriber, the prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date." [1] Additionally, either the prescription label or the pharmacy's record system must document the identification of the licensed pharmacist responsible for each dispensing of medication.[1]
    - [RCW 69.41.050](#) requires that a label for a legend drug include the name of the prescriber, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient, and date.[6]
    - A person who violates either section is guilty of a misdemeanor.[1,2]
- Under [RCW 18.64.005](#), the Pharmacy Quality Assurance Commission (Pharmacy Commission) has the authority to regulate the practice of pharmacy, and the distribution, manufacturing, and delivery of pharmaceuticals within and into Washington State.[3] The Pharmacy Commission "protects and promotes public health and safety by issuing licenses, registrations, and certifications to qualified persons and entities and responding to complaints or reports of unprofessional conduct."[4] It regulates all types of pharmacies in the state (e.g., retail, community, specialty, outpatient hospital, inpatient hospital, long-term care) and those located outside of Washington State that are licensed to provide services to people living in the state (i.e., nonresident pharmacies) (personal communication, Pharmacy Commission, February 2022).
    - [WAC 246-945-016](#) pertains to minimum requirements for outpatient labels on prescriptions.[5] It requires all Pharmacy Commission licensees who dispense legend drugs to outpatients to affix a label to the prescription container that meets requirements listed in RCWs 69.41.050 and 18.64.246 as well as additional requirements outlined in rule (e.g., drug quantity, number of remaining refills).
- The federal government has established requirements for meeting the needs of people with limited English proficiency (LEP) and recommended standards for effective language access. Federal laws include:
    - Title VI of the Civil Rights Act of 1964 "requires recipients of Federal financial assistance to take reasonable steps to make their programs, services, and activities accessible by eligible persons with [LEP]."[6]
    - In 2000, the President signed Executive Order 13166 "Improving Access to Services for Persons with Limited English Proficiency", which requires federal agencies to "examine the services they provide, identify any need for services to those with [LEP], and develop and implement a system to provide those services so LEP persons can have meaningful access to them."[7] Further, the guidance states that recipients of federal financial assistance comply to ensure that their

programs and activities provided in English are also accessible to people with LEP.[7]

- The U.S. Department of Health and Human Services (HHS) lists recipients of federal financial assistance.[8] For example, a pharmacy receiving federal funds for any part of its operation is required to provide meaningful language access services at no cost to people with LEP at all points of service.[9] To provide language access services means that "all parties are provided with high quality spoken and written language communications which allow them to comfortably discuss the patient's health and health care – to ensure meaningful access to services."[9] Language access must also be provided to those responsible for the patient's care (e.g., parents, guardians, relatives, other caretakers).[9]
  - In 2004, HHS developed standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS), with updates in 2014.[9] CLAS "refers to services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs."[10]
  - Section 1557 of the 2010 Patient Protection and Affordable Care Act (ACA) prohibits recipients receiving federal financial assistance from using criteria or methods of administration that effectively discriminate against race, color, or national origin, or substantially impairs a program's objective as it pertains to people of a particular race, color, or national origin.[11]
  - According to the HHS, "[a]lthough [federal] law does not require translation of every document, there are many best practices that could constitute reasonable steps that recipients can take to ensure meaningful access that are cost effective, reduce legal liability, and improve health outcomes."[11]
- Three states require pharmacies to provide translated prescription labels in a language the patient can read and understand when requested by the prescriber, patient, or an authorized representative of the patient.
  - New York State (Education Law § 6829, effective 2013) requires covered pharmacies (i.e., chain pharmacies and mail order pharmacies) to provide free, competent oral interpretation services and translation services of prescription drug labels, warning labels, and other written materials to each person with LEP filling a prescription unless the person is offered and refuses such services.[12,13] Pharmacy primary languages are determined by region (i.e., languages spoken by at least 1% of the population determined by U.S. Census data).[12] However, pharmacies are not required to provide services in more than 7 languages in any region.[12] The law also requires pharmacies to post a notification of the customer's right to translation and interpretation services in the pharmacy primary languages at or adjacent to the prescription drug counter.[12]
  - California (Assembly Bill 1073, effective 2016) requires a medication dispenser to provide translated directions for use on the prescription container, label, or on a supplemental document if requested by a patient or a patient representative.[14]

Medication dispensers must provide dual language instructions (English and the preferred language) on the prescription container or label whenever possible, and if not possible, then dual language instructions must be provided on a supplemental document.[14] Translations are made available in 15 languages by the California State Board of Pharmacy.[14] Results of a 2009 random sample survey of pharmacists in charge of community-based pharmacies indicated that a significant portion of California-based pharmacies were already providing translated multilingual prescription labels for patients with LEP prior to the adoption of this law.[15]

- o Oregon (Senate Bill 698, effective 2021) required the Oregon Board of Pharmacy to adopt rules to require pharmacies to print prescription labels in both English and the language requested.[16] Translated labels are required for 14 languages other than English spoken by 0.2% or more of Oregon's population when requested by a patient with LEP, their authorized representative, or prescribing practitioner.[16] Pharmacies are also required to post signage to provide notification of the right to free, competent interpretation and translation services for patients with LEP.[16]

- As a result of the 2019 Novel Coronavirus (COVID-19) pandemic, pharmacies have worked to provide COVID-19 testing and vaccinations,[17] which has impacted pharmacy wait-times, capacity to fill prescriptions, and staffing (personal communications, February 2022).

Summary of ESHB 1852
- Requires the Pharmacy Commission to adopt rules establishing the requirements for the translation of prescription drug labels and prescription information by July 1, 2024. The rules must:
  - o Require:
    - The translation of the directions for use and any auxiliary warnings on the drug label;
    - The translated version and English language version of the directions for use appear on the container or label; and
    - A pharmacy or nonresident pharmacy provide the translated materials upon the request of a patient, patient's representative, or prescriber.
  - o Establish:
    - The languages for which translation is required;
    - The elements of a prescription drug label or other information that must be translated;
    - The pharmacies and settings that the translation requirements apply to;
    - The process for procuring and providing the translations;
    - When a pharmacy or nonresident pharmacy must provide the translated prescription information; and
    - Any signage that a pharmacy must post to notify consumers of the availability of translated prescription information.

- Directs the Pharmacy Commission to determine at least 15 languages for which to provide translations.
  - Aim to provide translation in all languages spoken by at least 5% of the state population or 1,000 people in Washington State with LEP.
  - Directs the Commission to consult with the Washington State Office of Equity and the Governor's Interagency Council on Health Disparities.
  - Reassess, update, and increase the number of languages at least every 5 years.
- Requires the Pharmacy Commission to adopt rules establishing other accessibility requirements for people who are blind, low vision, or otherwise print disabled for prescription drug labels and prescription information by July 1, 2024.
- Requires the Pharmacy Commission to submit a report to the relevant legislative policy and fiscal committees on the rulemaking progress, including selection of languages and the process for procuring or providing the translations, by July 1, 2023.
- Establishes that the Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine (maximum $1,000) per violation for failure to comply with requirements.

Health impact of ESHB 1852
Evidence indicates that ESHB 1852 has the potential to result in more pharmacies providing translated prescription drug labels and other prescription information, improving access to culturally and linguistically appropriate services for some people with LEP, which would likely improve health outcomes and decrease health inequities.

Pathway to health impacts
The potential pathways leading from the provisions of ESHB 1852 to decreased health inequities are depicted in Figure 1. This review made the informed assumption that requiring the Pharmacy Commission to adopt rules establishing requirements for the translation of prescription drug labels and other prescription information would result in the Commission undertaking rulemaking and establishing translation requirements. This assumption is based on information from Pharmacy Commission staff. This review also made the informed assumption that the Pharmacy Commission undertaking rulemaking and establishing requirements for the translation of prescription drug labels and other prescription information would likely result in more pharmacies providing translated materials in the languages determined in rule. This assumption is based on information from the Pharmacy Commission, the Washington State Pharmacy Association, representatives of Washington State pharmacies, and the Oregon Board of Pharmacy as well as research on New York's implementation of prescription label translation requirements. This review also made the informed assumption that more pharmacies providing translated prescription drug labels and other prescription information would result in improved language access to pharmacy services and prescription information for some people with LEP in Washington State. This assumption is based on U.S. Department of Health and Human Services standards, National Council on Interpreting in Health Care recommendations, and information from key informants. There is a fair amount of evidence that improving language access to pharmacy services and prescription information for some people with LEP would improve health outcomes.[18-29] There is strong evidence that improving health outcomes would decrease health inequities for people with LEP.[20,23,28-31]

Scope
Due to time limitations, we only researched the most direct connections between provisions of the bill and health inequities and did not explore the evidence for all possible pathways. For example, we did not evaluate potential impacts related to:

- Provisions requiring the Pharmacy Commission to adopt rules establishing other accessibility requirements for people who are blind, low vision, or otherwise print disabled for prescription drug labels and prescription information by July 1, 2024. In September 2021, the Pharmacy Commission received a petition for rulemaking from the Washington Council of the Blind's Advocacy and Governmental Affairs Committees.[32] The petitioner requested the Pharmacy Commission create rules requiring pharmacies in Washington State to offer accessible labeling on medication bottles.[32] At an October 2021 meeting, the Pharmacy Commission discussed and voted to approve the petition and authorize rulemaking (personal communication, Pharmacy Commission, February 2022). Staff have begun this work (personal communication, Pharmacy Commission, February 2022).

- Pharmacy staffing, workforce shortages, and store closures. Key informants shared that the COVID-19 pandemic response has resulted in community pharmacy staff being overworked, which has worsened existing workforce shortages (personal communications, February 2022). For example, staff members continue to be called upon for pandemic response (e.g., providing oral antivirals, vaccines) (personal communications, February 2022). With the burden of the response, some key informants identified the 120-day implementation period as the most significant potential impact on pharmacy workforce (personal communications, February 2022). Key informants also expressed concern that potential implementation costs (e.g., translation service, software) could put some pharmacies in jeopardy of closing if not reimbursed for those services, particularly independent pharmacies and those in rural areas (personal communications, February 2022). If pharmacies closed, patients in impacted area could lose access to a local pharmacy (personal communications, February 2022). Such closures could result in patients needing to travel greater distances to access pharmacy services, which would increase transportation costs and travel times, and likely negatively impact health equity. Issues of staffing shortages and pharmacy closures are consistent with those discussed in national news articles.[17]

Magnitude of impact
ESHB 1852 would give the Pharmacy Commission rulemaking authority to establish the pharmacies and nonresident pharmacies that would need to comply with the requirements for translation of prescription drug labels. As part of the rulemaking process, the Pharmacy Commission would also be required to determine at least 15 languages for which translation is required. Therefore, the full impact of the bill on pharmacies and nonresident pharmacies and on people who speak a language other than English would be determined through rulemaking.

Pharmacies and nonresident pharmacies
There are 1,462 pharmacies in Washington State and 897 nonresident pharmacies (i.e., operating outside of the state) that are licensed by the Pharmacy Commission to provide prescription

services to people living in Washington State (personal communication, Pharmacy Commission, February 2022). The bill language states that the label translation requirements (outlined in Section 1) would only apply to outpatient prescriptions dispensed for home use that are intended for human use. Therefore, hospital pharmacies that only dispense inpatient prescriptions would likely be exempt from new translation requirements. Pharmacy Commission staff said it was too soon to determine which pharmacy settings the new translation requirements would apply to without having conducted the stakeholdering required as part of the rulemaking process (personal communication, Pharmacy Commission, February 2022).

Therefore, while ESHB 1852 has the potential to impact all pharmacies that offer outpatient prescription services (in-state and nonresident pharmacies), the rulemaking process will determine how many and which pharmacies and nonresident pharmacies would need to comply with the requirements for translation of prescription drug labels.

