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| Minutes | Oregon Board of Pharmacy – Rules Advisory Committee Prescription Labeling & Accessibility Rules January 22, 2020; 9-11am in Room 1B 800 NE Oregon Street Portland OR, 97232 |
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| Items | Desired Outcome |
| Welcome | <p>The following OBOP Staff & RAC Members introduced themselves and attended the meeting:</p> <p>Board Vice President, Shannon Beaman, Executive Director Joe Schnabel, Pharmacist Consultant Fiona Karbowicz and Operations Policy Analyst Rachel Melvin, Kate Ballard, Kristen Beiers-Jones, Cheryl Coon, Carma Cushman, Tim Frost, Rob Geddes, Tomson George, Emily Haugh, Linda Howrey, Michele Koder, Douglas Lang, Eric Lintner, Eric Morris and Evan Weibel.</p> |
| General Discussion | <p>Fiona began the discussion by stating that at the Board's direction, staff was tasked with creating a Rules Advisory Committee to seek input on legislation signed into Oregon law in 2019 related to Prescription Labeling & Accessibility – SB 698 and HB 2935. She presented a series of slides which described the purpose and responsibilities as a RAC member and stated that the members were invited to participate to inform the Board in an advisory capacity with information related to rules such as intent, implementation and fiscal realities for both 2019 SB 698 and 2019 HB 2935, not to write the rules. She went on to explain the definition of rules, when they are required and where to find Oregon Administrative Rules via the Secretary of State website.</p> <p>Statutory Review –</p> <p>Fiona provided an in-depth walk-through of the laws' directives and context for legislative intent, including how it supports the OBOP's mission of patient protection and safe medication use, protects & supports vulnerable patient populations by improving accessibility, medication adherence and reduce medication errors. She also pointed out that both laws were passed with operational dates and that OBOP doesn't have the authority to change a law's operational date when articulated in the law and signed by the Governor.</p> <p>Fiona reviewed the directives 2019 SB 698 related to prescription drug labeling which requires pharmacies in Oregon provide prescription container labels in both English and a readable language for patients with limited English proficiency (LEP). Visually impaired and LEP patients are more likely to experience medication errors due to an inability to read or understand prescription labels. It is estimated that 6.21% or 1 in 17 Oregonians (over 222,000 patients) are LEP. Section 2 of SB 698 states that these rules must:</p> <ul style="list-style-type: none"> • Require that labels be available in at least 14 languages other than English that are spoken in Oregon by individuals who are of limited English proficiency, as determined by the most recent American Community Survey from the US Census Bureau, and in consultation with the Oregon Health Authority and other necessary resources. <p>Fiona reviewed the directives for 2019 HB 2935 related to accessibility services for visually impaired patients and stated that it is estimated that 104,500 Oregon patients are visually impaired.</p> <p>She informed the RAC of some identified elements that will need to be articulated in the rules such as:</p> <ul style="list-style-type: none"> • Definitions for LEP/ Rx reader • Describe drug outlet applicability • Those that dispense any drug to a patient for self-administration, includes pharmacy & non-pharmacy dispensing outlets and non-resident pharmacies; outpatient only • 14 languages other than English spoken in Oregon by individuals who are of LEP • Signage, consistent with federal requirement • Operational, effective date |

Fiona then asked for Committee if they had any policy items or other impacts that were not mentioned, the members had nothing to add.

Committee Dialogue -

Fiona stated that OBOP is currently seeking information from OHA to inform the list of 14 languages and that a recommendation is forthcoming, which is a compilation of OHA's efforts with various stakeholders including community and refugee organizations, language experts and state agencies in consideration of the census data. The language provided will require justification and evidence to support recommendation provided. In formal rulemaking, this will be referred to as "documents relied upon". Ultimately, the Board will rely heavily on OHA opinion of what's most appropriate and defensible, when legally determining the list of 14 languages.

