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ARCHIVES DIVISION

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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 855
BOARD OF PHARMACY

FILED

04/25/2022 4:40 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Adds requirements for use of interpreters and modifies patient record requirements

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 05/24/2022 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: 05/24/2022

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 virtually via Microsoft Teams.

If you wish to present oral testimony during this hearing, sign up on our website at www.oregon.gov/pharmacy/pages/rulemaking-information or email your contact information to pharmacy.rulemaking@bop.oregon.gov to receive the link to join the virtual meeting. Please indicate which rule(s) you would like to comment on.

Alternatively, you may dial (503) 446-4951 Phone Conference ID: 114 068 944# for audio only.

You may file written comments before 4:30PM on May 24, 2022 by emailing your comments to pharmacy.rulemaking@bop.oregon.gov

NEED FOR THE RULE(S)

Revisions to Division 006/019/041/139 are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Per 2021 HB 2359, pharmacists and interns must work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services. Modifies patient records requirements to include patient's preferred language for communication and prescription labeling.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

2021 HB 2359 <https://olis.oregonlegislature.gov/liz/2021R1/Downloads/MeasureDocument/HB2359/Enrolled>

ORS 413.550 and ORS 413.558 related to health care interpreters

https://www.oregonlegislature.gov/bills_laws/ors/ors413.html

OAR 333-002 related to health care interpreters

<https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1218>

Title VI of the Civil Rights Act of 1964 <https://www.justice.gov/crt/fcs/TitleVI-Overview> prohibits discrimination on the basis of race, color, and national origin in programs and activities receiving federal financial assistance; Section 1557 of the Affordable Care Act <https://www.govinfo.gov/content/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf> prohibits discrimination on the basis of race, color, national origin, age, disability, or sex, in covered health programs or activities;

42 USC 18116 Nondiscrimination [https://uscode.house.gov/view.xhtml?req=\(title:42%20section:18116](https://uscode.house.gov/view.xhtml?req=(title:42%20section:18116)

Nondiscrimination %20edition:prelim)%20OR%20(granuleid:USC-prelim-title42-section18116)&f=treesort&edition=prelim&num=0&jumpTo=true

45 CFR Part 92 Nondiscrimination on the basis of race, color, national origin, sex, age, or disability in health programs or activities receiving federal financial assistance and programs or activities administered by the Department of Health and Human Services under Title I of the Patient Protection and Affordable Care Act or by entities established under such title. <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-92>

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

Patients from a variety of racial and ethnic backgrounds are of Limited English Proficiency. Approximately 222,000 Oregonians (1 out of every 17) cannot read the directions for their prescription medications provided in English and approximately 4,000 Oregonians communicate via American Sign Language (ASL). Interpreters offer a language and cultural bridge between a Pharmacist and an individual with LEP and those who prefer to communicate in a language other than English, including American Sign Language and other signed languages. Utilizing qualified interpreters will ensure that proper communication occurs to allow the individual with LEP and those who prefer to communicate in a language other than English, including American Sign Language and other signed languages, to achieve desired health outcomes. The ability to access an interpreter who can communicate in the patient's preferred language will have a positive impact on patients from a variety of racial and ethnic backgrounds who may have barriers to oral communication.

FISCAL AND ECONOMIC IMPACT:

The agency sent out a fiscal impact request associated with compliance, implementation and operation requirements related to services for use of Health Care Interpreters on April 6, 2022 to 13,617 recipients from the database for the following categories: Drug Outlet, PIC, Pharmacies, RPH, Rulemaking Notices & Adopted Rules. The agency received three responses:

A Pharmacist who owns a Pharmacy in Harrisburg, OR stated "I estimate it will cost me \$800 to \$1000 per month or \$9,000 to \$12,000 per year to have access to interpreters for all the languages you require. Signed language would have additional costs but I have not been able to make a good estimate of the amount."