People who speak a language other than English
There are approximately 246 languages spoken in Washington State.[33] Washington State does not have a single source of data to identify people who speak a language other English or people with LEP.[9]

Based on data from the U.S. Census Bureau's 2019 American Community Survey (ACS) 5-year estimate, 20.5% of people in Washington State lived in a household where a language other than English was spoken.[34] This percentage has increased over time.[34] In 2019, 7.6% of people in Washington State aged 5 years and older reported living in a household where English is spoken less than "very well".[34] This percentage varied by county, ranging from 0.5% to 29% of the county population.[35]
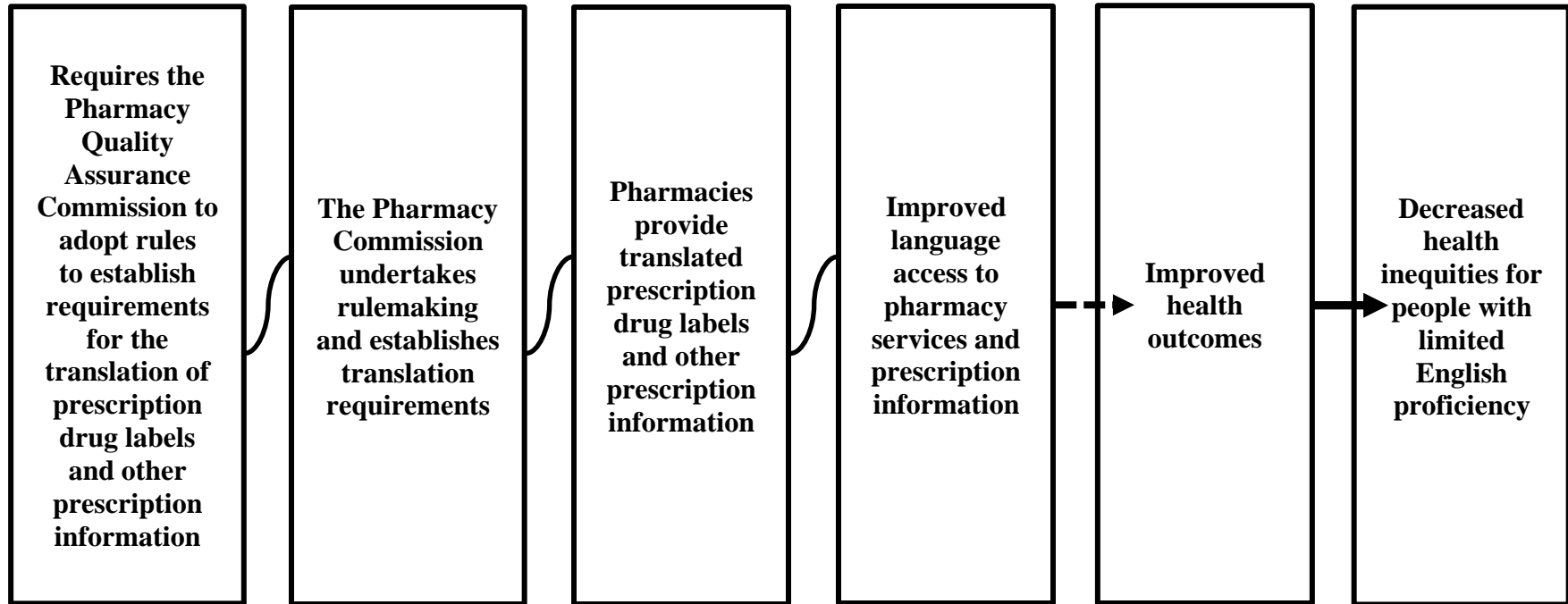
In 2016, the Office of Financial Management (OFM) published "Estimates of population with limited English proficiency for the state and counties" based on data from the Office of the Superintendent of Public Instruction's Comprehensive Education Data and Research System's (CEDARS) database.[33] CEDARS data reflect primary languages spoken by students in Washington State.[33] Spanish is the most common primary language of students who are English language learners; an estimated 12.7% of students primarily speak Spanish.[33]

Combining data from the U.S. Census Bureau and OFM, the Washington State Military Department, Emergency Management Division produced estimates of the number of languages spoken by 1,000 or more people or 5% of the population by county.[36] Twenty-five counties (out of 39 counties) in Washington State have at least one language other than English spoken by 1,000 or more people or 5% of the population.[36] King County has the greatest linguistic diversity, with 27 different languages other than English spoken by 1,000 or more people of 5% of the county population.[36]

Though preferred language spoken may not align with preferred written language, the bill has the potential to impact all people who speak a language other than English in Washington State. However, people who speak one of the 15 languages determined through rulemaking to be required for translation will be most impacted by the bill.

Overall, the full impact of the bill on pharmacies and nonresident pharmacies and on people who speak a language other than English in Washington State would be determined through rulemaking.

Logic Model

Requires the Pharmacy Quality Assurance Commission to adopt rules to establish requirements for the translation of prescription drug labels and other prescription information	The Pharmacy Commission undertakes rulemaking and establishes translation requirements	Pharmacies provide translated prescription drug labels and other prescription information	Improved language access to pharmacy services and prescription information	Improved health outcomes	Decreased health inequities for people with limited English proficiency

Figure 1:

Concerning language requirements for prescription drug labels

ESHB 1852

Key	
Very strong	
Strong	
A fair amount	
Expert opinion	
Informed assumption	
No association	
Not well researched	
Unclear	*
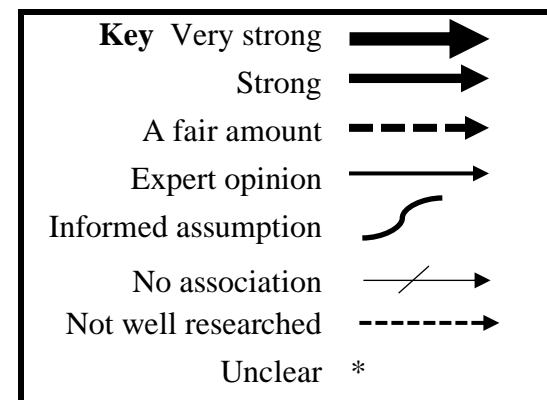
Summaries of Findings

Would requiring the Pharmacy Quality Assurance Commission to adopt rules establishing requirements for the translation of prescription drug labels and other prescription information result in the Commission undertaking rulemaking and establishing translation requirements?

We made the informed assumption that requiring the Pharmacy Quality Assurance Commission (Pharmacy Commission) to adopt rules establishing requirements for the translation of prescription drug labels and other prescription information would result in the Pharmacy Commission undertaking rulemaking and establishing translation requirements. This informed assumption is based on information from Pharmacy Commission staff.

Washington State law (RCWs 18.64.246 and 69.41.050) requires that a label be affixed to every box, bottle, jar, tube, or other container of a prescription which is dispensed in the state.[1,2] By statute (RCW 18.64.005), the Pharmacy Commission is responsible for regulating the practice of pharmacy, and the distribution, manufacturing, and delivery of pharmaceuticals within and into Washington State.[3] Currently, Pharmacy Commission's rules (WAC 246-945-016) detail minimum requirements for outpatient labels on prescriptions, which include those listed in statute as well as others adopted by rule (e.g., drug quantity, number of remaining refills).[1,2,5]

Provisions of ESHB 1852 direct the Pharmacy Commission to adopt rules establishing the requirements for the translation of prescription drug labels and prescription information by July 1, 2024. Specifically, the rules must require: 1) the translation of the directions for use and any auxiliary warnings on the drug label; 2) the translated version and English language version of the directions for use appear on the container or label; and 3) a pharmacy or nonresident pharmacy (i.e., a pharmacy located outside of Washington State licensed with the Pharmacy Commission to serve people living in Washington State) provide the translated materials upon the request of a patient, patient's representative, or prescriber. Additionally, the bill states that adopted rules must establish: 1) the languages for which translation is required (i.e., at least 15); 2) the elements of a prescription drug label or other information that must be translated; 3) the pharmacies and settings that the translation requirements apply to; 4) the process for procuring and providing the translations; 5) when a pharmacy or nonresident pharmacy must provide the translated prescription information; and 6) any signage that a pharmacy must post to notify consumers of the availability of translated prescription information.

If passed, Pharmacy Commission staff stated that the Commission would undertake rulemaking to establish requirements for the translation of prescription drug labels and other prescription information (personal communication, Pharmacy Commission, February 2022). Key informants noted that California, New York, and Oregon currently require translation for prescription drug labels, but that each state has taken a slightly different approach to those requirements (e.g., number of languages required for translation, what materials must be translated, entity responsible for translation) (personal communications, February 2022). For example, New York State's regulations only apply to chain pharmacies[37] (i.e., part of a group of 8 or more pharmacies owned by a corporate entity) and mail order pharmacies,[13] and the law limits the number of languages required to be translated per region (i.e., no more than 7 languages).[12] Meanwhile, Oregon's regulations apply to both chain and independent pharmacies and require

pharmacies to print prescription labels in any of 14 languages when requested by the patient (personal communications, Oregon Board of Pharmacy [OBP], February 2022). Key informants in Washington State explained that the rulemaking process would inform the approach the Pharmacy Commission would take to implement ESHB 1852 (personal communication, Pharmacy Commission, February 2022). Through this process, staff would engage stakeholders across the state to bring in various perspectives and build rules that would be workable for pharmacies and provide access for patients/customers who require translated materials (personal communication, Pharmacy Commission, February 2022).

Rulemaking considerations
Key informants noted that the pharmacy settings required to provide translations, the languages required to be translated, and the process for procuring and providing the translations could be approached in different ways through rulemaking.

First, the Pharmacy Commission would have authority to establish the pharmacies and nonresident pharmacies that would need to comply with the requirements for translation of prescription drug labels. As of February 2022, there are 1,462 pharmacies (e.g., retail, community, specialty, outpatient hospital, inpatient hospital, long-term care) in Washington State (personal communications, Pharmacy Commission, February 2022). The bill language states that the label translation requirements (outlined in Section 1) would only apply to outpatient prescriptions dispensed for home use that are intended for human use. Therefore, hospital pharmacies that only dispense inpatient prescriptions would likely be exempt from new translation requirements.

In addition to pharmacies located in Washington State, an additional 897 nonresident pharmacies (i.e., pharmacies operating outside of the state) are licensed by the Pharmacy Commission to provide prescription services to people living in Washington State (personal communication, Pharmacy Commission, February 2022). It is unknown how many of these nonresident pharmacies may already be subject to prescription label translation requirements established in other states (i.e., California, New York, or Oregon). If ESHB 1852 were to pass, the Pharmacy Commission could determine in rulemaking the extent to which nonresident pharmacies must comply with requirements for translation of prescription drug labels. However, nonresident pharmacies could choose not to operate in Washington State in lieu of complying with any new requirements (personal communication, Pharmacy Commission, February 2022).

The Pharmacy Commission would have discretion to require all pharmacies that offer outpatient prescription services (in-state and nonresident pharmacies) to provide translated prescription labels or to exempt some pharmacy types from new requirements. For example, New York State decided to limit language access requirements to pharmacy chains, as these pharmacies had substantial institutional resources to draw upon and were providing language access services to customers less often than independent pharmacies, which were more likely to meet the linguistic needs of their local communities (personal communication, New York Academy of Medicine [NYAM], February 2022).

Pharmacy Commission staff said it was too soon to determine which pharmacy settings the new translation requirements would apply to without having conducted stakeholdering required as

part of the rulemaking process (personal communication, Pharmacy Commission, February 2022). However, the goal would be to establish rules that are workable for pharmacies so that patients/customers who require translated prescription labels and other prescription information have access to these materials (personal communication, Pharmacy Commission, February 2022).

Second, the 15 languages required for translation would be determined during rulemaking. Key informants shared that one way to select required languages would be at the state level, using statewide data on the most common languages among Washingtonians with limited English proficiency (LEP) (personal communications, February 2022). Alternatively, languages could be selected on a regional basis, as is done under New York State law.[12,13] Some key informants thought a regional or county-level approach could prevent a handful of populous Western Washington counties from driving language selection that may not fit the needs of other parts of the state (e.g., rural communities) (personal communications, February 2022).

Third, the Pharmacy Commission would be required to establish the process for procuring and providing translated materials. In Oregon and New York, pharmacies are responsible for providing or contracting with a third-party to provide prescription translation services.[12,13,16,38] While California State Board of Pharmacy's regulations similarly allow for the use of translation services, the Board also provides 15 translations of standardized directions (e.g., "Take 1 pill at bedtime") in 6 languages that pharmacists can use on a prescription container if appropriate.[14] Funded by the California Endowment, these label translations were developed as part of the ConcordantRx Study to be patient-centered (i.e., considering patient literacy, language, and culture).[39] However, the translated instructions provided on the Board's website are limited and do not include other translated prescription information (e.g., auxiliary warnings, more specific prescription directions and information).[14]

While the specific approach to implement ESHB 1852 is unknown, key informants agreed that, if passed, the Pharmacy Commission would undertake rulemaking and establish translation requirements for prescription drug labels and other prescription information.

Would the Pharmacy Commission undertaking rulemaking and establishing requirements for the translation of prescription drug labels and other prescription information result in pharmacies providing required translated materials?
We have made the informed assumption that the Pharmacy Commission undertaking rulemaking and establishing requirements for the translation of prescription drug labels and other prescription information would likely result in more pharmacies providing translated materials in the languages determined in rule. This assumption is based on information from the Pharmacy Commission, the Washington State Pharmacy Association, representatives of Washington State pharmacies, and the Oregon Board of Pharmacy as well as research on New York State's implementation of prescription label translation requirements.

Currently, pharmacies across the state use various approaches to communicate with their patients with LEP. Some large chain pharmacies use software that can translate prescription labels for specific languages (personal communications, February 2022). Language line services are available in some pharmacies which allow a customer to speak with an interpreter via telephone

while picking up their prescription (personal communications, February 2022). However, key informants noted that this option may not be as accessible in pharmacy settings compared to other healthcare settings (e.g., cost of services, the non-scheduled nature of prescription drop-off/pick-up) (personal communications, February 2022). Some pharmacies have hired diverse bilingual or multilingual staff who can speak with and sight interpret medication labels for some of their customers in their preferred language (personal communications, February 2022). Similarly, in some cases pharmacists are fluent in another language and can translate instructions to include on the prescription label for their patients who share a common language (personal communications, February 2022). Another common approach is to talk with a customer's family member who speaks English (personal communications, February 2022). Pharmacists may also draw images on paper to help patients remember when to take medications (e.g., a rising sun for "morning", a full sun for "day", a dark circle or moon for "night") (personal communications, February 2022).

Key informants representing the Pharmacy Commission, the Washington State Pharmacy Association, and representatives of Washington State pharmacies agreed that if the Commission established requirements for the translation of prescription drug labels and other prescription drug information that pharmacies would do their best to become compliant with the new regulations (personal communications, February 2022). However, they noted that the ability to comply with regulations may vary by pharmacy type (e.g., retail, community, specialty, outpatient hospital, nonresident) and depending on implementation challenges or barriers faced (personal communications, February 2022). Violation of adopted rules by a nonresident pharmacy would be grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the Pharmacy Commission.[40]

Potential challenges or barriers to implementation
Key informants identified potential challenges or barriers to pharmacies being able to implement the requirements outlined in ESHB 1852. Specifically, they noted that limited space on labels, auxiliary warning translations, availability of appropriate translations and technology, health system coordination, and associated implementation costs as potential challenges or barriers.