RAC Member Beiers-Jones reported that she met with OHA on 1/21/2020 and they focused on a language list provided by DHS of people who had applied for services and Medicaid who requested that their language be incorporated and said that she has a list from the State Refugee Coordinator. She went on to say that OHA stated that they would like more time to work on the list of 14 languages with Kristen and colleagues. Per RAC Member Ballard, the data is from 2017 ACS estimates.

RAC Member Koder offered to give language data from Multnomah County because they have been tracking it for some time. RAC Member Frost asked Fiona if the Board will ultimately decide the 14 languages. Fiona stated that it's a combination of what is articulated in the law, which is why OHA is tasked with helping define the 14 languages. RAC Member Weibel stated that languages can be readily available using his company's technology and should the languages change, implementation is easy to adopt assuming the 14 languages are defined. Each language would be handled independently and requires its own resources. Systems are built using current SIG data and it's continuously being updated as new drugs are implemented quarterly. RAC Member Ballard stated that the primary intent was just for the directions of use for the script.

The Committee discussed the implementation realities, contracts, amount of time to implement the languages for all pharmacies in Oregon. RAC Member Lintner stated that it's problematic that his software vendor doesn't have an interface for the 14 languages and would have to use two vendors possibly. He is concerned about the "lack of real estate" on the bottle due to the interface to accommodate all of the content and wanted to know if the supplemental insert could be used. RAC Member Ballard asked about flagging bottles as an option but RAC Member Lang stated that it doesn't adhere well to the bottle, and mentioned that in NY and CA the label is in English and the insert has the additional language. RAC Member Coon stated that informational inserts vs. label was a large discussion when the bill was being written and that is why they decided not to follow how it's being done in CA. RAC Member Lang mentioned USP Chapter 17 and its relationship to the CA law requirements. RAC Member Beiers-Jones reported that her group called some NY and CA pharmacies and said that they are not putting English on the label.

RAC Member Beiers-Jones read the purposed preliminary draft list she brought to the meeting and stated that there is not a plan to include additional languages added and that it was a combination of 3 different lists derived from ACS data, DHS Medicaid data and Oregon refugee data.

She read the following draft list of languages to the Committee:

Spanish, Simplified Chinese, Vietnamese, Russian, *Ukrainian, Korean, Japanese, Tagalog, Arabic, Khmer/Cambodian, Farsi, Somali, Burmese, *Karen, Romanian, Nepali, Swahili and Amharic. (she stated that *Ukrainian could be paired with Russian and *Karen could be paired with Burmese).

Statement of Fiscal Impact – Review and Development

Fiona stated that the Board is seeking specific fiscal realities from the RAC members to assist in the rulemaking process including identifying state agencies, units of local government and members of the public, likely to be economically affected by the rule. An estimate of costs to comply, quantity and type of small businesses who may be impacted. Estimated costs related to reporting, recordkeeping, cost of professional services, equipment, supplies, labor and increased

administration to comply. She asked the RAC Members to briefly share information relevant to fiscal and implementation realities for both rules, making sure to identify each rule.

RAC Member Lintner stated that he couldn't speak to fiscal realities because he isn't sure how the reader law applies to his patients and isn't sure if he has to provide a reader in long term care based on their patient demographics. RAC Member George stated that fiscal impacts will depend on the 14 languages, and currently their system doesn't support all languages that were presented today, their printers may not print all characters and may not be compatible and will have potential hardware issues. He went on to say that one possible solution is to expand the label size to accommodate more characters; however, that will increase costs of the labels as 30 dram vials triple the volume and complicate automation. It will impact mail order, around 75 pharmacies in Oregon and on the retail side, implementation, and a subscription fee to vendor. He stated that in NY it cost around 2 million for implementation of 7 languages, 9 to 11 languages are in the law if it's located in the city.