A Pharmacist/Pharmacy Director from a health clinic in Medford, OR stated "Estimated Costs: Additional Record Keeping:\$3,900, Incremental Staff Time:\$208,000, Cost of Third-Party Interpreting Services:\$126,750, Additional costs related to ASL, etc. Equipment lease:\$3,500, Signing Services: \$760, Total Compliance-Related Costs:\$342,910 per year.

A Pharmacist/Director of Pharmacy of a pharmacy in Redmond, OR stated: "I contacted 4 medical interpretation service companies, 2 national companies commonly used by pharmacies and 2 Oregon companies. None of these companies said they have, or have plans to have, Oregon certified interpreters available for on-demand phone consultations for languages required by Oregon law. They did not know of any company to refer me to who could. One Oregon company has plans to launch Spanish only Oregon certified phone interpretation services by "mid-summer." They did not know the cost of this service. Several knowledgeable people explained to me that for on-demand phone interpretation they rely on national or international pools of interpreters, and it is not feasible to have them obtain Oregon certification. Quoted costs below are for non-Oregon certified interpretation services and are averaged between the four quotes: On-Demand phone interpretation (This assumes four 15-minute interpretation sessions per month)

- Average monthly service cost: \$151/month
- Dedicated phone line: \$40/month (our digital system cannot use 3-way calling + handsets per specs)
- Startup cost of phone equipment: \$200
- Startup cost of administrative time for research, contracting, procedures, training, and setup: \$2000

Adding American Sign Language (This assumes one 30-minute visit per month, costs are additional to above)

- Average monthly service cost: \$120/month
- Startup cost of computer, HD monitor, camera, headset: \$2400
- Startup cost of administrative time for additional research, contracting, procedures, training, and setup: \$500

Total startup costs: \$5100

Total monthly costs: \$311

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).

No anticipated fiscal impact is expected for the agency, other state agencies, units of local government or the public. Based on the responses the agency received from the fiscal impact request for requirements for use of health care interpreters, licensees may have startup costs and monthly/annual costs. Estimated costs range from \$9,000 to \$343,000 per year for items such as phone equipment, computer, monitor, camera, headset, administrative costs, training, equipment leases, signing services, etc.

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

Small businesses were not involved with the development of these rules, directives pursuant to 2021 HB 2359.

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

Proposed rules are a legislative directive of 2021 HB 2359 related to health care interpreters.

RULES PROPOSED:

855-019-0230, 855-041-1133, 855-041-1165, 855-139-0360, 855-139-0555

AMEND: 855-019-0230

RULE SUMMARY: Proposed amendments are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Requires Pharmacists and Interns to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services.

CHANGES TO RULE:

855-019-0230

Counseling ¶¶

(1) The ~~p~~Pharmacist or ~~i~~Intern ~~shall~~must orally counsel the patient or patient's agent on the use of a drug or device as appropriate.¶¶

(a) The ~~p~~Pharmacist or ~~i~~Intern ~~shall~~must counsel the patient on a new prescription and any changes in therapy, including but not limited to a change in directions or strength, or a prescription which is new to the pharmacy.¶¶

(b) Only the ~~p~~Pharmacist or ~~i~~Intern may accept a patient's or patient's agent's request not to be counseled. If, in their reasonable professional judgment, the ~~p~~Pharmacist or ~~i~~Intern believes that the patient's safety may be affected, the ~~p~~Pharmacist or ~~i~~Intern may choose not to release the prescription until counseling has been completed.¶¶

(c) ~~Effective July 1, 2008, t~~The ~~p~~Pharmacist or ~~i~~Intern that provides counseling or accepts the request not to be counseled ~~shall~~must document the interaction.¶¶

(d) A ~~p~~Pharmacist ~~shall~~must not allow non-~~p~~Pharmacist personnel to release a prescription that requires counseling, or accept the request not to be counseled.¶¶