Key informants representing Washington State pharmacies shared that limited space on labels would likely make it difficult to fit all the information required by the proposed bill (personal communications, February 2022). As written, it would require the drug label (or container) include the directions for use and any auxiliary warnings (e.g., eat with food, may cause drowsiness) in both the translated language and English. Oregon is the only other state that requires both language versions be printed on the label. Oregon Board of Pharmacy staff shared that balancing the inclusion of both language versions and legible font sizes was identified as challenging for pharmacies (personal communications, OPB, February 2022). Similarly, researchers who developed California's standardized patient-centered translated prescription instructions noted that it was difficult to manage changes in label spacing and formatting.[39] As translated instructions were usually longer than English versions, they used a different font and 10-point size.[39]

The requirement that auxiliary warnings be translated and included on the label presents another challenge. Currently, auxiliary warnings are not required to be included on prescription labels or

on a prescription drug container (personal communications, February 2022). Instead, pharmacists are responsible for using their professional judgment to decide when to add these notices (i.e., pre-printed stickers) (personal communications, February 2022). Key informants were not aware of any service that currently provides translations of auxiliary notices. One key informant representing pharmacies also noted that it is unclear how adding this requirement in statute would affect pharmacists' professional discretion (personal communication, February 2022).

Key informants also identified accessing appropriate translation technology (e.g., software) as a potential barrier, particularly for independent pharmacies. They shared that open access machine translations available online are not appropriate for these critical health communications as they often include inaccuracies (personal communications, February 2022). For example, computer generated translations may be incomplete or include misspellings or grammatical errors.[15] While some chain pharmacies may have already implemented systems in response to other states' regulations, many of the computer systems used to manage the day-to-day workflow in independent retail and community pharmacies do not include translation capabilities (personal communications, February 2022). Vendors may offer translation services for an additional fee through a third-party, which may involve integrating an overlay system into the pharmacy's workflow (personal communications, February 2022). However, such systems may include only a subset of languages (e.g., 1 to 24 languages) (personal communications, February 2022). Additionally, one key informant representing a large chain pharmacy operating in California, Oregon, and Washington noted that no software program currently has the capacity to print a Germanic language at the same time as a non-Germanic language (e.g., English and Chinese) (personal communication, February 2022). This is problematic as multiple lines that appear on a prescription label are printed simultaneously (personal communication, February 2022).

Moreover, while many healthcare providers submit prescriptions using e-prescribing software, the pharmacy's computer system may not accurately interface with various providers' systems (personal communications, February 2022). Without coordination with providers, a pharmacy may not know whether a prescription label needs to be translated (personal communications, February 2022). This technical issue creates workflow challenges if a prescription is filled and must be refilled with a new translated label (personal communications, February 2022).

Finally, the cost of translation services also presents a potential barrier for pharmacies (personal communications, February 2022). Key informants shared that start-up costs to integrate an additional translation service can cost thousands of dollars in addition to ongoing services charges (e.g., monthly subscription, fee per label) (personal communications, February 2022). Pharmacies may also need to pay for each additional language required for translation (personal communications, February 2022). Furthermore, pharmacies cannot offset these costs by raising prices as pharmacy benefit managers (i.e., companies that manage prescription drug benefits) determine how much pharmacies are paid for each prescription.[17,41] Key informants from Washington State and New York State indicated that technology costs may be particularly burdensome for independent and community pharmacies (personal communications, February 2022), which are more likely to have very thin profit margins.[17]

Implementation in other states
In 2012, New York State passed legislation requiring chain pharmacies to provide translation and interpretation services to patients who spoke one of the pharmacy primary languages, which were identified by region. Although the law went into effect in 2013, the State Pharmacy Board was not required to monitor compliance.[37] Using pharmacist survey data from 2006, primarily from multi-state chains, researchers studied language translation services offered in chain pharmacies in New York City prior to the implementation of state regulations and compared it with survey data from 2015, after pharmacies had implemented state regulations.[37] In 2015, pharmacists were more likely to report serving patients with LEP, more likely to report capacity to print translated prescription labels, and more likely to print translated labels daily.[37] Researchers found that despite early concerns expressed by pharmacies related to translation feasibility and liability exposure prior to the regulations being implemented there was measurable change in pharmacy practices that resulted in significant improvement of meeting the needs of certain portions of the population as pharmacies implemented state regulations.[37]

In 2019, Oregon passed its prescription label translation law, which officially became effective in 2021. However, due to the COVID-19 pandemic, the state opted to have a one-year phase-in of discretionary enforcement of the new rules rather than strict enforcement (personal communications, OBP, February 2022). The rules went into full effect January 1, 2022, and OBP began its first year of compliance inspections in February 2022 (personal communications, OBP, February 2022). While OBP does not yet have compliance data available, staff are aware that pharmacies have been working to come into compliance (e.g., adding additional languages) (personal communications, OBP, February 2022).

Key informants representing Washington, Oregon, and California pharmacies provided additional detail regarding implementation in Oregon and California. One key informant representing a large chain pharmacy operating in all three states shared that pharmacies operating in California have been able to easily comply with the California law as their systems are fully automated to include the translated instructions (personal communication, February 2022). However, in the company's Oregon-based pharmacies, where prescription labels are required to include both translated instructions and the English version, staff must at times print two separate labels (one with each language) (personal communication, February 2022). Staff must then cut and paste them on the bottle in a way that they will fit on a normal prescription bottle (personal communication, February 2022). Staff have expressed concern that the process may be prone to errors (e.g., unsure if the translated version is put on in the correct order) (personal communication, February 2022).

Many of the potential challenges or barriers that pharmacies may face in implementing ESHB 1852 will depend on the final rules adopted by the Pharmacy Commission and what options are available to them. Additionally, nonresident pharmacies could choose not to operate in Washington State in lieu of complying with any new requirements (personal communication, Pharmacy Commission, February 2022). However, all key informants agreed that if required by rule to provide translated prescription drug labels, pharmacies would do their best to come into compliance with the new law.

Therefore, based on information from key informants representing pharmacies and implementation efforts in New York and Oregon, we have made the informed assumption that the Pharmacy Commission undertaking rulemaking and establishing requirements for the translation of prescription drug labels and other prescription information would likely result in more pharmacies providing translated materials in the languages determined in rule.

Would pharmacies providing translated prescription drug labels and other prescription information result in improved language access to pharmacy services and prescription information?
We have made the informed assumption that more pharmacies providing translated prescription drug labels and other prescription information would result in improved language access to pharmacy services and prescription information for some people with LEP in Washington State. This assumption is based on U.S. Department of Health and Human Services (HHS) Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS) standards, National Council on Interpreting in Health Care (NCIHC) recommendations, and information from key informants.

CLAS "refers to services that are respectful of and responsive to individual cultural health beliefs and practices, preferred languages, health literacy levels, and communication needs."[10] HHS states, "CLAS helps [healthcare providers] meet the six aims for improving health care quality: the delivery of care that is safe, effective, patient-centered, timely, efficient, and equitable."[10] Language access can be obtained through interpretation (i.e., oral), translation (i.e., written), or sight translation (i.e., oral interpretation of written materials in the moment),[18] and is one component of providing services that are culturally and linguistically appropriate and meet patient needs. Researchers have noted that removing language barriers may increase access to prescription drugs, and "pharmacists should ensure that information on and instructions for using prescribed drugs reach [people] in a language they read or at least understand."[23]

ESHB 1852 would improve language access by providing translated prescription drug labels. However, people with LEP would need to be aware that prescription drug labels are available in their preferred language and translations must be accurate (personal communications, February 2022). While ESHB 1852 requires that a pharmacy post signage to notify consumers of the availability of translated prescription information, the bill does not require additional outreach or education to increase awareness about translated prescription drug labels and prescription information.

Translations must also be accurate. Key informants stated that it is critical that translations of prescription instructions be certified, or at least verified by bilingual speakers (i.e., English and the preferred language) as accurate and appropriate translations (personal communications, February 2022). Language services should be provided by qualified persons,[15] that may include bilingual providers and staff and trained interpreters and/or translators, who have been assessed for their professional skills with verified language proficiency, knowledge of medical terminology and concepts in each language, appropriate training, and knowledge of and adherence to codes of ethics and standards of practice for medical interpreters.[9] Use of informal interpreters (i.e., family members or untrained staff) carry the high potential for error related to

the instructions.[19,42] Medication-specific terminology may require a technical fluency an informal interpreter may not have (personal communications, February 2022).[19,42]

For example, for translations to be accurate, they need to replicate intended meaning of what is being translated (i.e., contextual versus literal translations).[43] Literal translations (i.e., word-for-word) may not account for differences in linguistic structure and can therefore cause confusion or be misleading.[43] Local language patterns and word use may vary by cultural background and/or country.[43] Some languages are more descriptive than representative, requiring concepts to be explained rather than represented by a single word or a phrase.[43] Thus, translations may be longer than the English version.[43] Additionally, some common concepts used in prescription instructions in the U.S. do not exist in some cultures.[43] For example, prescription instructions may include taking a pill "once in the morning and once in the evening." As Chinese does not have a commonly used equivalent term for the word "evening", one group of translators chose to translate "evening" with a phrase used to refer to the evening news on Chinese television broadcasts to indicate when a medication should be taken so that it could be more easily understood by patients.[39]

Lastly, NCIHC recommends asking patients their preferred language for written instructions (including prescriptions) as a clinical best practice.[18] In part, this helps to ensure that written instructions can be provided in a language accessible to the patient. For example, for written instructions to be effective, a person must have literacy skills and the inclination to use written material in their native language.[43] Translated instructions may not meet the needs of people with limited literacy, and not all languages have a written form. Hmong does not have a common written form and in such cases interpretation or sight translation may be preferable.[43] Literacy among groups of immigrant or refugee communities in Washington State may also vary. In some cultures, women may have limited educational opportunities and literacy may be limited to the language of religion (e.g., Arabic) rather than the language spoken. Therefore, asking a patient's preferred language for written instructions and providing translations in that language may help to ensure accessibility.

Overall, requiring pharmacies and nonresident pharmacies to provide translated prescription drug labels and other prescription information would likely improve access to culturally and linguistically appropriate pharmacy services. Providing a translated prescription label in the preferred language of the patient follows CLAS standards and is a recommended practice by NCIHC. While there are challenges to providing appropriate translations, since the capacity to develop appropriate translations exists, we have made the informed assumption that translating prescription drug labels has the potential to improve language access to pharmacy services and prescription information for some people with LEP.

Would improved language access to pharmacy services and prescription information for people with limited English proficiency improve health outcomes?
There is a fair amount of evidence that improving language access to pharmacy services and prescription information for some people with LEP would improve health outcomes. There is a body of research suggesting that language barriers may contribute to adverse health impacts, including impacts related to medication use and adherence, as well as a body of research showing that accurate use of prescription drugs can help to manage health conditions.

A 2020 systematic review of articles published between 2009 and 2019 examining the impact of language barriers on the delivery of healthcare cited results from a U.S.-based telephone survey suggesting that, among patients who spoke a language different than the healthcare provider, 34.7% were confused about how to use medication and 41.8% had trouble understanding the drug label.[20] Understanding medication instructions is one of many components that support improved health outcomes, and all key informants agreed that it is important for language access that a patient be able to understand the label on the medication they have been prescribed (personal communications, February 2022).

Language barriers impact health care delivery and miscommunication between patients and healthcare providers and may result in adverse health impacts for patients who speak a language other than English.[19-21,23,28] Results from a U.S.-based telephone survey found that 15.8% of patients who spoke a language different than the healthcare provider reported a bad reaction to medication due to difficulty understanding their healthcare provider's instructions.[20] Other studies have found that language barriers and miscommunication between patients and providers may result in incomplete prescribed treatment and increased medication complications.[20] Key informants shared that there have been "documented overdoses because 'once' is 11 in Spanish and 'once daily' shows up often on prescription labels" (personal communications, February 2022). Medication-related error is one of the most common types of medical error, affects substantial numbers of people, and accounts for a sizable increase in healthcare costs.[44] To help eliminate errors, NCIHC recommends that written instructions, including prescription instructions, sent home with a patient use a dual language format, where a patient has written instructions in both their preferred language and English so that healthcare providers (or others) can read the original text.[18] Moreover, if there was a question of error due to incorrect instructions, both sets of instructions could be compared.[18]

Evidence also indicates that, generally, about 1 in 5 new prescriptions are never filled.[27] Among prescriptions that are filled, nearly 50% are taken incorrectly (e.g., timing, dosage, frequency, duration).[27,45] The U.S. Centers for Disease Control and Prevention (CDC) cited evidence that nonadherence is associated with higher rates of hospital admissions, worse health outcomes, increased illness and death, and increased health care costs.[27] While nonadherence to medication regimens has several causes, one factor is not understanding or being unable to properly read the label.[27] Key informants shared that if people do not understand what medication they are taking they may be hesitant to take it, may take it incorrectly, or may not take it at all (personal communications, February 2022). Specifically, key informants representing Washington State pharmacies confirmed that if a patient does not understand the label on a medication they have been prescribed, then it is hard for them to adhere to the medication (personal communications, February 2022).