RAC Member Geddes stated that for Rx Reader law Albertsons is already complying due to ADA regulations and asked if the Board will state how much time pharmacies will be given for implementation and ongoing compliance. He said his company is currently using a "hub and spoke" approach which allows RFID printing and the devices to be shared between pharmacies. He stated that it was roughly a \$152,000 investment for implementation and an additional \$11,000 vendor fee for 107 locations in Oregon. He said that LEP dual labeling is more challenging. They use a 3rd party vendor dispensing system and have to rely on them to create the infrastructure to work with RxTran. He stated that the time to develop and implement for it to work RxTran is 12 months. Infrastructure roughly 1 million and \$700 license fee per store. He inquired about the enforcement timeline and if the Board could or would allow time for implementation. Fiona stated that OBOP inspection and compliance through education would be rolled out after rules were adopted. He continued and said that his company doesn't have the ability to add both languages to labels today. IT is challenging due to how IT projects are managed and the end result needs to be safe and translated properly and stated that they can't do a lot of pre-work with IT.

RAC Member Cushman stated that it will be challenging to achieve compliance by Jan 1, 2021. Kaiser Permanente's software solution will need to comply nationally for their organization and licensing will be \$1 million, and possibly \$2-3 million for 400 stores nationally.

RAC Member Morris has concerns about the most vulnerable population is not as mobile, especially outside of metro area. He thinks it's important that the Board consider writing how the pharmacies handle the availability timeline and access to the reader.

RAC Member Beiers-Jones stated that there isn't a half-way point for LEP, asked about a temporary solution for pharmacies to provide both labels in dual language using their software they have today. RAC Member Geddes stated that they do not have the ability to copy and paste into their operating system such as you could with "Word". Kristen recommended reaching out to a local Oregon pharmacy, @pharmacy.com as a reference and said that pharmacy is currently printing dual labels.

RAC Member Koder stated implementation for Multnomah County Health will be delayed due to the public contracting threshold, which exceeds their limits due to the cost of the readers.

RAC Member Frost stated that CVS's retail pharmacies can print a separate print out, and that it will impact 5 different areas, 10 operating systems, proprietary and can not be networked. Assessing the hardware, software and rewriting code, label size, his company is projecting cost estimates to be around \$30 million dollars. He stated Oregon has 1,381 pharmacies licensed as retail drug outlets that will be impacted by the implementation of this legislation, some of the operating systems will not be able to contract with vendor, ability to comply will easily take 2-3 years to be fully compliant and budget constraints at the end of fiscal year 2020 in order to find the funding in 2021 to build the system.

RAC Member George asked if it was necessary to have everything in every single pharmacy or if one pharmacy can service all patients using a "hub and spoke" type of model, as a way to partially comply until all IT systems are complete.

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| | <p>Implementation Realities-</p> <p>Fiona presented additional regulatory information that pharmacies are currently responsible for as it relates to Prescription Labeling & Accessibility such as:</p> <ul style="list-style-type: none"> • Title 6 of the Civil Rights Act of 1964 • Americans with Disabilities Act of 1990 • 2012 - Food and Drug Administration Safety and Innovation Act (workgroup created Best Practices for Making Prescription Drug Container Label Information Accessible to Persons Who are Blind, Visually Impaired or Who are Elderly) • Sec 1557 Affordable Care Act ("According to Section 904, the best practices are not mandatory" but these Oregon regulations make it mandatory for OR patients) • CMS (Centers for Medicare & Medicaid Services) reimbursement requirements for entities receiving federal funds <p>The Oregon regulations will streamline accessibility services to be consistent throughout the state for all citizens who take prescription medications. Fiona presented visual images of what dual language label looks like as well as options for a pharmacy label what is referred to as "flagged" when more characters are needed than what can fit on a traditional label. She went on to present visual images of Rx Readers that were described and presented during the legislative discussions for prescription readers, including a device for the countertop and a bottle that has an RFID tag which sits on the read and audibly conveys the label. The slide images also depicted a 2D barcode on a label that could be scanned by a smartphone app to audibly convey the prescription.</p> <p>Anticipated Rules Timeline –</p> <p>Fiona reiterated the important rule elements which will include:</p> <ul style="list-style-type: none"> • Definitions for LEP/ Rx reader • Describe drug outlet applicability • Those that dispense any drug to a patient for self-administration, includes pharmacy & non-pharmacy dispensing outlets and non-resident pharmacies; outpatient only • 14 languages other than English spoken in Oregon by individuals who are of LEP • Signage, consistent with federal requirement • Operational, effective date <p>Once staff has the OHA's list of languages, we will present draft rules to the Board for approval, most likely review/editing over multiple meetings during open session, once the Board approves the draft rules, they will be publicly noticed for rulemaking hearing which provides the opportunity for commentary by all stakeholders, including the public.</p> <p>Fiona stated that the RAC meetings primary objective was to collect factual information related to fiscal impact and implementation realities to inform the Board's rulemaking efforts as directed by these two laws. She thanked the members for attending and for providing their expertise and that the group could forward additional fiscal impact statements and implementation realities to the pharmacy.rulemaking@oregon.gov address. She stated that at this time, a secondary RAC meeting was not necessary, as the Committee achieved the meeting's objectives.</p> |
| Good of the Order | Adjourned |

