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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

10/22/2020 3:38 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Required prescription accessibility services mandated by 2019 SB 698

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 11/24/2020 4:30 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

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800 NE Oregon St., Suite 150
Portland, OR 97232

Filed By:
Rachel Melvin
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 11/24/2020

TIME: 8:30 AM

OFFICER: Rachel Melvin

ADDRESS: Oregon Board of Pharmacy
800 NE Oregon St., Suite 150
Portland, OR 97232

SPECIAL INSTRUCTIONS:

This hearing meeting will be held via telephonic conference call. To participate, call 1-877-873-8017, participant code 139360#. Email written comment to pharmacy.rulemaking@oregon.gov by 4:30PM on 11/24/2020.

Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

To implement legislative directive of 2019 SB 698 which requires an Oregon registered pharmacy to provide accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

2019 SB 698 <https://olis.oregonlegislature.gov/liz/2019R1/Measures/Overview/SB698>, Title VI of the Civil Rights

Act of 1964 (42 USC 2000d) <https://www.justice.gov/crt/fcs/TitleVI>, Oregon Language Statistics <https://olis.leg.state.or.us/liz/2019R1/Downloads/CommitteeMeetingDocument/168500>, Oregon LEP Statistic by County <https://olis.leg.state.or.us/liz/2019R1/Downloads/CommitteeMeetingDocument/168503>, Prescription Labeling & Accessibility Rules Advisory Committee (RAC) meeting minutes https://www.oregon.gov/pharmacy/Documents/Revsd.RACMinutes1.22.2020_Final.pdf

FISCAL AND ECONOMIC IMPACT:

This legislation has a significant fiscal impact to Oregon registered pharmacies and dispensing drug outlets.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) The Oregon Board of Pharmacy will incur costs associated with the validation of compliance.

(2) Small businesses will have a significant fiscal impact due to the costs associated with implementation, equipment, supplies, software/hardware, professional services and labor and increased administration required to comply with this legislation.

(a) All Oregon registered pharmacies and dispensing drug outlets are required to comply with this legislation and currently there are 1,648 registrants in Oregon who identify as a small business.

(b) It is estimated that the costs to comply consist of multiple factors including initial startup costs for software/hardware, implementation, ongoing maintenance/contract services costs, etc. According to Rules Advisory Committee (RAC) Member George representing one national pharmacy chain with 75 registered pharmacies in Oregon, initial implementation costs will depend on multiple factors, and stated that it cost around \$2 million dollars to implement 7 - 11 languages in their pharmacies located in New York. RAC Member Geddes stated that it will cost the national chain he represents, \$1 million dollars plus an additional \$74,900 in vendor license fees for their 107 Oregon locations. RAC Member Cushman stated that the national healthcare system she represents estimate it will be anywhere from \$1 to \$3 million dollars for 400 pharmacies located nationally. RAC Member Frost stated that the national chain he represents, estimate costs to be around \$30 million dollars for implementation.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

The Board hosted an Administrative Rule Advisory Committee meeting and invited various stakeholder groups along with local and national pharmacy representation.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

855-041-1035, 855-041-1040, 855-041-1132, 855-043-0005, 855-043-0436, 855-043-0541, 855-043-0736, 855-044-0061

AMEND: 855-041-1035

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-041-1035

Minimum Equipment Requirements (Both Retail and Institutional Drug Outlets) ¶

The minimum equipment requirement to open and operate a retail drug outlet and institutional drug outlet in the state of Oregon shall consist of not less than the following:¶

- (1) The most current issue of at least one pharmaceutical reference with current, properly filed supplements and updates appropriate to and based on the standards of practice for the setting.¶
- (2) Current and properly filed Oregon Revised Statutes, Chapters 689, and 475; current and properly filed Oregon Administrative Rules, chapter 855; and a minimum of three years of the Board of Pharmacy quarterly newsletters maintained in house or other readily retrievable means.¶
- (3) Official Poison and Exempt Narcotic Register if poisons and exempt narcotics are sold or distributed.¶
- (4) Suitable refrigeration.¶
- (5) A sink with running hot and cold water.¶
- (6) Equipment and supplies appropriate to and based on the standards of practice for the setting as determined by the Pharmacy and Pharmacist-in-Charge.¶
- (7) Failure to have and use equipment necessary to your practice setting constitutes unprofessional conduct for purposes of ORS 689.405(1)(a).¶
- (8) If an outlet files original prescriptions electronically, then the outlet must have a computer and software capable of storing and accessing electronically filed original prescriptions. ~~Exceptions to the above list may be approved by the Board of Pharmacy.¶~~
- (9) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.