People who have a greater understanding of medications are more likely to take medications correctly.[21-23] One study examining the impact of translated standard instructions versus translated patient-centered instructions provided for people with LEP showed that patients who received the translated patient-centered version were "significantly more likely than those who received [translated] standard instructions to demonstrate how to take a single [prescription] medication appropriately."[21] They were also "significantly more likely to dose more medications

correctly in a multi-drug regimen and to simplify medication use by consolidating when pills would be taken."[21] However, only a quarter of study participants demonstrated correct dosing of their medications, which could indicate that prescription labeling alone may not be sufficient in managing medication regimens.[21]

Lastly, it is generally accepted that use of prescription drugs can impact health outcomes. Healthy People 2030 includes a goal to reduce the proportion of people who cannot access prescription medications when needed.[24] They stated, "[p]rescription medicines are critical for managing many common diseases and disorders. When people can't get the medicines they need, treatable conditions may get worse."[24] For example, according to the CDC, there is evidence showing that, "[b]lood pressure medicines can help you keep your blood pressure at healthy levels and therefore greatly reduce your risk of heart disease, heart attack, and stroke."[25] The World Health Organization (WHO) stated that "lack of adherence is the most important cause of failure to achieve [blood pressure] control," which "significantly increases the risk of [heart attack], stroke, and hospitalization."[26] While this is just one example and effectiveness, adherence, optimal management, safety, etc. vary by medication and health outcome, there is evidence that some prescription drugs, when used accurately, may improve health outcomes.

We were unable to find any studies specifically evaluating the impact of translating prescription drug labels on patient outcomes, including on health outcomes. For this reason and the purpose of this analysis, we have downgraded the strength-of-evidence to a fair amount of evidence rather than strong evidence. Therefore, there is a fair amount of evidence that improving language access to pharmacy services and prescription instructions may improve health outcomes for people with limited English proficiency.

Would improved health outcomes decrease health inequities for people with limited English proficiency?
There is strong evidence that improving health outcomes would decrease health inequities for people with LEP.

English language proficiency, time in the U.S., and having health insurance are predictors of healthcare use and access.[23] It is well-established that increasing access to and use of healthcare services improves health. There is also a large body of evidence supporting the positive association between use of health services for the early detection and treatment of physical and mental health disorders[46] and improved health outcomes. People who speak a primary language other than English are less likely to seek healthcare or see a healthcare provider.[20,23,28,30] A 2020 systematic review examining the impact of language barriers on the delivery of healthcare cited a Canadian study that found "66.7% [of patients who spoke a language different than the healthcare provider] faced a barrier when accessing healthcare, and 20% did not seek healthcare services if these were not readily available for fear of not understanding their healthcare provider."[20] Another study examined healthcare spending differences by English proficiency status and the long-term health care utilization patterns of those with or without English proficiency.[30] Researchers found a persistent gap (as measured by spending on healthcare services) in use of care between Hispanic adults with and without English proficiency between 1999 and 2018.[30] Within the same time frame, the gap of use widened between Hispanic adults with LEP and non-Hispanic, English-proficient adults.[30] The researchers' analysis determined

that people with LEP showed substantial rates of missed age-appropriate health screenings.[30] Researchers discussed potential causes for language-based differences in health care utilization and the gaps as a potential result of language-based inequities and health care access: "Non-English speakers may be less likely to seek care for health concerns, anticipating that their needs might not be met […] Even when care is sought, the lack of language concordant clinical and administrative staff in many health care organizations may make navigating the health care system more difficult."[30]

A recent systematic review of 20 articles examined differences in outcomes in stroke care prevention, management, and recovery between patients with and without LEP in English-predominant healthcare settings.[28] However, 11 of the articles did not provide information about professional medical interpreter (PMI) availability or usage, and no studies evaluated the quality of available interpretation.[28] Overall, 4 studies examining pre-stroke preventive care found LEP was associated with "suboptimal results across multiple important metrics of pre-stroke care, showing that [people with LEP] have lower awareness of stroke symptoms and experience greater difficulty with medication regimens."[28] Authors recommended healthcare systems provide accessible translation services for written information to complement patient-provider discussions.[28] Specific to acute care, after accounting for sociodemographic factors and stroke severity, patients who preferred a language other than English and did not receive a PMI were statistically significantly less likely to receive defect-free care (i.e., receipt of all treatment measures for which a patient was eligible) compared to patients who did receive PMI.[28] Finally, when assessing post-stroke care, one study found that patients with LEP viewed "rehabilitation tasks as tests of competence rather than constructive activities" and "felt little agency in the decision of whether or not to involve a PMI".[28] Similarly, in another study, rehabilitation therapists reported that rehabilitation was affected by language barriers and a lower likelihood of providing written materials to their patients with LEP due to absence of translation services.[28] The systematic review concluded that without consideration of language access, studies "may fail to observe the vulnerability of [patients with LEP] who do not receive proper PMI services in a language discordant environment."[28]

These inequities are exacerbated by determinants of health like racism, which "contributes to social inequities (e.g., poverty) that shape health behaviors, access to healthcare, and interactions with medical professionals."[47] Institutionalized racism results in differential access to resources, services, and opportunities, including access to healthcare, by race.[48] For example, in Washington State, Spanish is a common primary language of people with LEP,[33] and data have shown that Hispanics were most likely to report fair or poor health as compared to all other racial/ethnic groups (36% versus 16% state average).[31]

Since people with LEP experience greater barriers in accessing healthcare and worse health outcomes, in part due to language access barriers, and since ESHB 1852 would likely improve language access for some people with LEP, there is strong evidence that ESHB 1852 would decrease health inequities for people with LEP in Washington State.

Annotated References

1.   **RCW 18.64.246 Prescriptions—Labels—Cover or cap to meet safety standards—Penalty, Revised Code of Washington(2013).**
This RCW within the Pharmacists chapter establishes prescription drug label requirements. Violation of this section is a misdemeanor.

2.   **RCW 69.41.050 Labeling requirements—Penalty., Revised Code of Washington (2003).**
This RCW within the Legend Drugs—Prescription Drugs chapter establishes labeling requirements and associated penalties for violations of those requirements.

3.   **RCW 18.64.005 Commission—Powers and duties, Revised Code of Washington (2013).**
This RCW establishes the statutory authority of the Pharmacy Quality Assurance Commission. Listed among its powers and duties is to promote "rules for the dispensing, distribution, wholesaling, and manufacturing of drugs and devices and the practice of pharmacy for the protection and promotion of the public health, safety, and welfare." Any violation of the Commission's rules "shall constitute grounds for refusal, suspension, or revocation of licenses or any other authority to practice issued by the commission."

4.   **Pharmacy Commission. Tumwater, Washington.**
This Washington State Department of Health web page provides an overview of the Pharmacy Quality Assurance Commission.

5.   **WAC 246-945-016 Prescriptions—Outpatient labels—Minimum requirements, Washington Administrative Code(2020).**
This Pharmacy Quality Assurance Commission rule details the requirements for labeling prescription containers that licensees must follow when dispensing legend drugs to outpatients.

6.   **U.S. Department of Health and Human Services. Limited English Proficiency (LEP). Available at: https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/index.html. Accessed February 21, 2022.**
This U.S. Department of Health and Human Services webpage provides resources for people whose primary language is not English.

7.   **Executive Order 13166. Improving Access to Services for Persons with Limited English Proficiency 2000; Available at: https://www.justice.gov/crt/executive-order-13166. Accessed February 15, 2022.**
This DOJ web page provides an overview of Executive Order 13166 "Improving Access to Services for Persons with Limited English Proficiency" (2000), which " requires Federal agencies to examine the services they provide, identify any need for services to those with limited English proficiency (LEP), and develop and implement a system to provide those services so LEP persons can have meaningful access to them." It provides guidance and materials which offer informal non-binding guidance to assist in understanding the order.

8.   **What qualifies as "Federal financial assistance" for purposes of civil rights complaints handled by OCR? Available at: https://www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-federal-financial-assistance/301/index.html. Accessed February 21, 2022.**
This webpage provides a list of recipients of federal financial assistance from the U.S. Department of Health and Human Services.

9.   **Access Washington State Coalition for Language. Washington State Coalition for Language Access Tools for Health Language Access in Healthcare for LEP Persons: What Providers in Washington State Need to Know. 2015.**
Washington State Coalition for Language Access (WASCLA) created a fact sheet for healthcare providers as a resource related to language access in healthcare. The fact sheet refers to research documenting that when a patient speaks limited English, they are at an increased risk for medical errors, including those with prescriptions drugs; have more unnecessary diagnostic testing and procedures; have increased rates of hospitalization, longer hospital stays and more re-admissions; have worse outcomes; and accrue both higher personal and system expenses. The fact sheet cites that the Supreme Court has ruled that language can be an identifier of national origin, and therefore is encompassed in Title VI of the 1964 Civil Rights Act. The Affordable Care Act (ACA) also established mandates for meeting the needs of people with limited English proficiency. The United States Department of Health and Human Services developed standards for Culturally and Linguistically Appropriate Services in Health and Health Care (CLAS) in 2004 and updated in 2014. A covered entity receiving federal funds for any part of its operation is required to provide no-cost meaningful language access services to people with limited English proficiency at all points of service. Language assistance must be provided to those responsible for the patient's care, as well (e.g. parents, relatives, guardians). Licensed healthcare providers working for a covered entity receiving federal funds must comply with Title VI (i.e., hospitals, nursing homes, Medicaid agencies, outpatient clinics, and pharmacies). The fact sheet states that to provide language assistance services means that "all parties are provided with high quality spoken and written language communications which allow them to comfortably discuss the patient's health and health care – the ensure meaningful access to services." Language translation means translating done between written languages – the source language and the target language. Language services should be provided by qualified persons, that may include of bilingual providers and staff and trained interpreters and/or translators, who have been assessed for their professional skills with verified language proficiency, knowledge of medical terminology and concepts in each language, appropriate training, and knowledge of and adherence to codes of ethics and standards of practice for medical interpreters. A patient's family member, friend, or accompanying minor may not be required to interpret for the patient except in emergency situations. It is estimated that only one third of the English-speaking public has adequate health literacy.

10.   **Health Think Cultural. CLAS, cultural competency, and cultural humility. US Department of Health and Human Services; US Department of Health and Human Services Office of Minority Health.**
This document is a one-page resource on how to improve quality of care through the concepts of CLAS, cultural competency, and cultural humility. Culturally and linguistically appropriate services (CLAS) "refers to services that are respectful of and responsive to individual cultural

health beliefs and practices, preferred languages, health literacy levels, and communication needs." Cultural competency is described as "a developmental process in which one achieves increasing levels of awareness, knowledge, and skills along a continuum, improving one's capacity to work and communicate effectively in cross-cultural situations." Cultural humility is described as a "process of understanding one's biases and privileges, managing power imbalances, and maintaining a stance that is open to others in relation to aspects of their cultural identity that are most important to them."

11. **HHS Continues to Improve Access for LEP Individuals. Available at: https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/hhs-continues-to-improve-access-for-lep-individuals/index.html. Accessed February 21, 2022.**
This webpage provides an overview related to how the U.S. Department of Human Services is reducing barriers for people with limited English proficiency, including how covered entities must comply with federal law.

12. **§ 6829. Interpretation and translation requirements for prescription drugs and standardized medication labeling, (2013).**
This document provides the text of New York State's law requiring interpretation and translation for prescription drugs and standardized medication labeling. Passed in 2012, the law became effective Marcy 30, 2013, and has not been updated since enacted.

13. **N.Y. Comp. Codes R. & Regs. Tit. 8 § 63.11 - Interpretation and translation requirements for prescription drugs, (2014).**
This section of the New York Codes, Rules, and Regulations detail the requirements for interpretation and translation for prescription drugs to implementation Education Law section 6829(3).

14. **Translations of Pill Directions as Specified in 16 California Code of Regulations Section 1707.5. Available at: https://www.pharmacy.ca.gov/publications/translations.shtml. Accessed February 20, 2022.**
The webpage provides the 2016 requirements for translated prescription levels to establish a mechanism by which patients may obtain translated instructions on prescription labels.