**The meeting location is accessible to persons with disabilities. A request for hearing impaired assistance and accommodations for persons with disabilities should be made to Karen MacLean at 971-673-0001 at least 48 hours prior to the meeting.*

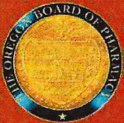
Prescription Labeling and Accessibility

OREGON BOARD OF PHARMACY

RULES ADVISORY COMMITTEE MEETING – JANUARY 22, 2020



OBOP MISSION



The Oregon Board of Pharmacy serves to promote and protect public health, safety and welfare by ensuring high standards in the practice of pharmacy and through effective regulation of the manufacture and distribution of drugs.

Rules Advisory Committee (RAC)

What is a RAC?

- A RAC may be established and used for rules in which there are issues that may substantially impact the interests of persons or entities ("stakeholders"), who will likely be affected by the proposed rulemaking.

What is the purpose of a RAC?

- Involve the public in the development of public policy
- Estimate financial impact on interested persons/entities, including small businesses, as well as the fiscal impact on the public
- Members must represent interests of persons likely to be affected by the rule

A RAC's role is advisory only.

Rules

What is a rule?

- Any agency directive, standard, regulation or statement
- Of general applicability
- That implements, interprets or prescribes law or policy, or
- That describes the procedure or practice requirements of any agency.

When is a rule required?

- When required by / written into statute
- Agency interpretation of broad statutory authority
- To amend, suspend, or repeal existing rule

Where are rules found?

- Oregon Administrative Rules (OAR)-official compilation of rules & regulations having the force of law in Oregon
- http://sos.oregon.gov/archives/Pages/oregon_administrative_rules.aspx

ORS 183.310(9)

Directives of 2019 SB 698

SB 698 Elements, amending [ORS 689.505](#):

The Board of Pharmacy shall adopt rules to require:

- A pharmacy to dispense a prescription drug bearing a label in both English and in the language requested;
- At the request of a patient who is of limited English proficiency (LEP); or at the request of the prescribing practitioner or an authorized representative of the patient

The rules adopted must:

- Define "limited English proficiency" (LEP);
- Determine pharmacy applicability, including at least retail drug outlets and other drug outlets that dispense prescription drugs (does not apply to institutional drug outlets);
- Determine for which prescription drugs it is appropriate to include an informational insert* in addition to the label, considering the complexity and length of the prescription's directions for use
- Must be available in at least 14 languages other than English that are spoken in Oregon by LEP individuals, as determined by the most recent American Community Survey from the US Census Bureau AND in consultation with the Oregon Health Authority (OHA) and other necessary resources.
 - Board to reassess and update languages as necessary, at least once every 10 years, with OHA and stakeholders

Directives of 2019 SB 698

SB 698 Elements (continued):