Statutory/Other Authority: ORS 689.205, 689.508

Statutes/Other Implemented: ORS 689.205, 508, ORS 689.508, 155

AMEND: 855-041-1040

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-041-1040

Drug Outlet Procedures ¶¶

Each drug outlet is accountable for establishing, maintaining, and enforcing their written procedures for:¶¶

- (1) Securing their legend drugs and the area in which they are prepared, compounded, stored or repackaged;¶¶
- (2) Performing mandatory prospective drug utilization reviews; on all prescriptions both new and refilled;¶¶
- (3) Verifying the accuracy of all completed prescriptions and medical orders before they leave the pharmacy's secured legend area;¶¶
- (4) Documenting the identification of the pharmacist responsible for the verification of each dispensed medication;¶¶
- (5) Ensuring the delivery of each completed prescription to the correct party;¶¶
- (6) Providing appropriate confidential professional advice concerning medications to patients or their agents;¶¶
- (7) Prescribing services and maintenance of records for prescribing pharmacist;¶¶
- (8) Ensuring that all who work in the pharmacy are appropriately licensed and adequately trained to perform their duties ~~and~~;¶¶
- (9) Establishing and maintaining a Continuous Quality Assurance Program; and ¶¶
- (10) Providing oral interpretation and translation services for any patient who is of limited English proficiency, and prescription readers for a visually impaired patient as required by OAR 855-041-1131 and OAR 855-041-1132.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508

ADOPT: 855-041-1132

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-041-1132

Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205

AMEND: 855-043-0005

RULE SUMMARY: The proposed revisions to the rule are a result of the board's 2020-2024 Strategic Plan to proactively review and update rules to ensure clarity, transparency and promote patient safety.

CHANGES TO RULE:

855-043-0005

Practitioner Labeling ¶¶

All drugs dispensed by a practitioner must be labeled with the following information:¶¶

(1) Name, address and telephone number of the practitioner;¶¶

(2) Date;¶¶

(3) Name of the patient or the owner of the animal for which the drug is dispensed. If the prescription is for an animal, the species of the animal for which the drug is dispensed;¶¶

(4) Name of drug, strength, the quantity dispensed. When a generic name is used, the label must also contain the name of the manufacturer or distributor;¶¶

(5) Directions for use;¶¶

(6) Required precautionary information regarding controlled substances;¶¶

(7) Such other cautionary information as required for patient safety; and¶¶

(8) An expiration date after which the patient should not use the drug or medicine. The expiration date on a drug dispensed must be the same as that on the original container unless, in the practitioner's professional judgment, a shorter expiration date is warranted. A drug must not be dispensed after the expiration date of the drug.¶¶

(9) Notwithstanding the labeling requirements in this rule, when a drug is dispensed in the practice of an Expedited Partner Therapy treatment protocol, the name of the patient or the patient's partner may be omitted from the label.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.505, ~~2009 OL Ch 522~~

ADOPT: 855-043-0436

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-043-0436

Supervising Physician Dispensing Outlet - Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205

ADOPT: 855-043-0541

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-043-0541

Dispensing Practitioner Drug Outlet - Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205

ADOPT: 855-043-0736

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-043-0736

Community Health Clinic (CHC) - Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205

ADOPT: 855-044-0061

RULE SUMMARY: Directive of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended for all prescription drugs dispensed directly to patients, and requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-044-0061

Charitable Pharmacies - Limited English Proficiency and Accessibility

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

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

(a) Spanish;

(b) Russian;

(c) Somali;

(d) Arabic;

(e) Chinese (simplified);

(f) Vietnamese;

(g) Farsi;

(h) Korean;

(i) Romanian;

(j) Swahili;

(k) Burmese;

(l) Nepali;

(m) Amharic; and

(n) Pashtu.

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

(4) A pharmacy that dispenses prescriptions for a patient's self-administration must post signage to provide notification of the right to free, competent oral interpretation and translation services for patients who are of limited English proficiency, in compliance with federal and state regulations.

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205