15. **Zargarzadeh A. H., Law A. V. Access to multilingual prescription labels and verbal translation services in California.** *Res Social Adm Pharm.* **2011;7(4):338-346.**
Zargarzadeh and Law conducted a cross-sectional, observational study of pharmacists in California "to examine (1) self-reported capability for and actual provision of prescription labels or verbal medication information in languages other than English by California pharmacies and (2) characteristics of pharmacies that provide such services." Authors cited evidence that patients with limited English proficiency (LEP) have "difficulty understanding written medication instructions handed out by pharmacists and have lower adherend rates to medications." A total of 691 pharmacists in charge of retail pharmacies (i.e., community pharmacies) were randomly selected throughout California to participate in a telephone interview conducted in from August through November 2009. This study was completed prior to CA's requirements (2015) that medication labels be printed in a patient with LEP's preferred language. A total of 552

participated (79.9% response rate). "More than half 59% of the 139 pharmacies that did not participate were independent pharmacies." Some could not be reached (36.7%), lacked interest (32.4%), did not have time (20.8%), or deferred an interview to a different time or the corporate office (10.1%). However, the proportion of responding chain and independent pharmacies did not statistically differ from the distribution in the state (65.4% and 34.6%, respectively). Similarly, the proportion of participating urban and rural pharmacies was reflective of the proportions in the state. The study's main outcome measures were the "number of pharmacies that could and did provide multilingual labels (MLs) and/or offer medication information verbally in the patient's preferred language." Researchers used 3 independent variables in regression models (i.e., type of pharmacy [chain vs. independent], location [rural vs. urban], and % of patients with LEP as reported by pharmacists). Results showed that "69% of the pharmacies surveyed could provide MLs, and 67.9% did provide MLs routinely on patient request." These results are similar to findings reported by a study of Georgia, North Carolina, Colorado, and Texas (65% of pharmacies provided limited or full translations of prescription labels). Authors noted, "of these, 78.9% (299) of the pharmacies could print labels in Spanish." Other available languages included: Chinese, Vietnamese, French, Farsi, Arabic, Korean, Tagalong, Hindi, Russian and Italian. Some chain stores could provide labeling in as many as 17 languages. Most (97.4%) of those generating MLs used computer software for translation. Of the 170 pharmacies without the capability to providing MLs, 81.2% believed in providing MLs and believed it would be useful for patients with LEP. Meanwhile, 82.4% of pharmacies provided interpretation (verbal) of labels or other medication information such as leaflets, pamphlets, and guides to patients. Chain pharmacies reported a statistically significantly higher capability to provide MLs than independent pharmacies. Authors hypothesized this may be because chain pharmacies have networked software databases and are able to cover the costs. Pharmacies located in rural areas (i.e., a town with population of 25,000 or less, not adjacent to a large city or part of a continuous urban area) also reported higher availability of MLs than pharmacies in urban areas. Authors thought this may be in response to demand for these services due to the large number of people with LEP who live in rural areas where they may be employed as agricultural workers. Finally, "pharmacies with higher number of estimated limited English proficient (LEP) patients reported higher availability of MLs […] and verbal translations." Researchers highlighted that "results do not necessarily reflect that two-thirds of [patients with LEP] actually receive MLs." They cite other studies that have shown that "there is a significant difference in capability and practice of multilingual medication instructions." Additionally, authors note that they did not evaluate the quality of the translations provided by pharmacies.

16.   **Pharmacy Oregon Board of. Prescription Labeling & Accessibility Rules. 2020.**
The minutes of the Oregon Board of Pharmacy Rules Advisory Committee included a PowerPoint presentation by the Rules Committee outlining the directives of OR SB 698 (2019). The presentation included stated objectives and impacts of the bill, and context and consideration for rulemaking.

17.   **Hawryluk M. Independent pharmacies are fighting to stay in business through the pandemic.** *Fortune.* **29 April 2021, 2021.**
This online news article by Hawryluk and Kaiser Health News discussed the impact of the COVID-19 pandemic on pharmacies, particularly independent pharmacies. The article notes that independent pharmacies were challenged to remain open before the pandemic. For example,

"The Rural Policy Research Institute found that 1,231 independently owned rural pharmacies, about 16%, closed for good from 2003 to 2018, well before the pandemic pinch." Similarly, the Drug Channels Institute found, "after five years of declines, the number of urban and rural independent pharmacies dipped below 20,000 for the first time in 2020." While 20 years ago pharmacies could see gross profit margins of 36%, the article reports "[n]ow independent pharmacies are fortunate to see margins of 3% to 5%, if they survive the pandemic at all." The author states that, "Much of that decline comes from the impact of pharmacy benefit managers (PBMs), which manage commercial and public health plans' prescription drug reimbursements to pharmacies. Those PBMs, often aligned with large drugstore chains". Despite most pharmacies seeing a decline in prescriptions in 2020, they experienced new costs (e.g., person protective equipment [PPE], phone services to handle calls for COVID-19 tests and vaccines).

18.   **Care National Council on Interpreting in Health. Sight Translation and Written Translation, Guidelines for Healthcare Interpreters Working Paper Series. 2010.**
The paper's focus is on the special demands of sight translation and written translation within the context of the work of spoken language interpreting and offers guidance for a spoken language interpreter for sight and written translation. Interpreting is defined as "the oral rendering of spoken or signed communication from one language into another" and is dependent on the interpreter's ability to comprehend oral communication in 2 languages and produce an accurate and complete conversion from one language to another, most often in real time. Written translation is defined as "the rendering of a written text in one language in a comparable written text in another language" with the ability to comprehend written text in one language and to produce a comparable rendition in another written language. Sight translation is defined as "the oral rendition of text written in one language into another language and is usually done in the moment" requiring the understanding of the written text in one language and the ability to produce an oral or signed rendition in another language. Interpreters follow the American Society for Testing and Materials' (ASTM) Standard Guide for Language Interpretation Services; the guidelines are not clear as to what an interpreter may be reasonably expected to sight translate. Interpreters are also not expected to provide "on-the-spot" written translations, other than very brief text, and if they do provide brief written translations, they cannot be held to the same standards as formally translated texts. The ASTM Standard Guide for Language Interpretation Services offers guidelines for languages that do not have a written form in common use; the ASTM of Patient/Guardian Literacy states: "If patients' ability to read their preferred spoken language is limited, and a durable record of instructions is needed, audio or video recordings of the oral text should be provided to the patient/guardian." The Guidance Memorandum on Limited English Proficiency Access issued by the Office of Civil Rights addressed the types of written materials that should be translated. The paper highlights that the language within the guidance memorandum include materials that are routinely provided in English" and "vital documents," and stated that these materials "should have already been translated in the 'regularly encountered languages other than English.'" The paper stated that having an interpreter sight translate print materials may not lead to clear communication and understanding. The authors of the paper reiterated the different skill sets needed for interpretation, translation, and site translation, and the authors called upon healthcare providers and facilities to understand that each require different skills. The authors of the paper outline the 4 types of typical documents that patients receive in healthcare settings, one of which are documents that contain specific instructions for patient care, such as prescriptions, preparation

for procedures, and discharge instructions. Specifically, National Council on Interpreting in Health Care's (NCIHC) recommends that "Documents with specific instructions are appropriate for sight translation, with the provider present, so that the patient's questions can be answered by the provider, not the interpreter." Furthermore, healthcare interpreters sight translations should be brief and non-technical (e.g. the dosage label on a medication package). NCIHC recommends a patient has written instructions in both English and their target language so that healthcare providers can read the original text, and, moreover, if there was a question of error due to incorrect instructions, both sets of instructions could be compared. Other NCIHC recommendations included inquiring what language a patient would prefer to receive a written document. NCIHC noted that not all patients may be able to read. For example, Hmong and Navajo do not commonly have a written form and in such cases, NCIHC recommended a healthcare setting being able to provide an alternative to written translation. The paper concluded stating "Wherever possible, in the interest of accuracy and efficiency, written texts in appropriate languages (or audio or video recordings of texts) must be prepared with the assistance of qualified translators in advance of their need in any particular provider-patient encounter."

19. **Quan K., Lynch J. The High Costs of Language Barriers in Medical Malpractice National Health Law Program: School of Public Health, University of California, Berkeley;2010.**
Quan et. al examined when language barriers may have resulted in harm to a patient by analyzing 35 medical malpractice claims of a malpractice carrier that insures patients in 4 states. These 35 claims represented 2.5% of the Carrier's 1.373 total malpractice claims from January 2005 through May 2009. Criteria for inclusion was based on whether the patient or physician spoke a primary language other than English, was unable to speak English, or was a person with limited English proficiency. Claims did not identify the name of any physician, health care provider, patient or any private health information. The study collected language proficiency, location of medical training, country of nativity, medical condition of the patient and the physician. The 35 cases were grouped by theme related to the provision of language services and included: failure to provide competent oral interpretation; failure to provide written translations of important documents; inadequate documentation; and allegations of discrimination. The claims highlighted that cases result in patients suffering death and irreparable harm. In the majority of cases (32 of 35), it was found that the healthcare provider did not use a competent or trained interpreter. Some cases documented in the study used a minor child as an interpreter. Minors are not trained interpreters; they may not interpret accurately, are prone to omissions, additions, substitutions, and volunteered answers. Further, they are less likely to comprehend medical terminology to accurately interpret either the English or in the language of the patient and likely not able to fully participate in a medical discussion. Failure to translate documents such as consent forms and discharge instructions was present in 12 of the 35 cases (34%). The study found patients signed English language consent forms, after a provider had acknowledged that a patient spoke or read limited to no English. The study documented legal cases (Macy v. Batchford and McQuitty v. Spangler) where courts have ruled that consent requires more than just a form and that a patient must understand the issues and information at hand. Further, [u]nder well-established common law, a patient must be given sufficient information about the treatment, benefits, risks and alternatives to make the consent meaningful." Neary all the cases were found to not provide adequate documentation of a person's limited English proficiency or the need for an interpreter. Some cases would record that a patient spoke little or limited English

but would not note the patient's spoken language consistently throughout key documents on a patient's record. There was infrequent documentation as to whether a patient was accompanied with a medical interpreter, or if the intake assessment used an interpreter. The researchers dicussed that when a patient's language is not consistently or accurately documented, providers can miss important relevant medical issues. Failure to document a patient's preferred language for communication can also result in the denial of language services. Further, "[i]f a provider cannot identify the patient's language, the provider may have difficulty meeting the patient's language needs in a timely manner." Medical teams more commonly assumed Asian patients assumed to have concordant race, ethnicity, or language with their physician, because "many providers tend to aggregate the diverse Asian languages and cultures as "Asian" or "Chinese." Providers were confused about the distinctions between Cantonese, Mandarin, other Chinese dialects and Vietnamese; and the nationalities, races, and cultures of patients from Hong Kong, Taiwan, Vietnam and Macau." Even if a patient's language was correctly identified, different language dialects were not always considered. The study included 2 discrimination claims in addition to medical negligence; the authors stated that it was "likely that the charge of discrimination would not have been made had it not been for the underlying malpractice claim." The authors concluded that there are monetary and non-monetary costs for healthcare providers, insurers, and patients, that could be avoided with effective communication: "[t]he investment in language services is far less than the direct and indirect costs of not providing language services." The authors recommend that providers collect and record accurate language data; recognize a patient's language needs at each key patient encounter; and document the language services provided throughout the series of patient-provider encounters" to endure there are appropriate plans in place to "ensure the timely provision of language services throughout the care continuum."

20.   **Al Shamsi H. , Almutairi A.G. , Al Mashrafi S. , et al. Implications of Language Barriers for Healthcare: A Systematic Review.** *Oman Medical Journal.* **2020;35(2):e122.** Al Shamsi et al. conducted a systematic review to investigate the impact of language barriers on the delivery of healthcare and to suggest solutions to address the challenges. Researchers searched two databases (i.e., PubMed and Medline) for research published between 2000 and 2019. A total of 1211 original articles were identified, of which (n=14) met inclusion criteria (i.e., focus on language barriers, peer-reviewed, primarily conducted in healthcare organizations. Of the included studies, 9 studies used a cross-sectional design, 2 used a prospective design, 2 used qualitative research, and 1 was a report. Studies were conducted in various countries including the U.S. (5 studies), Saudi Arabia (2), Switzerland (2), Canada (1), Germany (1), England (1), Norway (1), and South Africa (1). A total of 300, 918 participants were involved in the 14 studies, with the number of participants in each study ranging from 21 to 22,353. Studies focused on various components: 7 focused on language barriers and patient satisfaction, 2 on the impact of language barriers on healthcare provider satisfaction, 1 on the impact of language barriers on both healthcare providers and patient satisfaction, 2 on the cost of interpretation services, 1 on the quality of interpretation services, and 1 on online translation tools. A cross-sectional study conducted in Saudi Arabia with interviewees (n=116) found "among patients who received treatment from nurses who did not speak the local language, 30% had difficulty understanding medical instructions, 30% had a problem with the reliability of information, and 50% believed that the language barrier contributed to errors." Results of a U.S.-based telephone survey (n=1200) found that "among patients who did not speak the local language, 49% had

trouble understanding a medical situation, 34.7% were confused about how to use medication, 41.8% had trouble understanding label on medication, 15.8% had a bad reaction to medication due to a problem understanding their healthcare provider's instructions." Similarly, a Canadian study (n=297) found that "66.7% [of patients who didn't speak the local language] faced a barrier when accessing healthcare, and 20% did not seek healthcare services if these were not readily available for fear of not understanding their healthcare provider." Results of another U.S. study of 1,083 incident reports across 6 hospitals found that "many patients with limited local language proficiency experienced adverse events that resulted in detectable physical harm (49.1% of patients) or moderate temporary harm (46.8%) or experienced some failure in communication with medical providers (52.4%)." Results of a mailed survey to patients (n=2,746) from 11 health centers in the U.S. showed that "patients with language-discordant providers reported receiving worse interpersonal care and less health education." Authors note that language barriers contribute to miscommunication between medical providers and patients, which "contributes to a reduction in the satisfaction of both medical providers and patients, the quality of healthcare delivery, and patient safety." Additional studies indicate that "language barriers contribute to medial professionals' incomplete understanding of patients' situations, delayed treatment or misdiagnoses, poor patient assessment and incomplete prescribed treatment." Moreover, even when patients have access to healthcare, language barriers contribute to "decreased satisfaction with that healthcare, decreased understanding of their diagnoses, and increased medication complications." Although limited by access to and financial burden of, "the use of interpreter services contributes to increased patient satisfaction and improved patient care among patients [experiencing] language barriers." Specifically, "[i]nterpreter services have a significant association with increased physician visits, prescription drugs by physicians, and receipt of preventative services among patients." Healthcare professionals are also attempting to meet patient needs with translation software like MediBabble (an application created by medical students at the University of California, San Francisco) and Google Translate. Authors noted a limitation of this work is that there are only a few studies on the application of online translation tools in healthcare to address the problem of language barriers.

