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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED
04/16/2021 2:36 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Clarifies the definition and requirements for an informational insert

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/26/2021 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: 05/26/2021

TIME: 9:30 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 5/26/2021. Oral comment can be offered at the hearing on the date and time listed above.

NEED FOR THE RULE(S):

These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to Limited English Proficiency (LEP) patients. The requirements apply to pharmacies and dispensing drug outlets.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

ORS 689.505 https://www.oregonlegislature.gov/bills_laws/ors/ors676.html

FISCAL AND ECONOMIC IMPACT:

The clarification of the definition and requirements for an informational insert may have a fiscal impact to Oregon registered pharmacies and dispensing drug outlets. Additional costs for informational inserts may be included in the original estimates to comply with the directives of 2019 SB 698. The estimated costs for pharmacies to comply with the rules effective 1/1/2021 ranged from \$1-5M depending on the number of locations affected.

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).

There are no known economic impacts to the Oregon Board of Pharmacy, small businesses or members of the public.

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

Small businesses were not involved in the development of proposed revisions to these rules.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

A RAC was not necessary to clarify the definition and requirements of an informational insert.

RULES PROPOSED:

855-041-1001, 855-041-1132, 855-043-0002, 855-043-0436, 855-043-0541, 855-044-0005, 855-044-0061

AMEND: 855-041-1001

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-041-1001

Definitions ¶¶

(1) "Biological product" means, with respect to the prevention, treatment or cure of a disease or condition of human beings, a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component, blood derivative, allergenic product, protein other than a chemically synthesized polypeptide, analogous products or arsphenamine or any other trivalent organic arsenic compound.¶¶

(2) "Biosimilar product" means a biological product licensed by the United States Food and Drug Administration pursuant to 42 U.S.C. SC 262(k)(3)(A)(i) (12/26/2020).¶¶

(3)-"Drug room" is a drug storage area registered with the Board which is secure and lockable.¶¶

(4) "Informational insert" is an auxiliary document that is provided to the patient when directions for use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription container. ¶¶

(5) "Interchangeable" means, in reference to a biological product, that the United States Food and Drug Administration has determined that a biosimilar product meets the safety standards set forth in 42 U.S.C. SC 262(k)(4)-¶¶

(5)(12/26/2020).¶¶

(6) "Limited English proficiency" means not fluent in the English language.¶¶

(7) "Reference biological product" means the biological product licensed pursuant to 42 U.S.C. SC 262(a) (12/26/2020) against which a biological product is evaluated in an application submitted to the United States Food and Drug Administration for licensure of a biological product as a biosimilar product or for determination that a biosimilar product is interchangeable.

Statutory/Other Authority: ORS 689.205, ORS 689.522

Statutes/Other Implemented: ORS 689.155 & 342, 689.522, ORS 689.522, ORS 6890564

AMEND: 855-041-1132

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These 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~~ prescription labels and, when needed, an 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) An informational insert must only be used when the directions for use by the patient required under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. ¶

(5) When an informational insert is provided, the prescription label affixed to the prescription container must state in both English and the language requested by the patient that an informational insert is being used. ¶

(6) At a minimum, the informational insert must include the:¶

- (a) directions for use by the patient in both English and the language requested;¶
- (b) identifying number; ¶
- (c) name of patient;¶
- (d) name of drug and strength; and ¶
- (e) dispensing date.

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205

AMEND: 855-043-0002

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-043-0002

Definitions ¶¶

In this division of rules:¶¶

(1) "Administer" means the direct application of a drug or device whether by injection, inhalation, ingestion, or any other means, to the body of a patient by:¶¶

(a) A practitioner or the practitioner's authorized agent; or¶¶

(b) The patient at the direction of the practitioner.¶¶

(2) "Dispense" or "Dispensing" means the preparation and delivery of a prescription drug pursuant to a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to or use by a patient or other individual entitled to receive the prescription drug.¶¶

(3) "Formulary" means a list of drugs or classes of drugs, or a list of disease states, health conditions or preventative measures such as immunization or birth control approved by the Board or by the Department of Human Services (DHS).¶¶

(4) "Health Officer" means a physician licensed by the Oregon Medical Board or the Oregon Board of Naturopathic Medicine and employed by or under contract with a county or district health department or DHS.¶¶

(5) "Informational insert" is an auxiliary document that is provided to the patient when directions for use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription container. ¶¶

(6) "Limited English proficiency" means not fluent in the English language.¶¶

(7) "Supervising Physician Dispensing Outlet" (SPDO) means any clinic, office, health care center, treatment center, or other establishment from which a physician assistant dispenses drugs, but that is not otherwise registered with the Board in the category of Retail Drug Outlet.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.155, ORS 689.564

AMEND: 855-043-0436

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These 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~~pharmacy must provide ~~labels and~~ prescription labels and, when needed, an 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) An informational insert must only be used when the directions for use by the patient required under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. ¶

(5) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. ¶

(6) At a minimum, the informational insert, must include the:¶

- (a) directions for use by the patient;¶
- (b) identifying number; ¶
- (c) name of patient;¶
- (d) name of drug and strength; and ¶
- (e) dispensing date.

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205

AMEND: 855-043-0541

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These 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~~pharmacy must provide ~~labels and~~ prescription labels and, when needed, an 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: 855-044-0005

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These requirements apply to pharmacies and dispensing drug outlets, including non-resident pharmacies.

CHANGES TO RULE:

855-044-0005

Definitions ¶¶

(1) "Charitable Pharmacy" means a facility registered with the Oregon Board of Pharmacy for the purpose of receiving and distributing donated drugs.¶¶

(2) "Informational insert" is an auxiliary document that is provided to the patient when directions for use by the patient required under OAR 855-041-1130 do not fit on the label affixed to the prescription container. ¶¶

(3) "Limited English proficiency" means not fluent in the English language.¶¶

(4) "Point-of-Contact" means an individual designated by a charitable pharmacy who serves as the primary contact person for the charitable pharmacy and who is responsible for managing the charitable pharmacy at that location.

Statutory/Other Authority: ORS 689.205

Statutes/Other Implemented: ORS 689.772, ORS 689.774, ORS 689.564

AMEND: 855-044-0061

RULE SUMMARY: Address directives of 2019 SB 698, which requires accessibility services for limited English proficiency (LEP) patients. These rules are intended to clarify the definition and requirements for an informational insert when applicable for prescription drugs dispensed directly to LEP patients. These 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~~ prescription labels and, when needed, an 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.¶

(5) An informational insert must only be used when the directions for use by the patient required under OAR 855-041-1130 will not reasonably fit on the label affixed to the prescription container. ¶

(6) When an informational insert is provided, the prescription label affixed to the prescription container must state in the language requested by the patient that an informational insert is being used. ¶

(7) At a minimum, the informational insert, must include the:¶

- (a) directions for use by the patient;¶
- (b) identifying number; ¶
- (c) name of patient;¶
- (d) name of drug and strength; and ¶
- (e) dispensing date.

Statutory/Other Authority: ORS 689.564

Statutes/Other Implemented: ORS 689.205