- A pharmacy may contract with a third party for the translation of labels and informational inserts
- A pharmacy, pharmacist or pharmacy intern that dispenses a prescription drug in compliance with the requirements may not be held liable for injuries resulting from the actions of a third party if the pharmacy from which the label or insert was dispensed entered into a contract with the third party in good faith AND the pharmacy, pharmacist or pharmacy intern was not negligent with regard to the alleged misconduct of the third party
- In consultation with the OHA, the board shall adopt rules to require that a pharmacy post signage to provide notification of the right to free, competent oral interpretation and translations services for patients who are of limited English proficiency

* Regulations become operative on January 1, 2021

Directives of 2019 HB 2935

HB 2935 Elements:

"Prescription reader" means a device that is designed to audibly convey the information contained on the label of a prescription drug

The Board of Pharmacy shall adopt rules to require:

- A pharmacy shall notify each person to whom a prescription drug is dispensed that a prescription reader is available to the person upon request.
- If a person informs the pharmacy that the person identifies as a person who is blind, the pharmacy shall provide to the person a prescription reader that is:
 - Available to the person for at least the duration of the prescription; and
 - Appropriate to address the person's visual impairment.
- A pharmacy that provides a prescription reader shall ensure that the prescription label is compatible with the prescription reader.
- These requirements do not apply to prescription drugs dispensed by an institutional drug outlet.
- A "person who is blind" means a person who is:
 - Visually impaired; Print disabled; or as defined in [ORS 346.510](#)

* Regulations became operative on January 1, 2020

Stated Objectives & Impacts of 698/2935

- Protect and support vulnerable patient populations by improving accessibility, medication adherence and reduce medication errors
- Reduce harmful and costly medication errors by requiring that pharmacies in Oregon provide prescription container labels in both English and a readable language for patients with limited English proficiency (LEP)
- Visually impaired and LEP patients are more likely to experience medication errors due to an inability to read or understand prescription labels.
 - It is estimated that 6.21% or 1 in 17 Oregonians (over 222,000 patients) are LEP.
 - It is estimated that 104,500 Oregon patients are visually impaired.



Context / Considerations for Rules

SECTION 2 of SB 698 states that these rules must:

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

OBOP is seeking information from the OHA to inform
LIST of FOURTEEN LANGUAGES

Context / Considerations for Rules

List of 14 Languages

- Can gain insight from the [-1 amendment](#), proposed on [4/3/2019](#)
 - Spanish ➤ Arabic
 - Chinese ➤ Khmer
 - Vietnamese ➤ Persian
 - Russian ➤ Nepali
 - Korean ➤ Somali
 - Japanese ➤ Karen
 - Tagalog ➤ Swahili

Context / Considerations for Rules

Federal landscape related to pharmacy compliance:

- [Title VI Civil Rights Act](#)
- [ADA](#)
- [FDASIA](#)
- [ACA](#)
- CMS requirements

Current Pharmacy Provisions

- Meaningful access ([45 CFR 92.201](#)) includes various types of translation services:
 - Translated labels (*written materials*)
 - Phone call access to translator (*verbal interpretation services*)
 - Use/recommendation of apps

Options for labels



Options for Rx Readers



Committee
Discussion
FISCAL IMPACT

Agency rulemaking to include statement containing:

- Identification of any state agencies, units of local government and members of the public likely to be economically affected by the rule
- Effect on small businesses
 - Estimate number and type(s) impacted
 - Estimate costs to comply
- Estimate costs related to any reporting, recordkeeping, administrative activities needed to comply
- Estimate the cost of professional services, equipment supplies, labor and increased administration to comply

OBOP is seeking specific FISCAL REALITIES

Re: Language labeling AND Readers

Committee
Discussion
IMPLEMENTATION
REALITIES

OBOP is seeking insights related to
IMPLEMENTATION REALITIES

Rule Elements

- Definitions for LEP/ Rx reader
- Describe drug outlet applicability
 - Those that dispense any drug to a patient for self-administration, includes pharmacy & non-pharmacy dispensing outlets and non-resident pharmacies; outpatient only
- 14 languages listed
- Signage, consistent with federal requirement
- Operational, effective date

FINAL THOUGHTS

THANK YOU FOR YOUR
PARTICIPATION!