21.	**Bailey S. C., Sarkar U., Chen A. H., et al. Evaluation of language concordant, patient-centered drug label instructions. *J Gen Intern Med.* 2012;27(12):1707-1713.**
Researchers conducted "a randomized, experimental evaluation to test the efficacy of using the ConcordantRx instructions to improve comprehension among people with limited English proficiency (LEP) compared to standard instructions" and the "effect of the ConcordantRx instructions on regimen dosing and patients' regimen consolidation." Researchers recruited a convenience sampling of 202 adults with limited English proficiency from San Francisco and Chicago ((n=100 in San Francisco, n=102 in Chicago) who primarily spoke Chinese, Korean, Russian, Spanish, or Vietnamese (n=40 in Russian, Spanish, and Vietnamese, n= 41 in Chinese and Korean). The researchers defined limited English proficiency as the self-identified ability to speak English not well or not well at all, or preference to receive medical care in a person's native language. Participants randomly received either standard or ConcordantRx instructions printed on Rx labels and affixed to standard 40-dram vials. Standard instructions used typical terminology and times per day approach to explain when a medication should be taken and produced translations by one pharmacy's translation software. ConcordantRx translated instructions were developed using health literacy best practices, including terminology for 4 distinct time periods to explain when a medication should be taken. Researchers measured 3

outcomes: 1) understanding, 2) regimen dosing, and 3) regimen consolidation. Understanding was coded as correct or incorrect and the analysis considered study site, language, sex, and education characteristics. There was a significant difference in understanding standard versus ConcordantRx instructions in both bivariate analyses (66.0 % vs. 83.0 %, P> 0.0001) and multivariable analyses (relative risk ratio [RR]: 1.25, 95 % confidence interval [CI]: 1.06–1.48; P= 0.007). Education was found to be the only variable with significant association related to understanding during bivariate analyses. Dosing and consolidation were coded as counts respectively representing the number of medications a study participant correctly dosed in a 5-drug regimen or the number compartments used in a dosing tray. Considering regimen dosing, the median number of medications dosed correctly with standard instructions was 3; the median number of medications dosed correctly with ConcordantRX instructions was 4. Bivariate analyses examining regimen dosing showed that participants with lower levels of education and those who spoke Vietnamese were significantly less likely to dose medication regimens correctly. Multivariate analyses showed receipt of ConcordantRx instructions and lower levels of education were the only significant, independent predictors of Rx regimen dosing ability (incidence ratio rate [IRR]: 1.19, 95 % confidence interval [CI]: 1.03–1.39; P= 0.02 for instruction type; IRR: 0.75, 95 % CI: 0.57– 0.99; P= 0.04 for less than 9th grade education). Regimen consolidation showed the "median number of times daily that individuals dosed medication in the regimen was 6.0 for individuals receiving the standard instructions versus 4.0 for individuals receiving the ConcordantRx instructions," with bivariate analyses showing "statistically significant difference in consolidation by sex, with men being more likely to consolidate medications than women" and multivariate analyses showing receipt of the ConcordantRx label as the only significant, independent predictor of regimen consolidation (IRR: 0.76, 95 % Confidence Interval [CI]: 0.64–0.90; P= 0.001). Researchers concluded that LEP adults who received ConcordantRx instructions were significantly more likely than those who received standard instructions to demonstrate how to take a single Rx medication appropriately" and "significantly more likely to dose more medications correctly in a multi-drug regimen and to simplify medication use by consolidating when pills would be taken." They concluded that their research implied that people who have a greater understanding of medications are more likely to take medications correctly. Researchers also discussed that while there were clear benefits of ConcordantRX instructions, there were only a quarter of participants who correctly demonstrated correct dosing of their medications, which could indicate that Rx labeling alone may not be sufficient in managing medication regimens. Researchers framed their research within the context of patient safety, with poor comprehension of prescription instructions as the root cause of adverse drug events and medication errors.

22.   **Mohan A., Riley B. M., Boyington D., et al. Development of a Patient-Centered Bilingual Prescription Drug Label.** *Journal of Health Communication.* **2013;18(sup1):49-61.**
Researchers developed a qualitative study of Latino (n=30) and non-Latino (n=18) patients and pharmacists (n=9), recruited from two safety-net clinics and a university pharmacy. Patients from the safety-net clinics were more likely to have low incomes or to not have health insurance. The goal of the study was to develop and refine an evidence-based, bilingual, prescription container label that meets regulatory guidelines and includes additional enhancements to improve understanding." Patients were recruited via a convenience sample from February to June 2011 and were eligible if they spoke either English or Spanish, were at least 18 years old, and were taking one chronic medication. Researchers collected demographic information, cognitive

testing, and a single-item health literacy screening test in either English or Spanish. Researchers developed their own patient-centered medication label. Researchers 6 conducted focus groups 5 personal interviews with a total of 57 participants, inclusive of 5 patient focus groups (2 in English, 3 in Spanish) and 1 focus group with pharmacists. Personal interviews were conducted with 3 patients and 2 pharmacists. Participants were asked questions about their observations of the prescription label, what they found useful, and what they disliked or found confusing and to provide suggestions to improve the prescription label. Researchers used the grounded theory method to analyze focus group data, documenting dominant themes and compiling descriptive statistics. Researchers reported that "[c]ommunication barriers were most pronounced among Latino patients who also noted some language-related barriers. Participants noted that most pharmacies did not provide information in the patient's preferred language, or when they did, it was only upon request." The researchers summarized the focus group findings on both traditional and patient-centered labels: "[P]articipants found traditional labels difficult to understand. The amount of information presented, layout, and font size commonly made the information difficult to understand. In contrast, patients preferred a patient-centered label that grouped together content most important to patients (e.g., drug name, dose, indication, and directions for use), used plain language instructions in a larger font size, used a 4-time-of-day schedule for dosing instructions, and included illustrations to facilitate understanding." Pharmacists and Spanish speaking patients agreed having instructions in both English and Spanish would be helpful, also finding that providing Spanish and English on the same label serves the needs of patients and health care professionals. Researchers discussed barriers to a patient centered label in practice including concern of prescription label size and space constraints and related challenges in adopting larger bottles as a solution. Other considerations for pharmaceutical practice included consideration of including the drug indication on the bottle and the content of format of warning labels. Mohan et. al. concluded that their study findings add to the literature to support plain language medication instructions and illustrations for prescription medications.

23.   **Cheng T. C., Guo Y. Adult Immigrants' Utilization of Physician Visits, Dentist Visits, and Prescription Medication. *J Racial Ethn Health Disparities.* 2019;6(3):497-504.**
Researchers analyzed secondary data extracted from the National Health and Nutrition Examination Survey (NHANES) 2011–2012, and considered noninstitutionalized adults aged 18-64 years old, born outside of the United States and who identified as White, Black, Hispanic, or Asian (n=1,480 people). They used three dichotomous outcome variables representing health care utilization (e.g., visiting a physician, dentist, or using a prescription medication). Researchers used self-report health to represent medical need. Researchers considered explanatory variables of sex, age, and marital status. They also considered race and ethnicity, education level, income, health insurance coverage, eligibility for government-sponsored health insurance, and acculturation (considered through language spoken at home and citizenship status). NHANES data did not include survey respondents' geography, proximity to health services, or experience of acculturation. Through descriptive analysis, of 1,452 immigrant survey respondents, "43.1% had visited a physician, 52.5% had visited a dentist, and 35.5% had used prescription medication during the 12 months preceding the NHANES interview… 5.5% were non-Hispanic White, 9.6% were Black, 39.7% were Asian, and 45.2% were Hispanic." The analysis found that the likelihood of using prescription medication was associated negatively with self-reported health (OR = .68, p < .01), male gender (OR = .69, p < .01), and US citizenship (OR = .65, p < .01). Such likelihood was associated positively, however, with age

(OR = 1.07, p < .01), non-Hispanic White ethnicity (OR = 2.37, p < .01), having private insurance (OR = 2.02, p < .01), and having public insurance (OR = 3.14, p < .01)." The researchers discussed that results showed that survey respondents in poor health were more likely to use a prescription, inferring that people who perceive a need will access a prescription drug; this was not true of those respondents reporting poor health seeing a physician. The study found that "physician visits were associated negatively with Hispanic ethnicity, poverty-level family income, and English-language proficiency." Researchers did not find an association between use of prescription medication and educational attainment. Female respondents were also positively associated with prescription use and dental visits than males. Further "obtained odds ratio indicated that public health insurance was a stronger positive influence on utilization of prescription medication than private coverage was," which the researchers posited may be related to financial resources and accessible sales outlets. Researchers did not find association between the length of time a person lived in the US and doctor or dentist visits or prescription use. Researchers did not link English proficiency to prescription use, however, there was an association between spoken English proficiency and physician and dental visits, both of which the study implied, were negatively affected by limited language proficiency. Additionally, the study did show that limited English proficiency did not deter survey respondents from seeing a physician when ill, however the researchers did note that language barriers may lead to prescription-use errors that could threaten health. The researchers' concluded that removing language barriers would increase access to physicians, dentists, and prescriptions, adding that for medication safety purposes, "pharmacists should ensure that information on and instructions for using prescribed drugs reach immigrants in a language they read or at least understand."

24. **Healthy People 2030, Reduce the proportion of people who can't get prescription medicines when they need them -- AHS-06. 2020; Available at: https://health.gov/healthypeople/objectives-and-data/browse-objectives/health-care-access-and-quality/reduce-proportion-people-who-cant-get-prescription-medicines-when-they-need-them-ahs-06. Accessed 2/21/2022.**
The Healthy People 2030 objectives include a goal related to health care access and quality. Objective AHS-06 is to "reduce the proportion of people who can't get prescription medicines when they need them."

25. **Prevent and Manage High Blood Pressure: Blood Pressure Medicines. 2022; Available at: https://www.cdc.gov/bloodpressure/medicines.htm. Accessed, 2/21/2022.**
The U.S. Centers for Disease Control and Prevention (CDC) provides an overview of measures to prevent and manage high blood pressure, including the use of blood pressure medication.

26. **Brown M.T., Bussell J.K. Medication Adherence: WHO Cares?** *Mayo Clinic Proceedings.* **2011;86(4):304-314.**
Brown and Bussell conducted a review of literature to discuss the general aspects of medication adherence, using cardiovascular disease (CVD) as an example. They conducted a MEDLINE database literature search to identify articles (inclusive of English and non-English-language) published between January 1, 1990, and March 31, 2010. Of the 405 articles, 127 met inclusion criteria. Authors cited evidence from a 2003 World Health Organization (WHO) report that among developed countries approximately 50% of patients with a chronic illness do not take medications as prescribed. Such poor adherence contributes to "increased morbidity and death

and is estimated to incur costs of approximately $100 billion per year." For example, authors cited evidence suggesting that "as many as 50% to 80% of patients treated for hypertension are nonadherent to their treatment regimen." According to the WHO, "lack of adherence is the most important cause of failure to achieve [blood pressure] BP control. Failure to achieve BP control significantly increases the risk of [heart attack], stroke, and hospitalization." Whereas, "adherence to antihypertensive therapy reduces the risk of these events." The WHO identifies 5 categories of factors that affect adherence: 1) socioeconomic factors, 2) factors associated with the healthcare team and system in place, 3) disease-related factors, 4) therapy-related factors, and 5) patient-related factors. Poor understanding of medication instructions is among a variety of factors that contribute to a person not adhering to their medication. One of the recommended strategies to overcome this barrier is for healthcare providers working with patients whose first language is not English is to provide information in the patient's native language. Providing information in the patient's native language may also lessen the burden of poor health literacy (which affects speakers of all languages, including English). More information about provider-related and health system-related factors are discussed in this review.

27.   **Neiman A.B., Ruppar T. , Ho M. , et al. CDC Grand Rounds: Improving Medication Adherence for Chronic Disease Management — Innovations and Opportunities.** *Morbidity and Mortality Weekly Report.* **2017;66(45).**
This CDC Morbidity and Mortality Weekly (MMWR) discusses medication nonadherence and its medical consequences. It cites evidence that in the U.S., "3.8 billion prescriptions are written annually (3). Approximately one in five new prescriptions are never filled, and among those filled, approximately 50% are taken incorrectly, particularly with regard to timing, dosage, frequency, and duration." The direct healthcare costs of nonadherence in the U.S. have "grown to approximately $100-$300 billion" spent annually. Medication adherence is affected by a variety of factors along the continuum of care related to the patient, providers, and health systems. For example, unintentional patient-related factors (e.g., inadequate understanding of dose or schedule) often become worse with increasingly complicated medication regimens. Healthcare system related factors affecting adherence include "unclear medication labeling and instructions, limited availability of culturally appropriate patient education materials," etc. Authors suggest that "[i]nterventions to improve medication adherence could be more effective if patient's health literacy, cultural background, and language preference and proficiency are taken into account when designing communication and patient education materials."