(e) For a prescription delivered ~~outside of the pharmacy to a patient, except at a pharmacy or a pharmacy prescription locker~~, the ~~p~~Pharmacist ~~shall~~must offer in writing, to provide direct counseling and information about the drug, including information on how to contact the ~~p~~Pharmacist.¶¶

(f) For each patient, the ~~p~~Pharmacist or ~~i~~Intern ~~shall~~must determine the amount of counseling that is reasonable and necessary under the circumstance to promote safe and effective use or administration of the drug or device, and to facilitate an appropriate therapeutic outcome for that patient.¶¶

~~(2g) Counseling on a refill prescription shall~~When communicating (e.g. counseling, patient care services, billing) with a patient who prefers to communicate in a language other than English or who communicates in signed language, the Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 unless the Pharmacist is proficient in the patient's preferred language.¶¶

~~(2) Counseling on a refill prescription must~~ be such as a reasonable and prudent ~~p~~Pharmacist would provide including but not limited to changes in strength or directions.¶¶

(3) A ~~p~~Pharmacist may provide counseling in a form other than oral counseling when, in their reasonable professional judgment, a form of counseling other than oral counseling would be more effective.¶¶

(4) A ~~p~~Pharmacist or ~~i~~Intern ~~shall~~must initiate and provide counseling under conditions that maintain patient privacy and confidentiality.¶¶

(5) For a discharge prescription from a hospital, the ~~p~~Pharmacist must ensure that the patient receives appropriate counseling.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359

Statutes/Other Implemented: ORS 689.151, ORS 689.155, 2021 HB 2359

ADOPT: 855-041-1133

RULE SUMMARY: Proposed rules are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Requires pharmacists and interns to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services.

CHANGES TO RULE:

855-041-1133

Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Pharmacist is proficient in the preferred language of the person with limited English proficiency. The Pharmacist or drug outlet may not charge for these services.¶

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern: ¶

(a) Verifies that the Pharmacist or Intern has made a good faith effort needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558 and has found that none are available to provide interpretation; or ¶

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter. ¶

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern. ¶

(4) A Pharmacist or Intern must maintain records of:¶

(a) Each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry; or¶

(b) Each good faith effort to utilize a health care interpreter from the health care registry for each patient encounter in which the Pharmacist or Intern worked with an interpreter not on the health care interpreter registry and met one of the exceptions in (2) of this rule. ¶

(5) The records required in (4) must include: ¶

(a) The full name of the health care interpreter; ¶

(b) The health care interpreter's registry number, if applicable; and ¶

(c) The language interpreted. ¶

(6) Pharmacists, Interns, Certified Oregon Pharmacy Technicians, Pharmacy Technicians and Pharmacies are required to comply with ORS 413.559.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359

Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

AMEND: 855-041-1165

RULE SUMMARY: Proposed amendments are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Modifies patient records requirements to include patient's preferred language for communication and prescription labeling.

CHANGES TO RULE:

855-041-1165

Patient Medical Record ¶

A patient record system ~~shall~~must be maintained by pharmacies for all patients for whom prescription drug orders are dispensed, ~~except for those patients who the pharmacist has good reason to believe will not return to that pharmacy to obtain drugs.~~ The patient record system ~~shall~~must provide for readily retrievable information necessary for the dispensing ~~p~~Pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The ~~p~~Pharmacist ~~shall~~must make a reasonable effort to obtain, record, and maintain the following information:¶

(1) Full name of the patient for whom the drug is intended;¶

(2) Address and telephone number of the patient;¶

(3) Patient's ~~age or~~ date of birth;¶

(4) Patient's gender;¶

(5) Patient's preferred language for communication and prescription labeling;¶

(6) Chronic medical conditions;¶

(7) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;¶

(8) Known allergies, drug reactions, and drug idiosyncrasies; and¶

(9) If deemed relevant in the ~~p~~Pharmacist's reasonable professional judgment;¶

(a) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and¶

(b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508, 2021 HB 2359

ADOPT: 855-139-0360

RULE SUMMARY: Proposed rules are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Requires pharmacists and interns to work with health care interpreters from health care interpreter registry operated by Oregon Health Authority to provide interpretation services.

CHANGES TO RULE:

855-139-0360

Dispensing: Interpretation

(1) Except as provided in subsection (2) of this section, a Pharmacist or Intern from the RDSP Affiliated Pharmacy must work with a health care interpreter from the health care interpreter registry administered by the Oregon Health Authority under ORS 413.558 when communicating with a patient who prefers to communicate in a language other than English or who communicates in signed language, unless the Pharmacist is proficient in the preferred language of the person with limited English proficiency. The Pharmacist or drug outlet may not charge for these services.¶

(2) A Pharmacist or Intern who is otherwise required to work with a health care interpreter from the health care interpreter registry may work with a health care interpreter who is not listed on the health care interpreter registry only if the Pharmacist or Intern: ¶

(a) Verifies that the Pharmacist or Intern has made a good faith effort needed to obtain a health care interpreter from the health care interpreter registry in accordance with rules adopted by the authority under ORS 413.558 and has found that none are available to provide interpretation; or ¶

(b) Has offered the patient the services of a health care interpreter from the health care interpreter registry and the patient declined the offer and chose a different interpreter. ¶

(3) A Pharmacist or Intern must provide personal protective equipment, consistent with established national standards, to health care interpreters providing services on-site at no cost to the health care interpreter and may not suggest to the health care interpreter that the health care interpreter should procure the health care interpreter's own personal protective equipment as a condition of working with the Pharmacist or Intern. ¶

(4) A Pharmacist or Intern must maintain records of:¶

(a) Each patient encounter in which the Pharmacist or Intern worked with a health care interpreter from the health care interpreter registry; or¶

(b) Each good faith effort to utilize a health care interpreter from the health care registry for each patient encounter in which the Pharmacist or Intern worked with an interpreter not on the health care interpreter registry and met one of the exceptions in (2) of this rule. ¶

(5) The records required in (4) must include: ¶

(a) The full name of the health care interpreter; ¶

(b) The health care interpreter's registry number, if applicable; and ¶

(c) The language interpreted. ¶

(6) Pharmacists, Interns, Certified Oregon Pharmacy Technicians, Pharmacy Technicians and Pharmacies are required to comply with ORS 413.559.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359

Statutes/Other Implemented: ORS 689.155, 2021 HB 2359

AMEND: 855-139-0555

RULE SUMMARY: Proposed amendments are necessary to incorporate directives set forth in 2021 HB 2359, related to health care interpreters. Modifies patient records requirements to include patient's preferred language for communication and prescription labeling.

CHANGES TO RULE:

855-139-0555

Records: Patient

A patient record system must be maintained by pharmacies for all patients for whom a prescription drug is dispensed. The patient record system must provide information necessary for the dispensing Oregon licensed Pharmacist to identify previously dispensed drugs at the time a prescription is presented for dispensing. The Pharmacist must make a reasonable effort to obtain, record, and maintain the following information:

- (1) Full name of the patient for whom the drug is intended;
- (2) Address and telephone number of the patient;
- (3) Patient's age or date of birth;
- (4) Patient's gender;
- (5) Patient's preferred language for communication and prescription labeling;
- (6) Chronic medical conditions;
- (67) A list of all prescription drug orders obtained by the patient at the pharmacy maintaining the patient record showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber;
- (78) Known allergies, drug reactions, and drug idiosyncrasies; and
- (89) If deemed relevant in the Oregon licensed Pharmacist's reasonable professional judgment:
 - (a) Oregon licensed Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug; and
 - (b) Additional information such as chronic conditions or disease states of the patient, the patient's current weight, and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review.

Statutory/Other Authority: ORS 689.205, 2021 HB 2359

Statutes/Other Implemented: ORS 689.151, ORS 689.155, ORS 689.508, 2021 HB 2359