28.   **Clark J.R., Shlobin N.A., Batra A. , et al. The Relationship Between Limited English Proficiency and Outcomes in Stroke Prevention, Management, and Rehabilitation: A Systematic Review.** *Frontiers in Neurology.* **2022;13(February 2022).**
Clark et al. conducted a systematic review to "identify differences in outcomes in stroke care prevention, management, and recovery between individuals with and without English proficiency in English-predominant healthcare settings." Using the PubMed, Embase, Scopus, and Web of Science databases, researcher identified 891 unique articles, of which 20 (17 of good quality and 3 of poor quality) met inclusion criteria (i.e., published or translated into English, full-length journal article with full text available, content related to stroke and LEP, discussing prespecified outcomes [e.g., patient usage of and adherence to preventative stroke care regimens]). However, 11 of the 20 articles did not provide information about interpreter availability or usage, which authors noted limited "the ability to draw conclusions about the effect of LEP on measured

outcomes in these studies." Most studies were conducted in English-predominant countries (13 studies from the U.S., 4 from Australia, 2 from Canada, and 1 from the United Kingdom). Four studies examined pre-stroke elements of patient care (e.g., awareness of symptoms and preventative treatment), 12 studies looked at factors of acute stroke care (e.g., presentation, inpatient management, and outcomes), 5 studies considered post-stroke care (e.g., rehabilitation and quality of life), and 1 looked at acute and post-stroke outcomes. A cross-sectional U.S. study examining pre-stroke factors asked survey participants (n=25,426) to identify stroke symptoms. Results showed that "after adjusting for sociodemographic characteristics, healthcare access, and cardiovascular risk factors, Spanish-speaking Hispanic respondents were [statistically significantly] less likely than English-speaking Hispanic, non-Hispanic White, and non-Hispanic Black respondents to correctly identify all stroke symptoms listed in the study's survey" (18% of respondents vs. 31%, 50%, and 41%, respectively). Another study found that "not speaking English was independently associated with describing warfarin indication discordantly with acceptable responses, but not with providing discordant descriptions of stroke." Specific to acute care, "[m]ultivariate analysis accounting for sociodemographic factors and stroke severity showed that non-English-preferring patients who did not receive a [professional medical interpreter (PMI)] were less likely to receive defect-free care than patients who did receive PMI (61.5 vs. 73.9%, p=0.04, adjusted model odds ratio 0.49, 95% CI 0.25-0.94), where defect-free care represented receipt of all treatment measures for which a patient was eligible". Specific to post-stroke care, one study found that "patients often saw rehabilitation tasks as tests of competence rather than constructive activities, felt little agency in the decision of whether or not to involve a PMI, and commonly settled for 'getting by' in English despite varying levels of proficiency." On the other side, one study with rehabilitation therapists found that "rehabilitation was affected by language barriers…lower frequency of visits due to difficulty logistically arranging PMI services or interpreter unavailability for uncommon languages and dialects, extended sessions due to need for translation, and lower likelihood of providing written materials due to absence of writing translation services." Overall, 4 studies "associate LEP with suboptimal results across multiple important metrics of pre-stroke care, showing that [people with LEP] have lower awareness of stroke symptoms and experience greater difficulty with medication regimens, reflected by less TTR while undergoing chronic anticoagulation." Despite similar intensity of care, anticoagulation clinics showed poorer results for patients with LEP, "indicating that communication and adherence to regimens outside of the clinic may be principal sources of inequity." Authors recommend healthcare systems provide accessible translation services for written information to complement patient-provider discussions. Authors further discussed both acute stroke care and post-stroke care, noting that "providers should be aware that [patients with LEP] are at risk of lower post-stroke quality of life" and therefore strategies to communicate with patients with LEP should be considered in continuing care. The fact that 11 studies either lacked the ability to analyze rates of PMI usage or language concordant vs. discordant encounters or did not describe these data limited findings. Without consideration of language access studies "may fail to observe the vulnerability of [people with LEP] who do not receive proper PMI services in a language discordant environment." Additionally, no studies reviewed discussed the quality of interpretation services provided. Authors concluded that "stroke patients with LEP face barriers to equitable care at multiple stages […] [and] may benefit from tailored education regarding stroke symptom recognition and medication regimens." Moreover, "services which translate written material will enhance the ability of patients to participate fully in their care and recovery."

29.   **Lakhanpaul M., Bird D., Manikam L., et al. A systematic review of explanatory factors of barriers and facilitators to improving asthma management in South Asian children.** *BMC Public Health.* **2014;14(403).**

Lakhanpaul et. al. conducted a systematic review "of primary evidence exploring explanations of barriers and facilitators to asthma management [among] South Asians" (people of Indian, Pakistani, or Bangladeshi descent). Researchers searched databases and web resources for research published since 1990 to 2010. A total of 9,371 original articles were identified, of which (n=15) met inclusion criteria with a primary focus on "explaining barriers or facilitators to asthma management in South Asian children." Of the included studies, 3 were prevalence studies, 1 was a questionnaire-based interview, 9 were questionnaire studies, 1 was a focus group, and 1 was a cohort study. Most studies were quantitative (14), and 1 study was qualitative. Studies were conducted in various countries including Pakistan (2 studies), India (5) and the UK (8). A total of 25,755 children ages 2 through 17 years, 18,483 parents and caregivers, and 239 healthcare professionals were involved in the 15 studies. In 7 studies, outcomes measured knowledge, understanding, or beliefs about asthma; 3 studies measured symptom perception of 'wheeze,' 2 studies measured prescriptions and use of preventative medications; and 2 studies measured the impact of migration and 'westernization' on asthma and atopy. Researchers found evidence of under-diagnosis of asthma and under-prescription of preventer medication for South Asian patients. A prevalence study in the UK of children "reported significant discrepancies between the percentage of children with diagnosed asthma and those with symptoms of asthma." Another UK based prevalence study of children reported that "inhaled corticosteroid [ICS] prescriptions were lower in South Asian compared to White children […] despite no evidence for asthma severity variation." A UK focus group study of mothers found that South Asian children with acute asthma were "less likely to use the correct administration method or receive medications […] compared to White and Other inner-city children." Overall, 4 studies found it was more common for parents to not accept an asthma diagnosis, which the authors discussed may be due to stigmatization of asthma. This was suggestive that associated social stigma may impact compliance. The presence of an ethnicity-specific social stigma of asthma is likely lessened in the South Asian population as a result of acculturation. Results of 2 studies support the existence of a language barrier for South Asian children and the management of asthma. In a UK study of white and South Asian parents, 83.5% correctly identified a wheeze, however, a correct answer was less likely if English was not spoken as a first language. Lakenpaul et.al discussed that language barriers reflect being in a minority position rather than an ethnicity-specific issue. A UK study and South Indian study found that South Asian parents were less likely to administer medication than white parents. Lakhanpaul et. al. stated that different medication adherence between ethnic groups supports the "notion that knowledge and beliefs are closely linked and that misconceptions around medication side effects may underlie nonadherence." The authors identified key issues as ethnic-specific to South Asians that included the impact of impact of parental and professional knowledge and beliefs, health service utilization pattern explanations, and impact of prejudice and stigmatization. Language barriers, though not ethnic-specific, present a challenge as all healthcare materials are not translated nor interpreted; greater effort could ensure more effective communication. The authors stated that there is a need for research to link ethnic-specific beliefs, barriers, and management practice to clinical outcomes. They concluded that health inequalities and risks associated with under-treatment or mismanagement can be reduced with ethnic-specific

services and language support. Note: Although the study design and execution were appropriate, citations within the article and table presenting findings were incorrectly assigned. Therefore, analysts downgraded the execution rating for this resource.

30.   **Himmelstein J., Himmelstein D. U., Woolhandler S., et al. Health Care Spending And Use Among Hispanic Adults With And Without Limited English Proficiency, 1999-2018.** *Health Aff (Millwood).* **2021;40(7):1126-1134.**
The researchers examined health care spending differences by English proficiency status and the long-term health care utilization patterns of those with or without English proficiency. The researchers used nationally representative self-reported survey data of respondents 17 years old and older from the Healthcare Research and Quality's Medical Expenditure Panel Survey (MEPS) from 1998 through 2018. They compared Hispanic adults with limited English proficiency to both Hispanic and non-Hispanic adults who were English proficient. The researchers determined limited English proficiency based on whether the MEPS survey was taken in Spanish or in English. Health care utilization was assessed through mean annual health care expenditures per capita for each category of health services (e.g., outpatient visits, ED visits, hospitalizations, and prescriptions) and mean annual counts per capita for health services. Expenditures were adjusted to 2018 dollars. Modeling controlled for age, sex, income, self-reported health status, education, and census region. Unmeasured confounders included the survey respondents' state of residence, access to language services, and geographical variance of health care costs. The researchers pooled survey respondent data from 2014 through 2018 for all analyses except time trends for an optimized sample size (17,776 Hispanic adults with limited English proficiency, 14,936 Hispanic adults who were English proficient, and 87,834 non-Hispanic adults who were English proficient). Researchers' analysis showed that "[a]dults with limited English proficiency had lower expenditures than the comparison groups for every type of health service in both adjusted and unadjusted analyses… The number of visits and prescriptions per capita followed a similar pattern: Hispanic adults with limited English proficiency had markedly lower visit rates than either comparison group, as well as fewer inpatient days and filled prescriptions." For example, "expenditures per capita for Hispanic adults with limited English proficiency were $1,463 lower (98% CI: 1,030, 1,897), or 35 percent lower, than for Hispanic adults who were English proficient and $2,802 lower (98% CI: 2,356, 3,247), or 42 percent lower, than for non-Hispanic adults who were English proficient." The researchers discussed that limited English proficiency is associated with less health care use. Researchers found a persistent gap, as measured by spending on health care services, in use of care between Hispanic adults with and without English proficiency between 1999 and 2018. Within the same time frame, the gap of use has widened between Hispanic adults with limited English proficiency non-Hispanic, English-proficient adults. The researchers' analysis determined that people with limited English proficiency showed substantial rates of missed age-appropriate health screenings. Researchers discussed potential causes for language-based differences in health care utilization and the gaps as a potential result of language-based inequities and health care access: "Non-English speakers may be less likely to seek care for health concerns, anticipating that their needs might not be met… Even when care is sought, the lack of language concordant clinical and administrative staff in many health care organizations may make navigating the health care system more difficult…" The researchers contextually cited the number of people in the United States who speak Spanish at home (41 million people or 13.5% of the population) and the

number of people who have limited English proficiency (25 million people or 8.2% of the population).

31.   **Serafin M. Health of Washington State Report: Self-reported Health Status. Data Update 2016. Washington State Department of Health;2016.**
Serafin presents data from Washington state on self-reported health status. The data show that after accounting for age, education, race and ethnicity, household income was a strong predictor of self-reported health status. Health status varied by race and ethnicity, with close to 20% of Native Hawaiian/Other Pacific Islander reporting fair or poor health.

32.   **Commission Pharmacy Quality Assurance. October 22, 2021 Pharmacy Quality Assurance Commission Public Meeting Materials as of October 20, 2021. Tumwater, Washington2021.**
This document presents the meeting materials for the Pharmacy Quality Assurance Commission's October 22, 2021 meeting. Page 49 of the packet is the Washington Council of the Blind's Advocacy and Governmental Affairs Committees' request for rule making for accessible medication labels.

33.   **Management Washington State Office of Financial. Estimates of population with limited English proficiency (LEP) for the state and counties. 2016.**
The Washington State Office of Financial Management (OFM) produced estimates of the population with limited English proficiency at the state and county level. This dataset presents information from the Comprehensive Education Data and Research System's (CEDARS) database maintained by the Office of the Superintendent of Public Instruction (OSPI). The data represents student enrollment on March 15, 2016. CEDARS data reflect primary languages by spoken students in Washington State. Spanish is the most common primary language of students who are English language learners; an estimated 12.7% of students identified as English language learners and primarily speak Spanish. In addition, CEDARS data provides an estimate of the number of languages spoken in Washington State by at leaet one person. In 2016, there were 246 languages spoken in Washington State.

34.   **Management Washington State Office of Financial. Language spoken at home: Persons Living in Households Where Language Other Than English Is Spoken. 2021.**
The Washington State Office of Financial Management (OFM) provides summary data from the U.S. Census Bureau's American Community Survey 5-year-estimates. In 2019, 20.5% of people in Washington State lived in a household where a language other than English is spoken, and this percentage has increased over time. In 2019, 7.6% of people in Washington State age 5 years and older reported living in a household where English is spoken less than "very well".

35.   **Survey American Community. Selected Social Characteristics in the United States 2019.**
Data was obtained through the 2019 American Community Survey 5-year estimate data profiles and pulled for all counties in Washington State. Data included the estimated number and percentage of people in each Washington county who spoke English less than "very well." For example, the ACS shows that in Adams county, 29% of the population reports to have difficulty speaking English, the highest proportion of all Washington counties. In Pend Oreille county,

0.5% of the population reports difficulty speaking English, the lowest proportion of Washington counties.

36. **Washington State Military Department Emergency Management Division. Limited English Proficiency v2 Map. In: Officer WSOotCI, ed2019.**
The Washington State Office of the Chief Information Officer maintains the Washington Geospatial Open Data Portal. In 2019, the Washington State Military Department, Emergency Management Division combined data from the 2016 Office of Financial Management "Estimates of population with limited English proficiency for the state and counties" and 2015 U.S. Census "Language spoken at home by ability to speak English for the population 5 years and over." Using these datasets, they estimated the number of languages spoken by 1,000 or more people or 5% of the population by county. Twenty-five counties (out of 39 counties) in Washington State have at least one language other than English spoken by 1,000 or more people or 5% of the population. King County has 27 different languages other than English spoken by 1,000 or more people of 5% of the population.

37. **Weiss L., Scherer M., Chantarat T., et al. Assessing the Impact of Language Access Regulations on the Provision of Pharmacy Services.** *J Urban Health.* **2019 96(4):644-651.**
The researchers introduced the study by contextualizing that people with limited English proficiency (LEP) are more likely to have reduced access to health care, have limited comprehension of health information, report lower levels of satisfaction with health care services, and may face higher medical costs. The researchers examined characteristics and impact of language access regulations on services available to LEP patients focused on "capacity to provide written translation and oral interpretation of medication instructions, provision of translated materials, and systematic approaches to identifying language needs among NYC chain pharmacies." Between 2008 and 2012, New York City and New York State adopted regulations to require translation and interpretation services for pharmacy patients speaking the most common non-English languages; the State Pharmacy Board was not required to monitor compliance. Researchers reported on two random sample telephone surveys conducted in 2006 and 2015 of New York City chain pharmacies that used samples from lists of licensed New York State pharmacies. The surveys were part of a larger project on language services in chain pharmacies being implemented in New York State, New Jersey, and Connecticut. The 2006 survey considered a sample of 48 pharmacies and the 2015 survey considered a sample of 77 pharmacies. The researchers limited their study sample to pharmacies in zip codes having at least a 10% foreign born population and a population of 10,000 or more, according to the 2014 American Community Survey. To reduce potential bias of survey reporting, researchers made structured site visits to 30 randomly selected pharmacies focused on adherence to signage requirements of language access laws. Researchers examined 1) translation of medication instructions; 2) access to telephone interpretation; 3) language access signage; and 4) indication of language need in patient records. The study found that pharmacists surveyed in 2006 were "less likely to report patients with limited English proficiency than were pharmacists surveyed in 2015 (93.8 vs. 100%, $p < .05$)." Pharmacies in 2015 "were significantly more likely to report capacity to print translated prescription medication labels (80.4% in 2006 versus 100% in 2015, $p < 0.001$), translating labels daily (15.4 vs. 66.7%, $p < 0.001$), access to a telephone interpretation service (20.8% vs. 90.8%, $p < 0.001$), and use of the telephone service (20.8 vs. 68.8%, $p < 0.001$). In addition, there were reported increases in language needs being part of the

patient record (19.4 vs. 49.4%, p < 0.01) and written notices or signs indicating access to language services (7.7 vs. 85.7%, p < .001)." There was significant improvement of meeting the needs of certain portions of the population as pharmacies adapted and adopted imposed state regulations. The researchers are continuing to examine whether the change in practice was a result of the legislation specifically, or if the shift was more of a general change of practice. In discussion of the study results, the researchers noted early concerns of feasibility and liability exposure. As most pharmacies in this study were part of multi-state chains, the researchers discussed that promoting and utilizing the language access systems outside of New York may be easily transposed to other states. The study was limited in its examination and could not assess language-appropriate instructions, improved comprehension, reduced medication errors, or better health outcomes.

38. **SB 698 - Relating to prescription drug labeling; creating new provisions; amending ORS 689.505; and prescribing an effective date.** *Oregon Revised Statutes*. **2019 Regular Session ed2019.**
This Oregon State bill passed during the 2019 Legislative Session and directed the State Board of Pharmacy to adopt rules to: 1) require prescription drugs for specified persons be labeled or dispensed with informational insert in English and other language; 2) specify languages other than English need to be used on label and insert; and 3) post signage regarding patients' right to free, competent oral interpretation and translation services. It required the rules to become operative on January 1, 2021.

39. **Bailey S.C. , Hasnain-Wynia R. , Chen H.M., et al. Developing Multilingual Prescription Instructions for Patients with Limited English Proficiency.** *Journal of Health Care for the Poor and Underserved.* **2012;23(1):81-87.**
Bailey et al. described the development of a set of patient-centered, multilingual prescription (Rx) instructions and reported the challenges and lessons learned from this process. Funded by The California Endowment, the ConcordantRx Study developed patient-centered Rx instructions for Chinese, Korean, Russian, Spanish, and Vietnamese-speaking populations in the U.S. "To be patient-centered […] instructions took into account patient 1) literacy, 2) language, and 3) culture." As LEP people are more likely than English-proficient adults to have low health literacy, Rx instructions used health literacy best practices. Specifically, they "were written in Arial (a sans-serif font), used numbers instead of the written equivalent (e.g., 2 instead of two), and were written in sentence format, with only the first letter capitalized. When possible, simpler terms were utilized instead of less familiar or difficult terms (e.g., pill instead of tablet)." The content of ConcordantRx instructions provided explicit guidance on when to take medications. Based on prior research on grounded instructions, they used four distinct time periods (morning, noon, evening, and bedtime) to describe when to take medications. For example, instead of reading: "take two tablets twice daily" (standard Rx), patient-centered Rx instructions read "Take 2 pills in the morning and [return / new line] 2 pills at bedtime." Next, the team used a committee approach to translate Rx instructions into Chinese, Korean, Russian, Spanish, and Vietnamese. For each study language, "three bilingual, bicultural translators each independently translated the English-language Rx instructions into another language […] then convened and discussed the instructions as a team, and with help of a moderator, achieved consensus on the most appropriate translations." Finally, while opportunities to take culture into account were limited due to the brevity of instructions, translators suggested avoiding any mentions of meals

in directions (e.g., "at breakfast") as many immigrants are more accustomed to eating at times consistent with their country of origin or may be adherent to religious customs that involve fasting for periods of time. Researcher noted that "[d]espite such efforts to address literacy, language, and culture, a number of challenges arose. These can be broadly categorized as difficulties related to 1) finding equivalent terms [e.g., 'evening' meaning between 4:00-6:00 p.m.], 2) ensuring similar reading levels, 3) accounting for regional differences, and 4) managing changes in label spacing and formatting [translated instructions were usually longer so a different font and 10 point size was used]." Lessons learned included: 1) put aside the appropriate amount of time and resources; 2) involve a diverse set of experienced translators to promote universality (e.g., different dialects); 3) include a moderator and subject matter expert in discussions (e.g., health professional); 4) take a broad approach to translation instead of seeking direct English equivalence (i.e., think of broad messages that need to be communicated and work with translators to come up with best phrasing); 5) consider the final product; and 6) pilot-test all translations among the target population.

40. **RCW 18.64.390 Nonresident pharmacies—Violations—Penalties., Revised Code of Washington (1991).**
This RCW establishes the conditions under which the Pharmacy Commission may deny, revoke, or suspend a nonresident pharmacy license or impose a fine.

41. **Cuthill C. Oregon pharmacies are short on staff and drug price managers have something to do with it. Oregon Public Broadcasting; 2021.**
This article was published by Oregon Public Broadcasting. The article features the Central Oregon Regional Director on the Oregon State Pharmacy Association Board and discussed the role of Pharmacy Benefit Managers role setting the price of prescription drugs.

42. **Weiss L. , Gany F., Rosenfeld P., et al. Access to Multilingual Medication Instructions at New York City Pharmacies.** *Journal of Urban Health: Bulletin of the New York Academy of Medicine.* **2007;84(6):742-754.**
Weiss et. al. examined the knowledge gap of pharmacists and pharmacists' access to, provision of, and perceptions of written and verbal prescription medication information for patients with limited language proficiency, with a focus on translated instruction labels. The researchers conducted a cross-sectional random sample telephone survey of 200 New York City pharmacists. Researchers collected pharmacy characteristics (e.g., pharmacy type, language competencies of pharmacy staff, ability to print translated medication labels and instructions, access to telephone interpretation services) and demographic information of pharmacists. Researchers also collected patient characteristics including language and frequency of patients with limited English proficiency. Researchers' main outcome of interest was a pharmacist's self-reported provision of translated prescription medication labels on a daily basis, with secondary outcome measures that included verbal and written translation capabilities and barriers to the provision of linguistically accessible medication information. Of the 200 survey participants, "38% were born in the US (including Puerto Rico) or Canada; 37.5% were born in Asia or the Pacific Islands. Approximately one third (35.5%) of the participants worked in a chain (including supermarket) pharmacy, 59.5% worked in an independent pharmacy, and 5.0% worked either in a hospital outpatient or clinic pharmacy." Most pharmacists (88%) reported serving patients with limited English proficiency daily, with the most common languages being Spanish, a Chinese language,

and Russian. Just under half of the surveyed pharmacies were translating medication labels on a daily or weekly basis. In a bivariate analysis, researchers found that pharmacist birthplace, pharmacy type, and proportion of patients with limited English proficiency in a census tract (overall, Spanish-speaking, and other European languages) were significantly associated (p=.05) with daily translation of medication labels. In a multivariate analysis, pharmacy type (OR= 4.08 for independent pharmacy and OR= 6.43 for clinic/outpatient hospital pharmacy, p=0.05) and the proportion of Spanish speakers in a census track were significantly associated with a pharmacy translating labels. Most of the pharmacists reported being able to provide translated labels in at least one language, the most common being Spanish, and most pharmacists reported having a bilingual staff member. However, less than half had a bilingual staff member qualified to provide medication counseling. Researchers surveyed the process that would lead to a translated prescription label. Over half identified that the need would be determined through interactions that occurred prior to filling a prescription and a third of pharmacists reported that a patient would request a translation. Researchers noted that pharmacies lack a systematic methodology for the identification and documentation of patient need for translated medication instructions. Researchers discussed the increase of the immigrant population coupled with the expanding use of medications and the limited availability for people who have limited English proficiency as a cause for concern. The researchers stated that the gap in availability of translated medication instructions could be due to insufficient human and technological capacity, lack of trust in translations, or lack of awareness for either the need or the process to meet the needs of patients with limited language proficiency

43.   **Services Centers for Medicare & Medicaid. Understanding and using the "Toolkit Guidelines for Culturally Appropriate Translation". U.S. Department of Health and Human Services; 2010.**
The toolkit is part of an 11-part health literacy resource from the Centers for Medicare and Medicaid Services. The toolkit is focused on the translation of written material to meet needs of people who have limited English proficiency, with guidelines for culturally appropriate translations.

44.   **Kohn L.T., Corrigan J.M. To Err Is Human: Building a Safer Health System. In: Committee on Quality of Health Care in America IoM, ed. Washington, D.C.: National Academy Press; 2000.**
This report focused on the Quality of Health Care in America project approved by the Governing Board of the National Research Council. This first report examined medical error. It discussed the frequency of medical errors, factors contributing to errors, the cost of errors, and public perception of safety. It includes recommendations to build leadership and knowledge for patient safety, error reporting systems, setting performance standards and expectations, and creating systems in healthcare organizations. Findings were reviewed by individuals chosen for their diverse perspectives and technical expertise.

45.   **Promotion National Center for Chronic Disease Prevention and Health. Strategies and Emerging Interventions for Improving Medication Adherence.** *Science-in-Brief Feature | Turning Science into Action***. Atlanta, Georgia: Centers for Disease Control and Prevention; 2017.**

This CDC Science-in-Brief feature focuses on medication adherence. Medication nonadherence is when a patient does not take medications as prescribed. It cites evidence that 20%-30% of medication prescriptions are never filled, "and patients do not continue treatment as prescribed in about 50% of cases." In the U.S., "medication nonadherence accounts for about 125,000 deaths and $100 billion to $300 billion in both direct and indirect health care costs each year."

46. **American Psychological Association. Evidence-Based Practice in Psychology: APA Presidential Task Force on Evidence-Based Practice. 2006;61(4):271-285.**
The American Psychological Association (APA) created a policy indicating that the evidence-base for a psychological intervention should be evaluated using both efficacy and clinical utility as criteria. The Association President appointed the APA Presidential Task Force on Evidence-Based Practice and the task force published this document with the primary intent of describing psychology‟s commitment to evidence-based psychological practices. This document, though, also references many research articles providing evidence for the efficacy of a number of psychological treatments and interventions. The reference list for this document highlights the growing body of evidence of treatment efficacy from the 1970s through 2006. Note that this does not indicate that all treatments are effective, but rather than there is a very large body of evidence supporting that evidence-based treatments are available.

47. **Prather Cynthia, Fuller Taleria R., Marshall Khiya J., et al. The Impact of Racism on the Sexual and Reproductive Health of African American Women.** *Journal of Womens Health (Larchmt).* **2016;25(7):664-671.**
Prather et al. use the socioecological model to describe racism and its effect on African American women's sexual and reproductive health. Authors examine the historical context of racism (e.g., medical experimentation) as well as institutional racism (society), personally mediated racism (neighborhood/community), and internalized racism (family/interpersonal supports and individual). Authors concluded, "[i]n both historical and contemporary contexts, race-based mistreatment has been shown to place African American women at increased risk for HIV/STIs, pregnancy-related complications, and early mortality."

48. **Alhusen J.L. , Bower K.M., Epstein E., et al. Racial Discrimination and Adverse Birth Outcomes: An Integrative Review.** *Journal of Midwifery.* **2016;61(6):707-720.**
Alhusen et al. conducted a review of literature to assess the relationship between racial discrimination and adverse birth outcomes. Fifteen studies met inclusion criteria, and "the majority of studies found a significant relationship between racial discrimination and low birth weight, preterm birth, and small for gestational age." Findings of qualitative studies discussed participants' experiences of institutionalized racism related to access and quality of prenatal care. Overall, evidence indicated that "racial discrimination was a significant risk factor for adverse birth outcomes."